13

How External Factors Shaped Domestic Intellectual Property Law in Latin America

Juan I. Correa

ABSTRACT

This chapter aims to examine how diverse external factors have influenced the implementation of intellectual property (IP) standards in Latin America. To this end, it first refers to adopting TRIPS-consistent legislation in the region during the transition period granted to developing countries. Second, it examines the influence of the interpretation of domestic IP legislation under the WTO Dispute Settlement Understanding and provides an overview of TRIPS-plus provisions included in some of the free trade agreements signed in the region, among them the most recent ones, the USMCA and the Agreement between the European Union and MERCOSUR (which is not yet in force). Third, it analyzes other external factors which also affect the implementation of national IP regulations, such as the reports regarding the enforcement of IP provisions produced by the United States or the European Union. Fourth, it analyzes situations in which IP rules are deemed directly applicable by national courts – following the constitutional provisions and practices – thereby reducing the room for maneuver to shape domestic legislation. This analysis shows how the recent evolution of IP policy and legislation in Latin America can only be understood based on the external factors that influenced or determined them.

TABLE OF CONTENTS

https://doi.org/10.1017/9781009071338.018 Published online by Cambridge University Press

A. INTRODUCTION

Significant changes have taken place in intellectual property (IP) rights – known as IPRs – in the last decades. These changes have notably been the result of the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights[1] (hereinafter "the TRIPS Agreement") and more recently of free trade agreements (FTAs) entered into by a number of Latin American countries that provide for TRIPS-plus standards.[2] Such changes have also been induced in some cases by other international instruments with IP-related provisions[3] and the threat of unilateral trade sanctions, such as those that may be imposed under the Special Section 301 of the US Trade Act.[4] Thus, the IP landscape in Latin America became far more reflective of the interests of right holders as the legislation expanded the scope of protection and the set of conferred exclusive rights. In many cases the beneficiaries of this protection are foreign right holders who seek registration of their

[1] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994; Marrakesh Agreement Establishing the World Trade Organizations, Annex 1C, 1869 UNTS 299, 33 ILM 1197.

[2] See, for example, FTA between United States and Peru; FTA between United States and Colombia; FTA between the EU and Chile; FTA between Australia and Chile; FTA between EFTA and Peru.

[3] See Convention on Biological Diversity, 1760 UNTS 79, 31 ILM 818 (1992); FAO, International Treaty on Plant Genetic Resources for Food and Agriculture, ITPGRFA (2001); Paris Agreement to the United Nations Framework Convention on Climate Change, Dec. 12, 2015, T.I.A.S. No. 16-1104.

[4] See in general Carlos M. Correa, "Special Section 301: US Interference with the Design and Implementation of National Patent Laws" (South Centre 2020) 115 https://www.southcentre.int/wp-content/uploads/2020/07/RP-115.pdf accessed October 9, 2020.

titles but do not invest or otherwise contribute to the socio-economic development of the Latin American countries where the protection is conferred.

Although a number of flexibilities are allowed by the TRIPS Agreement that may potentially mitigate certain unbalances between right holders' and public interests,[5] such flexibilities are potentially subject to interpretation by WTO panels and the Appellate Body (AB). In addition, as new multilateral, regional or bilateral agreements are signed up and domestically implemented by Latin American countries, new layers of normative requirements are added to the already existing and complex grid of IPRs. In particular, FTAs have narrowed down the room for the domestic implementation of the TRIPS Agreement through the inclusion of IP chapters that contain TRIPS-plus provisions.[6] The ensuing strengthening and expansion of IPRs has come into tension with other international and domestic legal regimes, such as in the field of human rights.[7] As IPRs are constitutionally protected in Latin

[5] See in general Frederick M. Abbott, "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO" (2002) 5 *Journal of International Economic Law* 469; Robin Wright, "The 'Three-Step Test' and the Wider Public Interest: Towards a More Inclusive Interpretation" (2009) 12 *The Journal of World Intellectual Property* 600; Henning Grosse Ruse-Khan, "Assessing the Need for a General Public Interest Exception in the TRIPS Agreement," in Annette Kur (ed.), *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS* (Edward Elgar 2011), pp. 167–207.

[6] Henning Grosse Ruse-Khan et al., "Principles for Intellectual Property Provisions in Bilateral and Regional Agreements" (2013) 44 *IIC – International Review of Intellectual Property and Competition Law* 878; Carlos M. Correa, "TRIPS and TRIPS-Plus Protection and Impacts in Latin America," in Daniel Gervais (ed.), *Intellectual Property, Trade and Development* (Oxford University Press 2014) https://oxford.universitypressscholarship.com/view/10.1093/acprof:oso/9780199684700.001.0001/acprof-9780199684700-chapter-6 accessed October 13, 2020; Carlos M. Correa and Juan I. Correa, "*20 Años de La OMC: La Instrumentación del Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual Relacionados con el comercio en América Latina*," in Valentina Delich and Dorotea López (eds.), *20 Años de la OMC una perspectiva desde Latinoamérica* (FLACSO Argentina, 2016) https://www.flacso.org.ar/wp-content/uploads/2016/07/Libro-20-Anos-de-la-OMC.pdf accessed October 10, 2020.

[7] See in general Laurence R. Helfer and Graeme W. Austin, *Human Rights and Intellectual Property: Mapping the Global Interface* (Cambridge University Press 2011); Christophe Geiger, "Reconceptualizing the Constitutional Dimension of Intellectual Property – An Update" (2019) SSRN Electronic Journal https://www.ssrn.com/abstract=3496779 accessed October 12, 2020; Christophe Geiger, *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar Publishing 2015) http://www.elgaronline.com/view/9781783472413.xml accessed October 12, 2020; Paul L. C. Torremans, Intellectual Property and Human Rights (2020) 4th ed., Kluwer Law International http://www.kluweriplaw.com/book-toc?title=Intellectual%20Property%20and%20Human%20Rights%2C%20Fourth%20Edition accessed October 31, 2020; World Intellectual Property Organization, United Nations and Office of the High Commissioner for Human Rights (eds.), "Intellectual Property and Human Rights: A Panel Discussion to Commemorate the 50th Anniversary of the Universal Declaration of Human Rights, *Geneva, November 9, 1998*" (World Intellectual Property Organization, 2000); OHCHR, "Copyright Policy and the Right to Science and Culture" (Human Rights Council, 2015) A/HRC/28/57 https://undocs.org/en/A/HRC/28/57 accessed 10 October 2020; OHCHR, "Patent Policy and the Right to Science and Culture" (Human Rights Council 2015) A/70/279 https://undocs.org/en/A/70/279 accessed October 10, 2020; OHCHR, "Intellectual Property Rights and Human Rights: Sub-Commission on Human Rights resolution 2000/7"

America,[8] their compatibility with other constitutional principles and goals – such as those that mandate the respect of the human right to health, education or culture – has also become problematic.[9]

The FTAs have been one of the main channels for erosion of the TRIPS flexibilities. They had distinctive effects on the national landscape. While TRIPS sought to set out minimum standards in most areas of IP regulations, FTAs sought to implement TRIPS-plus provisions that reduced countries' room for maneuver in national implementation otherwise guaranteed under Articles 1, 7[10] and 8[11] of the Agreement.[12]

Latin American countries usually are driven toward the inclusion of IP chapters by developed countries as condition *sine qua non* for negotiations.[13] There are few instances of prior studies on the potential impact of the obligations contained in the

(Human Rights Council 2007) 2000/07 https://ap.ohchr.org/documents/E/SUBCOM/resolutions/E-CN_4-SUB_2-RES-2000-7.doc accessed October 10, 2020; General Assembly, "The Right to Food. Seed Policies and the Right to Food: Enhancing Agrobiodiversity and Encouraging Innovation" (United Nations 2009) A/64/170 https://digitallibrary.un.org/record/663241.

[8] Constitutional clauses referring to IP rights can currently be found in most Latin American countries, as shown by the following examples: The Argentine Constitution as adopted in 1853, Article 1 in Brazil, the Federal Constitution establishes in its (Article 5) XXVII and Article XXIX, the Political Constitution of Chile Article 19.25, Colombia's Constitution Article 61, Ecuador, Article 322, the Mexican Constitution Article 73 and Article 73 XXV, the Political Constitution of Peru, Article 2.8, and Uruguay's Constitution, Article 33.

[9] See in general Gustavo Ghidini, *Rethinking Intellectual Property: Balancing Conflicts of Interests in the Constitutional Paradigm* (Edward Elgar Publishing 2018).

[10] Importantly, Articles 7 and 8 of the TRIPS Agreement make it clear that IP should serve to achieve socio-economic welfare and not just the right holders' interests as interpreted by WTO case law. Therefore, when implementing policies related to IPRs, WTO Members can take these articles into consideration in order to safeguard the public interest and adapt as far as possible the IP regime to their particular circumstances and needs.

[11] In the WTO's Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, the Panel noted that

> the principles reflected in Article 8.1 express the intention of the drafters of the TRIPS Agreement to preserve the ability for WTO Members to pursue certain legitimate societal interests, at the same time as it confirms their recognition that certain measures adopted by WTO Members for such purposes may have an impact on IP rights, and requires that such measures be "consistent with the provisions of the [TRIPS] Agreement."

[12] Josef Drexl, Henning Grosse Ruse-Khan and Souheir Nadde-Phlix (eds.), *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?* vol. 20 (Springer Berlin, Heidelberg, 2014), p. 37 http://link.springer.com/10.1007/978-3-642-39097-5 accessed October 24, 2020.

[13] When negotiating among themselves, Latin American countries generally do not include IP chapters with TRIPS-plus provisions. See, for example, FTA between Chile and Colombia, available at: http://www.sice.oas.org/Trade/CHL_COL_FTA/CHL_COL_ind_s.asp; see FTA between Chile and Peru, Article 19.7, available at: http://www.sice.oas.org/Trade/CHL_PER_FTA/Text_s.asp#Art19.7; FTA between Mercosur and Peru Title XVII, available at: http://www.sice.oas.org/Trade/MRCSRPerACE58/acuerdo.ASP#T%C3%8DTULO%20XVII.

FTAs and entered into in negotiations, with no clear assessment of the possible implications of the new IP[14] commitments. Hence, these agreements usually lead to international IP rules that do not adequately address the interests of both parties. Until now, the Latin American countries that have subscribed to FTAs have experienced difficulties in reconciling the more stringent and wide-ranging obligations[15] included in these agreements with the need to build up balanced IP protection and enforcement regimes that respond to the overall fundamentals of the system and their national interests.

Several FTAs signed up by Latin American countries include detailed IP chapters,[16] which are regularly requested as part of the negotiated agreements by the United States and the European Union (EU) – but not exclusively by them[17] – while other FTAs include general provisions regarding IP.[18] More recently two FTAs were concluded: the USMCA[19] and the EU–MERCOSUR Agreement (concluded but not ratified yet). Although both agreements contain TRIPS-plus provisions, they focus on different aspects of IPRs. The MERCOSUR Agreement reflects the EU's strong interest in geographical indications (GIs), while the USMCA reflects the US interests in patent law and test data protection.

The purpose of this paper is to analyze how external factors affected the design and implementation of IP legislation in Latin America. To this end, it first refers to the process of adoption of TRIPS-consistent legislation in the region during the transition period granted to developing countries. Second, it examines the possible influence of the interpretation of domestic IP legislation under the WTO Dispute Settlement Understanding (DSU) and provides an overview of TRIPS-plus provisions included in some of the FTAs signed in the region. Third, it analyzes other external factors, such as the reports produced under the Special Section 301 of the

[14] Generally IP serves as a trade-off in the universe of subject areas covered by the agreements (e.g. tariff concessions, services, foreign direct investment and public procurement). See Henning Grosse Ruse-Khan et al., "Principles for Intellectual Property Provisions in Bilateral and Regional Agreements" (2013) 44 *IIC – International Review of Intellectual Property and Competition Law* 878.

[15] See Pedro Roffe, "Free Trade Agreements and the Americas" (2013) *IIC – International Review of Intellectual Property and Competition Law*, 44(8), pp. 932–942.

[16] See, for example, USA–Chile, USA–Colombia, USA–Peru, EU–Peru, EU–Colombia, DR–CAFTA among others, available at: http://www.sice.oas.org/agreements_e.asp.

[17] See, for example, FTA between Colombia–EFTA, Article 6.11 regarding data exclusivity for pharmaceutical products, available at: http://www.sice.oas.org/Trade/COL_EFTA/Final_Texts_e/Text_e.asp#a69.

[18] See, for example, the FTA between Chile and China, Article 111, Intellectual Property. http://www.sice.oas.org/Trade/CHL_CHN/CHL_CHN_e/Text_e.asp#111; Canada–Peru FTA, available at: http://www.sice.oas.org/Trade/CAN_PER/CAN_PER_e/CAN_PER_index_e.asp#FullDoc; see Chile–EFTA Article 46, available at: http://www.sice.oas.org/Trade/Chi-EFTA_e/Text_e.asp#ARTICLE%2046.

[19] United States–Mexico–Canada Agreement, Office of the United States Trade Representative (Nov. 30, 2018), https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement [hereinafter USMCA].

https://doi.org/10.1017/9781009071338.018 Published online by Cambridge University Press

US Trade Acts and pursuant to the similar mechanism put in place by the EU. Fourth, it analyzes situations in which IP rules are deemed to be directly applicable by national courts – in accordance with the constitutional provisions and practices – thereby reducing the room for maneuver to shape national legislation. Finally, some case law by domestic courts relating to IP standards induced by the TRIPS Agreement or FTAs is summarily mentioned.

B. ADOPTION OF NATIONAL LEGISLATION FOR TRIPS AGREEMENT IMPLEMENTATION

The adoption of the TRIPS Agreement[20] marked a paradigm shift in IP law at the global scale. It required the Members of the World Trade Organization (currently numbering 164) to establish minimum standards on patent law as well as on other areas of IP, thereby significantly limiting the flexibilities available to design national policies on the matter and to determine how to balance right holders' and public interests.[21] While it has been argued that changes to patent laws aiming at strengthening and expanding the scope of IPRs would have taken place anyway – because both the United States and the EU could have used bilateral and regional agreements to increase the levels of protection to the benefit of their industries[22] – the TRIPS Agreement enormously simplified that process. It does so by addressing most areas of IP and because it is associated with a mechanism of enforcement that may lead to trade retaliations in case of non-compliance with the minimum standards set forth in the Agreement.[23] The TRIPS Agreement has had a decisive influence in shaping the IP regimes in Latin American countries.[24]

The developing countries considered that the concessions granted in the TRIPS Agreement would be sufficient to satisfy the demands of developed countries regarding the expansion of IPRs.[25] However, immediately after the entry into force of the Agreement, such countries – in particular the United States and the

[20] TRIPS (n 1).

[21] See generally Ruth L. Okediji and Margo A. Bagley (eds.), *Patent Law in Global Perspective* (Oxford University Press 2014) http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780199334278.001.0001/acprof-9780199334278 accessed May 20, 2020.

[22] Frederick Abbott, "Rethinking Patents: From 'Intellectual Property' to 'Private Taxation Scheme'," in Peter Drahos, Gustavo Ghidini and Hanns Ullrich (eds.), *Kritika, Essays on Intellectual Property*, vol. 1 (Edward Elgar Publishing Limited 2015), pp. 2–7.

[23] See Part III of the TRIPS Agreement.

[24] Correa and Correa (n 6), pp. 239–306.

[25] Bryan Mercurio, "TRIPS-Plus Provisions in Ftas: Recent Trends," in Lorand Bartels and Federico Ortino (eds.), *Regional Trade Agreements and the WTO Legal System* (Oxford University Press 2006) http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780199206995.001.0001/acprof-9780199206995-chapter-10 accessed July 17, 2020. See in general Peter K. Yu, "Currents and Crosscurrents in the International Intellectual Property Regime" (2004) 38 *Loyola of Los Angeles Law Review* https://digitalcommons.lmu.edu/llr/vol38/iss1/7.

EU – undertook bilateral or regional negotiations aimed at strengthening IPRs with higher standards than those in the TRIPS Agreement.[26] Therefore, while developing countries were struggling to internalize the Agreement's standards, developed countries started to deploy a bilateral or regional strategy that would allow them to increase the protection standards. In particular, they were successful in incorporating new disciplines and in weakening the "flexibilities" allowed by the Agreement, particularly in relation to patents and undisclosed information.[27]

The expansion of IPRs generated concern among developing countries' governments, civil society and academics, particularly in relation to the impact on access to medicines – and more broadly, access to knowledge.[28] Thus, it was noted that the "[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."[29]

Given the "developing country" status of Latin American countries, they were allowed, under the transition periods provided for in Article 65 of the TRIPS Agreement, to comply with their obligations as of January 1, 2000, and many developing countries passed TRIPS related legislation only weeks before their January 2000 deadline for its implementation. They were also allowed to delay the granting of product patent protection to areas of technology that were not protectable in their territory until that date, for an additional period of five years. However, no Latin American country made full use of this possibility.[30] A number of laws

[26] See in general Maximiliano Santa Cruz S., "Intellectual Property Provisions in European Union Trade Agreements: Implications for Developing Countries" (ICTSD 2007) Issue Paper No. 20; Grosse Ruse-Khan et al. (n 6); Pedro Roffe and Luis Mariano Genovesi, "*Implementación y administración de los capítulos de propiedad intelectual en los acuerdos de libre comercio con Estados Unidos: La experiencia de cuatro países de América Latina*" (BID 2011) BID-PB-129 https://publications.iadb.org/publications/spanish/document/Implementaci%C3%B3n-y-administraci%C3%B3n-de-los-cap%C3%ADtulos-de-propiedad-intelectual-en-los-acuerdos-de-libre-comercio-con-Estados-Unidos-La-experiencia-de-cuatro-pa%C3%ADses-de-Am%C3%A9rica-Latina.pdf accessed June 10, 2020.

[27] *Op. cit.* Mercurio (n 25).

[28] See in general Mercurio (n 25); Carlos M. Correa, "TRIPS and TRIPS-Plus Protection and Impacts in Latin America," in Daniel Gervais (ed.) (n 6) https://oxford.universitypressscholarship.com/view/10.1093/acprof:oso/9780199684700.001.0001/acprof-9780199684700-chapter-6 accessed October 14, 2020; Josef Drexl, "The Concept of Trade-Relatedness of Intellectual Property Rights in Times of Post-TRIPS Bilateralism," in Hanns Ullrich et al. (eds.), *TRIPS plus 20* (Springer Berlin, Heidelberg, 2016) http://link.springer.com/10.1007/978-3-662-48107-3_2 accessed March 24, 2020; Josef Drexl, Henning Grosse Ruse-Khan and Souheir Nadde-Phlix (eds.) (n 12); Okediji and Bagley (n 21).

[29] Grosse Ruse-Khan et al. (n 6).

[30] Carlos M. Correa, "Implementing the TRIPs Agreement in the Patents Field: Options for Developing Countries" (1998) *The Journal of World Intellectual Property* 1, no. 1, pp. 75–99, https://doi.org/10.1111/j.1747-1796.1998.tb00004.x; Maria Auxiliadora Oliveira et al., "Has the implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favours public health?" Bulletin of the World Health

were, in fact, enacted between 1995 and 2000 in some Latin American countries to comply with the TRIPS Agreement.[31]

Despite the rush to introduce domestic standards consistent with WTO obligations, a few countries in the region were the subject of disputes before the WTO's Dispute Settlement Body (DSB). Both Argentina and Brazil were the subject of actions by the United States. Specifically, the United States attempted to promote a broad interpretation of some provisions in the Agreement, notably in relation to test data and some aspects of patent law.[32]

For instance, in the case of Argentina, in 2000 the United States questioned the consistency of the country's Patent Law with Article 31 of the TRIPS Agreement, in particular, the provisions of the Argentine Patent Law No. 24,481 on the availability and grant of compulsory licenses to remedy anti-competitive practices. The objection of the United States concerned the process of granting such licenses, as it wanted to make it clear that there should be an intervention and decision by the competition authority. The United States and Argentina reached an agreement that confirmed that "to justify the granting of a compulsory license the National Commission for the Defense of Competition (or the body that could replace it in the future) must have analyzed the practice in question and issued a decision, based on Law No. 25,156 (Competition Law)."[33]

Organization, no. 11 (November 2004), pp. 811–890, http://www.who.int/bulletin/volumes/82/11/en/815.pdf accessed October 24, 2020; Carolyn Deere, "The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries" (Oxford University Press, 2008).

[31] See, for example, Argentina: Law No. 24.766, passed on December 18, 1998, and published in the *Boletín Oficial* on December 20, 1996, enacts the Law on Confidential Information; Law No. 24.376 on the Protection of New Varieties of Plants, published in the *Boletín Oficial* on October 25, 1994, enacts the International Convention for the Protection of New Varieties of Plants, adopted in Paris on December 2, 1961, and revised in Geneva in 1972 and 1978; Ratification of the Rome Convention of 1961, Law No. 23.921 of March 2, 1993, and the Berne Convention (Paris Act of 1971; Law No. 25.140 of September 24, 1999; regarding copyright, several laws were introduced to comply with TRIPS obligations: Law No. 25.036 of November 11, 1998; Law No. 24.780 of September 16, 1997, Law No. 25.006 of July 15, 1998); geographical indications were enacted by Law No. 25.163; finally, regarding patents, Decree No. 260/96, which was published in the *Boletín Oficial* on March 22, 1996. Annex I of the Decree contains the harmonized text of Law No. 24.481 on Patents and Utility Models, as amended by Law No. 24.572. Brazil: regarding industrial property rights, TRIPS was implemented in May 1996 by the Law on Industrial Property (Law 9.279 of 1996, which covers patents, trademarks and GIs, among others); regarding copyright, the Law No. 9.610 was enacted in 1998. In Mexico, regarding Plant Varieties, the Federal Law on Plant Varieties was published in the *Diario Oficial de la Federación* (Official Journal) on October 25, 1996. A new Federal Law on copyright was enacted in 1997. Regarding industrial property, the Industrial Property Law entered into force in 1994, product of the NAFTA, which already was considered to be in accordance with TRIPS standards.

[32] Jean-Frédéric Morin, "Multilateralising TRIPS-Plus Agreements: Is the US Strategy a Failure?" (2009) 12 *The Journal of World Intellectual Property* 175, pp. 185–187.

[33] See WTO documents WT/DS171/3, WT/DS196/4, IP/D/18/Add.1, IP/D/22/Add.1.

The United States requested consultations with Brazil regarding the provisions of Brazil's 1996 industrial property law and other related measures that established a "local working" requirement for the enjoyability of exclusive patent rights. The United States asserted that the "local working" requirement could only be satisfied by the local production – and not the importation – of the patented subject-matter.[34] More specifically, the United States noted that Brazil's "local working" requirement stipulated that a patent shall be subject to compulsory licensing if the subject-matter of the patent was not "worked" in the territory of Brazil.[35] The United States further noted that Brazil explicitly defined "failure to be worked" as "failure to manufacture or incomplete manufacture of the product" or "failure to make full use of the patented process"; the United States considered that such a requirement was inconsistent with Brazil's obligations under Articles 27 and 28 of the TRIPS Agreement as well as Article III of the GATT 1994.[36] As in the Argentinian process, the United States and Brazil reached a compromise before the establishment of a panel, as the Brazilian Government agreed that, in the event it was deemed necessary to apply Article 68 to grant compulsory license on patents held by the US companies, prior talks on the matter would be held with the US Government.[37]

While both disputes were settled between the parties, they demonstrate the intention of the United States to use the DSU as a mechanism to restrict countries' space in the interpretation of the TRIPS Agreement's provisions, while ensuring consistency of national provisions with the Agreement, which had already resulted in considerable reduction of the room for maneuver in the implementation of IP in the light of other public policies.

The rush to implement the obligations under the Agreement may be one of the reasons why some countries did not develop a balanced IP policy, as shown years later – for instance, in relation to patentability of pharmaceutical products or patentable subject-matter[38] or the extension of the term of copyright protection.[39]

[34] See DS199: Brazil – Measures Affecting Patent Protection, https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm.

[35] Ibid.

[36] Ibid.

[37] See G/L/454 IP/D/23/Add.1 Brazil – Measures Affecting Patent Protection – Notification of Mutually Agreed Solution of July 19, 2001

[38] Carlos M. Correa and Abdulqawi Yusuf (eds.), *Intellectual Property and International Trade: The TRIPS Agreement* (3rd ed., Wolters Kluwer 2016), pp. 265–274.

[39] Christophe Geiger, *Droit d'auteur et droit du public à l'information: approche de droit comparé* (Litec, 2004); Ruth Dreifuss and Festus Gontebanye Mogae, "High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies" (UN Secretary General 2016) http://www.unsgaccessmeds.org/final-report accessed October 10, 2020; Satish Verma, "TRIPS Agreement and Access to Medicines" https://www.kansai-u.ac.jp/ILS/publication/asset/nomos/29/nomos29-06.pdf accessed June 10, 2020; Jeroen Van Wijk, "How Does Stronger Protection of Intellectual Property Rights Affect Seed Supply? Early Evidence of Impact" (1996) Overseas Development Institute, London http://hdl.handle.net/10535/4379 accessed November 2, 2020.

The effects of stronger IP rights in developing countries had a direct effect on the procurement of HIV drugs.[40] For example, in Brazil, by the late 1990s, the annual per-patient cost of HIV treatment was nearly US$5,000 – at a time when treatment featured almost exclusively unpatented drugs. As more people began treatment and as patients migrated to expensive second-line regimens based on drugs that were patented under Brazil's new IP law, the program would become unsustainable. Hence, Brazil undertook several modifications of its patent policy in order to improve local capacity and to acquire less expensive generic versions of newer drugs from both foreign and local suppliers, including (for instance) the reform of the compulsory licenses regime.[41]

Not only was the implementation of the TRIPS Agreement by many Latin American countries premature. In addition, despite knowing the implications of such implementation, as noted above, several countries in the region entered into negotiations of a number of trade agreements that would end up reducing the margin provided for in TRIPS Agreement even further. Another important aspect to analyze in the implementation of national regulations is the threat of potential claims under the DSU, as discussed below.

C. MULTILATERAL AND BILATERAL FACTORS IN DOMESTIC IMPLEMENTATION

I. *Analysis of Domestic Legislation under WTO Rules*

Another factor that can influence the design and implementation of domestic IP regulations is the way in which panels and the AB of the WTO interpret the TRIPS provisions. Narrow interpretations, in particular, may expose WTO Members to complaints and eventually trade retaliations by other Members. Although no direct evidence exists how this might have influenced the implementation of the TRIPS Agreement in Latin America, it can be presumed that it is a factor that regulators have considered in adopting the implementing regulations. One possible example is the fact that, except Brazil and Argentina, other Latin American countries have not maintained or introduced compulsory licenses on the grounds of lack of working of a patent, which may be attributed to the ambiguity of the TRIPS Agreement in this regard[42] and the risk of complaints under the DSU. As pointed out by Gazzini, the obligations deriving from Membership in the WTO

[40] Kenneth C. Shadlen, "The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies" (2009) 42 *Comparative Politics* 41, pp. 47–50.

[41] Ibid., pp. 4–7.

[42] Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary* (2nd ed., Oxford University Press 2020), p. 309.

> are never inherently indivisible or erga omnes in the sense elaborated by the International Court of Justice in the field of human rights. As a rule, remedies for violations of WTO obligations remain available only to the Member(s) whose international trade interests have been affected, in actual or potential terms. Nonetheless, contracting parties have decided to extend to a limited number of WTO obligations the legal regime of indivisible obligation and to consider immaterial for the purpose of resorting to the dispute settlement system the effects of their violations. WTO obligations, therefore, are not a monolithic bloc.[43]

Hence, the violation of a WTO rule may affect or threaten to affect the legally protected interests of one or more – but not necessarily all – Members. As a rule, resort to the WTO dispute settlement system is open to Members whose trade has suffered, in actual or potential terms, from the violation of WTO obligations.[44] However, Article 3(8) of the DSU introduces the presumption that violations of WTO obligations cause nullification or impairment of the benefits of the Members. The respondent can challenge such a presumption, and if the challenge is successful then adjudication is precluded.[45]

The possibility, and admissibility, of differences in the implementation of the provisions of the TRIPS Agreement are expressly recognized in Article 1.1 of the Agreement: "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice." But such possible differences are subject to limits, as this provision only allows for choices regarding the "method of implementation" but not the substantive or enforcement standard as such.

In many cases, the space for different interpretations derives from general expressions or ambiguities in the text resulting from compromises reached in the negotiation of the Agreement. The room for different interpretations may also result from the absence of definitions. An example is the lack of one definition of the concept of "invention,"[46] which differs among countries and allows WTO Members not to grant patents, for instance, on developments without a technical effect (such as under European law), or to grant or not grant patents on genetic materials as found in nature.[47] Thus, the Brazilian patent law expressly excludes from the concept of

[43] Tarcisio Gazzini, "The Legal Nature of WTO Obligations and the Consequences of their Violation" (2006) 17 *European Journal of International Law* 723.

[44] Ibid.

[45] See EC – Regime for the Importation, Sale and Distribution of Bananas, Appellate Body, WT/DS27/AB/R.

[46] For example, it is possible to find distinctions in the interpretation of Article 27 of TRIPS Agreement made by Latin-American countries of the requirement of invention in patent law. In the case of Argentina, Chile, Costa Rica and Mexico, their legislation includes express references to the concept of invention, while Decision 486, which governs the countries of the Andean Community, in particular Colombia and Peru, does not establish a concept of invention. The same occurs in the cases of Brazil and Uruguay.

[47] Mari Minn, "Patenting of Genetic Research in Europe and the U.S.: A Questionable Future for Diagnostic Methods and Personalized Medicines," *Biotechnology Law Report*, vol. 38, No.

invention the area of isolated genes,[48] a provision that is absent from other laws in the region.

WTO jurisprudence has already established, through several decisions, the degree of scrutiny available to the DSB over a Member country's domestic legislation. In particular, it has established that in order to determine whether the implementation of legislation is contrary to TRIPS Agreement, the DSB must analyze such provisions to determine the extent of a country's violation.

A first significant distinction is whether the legislation that is the object of a complaint is mandatory or discretionary – meaning the law as such or the application of that law. Only legislation that mandates a violation of WTO obligations can be found as such to be inconsistent with those obligations. By contrast, legislation that merely gives discretion to the executive authority of a Member to act inconsistently with the WTO Agreement cannot be challenged as such. Thus, where discretionary authority is vested in the executive branch of a WTO Member, it cannot be assumed that the Member will fail to implement its obligations under the WTO Agreement in good faith. According to this approach, the test is whether or not the legislation in question allows the administrative authorities to abide by that Member's WTO obligations.[49]

Another important issue, which may influence domestic implementation, is the extent to which WTO panels or the AB may interpret domestic law in order to establish a violation of the TRIPS Agreement (and other WTO agreements). In the *India – Patents (US)* case, the AB stated that "[i]t is clear that an examination of the relevant aspects of Indian municipal law … is essential to determining whether India has complied with its obligations under Article 70.8(a) [of the TRIPS Agreement]. There was simply no way for the Panel to make this determination without engaging in an examination of Indian law."[50] This was further developed in the US Section 301 case, where the AB indicated that:

> Our mandate is to examine Sections 301–310 solely for the purpose of determining whether the US meets its WTO obligations. In doing so, we do not, as noted by the

2 (2019) https://www.liebertpub.com/doi/10.1089/blr.2019.29108.mm accessed November 10, 2020.

[48] Presidency of the Republic, Law on Industrial Property Law No. 10.196 that modifies and adds provisions to Law No. 9.279 of May 14, 1996 (2001). Chapter II, Section 1 Article 10.IX excludes from patentability "all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes."

[49] WT/DS152/R United States – Sections 301–310 of the Trade Act of 1974 – Report of the Panel, p. 305. https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds152_e.htm accessed November 5, 2020.

[50] Appellate Body Report on India – Patent Protection for Pharmaceutical and Agricultural Chemical Products ("India – Patents (US)"), WT/DS50/AB/R, para 66.

> Appellate Body in India – Patents (US)634, interpret US law "as such", the way we would, say, interpret provisions of the covered agreements. We are, instead, called upon to establish the meaning of Sections 301–310 as factual elements and to check whether these factual elements constitute conduct by the US contrary to its WTO obligations.[51]

It may be noted that in the US case against India on TRIPS, the United States had complained that the Indian law did not provide specifically the so-called "mailbox" provisions for the patent authority to receive applications for process or product patents in the pharmaceutical and chemical sector. The panel and the AB found that India had not complied with its obligations under Article 70.8 and 70.9, thus India was in violation of its WTO obligations over its failure to enact a specific law in terms of its WTO obligations.

In the case of the US Section 301 laws, the EC indicated that "Section 301 provides uncertainty about the possible use by the United States of unilateral measures 'inconsistent with the Uruguay Round dispute settlement rules'." This defeats the purpose pursued by the Uruguay Round participants when they agreed to adopt the DSU, namely, to provide security and predictability to the multilateral trading system (Article 3.2 of the DSU)[52] and Article 23 of the DSU, which prohibits unilateralism in the framework of the WTO dispute settlement procedures. Members must await the adoption of a panel or AB report by the DSB or the rendering of an arbitration decision under Article 22.

At issue in the case were the interpretation of these provisions of US law, how far they comply with the requirements of the WTO and its dispute settlement understandings, and whether the US law was discretionary or mandatory on the administration. Contrary to the Indian case, the panel found that the challenged sections of the US Trade Act of 1974 were not inconsistent with Article 23.2(a) or (c) of the DSU or with any of the GATT 1994 provisions cited. In particular, the panel noted that the language provided in the US Statement of Administrative Action approved by the US Congress at the time it implemented the Uruguay Round agreements and confirmed in the statements by the United States to the panel was enough to comply with US obligations under the WTO.[53]

This jurisprudence limits the degree of interference that WTO panels and the AB may have in influencing national or regional IP regulations, but does not prevent them from providing "clarifications" of the TRIPS Agreement that may narrow down the flexibilities available to WTO Members. It is worth recalling that Latin

[51] United States – Sections 301-310 of the Trade Act of 1974, WT/DS152/R, adopted January 27, 2000, para. 7.18.
[52] Ibid., para 4.40.
[53] Ibid., para. 8.1.

American countries were bound to implement the TRIPS Agreement's obligations by January 1, 2000, before any significant case law on the interpretation of some of its key provisions[54] and, importantly, before the adoption of the Doha Declaration on the TRIPS Agreement and Public Health – which confirmed some of the flexibilities allowed under the Agreement and the interpretive value of its Articles 7 and 8.[55] As shown by the limited recognition of such flexibilities in most Latin American IP laws.[56] governments in the region in general adopted a cautious approach in the interpretation of the Agreement's provisions.

II. *IP Provisions in FTAs*

Since the 1990s, more than seventy FTAs have been signed by Latin American countries, with other developing or developed countries. In particular, FTAs signed between Latin American and developed countries have introduced TRIPS-plus standards on patents, test data, copyright, trademarks, plant varieties protection and other IP categories.

Interestingly, the EU did not pursue agreements with ambitious IP provisions until 2006. Prior to that, IP clauses were general and had a greater focus on GIs. Since 2006, the level of protection asked for by the EU has increased considerably. The EU's new external IP policy seems to follow, in many respects, the aggressive stance taken by the United States on IP in its own FTAs.[57] The following subsections present an overview of such TRIPS-plus provisions in both FTAs signed by the United States and the EU.

[54] The jurisprudence of the WTO regarding implementation of domestic polices and IP shows that when a Member State has to address a policy objective, such as public health, the TRIPS Agreement provides for some policy space to establish a balance between public interests and the right-holders' exclusive rights. It also reaffirms the rights of the Members to establish policies in conformity with Articles 7 and 8 of TRIPS. See for example *EC – Trademarks and Geographical Indications WT/DS290*, *Canada – Patent Protection of Pharmaceutical Products WT/DS114/13*; *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging WT/DS435/28 WT/DS441/29*.

[55] See Peter Yu, "The Objectives and Principles of the TRIPs Agreement" (2009) 46 *Houston law Review* 797.

[56] For example, not many countries have granted or clear procedures for compulsory licenses. See Carlos M. Correa (2015), "The Use of Compulsory Licences in Latin America" in Hilty R. and Liu K. C. (eds.), *Compulsory Licensing: MPI Studies on Intellectual Property and Competition Law*, vol 22., Springer Berlin, Heidelberg https://doi.org/10.1007/978-3-642-54704-1_3 accessed November 10, 2020.

[57] Anke Moerland, "Do Developing Countries Have a Say? Bilateral and Regional Intellectual Property Negotiations with the EU" (2017) 48 *IIC – International Review of Intellectual Property and Competition Law* 760, p. 763.

In the area of patents, the FTAs negotiated by the United States with Chile,[58] Colombia[59] and Peru,[60] as well as the DR–CAFTA[61] regarding the Andean Community with the EU,[62] state that the contracting parties shall extend the term of protection a patent "to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the first marketing approval of that product in that party."

For instance, the FTAs with the United States require each party, at the request of the patent owner, to adjust the duration of a patent "to compensate for unreasonable delays in the granting of the patent" (Chile–US Article 17.9.6; DR–CAFTA, Article 15.9 0.5). The FTAs with the United States – namely Chile (Article 17.10.2 (a)) and DR–CAFTA (Article 15.9.6 (b)) – also contain a provision requiring an extension of the patent term to compensate the patent holder for an "unreasonable" delay in approving the marketing of pharmaceutical or agricultural chemical products. In the EU–Colombia/Perú/Ecuador FTA, Article 231 includes a "best efforts" obligation to process the corresponding application expeditiously with a view to avoiding unreasonable delays.[63]

Regarding copyright, several FTAs extended the duration of protection to the life of the author plus seventy years from his or her death for most works (including photographic works). The term of protection of sound recordings and audiovisual works was also extended to seventy years from their publication.[64] Other rules

[58] Free Trade Agreement Chile–United States in force since 2004. Chapter 17, available at: http://www.sice.oas.org/Trade/chiusa_s/Text_s.asp#Chap17s.

[59] FTA between United States and Colombia, entry into force 2012, Chapter 16 – Intellectual Property, available at: http://www.sice.oas.org/Trade/COL_USA_TPA_e/Index_e.asp.

[60] FTA between United States and Peru, entry into force 2009, Chapter 16 – Intellectual Property, available at: http://www.sice.oas.org/Trade/PER_USA/PER_USA_e/Index_e.asp.

[61] DR–CAFTA, Free Trade Agreement between United States, Central-America and Dominican Republic, in force for Costa Rica since January 2009, available at: http://www.sice.oas.org/Trade/CAFTA/CAFTADR/CAFTADRin_s.asp#IPR.

[62] See, for example, Free Trade Agreement between the EU and Colombia and Peru, Article 230. Patents, in force since 2013, available at: http://www.sice.oas.org/Trade/COL_PER_EU_FTA/COL_EU_Accord_e.pdf; DR–CAFTA, Free Trade Agreement between United States, Central-America and Dominican Republic, in force for Costa Rica since January 2009, available at: http://www.sice.oas.org/Trade/CAFTA/CAFTADR/CAFTADRin_s.asp#IPR; USMCA (Agreement between United States, Mexico and Canada), in force since 2020, available at: https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/20%20Intellectual%20Property%20Rights.pdf.

[63] See FTA between the EU and Colombia and Peru, Article 231.

[64] See, for example, Free Trade Agreement between the United States and Chile, Article 17.5. Obligations Common to Copyright and related Rights, in force since 2004, available at: http://www.sice.oas.org/Trade/chiusa_e/chiusaind_e.asp; Free Trade Agreement between the United States and Colombia, Article 16.5. Obligations Common to Copyright and related Rights, in force since 2012, available at: http://www.sice.oas.org/Trade/COL_USA_TPA_e/Index_e.asp; Free Trade Agreement between the EU and Colombia and Peru, Article 218. Patents, in force since 2013, available at: http://www.sice.oas.org/Trade/COL_PER_EU_FTA/COL_EU_Accord_e.pdf.

introduced by FTAs include the reproduction rights of transitory copies; the right to control any technological form of transmission of works, including interactive transmissions over electronic networks such as the Internet, with minor exceptions for analog reproductions and transmissions of sound recordings and performances; technological protection measures (TPMs), with limited exceptions;[65] and the prohibition of the removal or alteration of electronic rights management information.[66]

Concerning plant varieties protection, the FTAs signed by the United States and the EU forced some Latin American countries to join UPOV 1991,[67] a less flexible regime compared to UPOV 1978, particularly in relation to the "farmer's privilege." As a result, Costa Rica, Chile, Dominican Republic, Panama and Peru are now parties to UPOV 1991.[68]

Regarding trademarks, several FTAs in Latin America integrate sound marks as a mandatory subject-matter, and scent as an optional one.[69] Many US FTAs prohibit the denial of trademark registration solely on the grounds that the sign of which it is composed is a sound or a scent. An enhanced protection of well-known marks is also provided for in all US and EU FTAs. Internet-related IP referred to in the US FTAs includes domain names. In order to address the problems of trademark cyberpiracy, the US FTAs require that a party's country-code top level domain (ccTLD) provides

[65] See, for example, Free Trade Agreement between the United States and Chile, Article 17.7.4. Obligations Common to Copyright and related Rights, in force since 2004, available at: http://www.sice.oas.org/Trade/chiusa_e/chiusaind_e.asp; Free Trade Agreement between the United States and Colombia, Article 16.7.4. Obligations Common to Copyright and related Rights, in force since 2012, available at: http://www.sice.oas.org/Trade/COL_USA_TPA_e/Index_e.asp; Free Trade Agreement between the EU and Colombia and Peru, Article 221–222. Patents, in force since 2013, available at: http://www.sice.oas.org/Trade/COL_PER_EU_FTA/COL_EU_Accord_e.pdf.

[66] See, for example, Free Trade Agreement between the EU and Colombia and Peru, Article 230. Patents, in force since 2013, available at: http://www.sice.oas.org/Trade/COL_PER_EU_FTA/COL_EU_Accord_e.pdf.

[67] See, for example, USMCA (Agreement between United States, Mexico and Canada), in force since 2020, available at: https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/20%20Intellectual%20Property%20Rights.pdf; Free Trade Agreement between the EU and Colombia and Peru, Article 230. Patents, in force since 2013, available at: http://www.sice.oas.org/Trade/COL_PER_EU_FTA/COL_EU_Accord_e.pdf.

[68] UPOV, "Members of the International Union for the Protection of New Varieties of Plants" (UPOV 2020) https://www.upov.int/export/sites/upov/members/en/pdf/pub423.pdf accessed October 10, 2020.

[69] See, for example, Free Trade Agreement between the United States and Chile, Article 17.2.1 Obligations Common to Copyright and related Rights, in force since 2004, available at: http://www.sice.oas.org/Trade/chiusa_e/chiusaind_e.asp; DR-CAFTA, Article 15.2.1, Free Trade Agreement between United States, Central-America and Dominican Republic, in force for Costa Rica since January 2009, available at: http://www.sice.oas.org/Trade/CAFTA/CAFTADR/CAFTADRin_s.asp#IPRz.

a dispute procedure based on the uniform domain-name policy (UDP) as well as online public access to a database of contact information.[70]

Finally, regarding GIs, the FTA signed between the EU and Colombia and Peru shows the profound asymmetry in the economic interests of the parties with respect to the protection of these indications. While the EU obtained the recognition of a list of several pages of GIs, only two Colombian and four Peruvian indications are recognized.[71] While the European approach in the FTA has been the *sui generis* form of protection for GIs as applied in European countries, the FTAs signed with the United States provide for the protection of GIs through trademarks or a *sui generis* system or other legal means.[72] The GI protection has been significantly enhanced in FTAs with the EU but not in FTAs with other countries. For instance, in the FTA between South Korea and Chile, while the protection of GIs is included, the list consists of only three GIs from Chile (other than for wines, for which the number is larger), and the same number from South Korea,[73] while the FTA between Korea and the EU includes a greater number of South Korean GIs.[74]

The bilateral and regional approaches used by the United States and the EU in Latin America – as well as in other regions[75] – increased the tension between IPRs and constitutionally guaranteed human rights. In effect, by using regional or bilateral processes, in which developing countries have limited negotiating capacity, the FTAs introduced obligations that may undermine the realization of human rights.[76]

[70] See, for example, Free Trade Agreement between the United States and Chile, Article 17.3.2 Obligations Common to Copyright and related Rights, in force since 2004, available at: http://www.sice.oas.org/Trade/chiusa_e/chiusaind_e.asp; Free Trade Agreement between the United States and Colombia, Article 16.4.2 Obligations Common to Copyright and related Rights, in force since 2012, available at: http://www.sice.oas.org/Trade/COL_USA_TPA_e/Index_e.asp; DR–CAFTA, Article 15.4.2, Free Trade Agreement between the United States, Central-America and Dominican Republic, in force for Costa Rica since January 2009, available at: http://www.sice.oas.org/Trade/CAFTA/CAFTADR/CAFTADRin_s.asp#IPR; Free Trade Agreement between the United States and Peru, Article 16.4.2, in force since 2004, available at: http://www.sice.oas.org/Trade/PER_USA/PER_USA_e/PER_USA_text_e.asp#a168.

[71] Free Trade Agreement between the EU and Colombia and Peru, Article 230. Patents, in force since 2013, available at: http://www.sice.oas.org/Trade/COL_PER_EU_FTA/COL_EU_Accord_e.pdf.

[72] See USMCA (Agreement between the United States, Mexico and Canada), Article 20.29, in force since 2020, available at: https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/20%20Intellectual%20Property%20Rights.pdf.

[73] See Free Trade Agreement Chile–Korea, Annex 16.4.3, 16.4.4, 16.4.5, in force since April 2004, available at: http://www.sice.oas.org/Trade/Chi-SKorea_e/ChiKoreaind_e.asp.

[74] See Annex 10-A, PART B, GEOGRAPHICAL INDICATIONS FOR AGRICULTURAL PRODUCTS AND FOODSTUFFS ORIGINATING IN SOUTH KOREA, available at: https://publications.europa.eu/resource/cellar/09667d5d-f987–4dc5–82d7–69260c796508.0006.03/DOC_1#ntr1-L_2011127EN.01131901-E0001.

[75] See, for example, Christoph Antons and Reto M. Hilty (eds.), *Intellectual Property and Free Trade Agreements in the Asia-Pacific Region* (1st ed., Springer Berlin, Heidelberg, 2015).

[76] Peter Yu, "EU Economic Partnership Agreements and International Human Rights," in Drexl, Grosse Ruse-Khan and Nadde-Phlix (n 12), pp. 123–125.

As noted in a set of principles issued by the Max Planck Institute for Intellectual Property and Competition Law,

> [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.[77]

The above-mentioned TRIPS-plus provisions in accordance with the European and US standards on IPRs, as transplanted through FTAs, are not generally adapted to the situation and needs of the receiving jurisdictions. As the prescriptive language used does not leave much policy space for adaptations during the implementation phase,[78] the effect is that the provisions may stay extraneous to the system. Also, it is important to note that the exceptions, limitations and other checks and balances present in the EU domestic system are mostly not transcribed into the FTAs. The effect is that the partner country is left with a higher level of IP protection and enforcement than the EU in its domestic law.[79]

The most recent FTAs signed by Latin American countries present specific features that are briefly described below. It is, in particular, interesting to note what may be seen as a change in EU policy regarding TRIPS-plus provisions on patents and data protection, which is somehow reminiscent of the EU position in the CARIFORUM Agreement.[80]

III. *Trends in the Most Recent FTAs Involving Latin American Countries*

1. The USMCA Free Trade Agreement

In late 2018, the United States, Canada and Mexico signed a new trade agreement, known as the United States–Mexico–Canada Agreement or USMCA. It updates and replaces the old North American Free Trade Agreement (NAFTA) and introduces new provisions regarding IPRs. In particular, the United States was able to introduce IP provisions included in the draft Trans–Pacific Partnership (TPP), from which the

[77] Grosse Ruse-Khan et al. (n 6).

[78] See, however, Carlos M. Correa, "Mitigating the Regulatory Constraints Imposed by Intellectual Property Rules under Free Trade Agreements" (South Centre 2017) Research Paper 57, p. 27, https://www.southcentre.int/wp-content/uploads/2017/02/RP74_Mitigating-the-Regulatory-Constraints-Imposed-by-Intellectual-Property-Rules-under-Free-Trade-Agreements_EN-1.pdf accessed February 2, 2021.

[79] Moerland (n 57), 765.

[80] See Economic Partnership Agreement between the CARIFORUM States and the European Community, Provisional application since December 29, 2008, Chapter 2 http://www.sice.oas.org/Trade/CAR_EU_EPA_e/careu_in_e.ASP.

United States withdrew in January 2017,[81] and which were subsequently suspended in the Comprehensive and Progressive Agreement for Trans–Pacific Partnership (CPTPP).[82]

It is interesting to note that the NAFTA largely reflects the TRIPS Agreement, as several of its provisions were taken by the United States from the text under negotiation in GATT. In this respect, NAFTA represents the first major agreement, modeled on the TRIPS Agreement but going beyond it in a number of areas, such as regulated products and enforcement issues.[83]

In the field of patent law, the USMCA goes beyond the level of protection seen in previous FTAs, as it introduces most of the provisions negotiated in the failed TPP Agreement. This is particularly the case in the area of "secondary" patents. The USMCA text indicates that patents have to be available for "new uses of a known product, new methods of using a known product, or new processes of using a known product."[84] This provision requires the patentability of second indication patents, which facilitates "evergreening" of pharmaceutical patents.[85] Under Mexican law, before the USMCA, patents cannot be granted for new uses, which was fully consistent with TRIPS, hence in order to implement the new provision the industrial property law was amended.[86]

[81] See USTR, Press release: The United States Officially Withdraws from the Trans-Pacific Partnership (USTR 2017), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2017/january/US-Withdraws-From-TPP accessed January 23, 2021.

[82] In 2017, then-US President Donald Trump signed an executive order withdrawing the United States from the TPP. Although it was thought that the TPP would not enter into force, the Asia-Pacific Economic Cooperation (APEC) summit gave new life to the TPP agreement by renaming it the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). The new text regarding IP limits the scope of provisions and suspensions of some of the provisions in TPP Agreement; see Pratyush Nath Upreti, "From TPP to CPTPP: Why Intellectual Property Matters" (2018) 13 *Journal of Intellectual Property Law & Practice*, p. 100.

[83] Drexl, Grosse Ruse-Khan and Nadde-Phlix (n 12); Susy Frankel, "The Trademark Provisions in Post-TRIPS Mega-Regional Trade Agreements," in Irene Calboli and Jane C. Ginsburg (eds.), *The Cambridge Handbook of International and Comparative Trademark Law* (1st ed., Cambridge University Press 2020) https://www.cambridge.org/core/product/identifier/9781108399456%23CN-bp-4/type/book_part accessed May 13, 2021; "NAFTA Is Renegotiated and Signed by the United States" (2019) 113 American Journal of International Law 150; Peter K. Yu, "Data Exclusivities and the Limits to TRIPS Harmonization" (2019) 46 Fla. St. U. L. Rev. 641 available at: https://scholarship.law.tamu.edu/facscholar/1342.

[84] USMCA (n 19), Article 20.36 paragraph 2.

[85] See in general Bhaven N. Sampat and Kenneth C. Shadlen, "TRIPS Implementation and Secondary Pharmaceutical Patenting in Brazil and India," (2015) 50 *Studies in Comparative International Development* 228; Gaurav Dwivedi, Sharanabasava Hallihosur and Latha Rangan, "Evergreening: A Deceptive Device in Patent Rights" (2010) 32 *Technology in Society* 324.

[86] Article 45 of the New Industrial Property Law of Mexico established that any substance, compound or composition included in the prior art shall not be excluded from patentability, provided that its use is new. Translated by the author. See México, *Ley Federal de Protección a la Propiedad Industrial*, DOF-01-07-2020, published July 1, 2020, available at: http://www.diputados.gob.mx/LeyesBiblio/pdf/LFPPI_010720.pdf.

Another TRIPS-plus commitment relates to the patent term adjustment (i.e. extension) for "unreasonable" delays by a granting authority, which sets out a period of five years from the date of filing of an application, or three years from the request of examination, as the periods "reasonable" for the granting of a patent.[87] The text also includes a patent term extension for "unreasonable or unnecessary" delays in the marketing approval of pharmaceutical patents.[88] This provision evokes the patent term extension available under the 1984 Drug Price Competition and Patent Restoration Act, also known as the Hatch–Waxman Act in the United States and the Supplementary Protection Certificates established in the EU.[89] This provision – also included in several FTAs as seen in the previous section – may bring about major difficulties to the health sector and economies of the partner countries.[90] However, contrary to the United States and EU regulations, the FTA does not provide for a limit to the length of the patent term extension.[91]

The USMCA also provides TRIPS-plus commitments regarding the protection of undisclosed test or other data submitted to regulatory authorities, which prevent regulators from using the clinical trial data submitted by the originator company to assess an application from a generic company for a period of time (at least five years for new pharmaceutical products, and either an additional three years for test data submitted to support a new use or formulation, or five years for combination products including a drug that has not previously been approved).[92] It further provides a ten-year period of "effective market protection" for biologicals (medicines produced from living cells and other biological materials via biotechnology processes),[93] the longest period of market protection for such drugs negotiated in a trade agreement to date.[94]

[87] USMCA (n 19) Article 20.44., para. 4.
[88] Ibid., Article 20.46.
[89] See in general John Miles, "Supplementary Protection Certificates for Medicinal Products: Where Are We Now and What Challenges Lay Ahead?" (2012) 1 *Pharmaceutical Patent Analyst* 275; "Explanatory Memorandum to the Proposal for a European Parliament and Council Regulation (EC), of 9 December 1994, Concerning the Creation of a Supplementary Protection Certificate for Plant Protection Products" (European Commission 1994) (COM (94) 579 final) https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1994:0579:FIN:EN:PDF.
[90] See in general Daniel Acquah, "Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU – Is There a Need to Rebalance?" (2014) 45 *IIC – International Review of Intellectual Property and Competition Law* 256.
[91] Carlos M. Correa, "Implications of Bilateral Free Trade Agreements on Access to Medicines" (2006) 84 *Public Health reviews*, https://www.who.int/bulletin/volumes/84/5/399.pdf?ua=1 accessed February 3, 2021.
[92] USMCA (n 19), at Article 20.48.
[93] Ibid., at Article 20.49.
[94] Ronald Labonté et al., "USMCA (NAFTA 2.0): Tightening the Constraints on the Right to Regulate for Public Health" (2019) 15 *Globalization and Health* 35.

The USMCA also includes the "patent linkage"[95] obligation found in other FTAs, which establishes a linkage between the patent status of medicines and the marketing approval process, potentially delaying the market entry of generics while disputes over possible patent infringement are resolved.[96]

Regarding trademarks, the USMCA established that a sign does not need to be visually perceptible as a condition of registration. This indicates that parties cannot deny a registration of a trademark solely on the ground that the proposed mark is a sound. Hence, it limits the grounds for denying registration.[97] That is not all: the USMCA also broadened the scope of protection on the use of identical or similar signs. In both agreements, it is prohibited to use similar or identical trademarks, including subsequent GIs, without consent from the owner for goods or services that are "related" to those goods and services in respect of which the owner's trademark is registered. The TRIPS uses the wording "identical and similar," which is a tighter definition than "related." The USMCA also requires that Article 6bis of the Paris Convention apply *mutatis mutandis*, which means that countries may make necessary alterations to adapt their laws to the required protection.[98]

In addition, the USMCA has included several grounds on which the parties cannot refuse to provide protection for well-known marks. These grounds include that the mark must be registered in the party providing the protection or in another jurisdiction; or that it is given recognition as a well-known trademark. Although "well-known" is not fully defined, the parties agree to "recognize the importance" of WIPO's Joint Recommendations Concerning Provisions on the Protection of Well-Known Marks.[99] Well-known mark protection in a global setting is controversial because such protection tends to favor the multinational businesses of large and developed nations, whose cultures dominate much of the globe. This problem is not just a small market economy problem; it is even true for large economies whose global presence may be limited because of language barriers.[100]

[95] USMCA (n 19), at Article 20.51.

[96] See Kyung-Bok Son et al., "Moderating the Impact of Patent Linkage on Access to Medicines: Lessons from Variations in South Korea, Australia, Canada, and the United States" (2018) 14 *Globalization and Health* 101.

[97] USMCA (n 19), at Article 20.21.

[98] The relevant substantive obligation of the Paris Convention requires Member States to refuse or to cancel the registration, and to prohibit the use of a trademark which constitutes a reproduction, an imitation, or a translation, liable to create confusion of a mark considered by the competent authority of the country of registration or use to be well known in that country as being already the mark of a person entitled to the benefits of this Convention and used for identical or similar goods. These provisions shall also apply when the essential part of the mark constitutes a reproduction of any such well-known mark or an imitation liable to create confusion therewith. See TRIPS (n 1).

[99] See Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks, Article 2, World Intellectual Property Organization, WIPO Doc. 833(E) (Sep. 29, 1999), https://wipo.int/edocs/pubdocs/en/marks/833/pub833.pdf. The Joint Recommendation details criteria that are applicable to determining matters such as what is well-known.

[100] Frankel (n 83).

In the field of GIs, the Agreement establishes (Article 20(31)) that the protection of GIs may be denied, opposed or cancelled, namely on the ground that it is considered "a term customary in common language as the common name for the relevant good in the territory of the Party." In addition, Article 20(32) establishes guidelines for determining whether a term is customary in the common language as the common name for the relevant good in a party's territory.[101]

Finally, one of the most controversial provisions in the Agreement has been Mexico's obligation to accede to UPOV 91, which is opposed by farmers and farmers' organizations[102] as it tightens the protection of breeders' rights, particularly in relation to what is known as the "farmers' privilege."[103]

The USMCA establishes clear timelines for each party to introduce the required changes in its legislation in order to fully comply with the FTA for different categories of IP. The United States, however, does not have to introduce further modifications to its legislation.[104]

Some of the obligations have already been implemented by the Mexican legislation. Thus, the *Ley Federal de Protección a la Propiedad Industrial* in 2020 introduced the patent term extensions through complementary patent certificates. Articles 126 through 136 of the law established that certificates can be granted in case of "unreasonable" delays in the granting of a patent. On the other hand, the *Ley Federal de Derecho de Autor*, enacted in 2020, introduced most of the required reforms regarding copyright and internet service providers. The amendments to these IP regimes show that Mexico has not fully used the transition periods available under the USMCA in respect of certain topics. But this does not apply to other topics, such as the accession to UPOV 1991, which confronts a lot of internal opposition.[105]

[101] Alberto Ribeiro de Almeida and Suelen Carls, "The Criteria to Qualify a Geographical Term as Generic: Are We Moving from a European to a US Perspective?"(2021) 52 *IIC – International Review of Intellectual Property and Competition Law* 444, p. 452.

[102] Gerardo Suarez, "*La Privatización De Las Semillas Representaría Un Golpe Para Las Familias Y Las Economías Campesinas. Atentaría Gravemente Contra Sus Derechos – Consejo Civil Mexicano Para La Sivilcultura Sotenible*" (*Consejo Civil Mexicano para la Sivilcultura Sotenible* 2021) https://www.ccmss.org.mx/aprobar-la-privatizacion-de-semillas-seria-un-golpe-tremendo-para-las-familias-y-la-economia-campesinas/ accessed May 16, 2021; "*la Vía Campesina México: Carta En Defensa De Las Semillas Y La Agricultura Campesina E Indígena – Via Campesina*" (*Via Campesina Español* 2021) https://viacampesina.org/es/mexico-carta-en-defensa-de-las-semillas-y-la-agricultura-campesina-e-indigena/ accessed May 16, 2021.

[103] Jonathan Curci, *The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property* (Cambridge University Press 2010), p. 62, http://proxy.cegepat.qc.ca/login?url=http://search.ebscohost.com/login.aspx?direct=true&scope=site&db=nlebk&AN=323965 accessed May 16, 2021.

[104] See USMCA (n 19), at Article 20.90.

[105] See, for example, CCMSS, "*La privatización de las semillas representaría un golpe para las familias y las economías campesinas. Atentaría gravemente contra sus derechos*" (CCMSS, 2020), https://www.ccmss.org.mx/aprobar-la-privatizacion-de-semillas-seria-un-golpe-tremendo-

2. The EU–MERCOSUR FTA[106]

The negotiation of the FTA between the Member States of MERCOSUR and the EU has a long history. It began in 1999, when the First Summit of Presidents and Heads of State of MERCOSUR and the EU was held. Since then, the negotiations have been suspended and restarted several times.[107] The last round started in 2016.[108] Since the earliest biregional meetings of the MERCOSUR–EU Working Group on Intellectual Property, MERCOSUR had rejected the EU demand to incorporate a specific chapter on IP into the FTA, on the assumption that the EU would aim at imposing TRIPS-plus obligations as a trade-off for agricultural market access. Instead, MERCOSUR proposed a "biregional dialogue" on the subject. The rationale for MERCOSUR's refusal was to avoid the standards set out in the IP chapters negotiated by EU with other developing countries, which had included many TRIPS-plus obligations.[109] Despite these concerns, the outcome of the negotiation is a text with balanced commitments, with the sole exception of the disciplines on GIs.

There are no significant commitments in the field of patent law. The patent section includes a "best efforts" provision regarding the Patent Cooperation Treaty (PCT); this is the only provision regarding patents. This is highly significant, as it is the first time that the EU has made such a concession in an FTA. By not establishing provisions regarding patents, the FTA preserves room for maneuver with respect to the domestic implementation of patent policies, for instance, in relation to access to medicines. It is important to point out that Argentina, Paraguay and Uruguay are

para-las-familias-y-la-economia-campesinas/; Sputnik News, "*Por qué la privatización de las semillas rompería la cohesión social y cultural de México*" (2020), https://mundo.sputniknews.com/20200622/por-que-la-privatizacion-de-las-semillas-romperia-la-cohesion-social-y-cultural-de-mexico-1091830301.html?utm_source=push&utm_medium=browser_notification&utm_campaign=sputnik_inter_es.

[106] See European Commission, EU-MERCOSUR Trade Agreement, Intellectual Property Chapter, published June 18, 2019, https://trade.ec.europa.eu/doclib/docs/2019/september/tradoc_158329.pdf.

[107] See European Commission, *MERCOSUR* (EU 2021), https://ec.europa.eu/trade/policy/countries-and-regions/regions/MERCOSUR/.

[108] In June 2019, the EU and MERCOSUR reached a political agreement and concluded the text-based negotiations. Until May 2021, there was no news regarding the ratification of the Agreement by the Parties. In March 2021, the EU Commission published a paper regarding the impact of the FTA on the Parties, which concluded "that the agreement will have a positive impact on the economies of both the EU and the MERCOSUR countries." See EU Commission, European Commission Services' position paper on the sustainability impact assessment in support of negotiations for the trade part of the European Union-MERCOSUR association agreement (DG TRADE, 2021) p. 21, https://trade.ec.europa.eu/doclib/docs/2021/march/tradoc_159515.pdf accessed May 2, 2021.

[109] Roxana Blasetti, in collaboration with Juan I. Correa, "Intellectual Property in the EU–MERCOSUR FTA: A Brief Review of the Negotiating Outcomes of a Long-Awaited Agreement" (South Centre 2021) Research Paper 128, p. 5, https://www.southcentre.int/wp-content/uploads/2021/02/RP-128.pdf accessed May 2, 2021.

not Members of the PCT, while Brazil has been a Member since 1978.[110] The available evidence on the impact of the PCT on the Latin American countries that – as a result of FTAs – were forced to join it shows that the main beneficiaries of the operation of the Treaty have been foreign applicants, particularly in intensive-patenting technology fields such as pharmaceuticals.[111]

Unlike other FTAs signed by the EU, the plant varieties section allows the parties to comply with UPOV 78 or 91 indistinctly,[112] thereby preserving the choice of most of MERCOSUR countries that adopted UPOV 78 (only Brazil has ratified the UPOV 1991 Act).[113]

It is possible to identify several TRIPS-plus provisions in the field of copyright. They incorporate legal remedies against the circumvention of technological measures.[114] Civil liability is established when an act is done deliberately and for commercial purposes. Regarding the terms of protection, the FTA allows MERCOSUR Members to maintain the terms provided for literary and artistic works, anonymous works, performers' rights and broadcasting organizations[115] by the Berne Convention and, if higher, by their domestic laws. It also introduces the resale right or *droit de suite*,[116] although the provision is not mandatory for the parties. All MERCOSUR countries except Argentina have introduced this right in their domestic legislation.[117]

In the field of trademarks, like in the USMCA, the text indicates that parties cannot refuse to provide protection for well-known marks. The grounds for such a protection include that the mark must be registered in the party providing the protection or registered in another jurisdiction. Differently to the USMCA, the parties "shall take into due consideration the principles established" by WIPO's Joint Recommendations Concerning Provisions on the Protection of Well-Known

[110] WIPO, The PCT now has 153 Contracting States (WIPO 2021), https://www.wipo.int/pct/en/pct_contracting_states.html, accessed May 2, 2021.

[111] See in general Juan I. Correa and Carlos M. Correa,"Impact of the Patent Cooperation Treaty in Latin America" (2020) 69 *GRUR International* 803; Juan de la Cruz Toledo, "*Impacto de La Adhesión Del Perú al Tratado de Cooperación En Materia de Patentes*," in Santiago Roca T., *Propiedad Intelectual y Comercio en el Perú: Impacto y Agenda Pendiente* (Surco 2007).

[112] See EU–MERCOSUR Agreement (n 106), at Article X.41.

[113] See UPOV, Members of the International Union for the Protection of New Varieties of Plants.

[114] See EU–MERCOSUR Agreement (n 106), at Article X.19.

[115] Blasetti (n 109), p. 12.

[116] Understood as the right held in many legislations by visual artists, such as painters, sculptors, draftsmen and photographers, to participate in a percentage of the price obtained in each resale of their works. See Catherine Jewell, "The artist's resale right: a fair deal for visual artists," WIPO Magazine June 2017, https://www.wipo.int/wipo_magazine/en/2017/03/article_0001.html#:~:text=At%20present%2C%20the%20artist's%20resale,cannot%20be%20sold%20or%20waived, accessed May 2, 2021.

[117] ADAGP, Indicative list of countries whose legislation provides for the resale right, https://www.adagp.fr/en/indicative-list-countries-whose-legislation-provides-resale-right accessed May 2, 2021.

Marks.[118] The trademark section of the IP chapter also includes the "coexistence" between trademarks and GIs.[119]

Finally, the general rules concerning the protection afforded to GIs are found in Articles 33 to 39. MERCOSUR agreed to extend the higher protection for wines and spirits provided for in TRIPS Article 23 to all agricultural products. Hence, it enhanced the TRIPS protection standards by incorporating evocation as an infringement of the holder's rights and the renouncement of invoking exceptions allowed under the TRIPS Agreement's Article 24. A crucial component of the FTA is Annex II, which contains the list of the mutually accepted GIs. Those in the list have the level of protection given by the FTA, which substitutes that accorded by national laws – which means that the rules governing in the field of (mutually) recognized GIs are the rules of the FTA.[120]

A distinctive feature of the GI section is Article 35.9, which lists the "particular cases" where a specific level of protection is defined for MERCOSUR countries that does not amount to full protection of the respective GIs. This provision allows for what are known as "grandfather" clauses. The continued use of terms by prior users is guaranteed but is "subject to certain conditions." The conditions are specified for each GI, but basically they require the term having been used in good faith and in a continuous manner without using references to the actual origin of the GI in the label. It is also remarkable that the continued use is only to the benefit of those prior users that are included in a list for each MERCOSUR country.[121]

If approved, the implementation of the GI section could be cumbersome as it will require addressing conflicts of interests between prior users in MERCOSUR countries and European GI rightsholders. The prior user's right is weaker than that of the GI holder as is it is subject to proof that the prescribed conditions are met. Therefore, concerns may arise regarding whether prior users may be subject to litigation with the aim of excluding them from the market.

The FTA also has rules on generic terms. Article 35.10 states that protected GIs shall not become generic in the territories of the parties. This is the main rule. However, it is also foreseen that a GI protected in a contracting party may not be protected in another contracting party if the term (identical to the GI) is considered a common name of the goods concerned in the territory of the latter party (Article 35.6). Nevertheless, the FTA does not establish the criteria to consider a GI as "generic" in another contracting party: the national rules will determine whether the term is generic or not.[122]

[118] EU-MERCOSUR (n 106), at Article X.24.
[119] Ibid., at Article X.25.
[120] Blasetti (n 109), p. 14.
[121] See Roxana Blasetti, "Geographical Indications: A Major Challenge for Mercosur" (2020) 69 *GRUR International* 1113.
[122] De Almeida and Carls (n 101), p. 452.

In a recent decision, an Argentinian court rejected the registration of a trademark based on the preeminence of a GI in Europe. In this case, the court rejected the application for the registry of "Gorgonzola" as a trademark by the Italian consortium Gorgonzola (manager of the Gorgonzola GI), based on the reasoning that "Gorgonzola" is not sufficiently distinctive vis-à-vis the generic term that identifies this particular type of cheese. The court also held that under Argentine trademark law, national or foreign GIs cannot be registered.[123]

In conclusion, the IP chapters of USMCA and the EU–MERCOSUR FTAs show a significant difference with respect to parties' concessions related to IP provisions. While there is some commonality with respect to trademarks and copyrights, in the field of patents, test data and plant variety rights, considerable room for maneuver is found in the EU–MERCOSUR FTA, while the USMCA goes even further with TRIPS-plus provisions.

D. STRENGTHENING AND EXPANSION OF IP PROTECTION BEYOND FTAS

I. *Domestic Implementation Process*

As discussed, the inclusion of comprehensive chapters on IPR protection in FTAs has become an important feature of the international trade policy of the EU and the United States. Not surprisingly, developing countries – and in particular Latin American ones – generally have a defensive position regarding the introduction of IP provisions in bilateral and regional FTAs that may further limit their policy space to address current systemic problems, such as access to health, food and knowledge.[124] The introduction of TRIPS-plus provisions entails adopting IP standards from developed countries,[125] thus shaping a complex network of provisions, which may not be harmoniously designed or aligned with the domestic needs and conditions. As pointed out by Seuba,

> the exportation of IP standards concerns the postimplementation of the IP system of countries that have negotiated with the United States, the EU and EFTA. The resulting legal framework resembles a patchwork, since it is the outcome of a mix of obligations that collect some of the strongest though not necessarily harmonious

[123] "CONSORZIO PER LA TUTELA DEL FORMAGGIO GORGONZOLA c/USDEC s/ CESE DE OPOSICION AL REGISTRO DE MARCA", Expte. n° 1.901/2018.

[124] Dreifuss and Mogae (n 39); Mercurio (n 25); Frankel (n 83); Santa Cruz (n 26); Correa, "Implications of Bilateral Free Trade Agreements on Access to Medicines" (n 91); Drexl, Grosse Ruse-Khan and Nadde-Phlix (n 12).

[125] Some provisions may also have to be implemented in those countries, as Drexl points out. See Josef Drexl, "Intellectual Property and Implementation of Recent Bilateral Trade Agreements in the EU," in Drexl, Grosse Ruse-Khan and Nadde-Phlix (n 12), pp. 266–270.

> provisions originating from OECD partners, which moreover are added to an already existing national and regional legal acquis.[126]

Once an FTA is finalized and signed, the domestic procedures for its implementation need to be initiated. There is a significant difference in the EU and US requirements for an agreement to enter into force domestically. On the EU side, the agreement enters into force once it is internalized and approved by the European Parliament, known as a "*saisine*." For "EU-only" agreements, the EU can notify its consent to the depository, and the agreement will apply in full ("enter into force") once the other party notifies its ratification. For "mixed" agreements, the EU now requires the ratification of all EU Member States.[127] In the meantime, the EU can only apply the agreement provisionally in full or otherwise in part.[128]

In the case of the United States, on the other hand, once an agreement is concluded, it must go through a "certification" process under the US law. This process is explained by the US International Trade Administration as follows:

> Before an FTA enters into force, US 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 US 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.[129]

This process, which is meant only to ensure the implementation of the agreed commitments by the US partner, has been used to further narrow down the partner's flexibilities, as in some cases additional obligations are imposed on the FTA counterpart. For instance, in the case of the US–Peru FTA, it was noted that during the "certification" many of the amendments aiming to reduce the negative impact of

[126] Ibid., p. 294.

[127] Before the Lisbon Treaty, IPRs were one of the so-called mixed competences, which meant that agreements on trade-related aspects of IP rights came into force only after all the EU Member States (national Parliaments) ratified them. The process of mixed agreements gave the Member States an opportunity to influence such agreements more significantly, in the stage of negotiations and during the national procedure of ratification. Since December 1, 2009, the last possibility to influence agreements with trade-related aspects has been open in the Council and European Parliament procedures. See Ludmila Štěrbová, *Concept of IPRs International Protection and Enforcement in EU Trade Agreements* (University of Economics, Prague, 2011), http://g-casa.com/conferences/zagreb/papers/Sterbova.pdf, accessed April 12, 2021.

[128] EU Commission, "Negotiating EU Trade Agreements: Who Does What and How We Reach a Final Deal" (DG TRADE, 2012) https://trade.ec.europa.eu/doclib/docs/2012/june/tradoc_149616.pdf, accessed April 20, 2021.

[129] International Trade Administration, Free Trade Agreement Compliance, https://legacy.trade.gov/fta/compliance.asp, accessed May 3, 2021.

IP rights were disregarded.[130] Significantly, there is no similar procedure applied to check the US implementation of its obligations under the FTA and, in fact, many of them are never implemented, such as in the case of the patent linkage provisions that go beyond the US legislation.[131]

Once an FTA enters into force, then the United States also observes the enforcement of IP provisions and notes any alleged deviation through bilateral committees and the reports produced in accordance with the Special Section 301 of the US Trade Act.

II. *Special Section 301*

The United States interferes in the domestic design and implementation of IP rules through a unilateral mechanism that aims to "identify third countries in which the state of IPR protection and enforcement gives rise to the greatest level of concern." The Special Section 301 was introduced in 1988 into the US Trade Act by the Omnibus Trade and Competitiveness Act, signed by President Ronald Reagan. This section was an elaboration – specifically for IP – upon Section 301, which was incorporated into the US Trade Act of 1974 granting the USTR a range of responsibilities and authorities "to investigate and take action to enforce US rights under trade agreements and respond to certain foreign trade practices."

Under the Special Section 301, the USTR is authorized to adopt, at its discretion, various measures to remedy foreign trade practices that affect US exports. It authorizes the USTR to (1) impose duties or other import restrictions, (2) withdraw or suspend trade agreement concessions or (3) enter into a binding agreement with the foreign government to either eliminate the conduct in question (or the burden to US commerce) or compensate the United States with satisfactory trade benefits. The USTR must give preference to duties (i.e. tariffs) if action is taken in the form of import restrictions.

Several Latin American countries are under the "inspection of the USTR's Special Section 301." In particular, Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Mexico, Paraguay, Peru and Venezuela were mentioned in the latest Special Section 301 Report.[132] In general, the United States complains regarding the following: the implementation of patent policies, such as limitations to the protection of patent subject-matter and delays in the examination process of patent

[130] See Santiago Roca, "*Demócratas, Salud Pública y Propiedad Intelectual En El APC Perú-EE.UU.*" (2009) X *Puentes* 5, pp. 5–7.

[131] F. M. Abbott, "Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law" (ICTSD 2006) 12, pp. 9–11, https://unctad.org/system/files/official-document/ictsd2006ipd12_en.pdf, accessed May 3, 2021.

[132] USTR, 2021 Special 301 Report (USTR 2021) Report https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20(final).pdf accessed May 3, 2021.

applications;[133] copyright enforcement measures in relation to broadcasting and digital platforms for distribution of copyrighted content[134] and test data protection.[135] Regarding GIs, the United States notes the negative effect of the expansion of GI protection through FTAs between the EU and third countries. Therefore, it includes, in the "watch list," those countries that are negotiating with the EU bilateral or regional agreements that include commitments to expand GIs protection.[136]

The main objective of Special Section 301 has been to allow the US Administration to exert pressure on other countries by threatening (and eventually implementing) trade retaliatory measures. As noted by one commentator, it "was shaped quite deliberately to give the Executive the tools to use diplomatic and economic pressure to achieve a more 'equitable' world trading system, to the benefit of US commerce."[137]

A clear example of the problems raised by the application of Special Section 301 is shown in the case of Chile, which entered into an FTA with the United States in 2004, but only in 2010 put in place a system for copyright content takedown. Under this system, unlike under the US Digital Millennium Copyright Act,[138] removal of content by intermediaries requires a court order to comply with Chile's constitution and its obligations under the American Convention on Human Rights. The FTA permits this interpretation, but the USTR has strongly criticized it, urging Chile "to amend its Internet service provider liability regime to permit effective action against any act of infringement of copyright and related rights." Chile remains on the Priority Watch List in the most recent Special 301 Report published by the USTR, for "the serious concerns regarding longstanding implementation issues with a

[133] The USTR's Special 301 Report of 2021 claims that Argentina, Brazil, Chile and Ecuador present several deficiencies regarding the legal protection for patents, in particular for pharmaceuticals. See USTR, Special Section 301. Countries under the Priority Watch List and Watch List.

[134] Along the same line, the USTR report claims that Argentina, Chile, Colombia, the Dominican Republic and Mexico, among others, have high levels of online piracy and lack effective enforcement.

[135] USTR (n 132). The USTR claims that pharmaceutical stakeholders remain concerned that law and regulations do not provide for a similar level of protection against unfair commercial use, as well as unauthorized disclosure of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products in Argentina, Brazil and Chile.

[136] In response to the EU's aggressive promotion of its exclusionary GI policies, the United States engages bilaterally to address concerns resulting from the GI provisions in existing EU trade agreements, agreements under negotiation and other initiatives, including with Argentina, Brazil, Chile, Ecuador, Mexico, Paraguay and Uruguay. Idem., p. 26.

[137] Shirley A. Coffield, "Using Section 301 of the Trade Act of 1974 as a Response to Foreign Government Trade Actions: When, Why, and How," 6 *North Carolina Journal of International Law and Commercial Regulation*, No. 3 (1981), p. 381.

[138] United States Congress, Senate, Committee on the Judiciary, "The Digital Millennium Copyright Act of 1998: Report Together with Additional Views [to Accompany S. 2037)" ([Washington, DC?]: [US GPO,], [1998] 1998) https://search.library.wisc.edu/catalog/999840447102121 accessed May 4, 2021.

number of intellectual property (IP) provisions of the United States–Chile Free Trade Agreement (Chile FTA)."[139]

III. *EU Report on the Protection and Enforcement of Intellectual Property Rights in Third Countries*

A mechanism similar to the US Special Section 301 has been adopted in the EU. The report on the protection and enforcement of IPRs in third countries identifies third countries in which the state of IPR protection and enforcement (both online and offline) raises concerns for the EU.[140] Like in the case of the United States, the EU Commission unilaterally determines which countries do not, in its view, comply with the desirable IP standards. For this purpose, it determines three priority levels, in which several Latin American countries are included.

Argentina, Brazil and Ecuador are classified as "Priority 3 countries." Priority 3, according to the EU, presents serious problems in the area of IP, causing considerable harm to EU businesses[141] In particular, the EU complains regarding the following: restrictive patentability criteria (Argentina); backlog for registration of patents and trademarks (Argentina, Brazil); copyright piracy (Brazil, Mexico); border measures for IP-protected goods (Argentina, Brazil, Mexico); test data to obtain marketing approval (Argentina, Brazil) and non-compliance with UPOV 1991 standards (Argentina, Brazil, Ecuador, Mexico).[142]

Additionally, in contrast to the United States, the EU pressures for the enforcement and strengthening of GI protection in Latin America. In the 2021 report, for instance, it noted that:

> The provisions on the protection of geographical indications contained in the EU–Colombia, Peru and Ecuador Trade Agreement and in the EU–Central America Association Agreement also need to be closely monitored with regard to issues related to the recognition of EU GIs as well as concerns regarding their effective protection, in order to make sure that any observed usurpation is addressed in an efficient manner. There are also concerns as regards proofs of prior users entitled to use protected terms and effective protection of individual terms of compound names.[143]

In conclusion, both the United States and the EU pursue policies that seek to dissuade Latin American and other developing countries from strengthening their

[139] USTR (n 132)., p. 39.
[140] EU COMMISSION, "Report on the Protection and Enforcement of Intellectual Property Rights in Third Countries" (European Commission 2021), Commission Staff Working Document SWD97(final) https://trade.ec.europa.eu/doclib/docs/2021/april/tradoc_159553.pdf accessed May 1, 2021.
[141] Ibid., p. 11.
[142] Ibid.
[143] Ibid.

national IP regimes. A central difference between the two policies is the potential impact that Special Section 301 has on the trade in goods, since it allows the United States to impose trade sanctions on countries that it considers are not implementing an "effective IP policy." The approach applied by the EU is different insofar as it does not involve the imposition of trade sanctions, but rather pushes for modifications through "cooperation" clauses included in the FTAs. However, this is not possible in those countries with which no FTAs have been concluded.

E. DIRECT APPLICABILITY OF INTERNATIONAL IP RULES

Many Latin American countries have a long-settled tradition of enforcing international treaties, including trade agreements, in their domestic systems through the direct application of their provisions by courts.[144] Treaty provisions can be invoked before and applied by national judges where they are deemed self-executing.[145]

There is substantial variation among monist states[146] as to which treaties require (or do not) implementing legislation.[147] While most Latin American countries follow a monist approach, there are differences regarding how the international treaties are incorporated into their national legal systems.

In Argentina, a binding treaty becomes part of the state's legal system.[148] This implies that it may be applied by judges and invoked by private parties once it is approved in accordance with the prescribed constitutional procedure.[149] In Brazil,

[144] Maria Angela Jardim de Santa Cruz Oliveira, *International Trade Agreements before Domestic Courts* (Springer International Publishing 2015) http://link.springer.com/10.1007/978-3-319-13902-9 accessed June 1, 2021, p. 195.

[145] Cottier and Schafer indicate that "direct effect" is used to mean that a private person in a state (or Union, respectively) may base a claim in, and be granted relief from, the domestic courts of that state against another private person or the state on the basis of the state's obligations under an international treaty. Such claims can be made without a transformation of the obligation by national or regional rule-makers. They may equally be made against implementing legislation on grounds that such legislation is not compatible with international law. See T. Cottier, "The Relationship between World Trade Organization Law, National and Regional Law" (1998) 1 *Journal of International Economic Law* 83. In most Latin-American countries, the Human Rights Treaties are self-executory. This is a common feature of Latin-American countries, the openness of the domestic legal system to international human rights law, including by giving primacy to human rights treaties over national laws. In Argentina, for instance, the approach used was the direct and explicit constitutionalization of numerous human rights treaties.

[146] See, for example, Jean-Marie Henckaerts, "Self-Executing Treaties and the Impact of International Law on National Legal Systems: A Research Guide" (1998) 26 *International Journal of Legal Information* 56.

[147] See, for example, David Sloss, "Domestic Application of Treaties" (2020) *Santa Clara Law Digital Commons* 1, p. 4.

[148] Pfizer Inc. c/ Instituto Nacional de la Propiedad Industrial s/ denegatoria de patente 21/05/2002 – Fallos: 325:1056.

[149] Ibid., see in general André Luis Ribeiro Barbosa, "'Direct Effect' of International Agreements within the Brazilian Legal System: The Case of the TRIPS Agreement", https://www.wti.org/media/filer_public/da/83/da83bb7a-ed20-4c39-8fcb-bb2ba3ffa03b/andre_barbosa_thesis.pdf accessed February 2, 2021; José Dobovšek, "Inclusion of Treaties in Argentine Law" (2012) 6

international treaties, once incorporated, have the same validity and efficacy as federal law.[150] Paraguay has also established the direct applicability of international treaties[151] In Mexico, once an international treaty is ratified by the Senate, it becomes domestic law with self-executing character.[152]

The self-executing character of treaty provisions becomes an important element in the field of IP, because the parties loose the room they may have to define the way in which the treaty obligations will be applied at the national level and right holders can directly invoke them against third parties, even in the absence of domestic regulations incorporating the treaty provisions.[153] Interestingly, in order to avoid the self-executing character of the IP provisions in the EU–MERCOSUR FTA, a provision in the final negotiated text states that:

> Nothing in this Chapter shall be construed as conferring rights or imposing obligations on persons other than those created between the Parties under public international law, nor as permitting this Chapter to be directly invoked in the domestic legal systems of the Parties. A Party shall not provide for a right of action under its domestic law against the other Party on the ground that a measure of the other Party is inconsistent with this Chapter.[154]

This provision is of great interest for Argentina, since the issue of the direct application of the TRIPS Agreement was debated in the courts notably in relation to the grant of precautionary measures provided for by Article 50 of the TRIPS Agreement.[155] While this particular provision is highly relevant to preserve the margin of maneuver in Argentina and Paraguay, the situation in Brazil and

AEQUITAS-Virtual https://p3.usal.edu.ar/index.php/aequitasvirtual/article/view/1157/1401#:~:text=CONCLUSIONES-,a.,los%20jueces%20y%20los%20particulares.

[150] Jardim de Santa Cruz Oliveira (n 144), p. 68.

[151] Regarding IP, the decisions on Tabacalera Boqueron I and Tabacalera Boqueron II have established the direct applicability of the Paris Convention for the Protection of Industrial Property. See CSJ (Supreme Court of Justice of Paraguay), Acuerdo y Sentencia 22/2001, sala Penal, "Tabacalera Boquerón S.A. c/ Res. N 98, 2001, Paraguay; and CSJ (Supreme Court of Justice of Paraguay), Acuerdo y Sentencia 23/2001, sala Penal, "Tabacalera Boquerón S.A. c/ Res. N 48, 2001.

[152] Miranda J. and Partida J. C. "Mexico: Quasi-Judicial Review of Trade Remedy Measures by NAFTA Panels," in Yilmaz M. (ed.), *Domestic Judicial Review of Trade Remedies*, (Cambridge University Press, 2013).

[153] The judicial doctrines in monist states distinguish between treaty provisions that are directly applicable and those that are not directly applicable. Many states use the terms "self-executing and non-self-executing" to distinguish between these two classes of treaty provisions. See Miranda J. and Partida J. C. (2013), *op. cit.*

[154] EU–MERCOSUR (n 106), Article X.1.3.

[155] "*Informe Preliminar N° 1 Del Observatorio Del Acuerdo de La Unión Europea y MERCOSUR; Documento 3: Propiedad Intelectual*" (OBSERVATORIO DEL ACUERDO UNIÓN EUROPEA – MERCOSUR 2020) http://www.derecho.uba.ar/institucional/observatorio-acuerdo-MERCOSUR-ue/documentos/informe-preliminar-propiedad-intelectual.pdf accessed May 15, 2021, p. 6.

Uruguay[156] is different, since in any case in these countries parties cannot directly invoke international treaties in local courts.

In the Andean Community, the Cartagena Agreement[157] is self-executing and of immediate application. It does not require the Member States to adopt rules for its transposition to make effective its rules and those adopted pursuant to the Agreement; that is, the Community rules are directly integrated into the internal order of each country without the need of being approved by the legislative or executive bodies of any of the Member States.[158] Regarding international agreements, most Andean Members have recognized in their Constitutions the direct effect of international treaties including trade-related agreements, although they have no direct effect for the Community as a whole.[159]

Paradoxically, neither the United States nor the EU grant direct effects to trade agreements. In the United States, this was made explicit in the case of CAFTA, where it is stated that nothing in the FTA shall be construed to amend or modify any law of the United States or to limit any authority conferred under any law of the United States (Section 102 of the US implementation Act).[160] Furthermore, in the Uruguay Round Agreements Act, the US clarifies that: "No provision of any of the Uruguay Round Agreements, nor the application of any such provision to any person or circumstance, that is inconsistent with any law of the United States shall have effect."[161] The provision specifically indicates that in case of contradiction between a WTO rule and domestic law, the latter will prevail. Although it has been argued that US courts could nonetheless apply the WTO agreements, including their authoritative interpretations and the decisions taken by the dispute settlement bodies, to interpret statutes on the basis of the theory of consistent interpretation

[156] In Uruguay, the Constitution is silent regarding the domestic implementation of treaties. According to Courts International, treaties have the same hierarchy as laws and have to be domestically implemented by laws. See Herber Arbuet Vignali, "*¿QUIÉN PRIMA? El lastre de una teoría heredada, sobre un problema real del derecho en la posmodernidad*", CURI, Estudio 08/13, 2013, available at: http://curi.org.uy/archivos/estudiocuri08del13arbuet.pdf accessed May 15, 2021.

[157] The Cartagena Agreement signed in 1969 establishes the Andean Community through a subregional integration agreement. See Codification of the Andean Subregional Integration Agreement, http://www.sice.oas.org/Trade/Junac/Carta_Ag/cartag1e.asp.

[158] TJCA, *Proceso N° 07-AI-99 del 12 de noviembre de 1999, publicado en la Gaceta Oficial del Acuerdo de Cartagena N° 520 de fecha 20 de diciembre de 1999.*

[159] TJCA, PROCESO 01-AI-2001 *Acción de Incumplimiento interpuesta por la Secretaría General de la Comunidad Andina contra la República Bolivariana de Venezuela, alegando incumplimiento de los artículos 4 del Tratado de Creación del Tribunal y 16 de la Decisión 344 de la Comisión; así como de las Resoluciones Nos. 424 y 457 de la Secretaría General* 23 July 2002, https://www.tribunalandino.org.ec/decisiones/AI/01-AI-2001.pdf, accessed May 15, 2021.

[160] Dominican Republic–Central America–United States Free Trade Agreement Implementation Act, Law 109-53, 109th Cong., 1st sess. (2005)

[161] See "United States, The Uruguay Round Agreements Act" (URAA; Pub.L. 103–465, 108 Stat. 4809), enacted December 8, 1994, Sec. 102 regarding the Relationship of the Agreements to United States law and state law.

(Charming Betsy), nothing indicates that this has ever been the case in US courts' decisions.[162]

In the EU, the WTO agreements share the status of a "mixed agreement" because their subject-matter "falls in part within the competence of the Union and part with that of the Member States." The European Court of Justice (ECJ) has held that the GATT, although being an integral part of the Community and legal order and having binding effect, did not generate subjective rights for individuals that they could invoke.[163] And although the WTO is rule-based and its dispute settlement mechanism is juridical, the ECJ has denied the direct invocation of WTO agreements at the EC level, in Portugal *v.* Council.[164] This leads to a certain imbalance in the implementation of bilateral or regional treaties, since the United States and the EU preserve some room for adapting the agreed-upon rules to their respective legal systems, an option that many Latin American countries cannot exercise due to their constitutional approaches toward international treaties.

F. CONCLUSION

Ideally, IP policy should be defined in accordance with the level of technological and economic development and the particular conditions and needs of the country where IP protection is conferred. However, WTO Members are subject to the rules of the TRIPS Agreement that set out minimum standards that are to be interpreted by external bodies. While the Agreement provides for certain flexibilities, WTO case law and the Doha Declaration on the TRIPS Agreement and Public Health only confirmed some of them after Latin American countries were bound to adapt their legislations to comply with the Agreement. This temporal factor and the threat of trade retaliations under the DSU rules may explain why Latin American countries did not make full use of the policy space they had to establish IP rules more suitable to their national contexts and levels of technological and economic development.

Such room for action was further eroded by the negotiation and adoption of FTAs containing TRIPS-plus provisions and by committees created to discuss IP issues bilaterally, which restrict even more the margin of maneuver in IP policy. In addition, the pressure exerted through instruments such as Special Section 301 and its EU equivalent are likely to have discouraged the implementation of policies better adapted to the context of Latin American countries. While the

[162] H. R. Fabri, "Is There a Case – Legally and Politically – for Direct Effect of WTO Obligations?" (2014) 25 *European Journal of International Law* 151.

[163] Case 21/72, International Fruit Company NV and others *v.* Produktschap voor Groenten en Fruit, [1972] ECR 1219, at para. 21. See also Case C–280/93, Germany *v.* Council (the Bananas case), [1994] ECR I–4973, at para. 105, where the ECJ applies a test based on "the spirit, the general scheme and the terms of the GATT" to exclude direct effect.

[164] Case C–149/96, Portuguese Republic *v.* Council of the European Union, [1999] ECR I–8395, at paras 34–46.

interests of the developed countries promoting TRIPS-plus provisions have been generally the same, some divergences – especially in relation to the protection of GI issues – have become apparent, as the EU and the United States have conflicting interests in this field. This has put Latin American countries in a complex position while negotiating and implementing FTAs.

The impact of external rules in shaping Latin American IP regimes has been amplified in some countries by the fact that, unlike in the United States and the EU, constitutional rules accord direct effect to international treaties, including the TRIPS Agreement. This removes even further the room for maneuver of such countries for the implementation of their treaty obligations. National courts have played a still limited but important role in the process of interpretation and enforcement of IP rules adopted pursuant to the countries' international obligations and other external pressures.

In summary, the recent evolution of IP policy and legislation in Latin America can only be understood on the basis of the external factors that influenced or determined them, in the light of the particular features of the legal systems applied in the region.