

Ensuring incentives for innovation and access to medicines

The balance struck in the Trans-Pacific Partnership
Agreement on intellectual property
(patent and regulatory data)
protection for pharmaceutical products

Rosine M. Plank-Brumback



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Rosine M. Plank-Brumback



This document has been prepared by Rosine Plank-Brumback, Consultant at the Economic Commission for Latin America and the Caribbean (ECLAC) office in Washington, D.C.

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“We are disappointed that the Ministers failed to secure 12 years of data protection for biologic medicines, which represent the next wave of innovation in our industry...[I]t appears that the Ministers missed the opportunity to encourage innovation that will lead to more important, life-saving medicines that would improve patients' lives”.

*Pharmaceutical Research and Manufacturers of America (PhRma)*¹

“If adopted, the rules will delay generic and biosimilar competition, making the medicines upon which people depend to stay alive expensive for longer and, as a consequence, unobtainable”.

*Public Citizen's Global Access to Medicines*²

“We are actually at this time as IGBA recommending that governments look at science and regulatory convergence much more than intellectual property convergence or harmonization of intellectual property systems. We think there has been an overemphasis on that. We want to put more emphasis on some of the science and regulatory issues that are crucially important to bring these products to market”.

*International Generic and Biosimilar Medicines Association (IGBA)*³

¹ Pharmaceutical Research and Manufacturers of America, *PhRMA Statement on the Transpacific Partnership Negotiations* (Oct. 5, 2015) <http://phrma.org/media-releases/phrma-statement-on-the-transpacific-partnership-negotiations> [accessed June 12, 2016].

² Public Citizen's Global Access to Medicines, *TPP Transition Periods on Pharmaceutical Intellectual Property Rules: Bad Rules Coming Soon in a TPP Country Near You* (Oct. 9, 2015) <http://www.citizen.org/documents/TPPTransitionPeriodsonPharmaceuticals.pdf> [accessed June 12, 2016]. See also e.g., <http://www.msfaccess.org/about-us/media-room/press-releases/statement-msf-official-release-full-text-trans-pacific> [accessed June 12, 2016].

³ Jim Keon, Chair, International Generic and Biosimilar Medicines Association, remarks at *Working Session 10: Principles to Foster Trade in Generic and Biosimilar Medicines*, WTO Public Forum (Sept. 30, 2015). https://www.wto.org/audio/2015_09_30_pf15_work_session10.mp3. [accessed June 12, 2016]. Under regulatory convergence, the associations and companies comprising IGBA have identified the single development for generic medicines, the single development for biosimilars, and the mutual recognition of good manufacturing practices and inspections, as key issues.

Introduction

States have recognized that everyone has the right to enjoy the highest attainable standard of health and the benefits of scientific progress and its application, but they have also recognized the right of everyone to benefit from the protection of the moral and material interests resulting from one's authorship of any scientific, literary or artistic production. These human rights to health and to intellectual property protection have been stipulated in Articles 12.1, 15.1(b) and 15.1(c) of the International Covenant on Economic, Social and Cultural Rights (1966), which 164 member states of the United Nations, among which 30 states from the Western Hemisphere, have ratified or acceded to, and an additional 2 in the hemisphere have signed.⁴

The United Nations Economic Commission for Latin America and the Caribbean (ECLAC) commissioned this study to analyze the implications of the balance struck under the Trans-Pacific Partnership Agreement (TPPA) between the right to health and access to next-generation medicines on the one hand, and on the other, the private right to intellectual property protection and the need to maintain profit-earning incentives to spur innovation and research and development. The study focuses on the patent and data-related intellectual property protection provisions of the TPPA, specifically regarding pharmaceutical (small-molecule and biologic⁵) products, including on patent

⁴ International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, arts. 12.1, 15.1(b), & 15.1(c), 993 U.N.T.S. 3, available at https://treaties.un.org/doc/Treaties/1976/01/19760103%2009-57%20PM/Ch_IV_03.pdf. The treaty entered into force on January 3, 1976. The 30 states in the Western Hemisphere that have ratified or acceded to the Covenant are: Argentina, Bahamas, Barbados, Belize, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, St. Vincent and the Grenadines, Suriname, Trinidad and Tobago, Uruguay, and Venezuela. Cuba and the United States have signed the treaty. https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en [accessed June 12, 2016].

⁵ Biologics are therapeutic substances derived from the human body or animals, and products of biotechnology; e.g., vaccines, blood products, cellular and gene therapies (WHO, WIPO, and WTO, 2013, p. 34). Biologics are medical drugs derived from life forms. "These include proteins (including antibodies), and nucleic acids (DNA, RNA or antisense oligonucleotides) used for therapeutic or in vivo diagnostic purposes, and are produced by means other than direct extraction from a native (non-engineered) biological source." USDOC, "The Pharmaceutical and Biotech Industries in the United States" <https://www.selectusa.gov/pharmaceutical-and-biotech-industries-united-states> [accessed June 12, 2016]. "Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics

duration, linkage and term extensions as well as clinical test data protection and market exclusivity.⁶ The study considers the position of the United States in this respect, as it has been and remains the world's principal demandeur for high intellectual property rights (IPR) standards in trade agreements, including the TPPA.⁷

The TPPA is a free trade agreement among twelve Asia-Pacific countries; namely, Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States, and Viet Nam. If and when the TPPA enters into force^{8 9}, it will set new common IP protection

can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available." FDA <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm> [accessed June 12, 2016].

⁶ TPP trade ministers announced that they had concluded successfully their negotiations on Oct. 5, 2015 in Atlanta, Georgia, "Trans-Pacific Partnership Ministers' Statement," <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/trans-pacific-partnership-ministers> [accessed June 12, 2016]. The text of the TPP Agreement was released officially to the public on Nov. 5, 2015, and then underwent legal scrubbing by the TPP negotiating partner countries. This study relies on the full TPPA text released by the Ministry of Foreign Affairs and Trade of New Zealand on January 25, 2016 <http://tpp.mfat.govt.nz/text>, and specifically as regards intellectual property, chapter 18 of this version <https://www.mfat.govt.nz/assets/securedfiles/trans-pacific-partnership/text/18-intellectual-property-chapter.pdf> [accessed June 12, 2016]. New Zealand is the Depositary of the TPPA as designated under Article 30.7.1. This study also relies on summaries of the TPPA released by the negotiating governments, such as the TPP Fact Sheets prepared by the N.Z. Ministry <http://www.tpp.mfat.govt.nz/> and the TPP chapter summaries released by the White House <https://medium.com/the-trans-pacific-partnership> [accessed June 12, 2016].

⁷ Biosimilars, sometimes called "generic biologics," "follow-on biologics" or "subsequent-entry biologics," are products that are similar in terms of quality, safety, and efficacy to the originator or reference biologic products (WHO, WIPO, WTO, 2013, p.52).

⁸ The TPPA was signed by the 12 TPP negotiating governments on Feb. 4, 2016 in Auckland, New Zealand. <https://www.mfat.govt.nz/en/media-and-resources/news/trans-pacific-partnership-signing/> [accessed June 12, 2016] Article 30.5.1 of the TPPA provides that the Agreement shall enter into force 60 days after the date on which all the original signatories have notified the Depositary in writing of the completion of their applicable legal procedures (to ratify the Agreement). This can be called the first and most inclusive option for entry into force. Thus the earliest the TPPA could enter into force would be if all 12 signatory Parties were to ratify the agreement on or before Feb. 4, 2018, and then it would enter into force 60 days after the last signatory deposited its notification with New Zealand. If not all the 12 signatories have completed their respective procedures within two years of the signing of the Agreement (i.e., by Feb. 4, 2018), a second option under Art. 30.5.2 is that the TPPA enters into force 60 days after the expiry of the two-year period (i.e., on April 5, 2018), if at least 6 signatories (including the U.S. and Japan) have notified, and provided they account together for 85% or more of the combined GDP of the 12 signatories in 2013. A third option under Art. 30.5.3 when the first two have lapsed, is that the Agreement enters into force 60 days after 6 signatories (including the U.S. and Japan) have notified the Depositary that they have completed their legal procedures, with the same GDP proviso. The bottom line is that the TPP will not enter into force unless the United States notifies the Depositary in writing that it has completed its legal procedures, giving the U.S. blocking power. This is because even if the U.S. Congress accepts the TPPA, the U.S. administration can wait to provide written notification of U.S. completion of its legal procedures until it is satisfied with the implementation programs of the other signatories—as it has in previous FTAs—thus preventing the reaching of the requisite number of 12 original signatories under Art. 30.5.1 as the clock ticks for the 2-year post-signing deadline. And the US—with its more than \$17 trillion economy—can similarly block entry into force under the next two options, as there is no combination of TPP GDPs that can reach 85% of combined TPP GDPs without the U.S.—or without Japan. An original signatory notifying the Depositary that it has completed its legal procedures following the entry into force of the Agreement must pass approval by the Parties in order for the Agreement to enter into force for it within 30 days of its notification <https://www.mfat.govt.nz/assets/securedfiles/trans-pacific-partnership/text/30-final-provisions-chapter.pdf> [accessed March 31, 2015]. As the U.S. administration has said: "The TPP will enter into force with each partner only when the United States is satisfied that the other Party has

standards for its original member countries. These standards also will impact and influence the broader regional and global rules and marketplace, given the commercial might of the TPP member countries (40% of global economy and 800 million people), and the expectation that other countries will accede to the TPPA in the future.¹⁰ Moreover, TPP member states as members of the World Trade Organization (WTO) are obligated to extend national treatment and most-favored-nation (m-f-n) treatment under the WTO Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) (WTO, 1994, Annex 1C, arts. 3 and 4).¹¹ These WTO obligations require *inter alia* that "any advantage, favour, privilege or immunity" with respect to intellectual property granted to TPP nationals must be accorded to other WTO nationals. Examples of the kinds of benefits provided under the TPPA that would have to be extended on an m-f-n basis—if newly implemented by a TPP Party—are the grant of: a patent term adjustment/extension/restoration to compensate the patent holder for regulatory delays in the issuance of a patent or a marketing approval for a pharmaceutical product, or the minimum 8 (or comparable 5+)-year exclusivity period for undisclosed test data submitted to a regulatory authority on the safety and efficacy of a new biologic in order to obtain marketing approval for the product. Even if the TPPA does not impose any higher standard than a TPP Party already applies in a specific instance, the effect of consolidating the standard into an international requirement means that the Party cannot reverse course below the TPP norm, without running the risk of retaliation from other TPP Parties.

Patents are private monopoly rights granted by States that allow patent holders to exclude other competing commercial actors from the marketplace for a limited time with respect to their patented products or processes. There is little concordance in the empirical literature on the role of patent systems in encouraging pharmaceutical innovation and technology transfer (WHO, WIPO, and WTO, 2013, p. 56).¹² Nevertheless, surveys of the pharmaceutical industry indicate that these participants consider product and process patent protection as critical for incentivizing pharmaceutical research and development (USDOC, 2012, p. 9).

The World Health Organization (WHO) has pointed out that the price of medicines depends on many factors in addition to royalty payments for patented drugs, such as: "supply and demand; prescribing and consumption patterns; manufacturing costs; competitive conditions in the markets; taxes, exchange rates...; wholesale and retail mark-ups; degree of price elasticity for different drugs; and especially, government or private health plan coverage and payment policies" (WHO and WTO, 2002, p. 95). In addition, "the IP system more generally-- is only one element of the bigger challenge of access to medicines which includes such important factors as the public health system in general, drug regulatory authorities, financing, health insurance, infrastructure, procurement regimes and

taken the steps necessary for the proper implementation of the TPP Agreement." <https://medium.com/the-trans-pacific-partnership/final-provisions-29a2af5df02f> [accessed June 12, 2016].

⁹ On Nov. 5, 2015, President Obama provided the requisite 90-day notice to the U.S. Congress of his intention to sign the TPPA, consistent with section 106(a)(1)(A) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (Public Law 114-26, Title I) (also known as the TPA), signed on June 29, 2015, <https://www.whitehouse.gov/the-press-office/2015/11/05/letter-intention-enter-trans-pacific-partnership-agreement> [accessed June 12, 2016]. The 90-day period for Congressional review of the TPPA expired on Feb. 3, 2016. New Zealand hosted the signing ceremony with TPP trade ministers in Auckland the next day. Inside U.S. Trade, "TPP Countries Move Ahead With Feb. 4 Signing; Legal Scrub Finished," January 10, 2016. See also note 41.

¹⁰ Countries that have reportedly expressed interest in acceding to the TPPA are: Colombia, Indonesia, Philippines, South Korea, Taiwan, and Thailand.

¹¹ All states in the Western Hemisphere are WTO members, with the exception of the Bahamas. https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm [accessed June 12, 2016]

¹² "While one needs only to observe the market to see that patent protection is correlated with higher prices, the correlation between longer or stronger patents and an increased rate of invention is much less straightforward." Abbott, Frederick, "Trade in Medicines," (Smith *et al*, 2015, p. 135).

import tariffs applied to pharmaceutical products" (Taubman, Wager, and Watal , 2012, p. 179). In the broader picture of national and international actions to improve access to medicines, it has been noted that "alternative funding mechanisms, donations, partnership programmes and licensing agreements, as well as the increased application of tiered-pricing schemes by pharmaceutical companies have contributed to a positive change regarding access to medicines" (Taubman, Wager, and Watal , 2012, p. 194).¹³

The study begins by tracing the evolution of the multilateral trade rules on intellectual property from the initial GATT to the TRIPS Agreement and its subsequent interpretations supportive of public health and access to medicine. The TRIPS Agreement generally requires *inter alia* that WTO members make available patents for product or process inventions that are new, non-obvious, and useful, in all fields of technology, for a 20-year period from the patent filing date. The Agreement also obligates members to protect undisclosed test data submitted for marketing approval of pharmaceutical products that utilize new chemical entities, against unfair commercial use. Part of the balance negotiated under the TRIPS Agreement for patents included this broad subject matter patentability—including for pharmaceutical products and agricultural chemicals—coupled with regulatory data protection, domestic remedies against patent infringement, and enforceability of IP standards through the WTO dispute settlement system. The other part of the balance included requirements for inventors to disclose their inventions, as well as provisions allowing limited exceptions to the exclusive rights conferred by patents and other carve-outs for patent use without the holder's authorization, such as to meet a national emergency or other circumstances of extreme urgency or public non-commercial use. Additionally there were provisions for transitional arrangements and technical cooperation.

The WTO regime served as the platform for building the TRIPS-plus provisions of the bilateral and regional free trade agreements subscribed to by the United States. The agreements are compared in the next section III against the backdrop of Congressional mandates to the US executive branch to pursue foreign practices that deny adequate and effective IP protection for US exports, with IP protection under US domestic law as the baseline for judging the results achieved. This US approach is driven by the importance to the US economy and its global competitiveness, of industries that depend particularly on intellectual property protection, including the pharmaceutical industry, as well as by the political influence that these industries wield. Certain key trends in the global pharmaceutical market are addressed in section IV, particularly mergers and acquisitions, trade, the growth potential for biologics, and the high costs of clinical investigations to bring these to market. The final section analyzes how certain aspects of the patent and regulatory data-related provisions of the TPPA with regard to pharmaceutical products expand IPR protections, and what impact these may have on the balance between encouraging innovation and promoting access to medicines, taking into account that other chapters of the agreement will affect trade in these products as well.

The study concludes by finding that many of the TPP patent and data exclusivity-related provisions for pharmaceutical products continue the trend in TRIPS-Plus IP protection in existing US FTAs with Latin American countries. Some of the new features that the TPPA offers include the promise of enhanced transparency on IP laws and rulings as well as greater cooperation among patent offices, which should prove favorable towards encouraging access to medicine. The effects of the TPP requirements on pharmaceutical patent term restoration, patent linkage, and regulatory data exclusivity, in tipping the scales toward innovation over access to medicines are attenuated by various factors. These include the transition periods granted to those TPP Parties that do not already apply these standards (*e.g.*, to Mexico and Peru), specific exceptions provided to individual TPP Parties (*e.g.*, to Chile and Peru), and the ambiguity surrounding how some provisions, particularly on data

¹³ According to PhRMA, for example, in the last decade, the biopharmaceutical industry has provided over \$9.2 billion in direct assistance to healthcare for the developing world, including donations of medicines, vaccines, diagnostics, and equipment, as well as other materials and labor. PhRMA "Special 301 Submission 2016," p. 5.

exclusivity, will be interpreted and implemented. A longer period of regulatory data exclusivity for biologics than currently exist in some TPP countries (including Mexico and Peru) taken alone would tend to delay the market entry for biosimilars in those markets. However, there are other perhaps more significant barriers to entry like the up to \$200 million investment needed to develop biosimilars, additional good manufacturing practice costs, the economy of scale required to achieve returns, and the slowness with which healthcare systems and patients may accept biosimilars as substitutes.

I. Multilateral trade rules for IPRs on pharmaceutical products

To better understand the patent and clinical test data-related IP standards provided under the TPPA and other free trade area (FTA) agreements entered into by the U.S., one must place them in the context of the multilateral GATT/WTO rules upon which the FTA rules are built. The multilateral rules serve as the reference point for comparison of FTA protection levels and policy flexibilities (see Table A.4).

A. GATT regime

Intellectual property protection did not receive much attention under the "old" GATT rules governing trade in goods that preceded the Marrakesh Agreement Establishing the WTO. The General Agreement on Tariffs and Trade dated Oct. 30, 1947 (GATT 1947)—which was largely copied in and updated by its WTO successor, the General Agreement on Tariffs and Trade 1994 (GATT 1994)—does not set any substantive standards for IP protection *per se*. It makes specific reference to intellectual property only in four instances. One such IP reference is in paragraph (d) of GATT Article XX (General Exceptions), which allows an exception to GATT rules for measures necessary to secure compliance with laws dealing with patent, trademark, copyright and anti-deceptive practices, provided these measures are not applied in an arbitrary or unjustifiably discriminatory manner and do not constitute a disguised restriction on international trade.¹⁴ The scope of this exception in relation to the national treatment obligation under GATT Article III:4 was examined by a GATT panel in a case concerning US judicial procedures applicable on the importation of allegedly IP-infringing goods, which differed from those applied to goods of domestic origin similarly challenged. The panel developed an “effective equality of opportunities” test for judging whether internal laws treat imported goods less favorably than domestic goods. While the GATT test was applied initially for the national

¹⁴ The other 3 instances where IP is covered under the General Agreement are: GATT Article IX:6, which promotes cooperation on geographical indications; and GATT Articles XII:3(c) and XVIII:10, which ban applying balance-of-payment restrictions that would undermine compliance with patent, trademark, copyright or similar procedures.

treatment of goods, it has been followed in WTO cases involving the national treatment of nationals for intellectual property protection; namely, the obligation under Article 3 of the TRIPS Agreement that requires a WTO member to accord to nationals of other WTO members treatment no less favorable than that it accords its own nationals with regard to IPR protection.¹⁵ The test may also be relevant for judging any eventual dispute under the similar national treatment obligation of the TPPA.¹⁶

The first attempt to go beyond the General Agreement in addressing IP was a US proposal made during the Tokyo Round in 1978 for a code or plurilateral agreement on border measures to combat counterfeit trademark goods. The proposal did not receive sufficient support to be included in the results of that Round.¹⁷

¹⁵ The scope of the GATT Article XX(d) exception vis-à-vis the national treatment obligation for internal laws affecting the sale and distribution of goods under GATT Article III:4, was examined in the GATT dispute settlement case brought against the *United States Section 337 of the Tariff Act of 1930* in 1987. General Agreement on Tariffs and Trade, "United States Section 337 of the Tariff Act of 1930: Report by the Panel adopted on 7 November 1989 (L/6439)," GATT BISD (36th Supplement), p. 345, Geneva, 1990. During the panel's examination of the case, the underlying US law at issue was amended by the Omnibus Trade and Competitiveness Act of 1988, which the panel took into account in its report. Under Section 337, US producers can obtain orders excluding the importation of goods found to be infringing US patent and other IP rights. The panel ruled that the minimum permissible standard for national treatment allowed under Art. III:4 was "effective equality of opportunities for imported products in respect of the application of laws, regulations and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use of products." *Id.*, para. 5.11. Using this standard, the panel found that certain US procedures when imported goods were challenged for IP infringement, constituted treatment less favorable than that accorded under federal district court procedures to products of US origin similarly challenged. These less favorable procedures included "the possibility that producers or importers of challenged products of foreign origin may have to defend their products both before the USITC and in federal district court, whereas no corresponding exposure exists with respect to products of United States origin." *Id.* para. 5.20(vi). The panel ruled that the less favorable treatment was inconsistent with GATT Article III:4 and that the inconsistencies could not be justified under Article XX(d). *Id.*, para. 6.3. The effective equality of opportunities standard for national treatment on the application of internal laws on the sale and distribution of imported goods under GATT Article III:4, has been affirmed as relevant by the Appellate Body, and followed by WTO panels, in cases interpreting the national treatment obligation for intellectual property protection of domestic and other WTO nationals under Article 3.1 of the TRIPS. WTO (2001) "United States - Section 211 Omnibus Appropriations Act of 1998: Report of the Appellate Body," WT/DS176/AB/R, Geneva, 2002, paras. 263-264. The Section 337 panel report was also cited and its "effective equality of opportunities" standard followed in the EC - Trademarks and Geographical Indications (US) and (Australia) panels. WTO (2005) "European Communities - Protection of Trademarks and Geographical Indications for Agriculture Products and Foodstuffs: Complaint by the United States, Report of the Panel," WT/DS174/R, Geneva, 2005, para. 7.131, and "European Communities - Protection of Trademarks and Geographical Indications for Agriculture Products and Foodstuffs: Complaint by Australia, Report of the Panel," WT/DS290/R, Geneva, 2005, para. 7.181. For a discussion of the GATT provisions and cases on IP, see Otten, Adrian "The TRIPS Negotiations: An Overview" (Watal and Taubman, 2015, pp. 55-57).

¹⁶ Article 18.8 of the TPPA requires a TPP member to accord "treatment no less favourable than it accords to its own nationals with regard to the protection of intellectual property rights." The quoted text is the same as Article 3.1 of the TRIPS Agreement, albeit this is subject to exceptions already provided in the Paris, Berne and Rome conventions. In footnotes to the respective national treatment obligation under both TRIPS and TPP agreements, it is stated that IPR protection extends *inter alia* to "matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically" covered by the TPPA IP Chapter or addressed in the TRIPS Agreement, respectively. The national treatment obligation under Article 18.8 of the TPPA would seem to cover IP rights such as patent extension, patent linkage, regulatory data protection, and patent term restoration relating to pharmaceutical products provided under this Agreement. These TPP-specific IP rights would have to be extended to all WTO nationals as noted in para. 1.3 of this study. A TPP member that considers that its nationals are being treated less favorably by another TPP member than it treats its own nationals with respect to these IPRs could challenge these measures under the dispute settlement procedures of the TPPA or the WTO.

¹⁷ Watal and Taubman 2015, p. 57.

The US was the main driver for including IP (and services) in the Uruguay Round, which it saw as key to maintaining its international competitiveness and to rallying domestic support for any trade liberalization package resulting from the round (Watal and Taubman, 2015).¹⁸ Under Section 301 of the US Trade and Tariff Act of 1974, Congress has required the US administration to attempt to remove foreign barriers to US exports and has authorized the right to retaliate against unreasonable foreign trade practices. The Congress defined the scope of “unreasonable” in 1984 as covering *inter alia* any practice denying “provision of adequate and effective protection of intellectual property rights.” This is commonly referred to as Special 301. Among the negotiating objectives for the Uruguay Round that the Omnibus Trade and Competitiveness Act of 1988 set when it provided fast track authority, was expanding the GATT to cover intellectual property.

B. TRIPS Agreement: overview

The TRIPS Agreement was one of the major results of the Uruguay Round concluded in 1994. It entered into force in 1995 as part of the single undertaking/package of the Marrakesh Agreement Establishing the WTO (WTO, 1994, Annex 1C). The TRIPS Agreement sets out general provisions and basic principles regarding intellectual property rights, including national treatment, most-favored-nation treatment, technological innovation and the transfer of technology, the protection of public health, and the exhaustion¹⁹ of intellectual property rights (IPRs). Part II of the TRIPS Agreement requires WTO members to have certain minimum standards in their national legislation for granting

¹⁸ "In the years following the end of the Tokyo Round, large parts of US industry as well as the US Government became increasingly of the view that what they saw as inadequate or ineffective protection of US IP abroad was unfairly undermining the competitiveness of US industry and damaging US trade interests. These concerns went beyond the issue of border controls to prevent the importation of counterfeit goods, to the substantive standards of IP protection in other countries and the effectiveness of means for their enforcement, internally as well as at the border. This, in turn, was part of a wider perception of many in the United States that the GATT system, while doing quite a good job in regard to standard technology manufactured goods where the United was losing international competitiveness, was doing a bad job, or none at all, in the areas of agriculture, services and IP where US competitiveness increasingly lay." Watal and Taubman, p. 58. "Achieving a strong agreement on IPR in the Uruguay Round negotiations was a top offensive objective for the United States. The United States saw IP as the future for US high-tech industries and economic growth, and industry was able to identify significant economic harm resulting from lack of protection and enforcement of IPRs. In addition, US policy makers believed that including IP in the Uruguay Round negotiating package and achieving an outcome that set the stage for increased trade in IP-based goods would build support for the results of the Round as a whole, and help overcome domestic objections to a result that addressed sensitive issues for the United States, such as textiles, safeguards and anti-dumping" Field, Catherine "Negotiating for the United States" (Watal and Taubman, 2015, p. 132).

¹⁹ "Exhaustion" is the principle whereby an IPR owner's exclusive right to control the marketing or distribution of a protected item lapses after it is first distributed. The principle is sometimes referred to as the first-sale doctrine. For countries with a national exhaustion regime, the right owner's commercial exploitation rights would be deemed exhausted only once the protected item is put on the domestic market with the holder's authorization. Under an international exhaustion regime, a right owner's distribution right in that country is exhausted regardless of where the first distribution or sale took place in the world. Parallel imports are products marketed by or with the consent of the right holder in one country, and subsequently imported into another country without the holder's authorization. They are legal in a country with an international exhaustion regime, even if the same product is sold at lower prices in other countries. However, parallel imports of the product first sold on other markets are illegal in a country with a national exhaustion regime. National exhaustion is said to favor differential pricing, product differentiation and differing release dates. Taubman, Wager and Watal, 2012, pp. 18-20 and 148; WIPO, "International Exhaustion and Parallel Importation," http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm [accessed June 12, 2016]. A WTO member country is free to adopt either a domestic or international exhaustion system and under Article 6 of the TRIPS; this cannot be challenged under WTO dispute settlement provided the national treatment and most-favored nation treatment obligations of Articles 3 and 4 are respected. This issue was clarified in the Doha Declaration on the TRIPS Agreement and Public Health and subsequent decisions (see paras. 2.21-2.24).

IPR protection for copyright, trademarks and service marks, geographical indications, industrial designs, patents, new varieties of plants, and layout designs of integrated circuits. For these IP fields, the TRIPS Agreement defines the subject matter eligible for protection, the scope of rights to be conferred, permissible exceptions, and where applicable, the minimum duration of protection. The protection of undisclosed information, including test data, and the control of anti-competitive practices in contractual licenses are also included for the first time in an international agreement. Part III of the TRIPS Agreement governs the enforcement of IPRs, including administrative, criminal, and border procedures and remedies against IPR infringements. Part IV addresses the procedures that members may require for acquiring and maintaining IPRs, including registration.

The TRIPS Agreement builds upon and incorporates by reference the main IP agreements administered by the World Intellectual Property Organization (WIPO), the Paris Convention for the Protection of Industrial Property, and the Berne Convention for the Protection of Literary and Artistic Works. Thus the main substantive provisions of these conventions became obligations of WTO members under the TRIPS Agreement, but TRIPS added obligations beyond the pre-existing conventions. It also established rules on administering and enforcing IPRs in members' domestic legal systems. Most important, disputes between and among members about compliance with their TRIPS obligations became subject to the dispute settlement system of the WTO, including sanctions.

C. TRIPS: patents

Section 5 (Articles 27-34) and Section 7 (Article 39) of the TRIPS Agreement specifically address patents and data exclusivity, respectively, which are the principal focus of this study. Section 5 (Patents) lays down rules and standards for patentable subject matter, rights conferred, conditions on patent applicants, exceptions to rights conferred, and other use without the right holder's authorization, revocation and forfeiture, term of patent protection and burden of proof in civil proceedings on process patents.

With respect to patentability, Article 27.1 provides that patents "shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application...patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." The TRIPS Agreement does not define the terms "patents" or "inventions." Neither does it define "new," but some jurisdictions refer to this as "novelty" and a footnote states that "inventive step" and "industrial application" may be synonymous with "non-obvious," and "useful," respectively (Taubman, Wager, and Watal 2012, pp. 98-100). The U.S. and European negotiators achieved their objectives in the Uruguay Round of ensuring the availability of product patents for pharmaceuticals and agricultural chemicals, as well as eliminating requirements to work or manufacture domestically a product in the country granting the patent within a certain time period. But these results were balanced against flexibilities provided in other provisions in the patent complex in the TRIPS Agreement (Watal and Taubman, 2015, pp. 141-142).

The TRIPS Agreement explicitly enumerates exceptions from patentable subject matter. WTO members are allowed to exclude inventions from patentability where preventing the commercial exploitation of the inventions is "necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment," provided such exclusion is not made merely because the exploitation is prohibited by their laws (Article 27.2 TRIPS Agreement). The latter condition was designed to clarify that inventions cannot be excluded from patentability merely because they have not received marketing approval from health regulatory authorities (Taubman, Wager, and Watal 2012, pp. 102-103). Other optional exclusions from patentability under Article 27.3 are: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and (b) plants and animals and essentially biological processes for their production. Members are required to provide patent protection for

micro-organisms and non-biological and microbiological processes for the production of plants and animals. Members that do not provide patent protection for new plant varieties are required to protect them through an effective *sui generis* system, such as the International Union for the Protection of New Plant Varieties (UPOV Convention).

The rights conferred on a product patent owner are defined under TRIPS Article 28.1(a) as the right to prevent others from "making, using, offering for sale, selling, or importing" the product without the owner's consent. With respect to a process patent right, it is the right under Article 28.1(b) to prevent others from using the process and from "making, using, offering for sale, selling, or importing" the product obtained directly by that process. Essentially, patents are private rights of patent owners/eligible inventors to exclude other competing commercial actors from the marketplace for a limited time with respect to their patented products or processes.

Part of the balance or social compact in granting patents to make investment in technological innovation attractive, is the condition that patent owners disclose their inventions to enable society to know and use the knowledge in the patent documents (WHO, WIPO, and WTO, 2013, p. 56; Taubman, Wager, and Watal, 2012, p. 96). Accordingly, TRIPS provides that WTO "Members shall require a patent applicant to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor..."(Article 29.1). The protection of undisclosed clinical test data submitted in the regulatory approval process from unfair commercial use is governed by Article 39 (see paras. 2.18-2.19).

Article 30 allows WTO members to provide "limited exceptions to the exclusive rights conferred by a patent, provided such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate rights of the patent owner, taking into account third parties' legitimate interests." Countries have used these provisions for limited exceptions, to allow for the early working or use of patented pharmaceuticals by third parties while the patent is in force, in order to obtain marketing approval of an equivalent product to sell after the relevant patent expires (see paras. 2.19 and 2.20 for further discussion of the regulatory review or "Bolar" exemption).

The TRIPS Agreement does not mention compulsory licensing but refers to "use without authorization of the right holder." Article 31 provides a long list of twelve-plus conditions that must be respected where a member's law allows for use of the subject matter of patent without the right holder's authorization, including use by the government or third parties authorized by the government, other than the "limited exception" provided under Article 30. These conditions include that the government's authorization of such use without the right holder's consent "shall be considered on its individual merits" (Art. 31 (a)) and "shall be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur" (Art. 31 (g)). They further include that such use shall be limited in scope and duration "to the purpose for which it was authorized" (Art. 31(c)), shall be "non-exclusive"²⁰ (Art. 31 (d)), and "non-assignable"²¹ (Art. 31 (e)), and that the legal validity of authorization of such use, and the remuneration provided shall be subject to judicial or other independent review (Art. 31 (i) and (j)). Of particular interest as regards the use of pharmaceutical patents without the right holder's authorization, are the following conditions:

- Such use may only be permitted if the proposed user has made prior efforts "to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This

²⁰ "Compulsory licenses must be non-exclusive, i.e., the licensee must not have the right to prevent the grant of other licences or the use of the invention by the patent owner" (Taubman, Wager, and Watal, 2012, p. 113).

²¹ Non-transferable to a third party.

requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly"(Art. 31 (b));

- "[A]ny such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use" (Art. 31. (f)); "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization" (Art. 31 (h)).
- The above conditions (b-f) are waived to remedy practices that have been determined judicially or administratively to be anti-competitive (Art. 31 (j)).

Finally there are conditions stipulated for authorizing the use of the subject matter of a (first) patent without the right holder's consent, to permit the exploitation of a second patent that involves an important technical advance of considerable economic significance, and that cannot be exploited without infringing the first patent. These conditions include that the first patent owner is entitled to a cross-license on reasonable terms to use the invention claimed in the second patent (Art. 31 (k)).

The above conditions are relevant for understanding the Doha Declaration on the TRIPS Agreement and Public Health of 2001 (WTO, 2001), and subsequent related actions (see paras. 2.21-2.24), which affect and in some cases waive the conditions set out in Article 31 (b), (f) and (h).

Article 32 stipulates that judicial review shall be available for any decision to revoke or forfeit a patent. The TRIPS Agreement does not set forth the specific grounds that may justify such revocation or forfeiture. There are apparently differing views as to whether the Agreement precludes a member from revoking a patent beyond the grounds that would have justified denying the grant on the underlying application in order to serve other societal goals (Taubman, Wager, and Watal, 2012, p. 115). The TRIPS-plus provisions in subsequent US FTAs with Latin American countries have delineated and broadened the scope for revoking or holding unenforceable the patent of a rights holder; *e.g.*, for fraud, misrepresentation, or inequitable conduct.

Article 33 states that the term of patent protection shall be for 20 years as of the filing date. This is the minimum obligatory period that WTO members must provide. The TRIPS Agreement does not require patent extensions, but the TRIPS-plus provisions in subsequent US FTAs with Latin American countries have provided for patent term extensions to compensate for regulatory delays in granting a patent or a marketing approval by authorities.

D. TRIPS: data protection

The TRIPS Agreement was the first international IP agreement to contain obligations on the protection of undisclosed test and other data required to be submitted to obtain regulatory or marketing approval for pharmaceutical or agricultural chemical products (Taubman, Wager, and Watal, 2012, p. 128). The data may consist of testing samples, good manufacturing practices, and/or pre-clinical and clinical trials submitted to a governmental agency as evidence of the safety, quality, and efficacy of the product. The generation of safety, quality and efficacy data through clinical trials is largely funded by companies seeking to introduce a new medical technology to the market (WHO, WIPO, and WTO, 2013, p. 66). The obligation to protect trade secrets or undisclosed information is stipulated in Section 7 (Protection of Undisclosed Information) Article 39, and applies independently of whether the pharmaceutical or agricultural chemical products are covered by patents. Patents and test data protection are distinct IP categories (WHO, WIPO, and WTO, 2013, p. 65), although patents and marketing exclusivity may perform similar functions of providing a more favorable market

position for originator pharmaceutical companies than would otherwise exist.²² Article 39.3 requires members to protect against unfair commercial use and disclosure, data about new chemical entities, the origination of which has involved considerable effort, except where necessary to protect the public, or unless steps have been taken to ensure against unfair commercial use.

There are differing views among members on how to implement Article 39.3 of the TRIPS Agreement and different approaches to data protection against unfair commercial use, a term the agreement does not define; nor does it specify how long a time period the data should be protected. Most developed and some developing countries grant the originator of the data—which may be different than the patent holder—a period of exclusivity during which the regulatory authorities must not rely on the data when approving other versions of the product (Taubman, Wager, and Watal, 201, p. 129; WHO, WIPO, and WTO, 2013, p. 65). Some WTO members such as the European Union and the U.S. allow an additional period of exclusivity for new indications and formulations (WHO, WIPO, and WTO, 2013, p. 65). As long as a data exclusivity period lasts, generic manufacturers will have to produce their own data to demonstrate safety, quality, and efficacy, or wait until the exclusivity period has expired to enter the market. Some countries apply exceptions and limitations to data exclusivity.²³

The TRIPS Agreement gave all members transition periods to meet their obligations, depending on their level of development. All of these periods have expired except for the transitional arrangements benefiting the least developed country members, which includes Haiti. Under the most recent time extensions, the least developed country members are exempt from applying the pharmaceutical product patent protection obligations under Sections 5 (Patents) and 7 (Protection of Undisclosed Information) as well as paragraphs 8 and 9 of Article 70 (Protection of Existing Subject Matter) of the TRIPS until Jan. 1, 2033 or the date on which they cease to be a least developed country Member, whichever date is earlier.²⁴ The TRIPS Agreement makes other accommodations for the development needs of members. Developed country members are obligated to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed country members (Article 66), and also to provide technical and financial cooperation in favor of developing and least developed country members, including assistance on preparing IPR laws and training personnel (Article 67).

²² *Supra* note 13 at p. 126.

²³ "US law shortens the period to four years where the applicant for a second product certifies that the patent is invalid or that the second product does not infringe the patent (subject to a possible stay during infringement proceedings). Canada does not provide data exclusivity if the originator product is not being marketed in its territory; nor do Chile or Colombia if the originator product is not marketed in their respective territories within 12 months of the grant of local marketing approval. Chile does not provide data exclusivity if the application for local marketing approval is filed more than 12 months after registration or marketing approval was first granted in a foreign country. Other exceptions may cover the protection of the public interest, such as in situations of health emergencies or for exports under compulsory licence under the Paragraph 6 System...Canada and the European Union decided to waive data protection for products produced under compulsory licence solely for export under the Paragraph 6 System. Chile does not provide data exclusivity if the product is the subject of any kind of compulsory licence." (WHO, WIPO, and WTO, 2013, p. 66). The Para. 6 System refers to follow-up action taken pursuant to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WTO, 2001 and 2003) and is discussed in further detail in paras. 2.21-2.24.

²⁴ As a UN-designated least developing country http://www.un.org/en/development/desa/policy/cdp/ldc/ldc_list.pdf [accessed June 12, 2016], Haiti is covered by the most recent extension of the exemptions provided under Part VI (Transitional Arrangements) of the TRIPS Agreement. Haiti is the only WTO member in the Western Hemisphere to be so exempted. On Nov. 6, 2015, the TRIPS Council adopted a decision to extend the pharmaceutical waiver for least-developed countries from the previously agreed deadline of Jan. 1, 2016 to January 1, 2033. "Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Member for Certain Obligations with Respect to Pharmaceutical Products: Decision of the Council for TRIPS of 6 November 2015," IP/C/73, Geneva, November 6, 2015 and "Least Developed Country Members – Obligations under Article 70.8 and 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products: Decision of the General Council Decision of 30 November, 2015," WT/L/971, Geneva, December 2, 2015.

E. WTO disputes on pharmaceutical patents and data protection

There have been relatively few WTO panel cases involving compliance with the patent-related obligations of the TRIPS agreement, and no jurisprudence on data exclusivity²⁵. Of particular interest to the focus of this study, was the challenge by the European Community against the regulatory review or early working exception provided for in Section 55.2(1) of Canada's Patent Act, which permitted producers of generic pharmaceuticals to use the patented invention without the patent owner's authorization during the patent term, for the purposes of obtaining government marketing approval. This facilitated sales of the generic product upon the patent's expiration. The panel found the regulatory review exception to be a "limited exception" consistent with Article 30 of the TRIPS Agreement.²⁶ However, the panel ruled that the stockpiling exception provided for in Section 55.2(2) of Canada's law that allowed generic competitors to manufacture and stockpile patented goods for six months before the 20-year patent term expired, constituted a substantial curtailment of the patent owner's exclusionary rights under Articles 28.1, and could not be considered as a limited exception within the meaning of Article 30.²⁷

Like Canada, other jurisdictions provide for regulatory review exceptions in their laws. These exemptions are referred to as "Bolar" provisions and may vary in nature and scope.²⁸

²⁵ On May 6, 1999, the United States formally requested consultations with Argentina, contending that its law did not provide product patent protection for pharmaceutical inventions or the grant of exclusive marketing rights. The U.S. further alleged that Argentina provided no effective protection against unfair commercial use of undisclosed test data submitted to Argentine regulatory authorities in support of application for marketing approval for agricultural chemical products. On 31 May 2002, the parties notified the WTO that they had reached an agreement on all of the matters raised by the US in its request for consultations. No further WTO action has been taken concerning this dispute Argentina — Certain Measures on the Protection of Patents and Test Data, WT/DS194/4, June 20, 2002.

²⁶ WTO, "Canada - Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States: Report of the Panel" WT/DS114/R, paras. 7.50 and 8.1(1), March 17, 2000. "The additional period of market exclusivity in this situation is not a natural or normal consequence of enforcing patent rights. It is an unintended consequence of the conjunction of the patent laws with product regulatory laws, where the combination of patent rights with the time demands of the regulatory process gives a greater than normal period of market exclusivity to the enforcement of certain patent rights. It is likewise a form of exploitation that most patent owners do not in fact employ. For the vast majority of patented products, there is no marketing regulation of the kind covered by Section 55.2(1), and thus there is no possibility to extend patent exclusivity by delaying the marketing approval process for competitors." *Id.*, para. 7.57. "It is often argued that this [Article 30-type] exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a 'legitimate interest' in using the patent disclosure to support the advance of science and technology. *Id.*, para. 7.69.

²⁷ *Id.*, paras. 7.36 and 8.1(2)

²⁸ "Bolar provisions" refer to a US law —the Hatch-Waxman Act— that was enacted to overturn a court ruling holding that the US did not provide for a research exemption, *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (1984). Mexican law similarly provides for a Bolar-like exemption although such protection is available only when a patent is within eight years of expiration for a biologic product, or within three years for a small molecule (*see also note 35*). Brazil, Chile, Colombia, Dominican Republic, Peru and Uruguay have put in place Bolar exemptions. Tridico, Anthony, Jeffrey Jacobstein, and Leythem Wall, "Facilitating Generic Drug Manufacturing: Bolar Exemptions Worldwide," *WIPO Magazine*, June 2014.

F. TRIPS and public health

Concerns about the possible interpretation under WTO dispute settlement of the scope of the flexibilities offered by the TRIPS Agreement in support of public health, particularly as regards compulsory licensing and parallel imports²⁹ under Article 31 (Taubman, Wager, and Watal, 2012, p. 180), led WTO members to adopt a Declaration on the TRIPS Agreement and Public Health, on the occasion of the WTO Ministerial Conference that launched the Doha Development Agenda or the Doha Round (WTO, 2001).³⁰ The Doha Declaration confirmed and clarified these TRIPS flexibilities. WTO Ministers recognized that each member had the right *inter alia* to:

- grant compulsory licenses on whatever grounds it determined (para. 5(b));
- determine "what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency" (para. 5(c));
- freely establish its own regime for IPR exhaustion without challenge, subject to the national and MFN treatment provisions of Articles 3 and 4 (para. 5(d)).

Under paragraph 6 of the Doha Declaration, Ministers instructed the TRIPS Council to find a solution for members with "insufficient or no manufacturing capacities in the pharmaceutical sector [that] could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement." While members can issue compulsory licenses for importation and domestic production without the patent owner's authorization, there was a potential problem of whether generic producers in countries with manufacturing capacity would be able to export sufficient quantities of the needed medicine, if it was patent-protected in those countries. Moreover, Article 31(f) requires that the production under a compulsory license be "predominantly for the supply of the domestic market." The problem was expected to be more acute after 2005 when developing countries with significant generic industries and export capacities, like India, became obligated to provide patent protection for pharmaceutical products under the transitional arrangements in Article 65.4 of the TRIPS Agreement (Taubman, Wager, and Watal, 2012, p. 184).

The solution found pursuant to the above-mentioned Ministerial instruction was the establishment of the "Paragraph 6 System" (WTO, 2013), which waives the obligations of an exporting member under Article 31(f) of the TRIPS Agreement, in order to grant a compulsory license to the extent necessary to produce a pharmaceutical product for, and export it to, an eligible importing member. The terms "pharmaceutical product," "eligible importing member" and "exporting member" are defined; there are extensive notification requirements in order to use this flexibility. An eligible importing member means any least-developed country member or a member that has notified the TRIPS Council it intends to use the system. The importing member's notification must include the name of the product and the quantities the member wants to import for each use, confirm that it has insufficient or no manufacturing capacity for the pharmaceutical product in question, and if the

²⁹ *Supra*, note 20 and para. 2.13.

³⁰ Among the 17 Sustainable Development Goals adopted by the United Nations General Assembly on Sept. 25, 2015 for a post-2015 development agenda is Goal 3: "Ensure healthy lives and promote well-being for all and for all ages." The targets for achieving this goal include: "3b. Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all." UN (United Nations, 2015), "Transforming our World: the 2030 Agenda for Sustainable Development," A/RES/70/1, p. 16, Oct. 21, 2015.

product is patented in its territory, that it has granted or intends to grant a compulsory license. The exporting member, in turn, must issue a compulsory license that permits production and exportation to the eligible importing member and must notify the TRIPS Council of the conditions attached to the license. The license must only be for the manufacture and export of the amount necessary to meet the importing member's needs and the products produced must be identified as having been produced under the System though labeling or marking. Prior to shipment, the licensee must post details of the shipment on a website, which it notified to the TRIPS Council. There has only been limited use made of the System; i.e., a Canadian compulsory license in 2007 to manufacture HIV/AIDS medicine for export to Rwanda (Taubman, Wager, and Watal, 2012, p. 193-194); Rwanda is the only member to have notified as an eligible importing member³¹.

For greater legal certainty and at the urging of African countries, the WTO General Council adopted a Protocol that would amend the TRIPS Agreement and submitted the Protocol for acceptance by members (WTO, 2005). The Protocol incorporates the above-mentioned solution/waiver adopted by the General Council (WTO, 2003). This laid down procedures allowing members to issue compulsory licenses to export pharmaceutical products to countries that cannot produce them for themselves in order to meet a national public health emergency or other circumstances of extreme urgency. Pursuant to Article X:3 of the WTO Agreement, two-thirds of the WTO membership (of currently 162 countries) must accept the amendment to the TRIPS Agreement, before it comes into force for those members that have accepted it. Only around half of WTO members have already formally accepted the amendment, of which 17 from the Western Hemisphere,³² more acceptances are needed to meet the threshold amount for entry into force by the latest extended deadline of Dec. 31, 2017.³³

A recent survey by the WIPO Secretariat of member states' experiences and case studies on the effectiveness of exceptions and limitations in addressing development issues does not suggest that there has been extensive use of such flexibilities.³⁴

³¹ WTO, Notification under Paragraph 2(A) of the Decision of 30 August on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health," IP/N/9/RWA/1, July 19, 2007.

³² The full list of members and their dates of acceptance can be found at https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm [accessed June 12, 2016]. From the Western Hemisphere, they are: Argentina, Brazil, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Grenada, Honduras, Mexico, Nicaragua, Panama, St. Kitts & Nevis, Trinidad & Tobago, United States, and Uruguay. The U.S. was the first country to accept formally the amendment.

³³ "Amendment of the TRIPS Agreement – Fifth Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement: General Council Decision of 30 November 2015," WT/L/965, Geneva, Dec. 2, 2015.

³⁴ For example, it was reported that the Ministry of Social Protection of Colombia had rejected an application for a declaration of public interest under the national compulsory licensing process with respect to the combination of HIV protease inhibitors known under the trademark Kaletra. Nevertheless following court proceedings, the Department of Trade and Industry sanctioned Abbott Laboratories of Colombia S.A. for selling Kaletra above the maximum allowed reference price. WIPO Secretariat, "Member States' Experiences and Case Studies on the Effectiveness of Exceptions and Limitations," SCP/23/3, Oct. 30, 2015, pp. 2-4. The Mexican government reported that it has adopted the regulatory or Bolar exception by means of Article 167bis of the Health Commodities Regulations adopted by a Decree in 2003, which has been applied successfully since generic drugs have been granted sanitary registration in a timely and adequate manner while respecting patent rights. Mexico has stipulated that it will only use the Paragraph 6 System as an importer in the event of a national emergency or under other circumstances of extreme urgency; no such eventuality has occurred and to date no public utility license has been granted. *Id.*, p. 5.

G. TRIPS-Plus

A number of FTAs provide for more extensive protection for patents and test data as well as tighter enforcement standards for trade in pharmaceutical products. These agreements form families that are each grouped around a hub. The European Free Trade Area (EFTA), the European Union, and the United States are the most important hubs in terms of the number of agreements containing more extensive IP protection than the minimum standards required by the TRIPS Agreement. As noted earlier, this more extensive protection must be made available to the nationals of all other WTO members. Moreover, on a practical level, it would be costly to tailor regulations to favor nationals originating from preferential partners (WHO, WIPO, and WTO, 2013, p. 84). The next section discusses the patent and data-related provisions of the free trade agreements subscribed by Western Hemisphere countries with the US.

II. The U.S. approach to intellectual property protection on pharmaceutical products and the factors driving it³⁵

A. IP industries in the U.S. economy

According to the U.S. Department of Commerce (USDOC), US industries that depend particularly on intellectual property protection³⁶ accounted for about \$5.06 trillion in value added or 34.8 percent of US GDP, and supported directly or indirectly 40 million or 30 percent of all jobs in the US in 2010. In addition, goods from these IP-intensive industries accounted for 61% of all US merchandise exports, and merchandise imports by these industries stood at 70% of total US merchandise imports in 2010 (USDOC, 2012, pp. vi-viii).³⁷

Among these US IP-intensive industries, the pharmaceutical and medicine industry was identified as being among the most patent-intensive and trademark-intensive industries, in terms of number of patents or trademarks per 1,000 workers, having generated 13,621 patents during FY 2004-2008 (USDOC, 2012, p. 8) for an average of 291,300 workers during CY 2004-2008 (USDOC, p. 8).

³⁵ Intellectual property protection in the United States is as old as the Republic. Rooted in colonial practice, the concept was enshrined in the patent and copyright clause of the U.S. Constitution, which grants to Congress the power to enact legislation "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. "The Framers drafted the Intellectual Property Clause against the immediate backdrop of the Articles of Confederation but within the overall framework of the English, colonial, and state practices regarding patents and copyright." Edward C. Walterscheid, "To Promote the Progress of Science and Useful Arts: The Background and Origin of the Intellectual Property Clause of the United States Constitution," 2 J. Intell. Prop. L. 1, 3 (1994).

³⁶ The U.S. Administration identified 75 intellectual property-intensive —out of a total 331— industries that are particularly dependent on patent, copyright, or trademark protection.

³⁷ According to the Peterson Institute of International Economics, citing official statistics from the Bureau of Economic Analysis, USDOC, the United States is the world's leading exporter of ideas, with licensing revenue generated by US intellectual property overseas exceeding \$130 billion in 2014 and a surplus of trade in ideas of \$88 billion. Branstetter, Lee, "TPP and the Conflict over Drugs Incentives for Innovation Versus Access to Medicines," (Schott and Cimino-Isaacs, 2016, p. 29).

More recent figures published by the Department indicate that more than 810,000 people work specifically in the biopharmaceutical industry in the U.S. as of 2012, and that the industry supports a total of nearly 3.4 million jobs. This includes jobs directly in biopharmaceutical companies, jobs with vendor companies in the biopharmaceutical supply chains, and jobs created by the economic activity of the biopharmaceutical industry workforce.³⁸ According to the Pharmaceutical Research and Manufacturers of America (PhRMA), the US exported over \$54 billion in biopharmaceuticals in 2014; US biopharmaceutical innovation generated \$97 billion in 2014 in economic value, with a total impact of \$790 billion annually.³⁹

In a survey conducted by researchers at Carnegie-Mellon University in 1994 of research and development (R&D) lab managers to questions concerning the effectiveness of different methods for protecting innovation, patents were ranked highest among those in the pharmaceuticals and medical equipment sectors. These R&D managers considered patents as being an effective mechanism for capturing the competitive advantage from more than half of product innovations and more than one-third of process innovations (USDOC, 2012, pp. 9-10). US drug companies reported that they used product patenting to prevent copying, to block competitors, to enhance the company's reputation, and to aid in negotiations (USDOC, 2012, pp. 46-47). A more recent survey conducted by researchers at the University of California at Berkeley of biotechnology entrepreneurs reported that patents were an important factor for them in obtaining funding.⁴⁰

B. U.S. first in international patent filings

The United States is the largest user of the international patent filing system under the Patent Cooperation Treaty (PCT). The US was the top country of origin, accounting for 61,492 out of a total 215,000 applications from 124 countries in 2014 (WIPO, 2015). As shown in table A.1 (see Annex), applicants from the US and its TPP partner Japan together filed almost half the total number of international patent applications. When the number of filings from China, Germany and the Republic of Korea are included, these five countries collectively filed three-quarters of all PCT applications (WIPO, 2015).

Table A.2 (see Annex) shows the number of PCT applications from all Western Hemisphere states. The U.S. and Canada (3,089) are the largest users of the PCT system in the hemisphere. As regards Latin America and the Caribbean, there were 1,411 international applications filed, with Brazil (581), Mexico (284), Barbados (175), Chile (144), and Colombia (102) being the leading regional filers in 2014.

Telecommunications was the field of technology with the most PCT applications in 2014. Pharmaceutical patents represented the seventh largest technological field among PCT filings, but relative to total filings they have been stagnating since 2007. There were 5,874 PCT applications related to biotechnology and 8,568 to pharmaceuticals in 2014. Merck Sharp & Dohme Corp., a US pharmaceutical company headquartered in New Jersey, was the largest pharmaceutical patent filer

³⁸ USDOC, *supra* note 6.

³⁹ Pharmaceutical Research and Manufacturers of America, "Written Submission of the Pharmaceutical Research and Manufacturers of America (PhRMA) before the U.S. International Trade Commission - Investigation No. TPA-105-001," Feb. 11, 2016, and PhRMA "Special 301 Submission 2016."

⁴⁰ "According to a patent survey conducted by researchers at the University of California Berkeley, 73% of the biotechnology entrepreneurs surveyed reported that potential funders, such as venture capitalists, angel investors, and commercial banks, etc. indicated patents were an important factor in their investment decisions." Biotechnology Industry Organization, "2015 Special 301 Submission," available along with all submissions at www.regulations.gov, docket number USTR-2014-0025 (citing Graham, Stuart J. H. and Sichelman, Ted M., "Why Do Start-Ups Patent?" (September 6, 2008). Berkeley Technology Law Journal, Vol. 23, 2008).

with 171 applications, followed by Novartis AG (141), F. Hoffmann-La Roche AG (135) and the University of California (111) in 2014 (WIPO, 2015).

C. Political spending by the U.S. pharmaceutical industry

According to the Center for Responsive Politics (CRP), the US pharmaceutical and health products industry, which includes drug manufacturers and dealers of medical products and nutritional and dietary supplements, is consistently near the top among federal campaign contributors, traditionally favoring Republican over Democratic candidates (58% to 42% in 2014). The industry's contribution amounts have fluctuated, averaging around US\$30 million annually and peaking at US\$50.7 million in 2012.⁴¹ Nearly \$6.7 million of the pharmaceutical industry's overall donations in 2014 went to members of the Senate Finance Committee, which must clear any trade legislation before it goes to a full Senate vote.^{42 43} Based on data from the U.S. Senate Office of Public Records, the CRP calculates that the pharmaceutical and health products industry is the top industry spender on lobbying activities, having spent a total of more than US\$3.3 billion for the 1998-2016 period.⁴⁴ Spending has averaged over US\$200 million a year, hitting a record of nearly US\$273.2 million on lobbying activities in 2009 around the time the Affordable Care Act was being debated in Congress,⁴⁵ and was US \$230.7 million in 2015.⁴⁶ Lobbying efforts focus on the patent system,⁴⁷ research funding, and Medicare. Over the eight years of TPP negotiations, hundreds of organizations have paid lobbyists to meet with or contact lawmakers and administration to discuss the pact. According to CRP's analysis of lobbying

⁴¹ The CRP is a research group that tracks money in US politics and its effects on elections and public policy. The top federal campaign contributors during the 2014 cycle were Pfizer Inc. (over \$1.5 million), Amgen Inc. (above \$1.3 million) and McKesson Corp. (more than \$1.1 million). <https://www.opensecrets.org/industries/background.php?cycle=2016&ind=H04> [accessed June 12, 2016].

⁴² Mindock, Clark, "Trans-Pacific Partnership Deal Has Mighty Lobbying Power on Its Side," April 9, 2015 <https://www.opensecrets.org/news/2015/04/trans-pacific-partnership-deal-has-mighty-lobbying-power-on-its-side/> [accessed June 12, 2016].

⁴³ The pharmaceutical and health products industry has been the largest campaign contributor in the political career of Senator Orrin Hatch, Chairman of the Senate Finance Committee, totaling more than US\$ 2.3 million since 1989. <https://www.opensecrets.org/politicians/summary.php?cycle=Career&type=I&cid=N00009869&newMem=N#funds> [accessed June 12, 2016]. The industry has donated more than \$672,000 to his campaign committee since 2011. <https://www.opensecrets.org/politicians/summary.php?cid=N00009869&cycle=2016#funds> [accessed June 12, 2016]. He is up for re-election in 2018. Since January 2015, Senator Hatch is the President *pro tempore* of the Senate (the second highest ranking Senate official and third in the line of succession to the presidency). He also serves on the Judiciary Committee as well as the Health, Education, Labor and Pensions Committee, which is responsible for how the FDA operates. Sen. Hatch was key in shepherding fast track authority through Senate passage last year. He has criticized the TPP negotiated deal for failing to require a 12-year regulatory data exclusivity period on biologics, which is the standard under US law. Calmes, Jackie, "Utah Senator Crucial Ally for the Pacific Rim Trade Deal, Is now its Main Hurdle." New York Times, Nov. 15, 2015. On Feb. 3, 2016, Sen. Hatch outlined the steps that the Administration must complete under the TPA before the TPPA can be submitted to Congress for consideration. <http://www.hatch.senate.gov/public/index.cfm/2016/2/as-trade-agreement-advances-hatch-warns-that-congress-won-t-be-a-rubber-stamp> [accessed June 12, 2016].

⁴⁴ <https://www.opensecrets.org/lobby/top.php?showYear=a&indexType=i> [accessed June 11, 2016].

⁴⁵ In terms of lobbying, key players in 2014 included the PhRMA (over \$17.2 million), Amgen Inc. (nearly \$8.6 million), Pfizer Inc. (nearly \$8.5 million), the BIO (almost \$8.3 million), Eli Lilly & Co. (around \$8.2 million), and Novartis AG (over \$6.5 million). <https://www.opensecrets.org/lobby/indusclnt.php?id=H04&year=2014> [accessed on June 12, 2016]. In the 2015 cycle, these organizations spent the following on lobbying: PhRMA (over \$18.9 million), Amgen Inc. (over \$10.5 million), Pfizer Inc. (\$9.4 million), Bayer AG (\$7.65 million), Eli Lilly & Co. (over \$7.1 million), Novartis AG (over \$6.7 million) and Johnson & Johnson (\$6.35 million). <https://www.opensecrets.org/lobby/indusclnt.php?id=H04&year=2015> [accessed June 12, 2016].

⁴⁶ <https://www.opensecrets.org/lobby/indusclnt.php?id=H04&year=a> [accessed June 12, 2016].

⁴⁷ <https://www.opensecrets.org/lobby/issuesum.php?id=CPT&year=2015> [accessed June 12, 2016].

reports, the TPP accounted for \$110 million of total lobbying expenditures by PhRMA since 2009.⁴⁸ Both PhRMA⁴⁹ and the Biotechnology Industry Organization (BIO) have criticized the TPP results on data exclusivity for biologics.⁵⁰

D. Congressional Mandates – Fast Track, Special 301, and May 10 Deal

Since the enactment of the Trade and Tariff Act of 1974 and its Section 301, as expanded by subsequent trade legislation,⁵¹ US Administrations have been required to go after “unreasonable foreign trade practices that are deemed unfair for US exports and to report annually on the progress made. Congress has made such unreasonable foreign practices—including lack of proper intellectual property protection—actionable for retaliation against foreign countries, like withdrawing GSP eligibility (*see* para. 2.5). Viewed in a benign light, Section 301 aims to ensure executive due diligence and responsiveness to trade grievances that are raised through broad public participation of multi-stakeholders; the provision is seen somewhat less generously by foreign governments which feel pressured to accede to US unilateral demands and by access to medicine advocates. Section 301 has withstood a WTO legal challenge and was found not inconsistent with US obligations, thanks to declared executive discretion on any determinations of WTO-consistency of foreign practices.⁵²

In its 2016 Special 301 Report on the state of IPR protection and enforcement in U.S. trading partners around the world, USTR has listed 34 trading partners on its Priority Watch List and Watch List with “the most onerous or egregious acts, policies or practices” that “have the greatest adverse impact (actual or potential)” on US products (USTR, 2016). Placement on these lists indicates that USTR considers that particular problems exist in the country with respect to IPR protection, enforcement, or market access for persons relying on IPR. The 2016 Priority Watch List includes: Argentina, Chile, and Venezuela, among others. USTR must develop action plans with benchmarks for these identified countries to encourage progress on high-priority concerns. The 2016 Watch List includes: Barbados, Bolivia, Brazil, Canada, Colombia, Costa Rica, Dominican Republic, Ecuador, Guatemala, Jamaica, Mexico, and Peru, among others. Additionally, USTR will conduct out-of-cycle reviews for Colombia to assess its commitments to the IP provisions of its FTA with the US, and to monitor Colombia’s implementation of its National Development Plan. Countries that were flagged

⁴⁸ Tucker, Will, “Millions spent by 487 organizations to influence TPP outcome” Oct. 6, 2015, <http://www.opensecrets.org/news/2015/10/millions-spent-by-487-organizations-to-influence-tpp-outcome/> [accessed June 11, 2016].

⁴⁹ *Supra* note 2.

⁵⁰ “While the TPP agreement will not impact the U.S. data protection period, we believe the failure of our Asian-Pacific partners to agree to a similar length of protection is remarkably short-sighted and has the potential to chill global investment and slow development of new breakthrough treatments for suffering patients.” Biotechnology Industry Organization, *BIO Statement on Data Exclusivity Provisions Within the Trans-Pacific Partnership* (Oct. 4, 2015) <https://www.bio.org/media/press-release/bio-statement-data-exclusivity-provisions-within-trans-pacific-partnership> [accessed June 12, 2016].

⁵¹ Including the Trade and Tariff Act of 1984, the Omnibus Trade and Competitiveness Act of 1988, the Uruguay Round Agreements Act, and the Trade Facilitation and Trade Enforcement Act of 2015 (19 U.S.C. § 2242).

⁵² The panel accepted that the US Administration undertook through the Statement of Administrative Action approved by the US Congress at the time it implemented the Uruguay Round agreements, and confirmed to the Panel, that it would exercise its statutory discretion in a way consistent with WTO obligations; i.e., base a determination whether WTO agreement rights had been denied on the results of WTO dispute settlement proceedings. WTO (1999), “United States – Sections 301-310 of the Trade Act of 1974: Report of the Panel,” WT/DS152/R, paras.7.116 and 8.1, Dec. 22, 1999.

for particular US concern in relation to pharmaceutical IPRs were: Argentina, Brazil, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Guatemala, Peru, and Venezuela.^{53 54}

⁵³ For Western Hemisphere countries that are TPP negotiating countries, USTR expressed the following concerns in its 2016 Special 301 report with respect to pharmaceutical IPRs:

Canada- serious concerns about the availability of appeal rights in Canada's administrative process for reviewing regulatory approval of pharmaceutical products as well as about the breadth of the Minister of Health's discretion in disclosing confidential business information; lack of clarity around, and the impact of, the heightened utility requirements for patents that Canadian courts have applied, with this unpredictability undermining incentives for investments in the pharmaceutical sector.

Chile-US urges Chile to implement an effective system for addressing patent issues expeditiously in connection with applications to market pharmaceutical products, and to provide adequate protection against unfair commercial use, as well as unauthorized disclosure of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products.

Mexico-need for improved coordination among federal and sub-federal officials, and the need to devote additional resources to enforcement, to bring more IPR-related prosecutions, and to impose deterrent penalties against infringers.

Peru- the widespread availability of counterfeit and pirated products in Peru; US encourages Peru to coordinate enforcement and pursue prosecutions under the law that criminalizes the sale of counterfeit medicines; lack of clarity in Peru's protections for biotechnologically-derived pharmaceutical products. (USTR, 2016, pp.49, 57, 58, and 63).

⁵⁴ In response to its public solicitation for comments on foreign IPR protection practices, USTR received submissions from 62 interested parties, including foreign governments, NGOs, private sector associations, including the International Generic Pharmaceutical Alliance (IGPA now IGBA), the Biotechnology Industry Organization (BIO) *supra* note 37, the Pharmaceutical Research and Manufacturers of America (PhRMA), and the U.S. Chamber of Commerce's Global Intellectual Property Center (GIPC), of which BIO and PhRMA are members. The submissions can be found at <https://www.regulations.gov/#!searchResults;rpp=25;po=0;s=docket%252Bnumber%252BUSTR-2015-0022;dt=FR%252BPR%252BN%252BO%252BPS> (accessed June 12, 2016). GIPC submitted its latest annual "scorecard" of national IP environments around the world. According to its index, GIPC assessed the IP protection for pharmaceutical products provided by Western Hemisphere countries that are TPP negotiating countries as follows:

Canada- onerous patentability requirements narrow the scope of inventions, particularly for life sciences, deficient pharmaceutical-related patent enforcement and resolution mechanisms under Canada's Patented Medicines Notice of Compliance regulations that do not provide patent holders with a right of appeal and the judicial proceedings on patent disputes are summary and not full processes; and unavailability of patent term restoration for pharmaceuticals. Adoption and implementation of the EU-Canada Comprehensive Economic and Trade Agreement (CETA) would introduce more effective rights of appeal for applicants before generic entry and CETA and TPP implementation would also ensure a minimum patent restoration period for pharmaceuticals. Canada amended its Food and Drug Act in November 2014 to allow the Health Minister to disclose confidential business information and trade secrets, submitted to Health Canada as part of the regulatory approval process for pharmaceuticals and medical devices. Questions remain under what circumstances information will be disclosed.

Chile-patentability of pharmaceutical inventions, absence of an effective pharmaceutical-related patent enforcement and resolution mechanisms, gaps in regulation governing pharmaceutical and agrochemical data protection; TPP implementation would strengthen Chile's national IP environment.

Mexico-the biopharmaceutical industry continues to experience major challenges with patent enforcement, lack of clarity that formulation patents are being recognized consistently by the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) when approving follow-on products; COFEPRIS continues to approve the use or import of large quantities of active pharmaceutical ingredients under patent protection for testing purposes; an average of 10 year delays for patent holders to secure damages in patent infringement cases at the administrative and judicial levels; it remains to be seen how the court ruling that notification to the patent holder and the ability to be heard during the marketing approval process is a constitutional right will be applied in practice; and ongoing concern as to the effective application of 2012 COFEPRIS guidelines that provide a maximum of five years' protection against the use of undisclosed test data (large and small molecules) by any person for purposes of marketing approval. In 2015, Mexican authorities reportedly indicated that regulatory data protection would not be applicable to biologics, and it is not clear whether this approach will remain in relation to Mexico's obligations under the TPPA.

Peru-patentability requirements lack clarity as to the protection of biotechnologically derived pharmaceutical products; treatment methods are not considered as patentable subject matter; Andean Court of Justice has barred the

As noted in previous sections, due to the importance of IP-intensive industries—including the pharmaceutical industry—in the US economy and to US competitiveness, the US was the main driver for greater international recognition and enforcement of IPRs in the Tokyo and Uruguay Rounds, and has pursued—and continues to pursue—these goals through bilateral and regional channels as well. It has also been noted that Congress, when granting fast-track authority and in Section 301, has stipulated as a US negotiating objective to advance IP protection for US innovative and creative industries. To clear the path for Congressional consideration of US FTAs with Peru, Colombia, Panama, and South Korea, the US (Republican) Administration and Congressional (Democratic) leadership agreed in May 2007 to a “new trade policy template” for agreements with developing country partners. This agreement is known as the “Bipartisan Trade Deal” or also the “May 10 Deal.”⁵⁵ For intellectual property, the aim was to incorporate certain flexibilities “further ensuring that developing country free trade agreement partners are able to achieve an appropriate balance between fostering innovation in, and promoting access to, life-saving medicines.” Specifically this meant:

- Clarification that the period of protection for test data for pharmaceuticals by developing country FTA partners will generally not extend beyond the period that such protection is available for the same product in the United States, coupled with a provision that will encourage our partners to process marketing approval applications for innovative drugs in a timely manner.
- Clarification that developing country FTA partners may implement exceptions to normal rules for protecting test data if necessary to protect public health.
- A more flexible approach, for developing country partners, to restoring patent terms to compensate for processing delays. This flexibility is accompanied by new provisions stipulating that trading partners will make best efforts to process patent and marketing approval applications expeditiously.
- More flexibility in terms of the types of procedures that developing country partners may implement to prevent the marketing of patent-infringing products.

recognition of second medical use patents within Andean Community member countries; patent examination process involves major delays and patent authorities tend to lack technical expertise; publicly available list of drug registration applications maintained on the Peruvian Health Authority’s (PHA’s) website does not suffice to provide an effective patent enforcement system given the challenges in securing timely relief through the court system, which can take on average over four years; lack of implementation of patent restoration provisions in Peru’s law as required under the US-Peru FTA. The handling of a request for a compulsory license on the antiretroviral atazanavir in 2015 suggests a fragmented approach within the Peruvian government on compulsory licensing PHA’s position that biologics do not fall under the ambit of the five-year regulatory data protection (RDP) for pharmaceutical products provided under Legislative Decree 1072 and industry reports that on average biopharmaceutical products that have benefited from RDP have only been granted a three-year protection term on average.

GIPC (2016), “The U.S. Chamber International IP Index: ‘Infinite Possibilities,’” Fourth Edition, February, pp. 75-83, 133-136, and 145-149, and GIPC (2016), “U.S. Chamber of Commerce’s Global Intellectual Property Center: 2016 Special 301 Submission,” February 5, pp. 42-48, 49-56, 103-106, and 108-111. Additionally in a Supplementary Statistical Analysis “IP as a Development Tool” annexed to the Index, several graphs are presented purporting to show that protecting IP rights related to the life sciences, such as patents, regulatory data protection, and patent term restoration has a very clear and direct correlation with an environment in which biotechnology can thrive, particularly in terms of levels of advanced biopharmaceutical R&D and innovation output. GIPC (2016), Annex, pp. 1-10 and 26-30).

⁵⁵ “Bipartisan Agreement on Trade Policy” (2007), USTR (Office of the United States Trade Representative) https://ustr.gov/sites/default/files/uploads/factsheets/2007/asset_upload_file127_11319.pdf [accessed June 12, 2016].

- Integration within the intellectual property chapter of a recognition that nothing in the chapter affects the ability of our FTA partners to take necessary measures to protect public health by promoting access to medicines for all, and a statement affirming mutual commitment to the 2001 Doha Declaration on the TRIPS Agreement and Public Health.

The deal also noted that notwithstanding the flexibilities incorporated with respect to pharmaceutical-related IPR provisions, the IP chapters in the four mentioned FTAs to be considered by Congress, represented “an enhancement of IPR protection for pharmaceutical products in those markets, compared to the status quo situation.” This was particularly so for “protecting against unfair commercial use of test and other data submitted in connection with product approval.”

E. Current U.S. FTAs with western hemisphere countries

Table A.4 (see Annex) compares the relevant patent and data protection provisions for pharmaceutical products in US FTAs with Western Hemisphere countries and the TRIPS Agreement. The table shows the expansion, at least in terms of verbiage, of the US FTA template at every iteration from NAFTA (which the TRIPS Agreement largely tracked) to the TRIPS-Plus provisions under the subsequent 5 FTAs with 10 Latin American countries (Chile, Central America and the Dominican Republic, Peru, Colombia and Panama).

On one side of the patent scale perhaps less favorable to pharmaceutical patent holders and more conducive to competition and access to medicine under these FTAs are:

- a broadening of the grounds for justifying revoking a patent or holding it unenforceable (to cover fraud, misrepresentation or inequitable conduct from US-Chile onwards), whereas the TRIPS Agreement only specified that patent revocations and forfeitures be subject to judicial review;
- specific provision for a regulatory review (“Bolar”) exception, allowing for the early working or use of the subject matter of a subsisting patent to support a marketing approval application (from US-Chile onwards);
- an affirmation that countries may take measures supportive of public health in accordance with the Doha Declaration on TRIPS and Public Health, the WTO Council waiver implementing its para. 6, and any TRIPS amendment (under US FTAs with Peru, Colombia, and Panama);
- provision that no Party may consider information in the public domain as undisclosed data (DR-CAFTA);
- provision for an expeditious administrative or judicial procedure for a person requesting marketing approval for a pharmaceutical product to challenge the patent covering that product (under US FTAs with Peru, Colombia, and Panama, albeit this is optional for the 3 as a method to implement the expeditious adjudication of patent infringement disputes); and
- provision for effective rewards for a successful challenge (under US FTAs with Peru, Colombia, and Panama, albeit this is optional for the 3 as a method to implement the expeditious adjudication of patent infringement disputes).

On another side of the patent scale that may be more favorable to patent seekers and access to medicine under these FTAs, are:

- No limitations on the Parties to allow abbreviated approval for pharmaceutical products based on bioequivalence and bioavailability studies (NAFTA, US FTAs with Peru, Colombia, and Panama);

- Best efforts by the Parties to process patent and marketing approval expeditiously (US FTAs with Peru, Colombia, and Panama, consistent with the Bipartisan Trade Deal);
- Disregard of information contained in public disclosures in determining whether an invention is novel or has an inventive step, if the disclosure was made or authorized by the patent applicant within 12 months of filing date (all US FTAs from US-Chile onwards). This “grace period” allows inventors to disclose research findings without forfeiting the ability to obtain patent protection.⁵⁶

But also favorable to patent seekers and holders are:

- Extension of the patent term at the patent holder’s request to compensate for regulatory delays in patent issuance of more than 5 years from the filing date or 3 years from the request for application examination (optional in general for delays in regulatory processes under NAFTA; US FTAs with Chile, Peru, Colombia, and Panama and DR-CAFTA require patent term adjustments for delays in patent issuance; this provision is optional under US FTAs with Peru, Colombia, and Panama, consistent with the Bipartisan Trade Deal);
- Extension/restoration of the patent term or rights for a pharmaceutical product subject to a patent to compensate for unreasonable curtailment of the effective patent term resulting from the marketing approval process (DR-CAFTA; this provision is optional under US FTAs with Peru, Colombia, and Panama, consistent with the Bipartisan Trade Deal).

The TRIPS Agreement does not provide for patent term extensions; NAFTA provides that extensions for unreasonable delays in regulatory processes may be made available.

Finally, on the side of the patent scale favorable to patent holders are the provisions dealing with data protection and patent infringement disputes, as indicated below. It should be recalled that the TRIPS Agreement goes no further than providing that regulatory test data for pharmaceuticals and agricultural chemicals, which were generated with considerable effort, must be protected against disclosure, with exceptions where necessary to protect the public and where other (undefined) steps have been taken to protect against unfair commercial use.

- A Party shall provide that no person may rely on the undisclosed data submitted by another person granted approval to market its pharmaceutical product (that utilizes a new chemical entity), without the latter’s consent, as evidence that a pharmaceutical product is safe and effective, or rely on that grant of approval, to support a product approval application, for a period of 5 years from the date the Party granted the approval to the person submitting the data (NAFTA, US-Chile, DR-CAFTA; for US-Peru, US-Colombia, US-Panama, data exclusivity is for a reasonable period, which “shall normally mean 5 years”);
- When a pharmaceutical product is covered by a marketing approval and a patent in a Party, and the patent terminates before the end of the exclusivity period, the Party shall not alter the exclusivity term (US FTAs with Peru, Colombia, and Panama);
- Provision for procedures and remedies for the expeditious adjudication of patent disputes concerning an approved pharmaceutical product or its approved method of use (DR-CAFTA, US FTAs with Peru, Colombia, and Panama);
- A Party shall implement measures in its marketing approval process to prevent persons, other than the person originally submitting safety or efficacy information for a product that was previously approved in a Party’s territory or in another country, from marketing

⁵⁶ *Supra* note 37 at 25.

- a product covered by a patent during the patent term (DR-CAFTA; optional under US FTAs with Peru, Colombia, and Panama as a method to implement the above provision);
- Notification to the patent owner that a person is requesting approval to enter the market during the patent term (DR-CAFTA; optional under US FTAs with Peru, Colombia, and Panama as a method to implement a transparent system to provide notice); and
- Sufficient time and opportunity for a patent holder to seek remedies, prior to the marketing of an allegedly infringing pharmaceutical product (US FTAs with Peru, Colombia, and Panama).

F. Relevant U.S. IP laws

The principal negotiating objectives for the United States as established by Congress in its recent grant of fast track authority (TPA) in 2015, include for trade-related intellectual property: “ensuring adequate and accelerated and full implementation” of the TRIPS, particularly with respect to enforcement obligations, and “ensuring that the provisions of any trade agreement governing IPRs that is entered into by the United States reflect a standard of protection similar to that found in United States law.”⁵⁷ Thus as stipulated in the TPA, the standard against which the IP provisions of the TPPA is being judged by Congress is that of IP protection under U.S. law. For small-molecule pharmaceutical patent and regulatory data protection, the relevant federal law is the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-4117), known as the Hatch-Waxman Act, which established a regulatory framework that seeks to encourage the manufacture and marketing of generic medicine, while retaining incentives for research and innovation for originator products.⁵⁸ The law sought to address *inter alia* the twin situations at either end of the patent term inherent in the requirement for pre-market regulatory approval by the Food and Drug Administration (FDA) that: (a) patent owners did not enjoy their full patent term as they awaited regulatory approval for commercial marketing in the early years; and (b) generic competitors could not immediately enter the market upon expiration of the patent because they were not allowed to begin testing necessary to receive regulatory approval distortions or situations before the patent expired. Hatch-Waxman amended certain sections of the Federal Food, Drug, and Cosmetic Act (Title 21 Chapter 9 U.S.C.). Some of the most salient features of this law for purposes of the focus of this study are as follows:

- Expanded the list of drugs for which manufacturers may file an Abbreviated New Drug Application (ANDA) for FDA approval of generic drugs, based on bioequivalence studies rather than costlier clinical data from human investigations to show that the proposed generic is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics and intended use to the originator or reference listed drug, thereby relying on the agency’s finding of safety and efficacy for the latter drug;
- Required new drug applicants to include patent information, which the FDA considers as part of its approval process; marketing approval will not be granted to a generic until the patent has expired or is found to be invalid. Thus generic marketing approval is “linked” to the expiration of the originator drug patent (patent linkage);

⁵⁷ Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (Public Law 114-26, Title I) (also known as TPA), signed June 29, 2015, section 102(b)5(A)(i)(I) and (II).

⁵⁸ See also *supra* note 29.

- Granted a 5-year exclusivity period to new drug applications for products containing chemical entities never previously approved by FDA either alone or in combination, during which period no other application may be submitted. Such period is 4 years if the application contains a certification of patent invalidity or non-infringement or 3 years for a drug containing a previously approved active moiety when there are new clinical investigations conducted by the applicants essential for application approval. A new chemical entity means a drug that contains no active moiety⁵⁹ approved by the FDA in another application.
- Provided that making and testing a patented drug solely for the purpose of developing and submitting information for an ANDA did not infringe the patent (“Bolar” exception);
- Enabled generic manufacturers to challenge the original patent in the courts but granted a 30-month stay to patent owners to file suit against their patent challengers; rewarded successful generic challengers with a 180-day market exclusivity period;
- Provided for extension of the patent term on a claimed “product, a method of using a product, or a method of manufacturing a product” to regain some of the time lost while awaiting pre-market regulatory approval;
- Provided for patent term extension if one active ingredient of a product containing multiple active ingredients has not been previously approved.⁶⁰

As regards biologics, the relevant US law is the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) (PL 111-148) 42 U.S.C. §262, which amended the Public Health Service Act (PHS Act), and was enacted as part of the Patient Protection and Affordable Care Act (commonly known as “Obamacare”) in March 2010. The objectives of the BPCI Act are conceptually similar to those of the Hatch-Waxman Act to establish an abbreviated licensing pathway for FDA approval of drug products, in this case, biological products shown to be biosimilar to, or interchangeable with, a biological reference product previously approved and licensed by the FDA.⁶¹ However, the implementation of such licensing presented challenges given the scientific and technical complexities that may be associated with the larger and typically more complex structure of biological products, as well as the processes by which such products are manufactured. Most biological products are produced in a living system such as a microorganism, or plant or animal cells, whereas small molecule drugs are typically manufactured through chemical synthesis.⁶² The BPCI Act includes, *inter alia*:

⁵⁹ “An active moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.” FDA <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069962.htm> [accessed June 12, 2016].

⁶⁰ FDA *supra* note 45 and USPTO <http://www.uspto.gov/web/offices/pac/mpep/s2750.html> [accessed June 12, 2016].

⁶¹ Section 262 (i) of the Federal Food Drug, and Cosmetic Act defines “biological product” as meaning “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings” and a biosimilar product as “highly similar to the reference [biological] product notwithstanding minor differences in clinically inactive components” and “there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.”

⁶² FDA (2015) “Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009: Guidance for Industry,” FDA, April 2015 <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444661.pdf> [accessed June 12, 2016]

- A bar on regulatory approval of a biosimilar application as biosimilar or interchangeable with a biologic product that references an approved biologic product, for 12 years from the date of first licensing of the reference biologic product (12-year exclusivity period for the reference biologic product);
- A bar on submissions of any biosimilar application referencing the approved reference biological product for 4 years from the date of first licensing of the reference product (4-year exclusivity for reference biologic product);
- An exclusivity period (earlier of 1 year after commercial marketing or 18 to 42 months depending whether there is patent litigation) for the first biological product determined to be interchangeable with the reference product for any condition of use, during which a second or subsequent biological product may not be determined interchangeable with that reference product (exclusivity for first licensed biosimilar);
- No exclusivity for licenses for a supplement for the reference biological product, or for an application by the same sponsor or manufacturer of the reference product for a change resulting in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or for any modification to the structure of the biological product that does not result in a change in safety, purity, or potency (no exclusivity for evergreening).⁶³

The above US law baseline against which the TPPA will be judged by Congress entails then provision for patent extensions, patent linkages, and 12 year data exclusivity for biologics. Data exclusivity is more attractive sometimes and a stronger right than patent protection for originator brand firms, as patents are vulnerable to challenge by third-party competitors as not being sufficiently novel, inventive or useful. This is one reason why these firms pushed so adamantly for 12-year exclusivity in the TPP negotiations⁶⁴ (see para. 3.5).

It should be noted that there was much Congressional debate on whether and how long to grant exclusivity for biologics; for example, from 5 to 14 years. Prior to the BPCI's passage, a report issued by the U.S. Federal Trade Commission—an agency whose mission is to prevent business practices that are anti-competitive or deceptive or unfair to consumers—concluded that patent protection and market-based pricing would promote competition by follow-on biologics (FOB), as well as spur biologic innovation. The report stated that a 12- to 14-year regulatory exclusivity period was too long to promote innovation by these firms. This was because they likely would retain substantial market share after FOB entry and that FOB manufacturers were unlikely to need additional incentives—such as a 180-day marketing exclusivity period—to develop interchangeable FOB products (USFTC, 2009, pp. v-x). Obviously, Congress thought differently. A financial model developed in 2011 by Duke University and other economists to evaluate how long a market exclusivity period would be required until a typical pioneer biologic earned a positive investment return, determined that a 12-year data exclusivity period for new biologics appropriately balanced potential cost savings from price competition from biosimilars with long-term incentives for investment in innovative biologics. These economists found that the 12-year data exclusivity period operated mainly as an insurance policy to encourage innovation when patent protection is limited.⁶⁵

⁶³ “Evergreening” describes a strategy of patenting new forms or other minor variations of existing products that have no additional therapeutic value and display limited inventiveness, in order to prolong patent protection in an inappropriate manner, thus creating a negative effect on access to medicines, as well as on further innovation (WHO, WIPO, WTO (2013) p. 131).

⁶⁴ See *supra* note 6 at pp. 127-128/.

⁶⁵ Grabowski, Henry G., Genia Long and Richard Mortimer (January, 2011) “Data Exclusivity for Biologics,” *Nature Reviews Drug Discovery*, Vol. 10, pp. 15-16 <http://fds.duke.edu/db/attachment/1592> [accessed June 12, 2016].

Questions have arisen since the BPCI's passage as to whether Congress has provided for test data or market exclusivity. Some Congressional proponents of the law wrote to the FDA clarifying that the law did not provide for market exclusivity for innovator products, but rather provided data exclusivity for 12 years from their date of FDA approval. Data exclusivity only prohibits the FDA from allowing another manufacturer to rely on the data of an innovator—and the agency's prior finding of safety, purity and potency for the innovator product—to support approval of another product. It does not prohibit or prevent another manufacturer from developing its own data to justify FDA approval of a full biologics license application rather than an abbreviated application that relies on the prior approval of a reference product. Congressional proponents stated moreover that no product can be granted bonus years of data exclusivity for mere improvements on a product. If a next generation product is approved by the FDA as a new product (significant changes in safety, purity, or potency) then that new biologic will receive its own 12-year period of data exclusivity.⁶⁶ One reading of the law would be that a competitor manufacturer could file a biosimilar application after four years from the date of the licensing of the reference biologic product, but the application would not be eligible for approval until after 12 years from the licensing date of the reference biologic product. Since the enactment of the BPCI, the administration's annual budget proposals have called consistently for a reduction of the 12 year exclusivity period to 7 years.⁶⁷ On March 6, 2015, the FDA approved the first biosimilar product to be approved in the U.S.⁶⁸

G. Domestic policy debate on drug prices

Health care has been a defining issue in U.S. campaigns and elections, especially since the passage of Obamacare in 2010. When Turing Pharmaceuticals raised the price of Daraprim by 5,455 percent⁶⁹ and with recent pharmaceutical mergers to avoid US corporate taxes (see para. 4.4), pharmaceutical pricing and profits moved to the fore of the agendas of some leading 2016 US presidential candidates.⁷⁰ A recently published report by a US pharmacy benefits manager found that the average price of brand-name prescription drugs rose 16.2% in 2015, 98.2% since 2011, and 164% since 2008 in the United States. Specialty pharmaceuticals (often biologics) accounted for 37% of drug expenditures in 2015, and are expected to reach 50% by 2018.⁷¹ Both Hillary Clinton and Bernie Sanders, Democratic presidential candidates, have called for legalizing prescription drug imports from Canada and other countries with similar safety standards as the US. Additionally, Clinton would require pharmaceutical companies that receive federal support to invest a sufficient amount of their

⁶⁶ Letter from U.S. House Representatives Anna Eshoo, Jay Inslee, and Joe Barton to Commissioner Margaret Hamburg, FDA, Dec. 21, 2010 and letter from U.S. Senators Kay Hagan, Michael Enzi, Orrin Hatch, and John Kerry to Commissioner Margaret Hamburg, FDA, Jan. 7, 2011.

⁶⁷ <https://www.whitehouse.gov/omb/budget> [accessed June 12, 2016]. See also <http://www.hhs.gov/about/budget/budget-in-brief/cms/medicare/index.html> [accessed June 12, 2016] for explanatory details on the administration's proposals to increase competition for biologics.

⁶⁸ Sandoz, Inc.'s Zarxio, which is biosimilar to Amgen Inc.'s Neupogen (filgrastim), which was originally licensed in 1991. FDA News Release (March 6, 2015), "FDA approves first biosimilar product Zarxio" <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm> [accessed June 12, 2016].

⁶⁹ Pollack, Andrew "Drug Goes from \$13.50 to \$750 Overnight," New York Times, Sept. 20, 2016. <http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>

⁷⁰ https://ballotpedia.org/2016_presidential_candidates_on_healthcare [accessed June 12, 2016].

⁷¹ The Express Scripts Lab (2016), "Express Scripts 2015 Drug Trend Report," March, 2016 <http://lab.express-scripts.com/lab/drug-trend-report> [accessed June 12, 2016]. The report also found that biosimilars could offer a savings opportunity in the US of \$250 billion over the next decade, including nearly \$39 billion over the next three years. See also Crow, David "Price of Branded Prescription Drugs in the US Doubles in 5 years," Financial Times, March 15, 2016.

revenue in research and development, not marketing or profits.⁷² Clinton's plan would eliminate corporate write-offs for direct-to-consumer advertising, simplify the R&D tax credit, and establish a mandatory FDA pre-clearance procedure for these ads funded through user-fees paid for by pharmaceutical manufacturers. She also proposes lowering the biologic exclusivity period from 12 to 7 years and providing prioritized, expedited FDA review of biosimilar applications that only have one or two competitors in the marketplace.⁷³ These proposals would require legislative passage to implement. Republican Presidential candidate, Donald Trump, has also called for great competition in medicine prices, including through access to imported drugs, and criticized the political spending by and influence of the pharmaceutical industry.⁷⁴ According to Trump's healthcare reform plan, "Though the pharmaceutical industry is in the private sector, drug companies provide a public service. Allowing consumers access to imported, safe and dependable drugs from overseas will bring more options to consumers."⁷⁵

⁷² The Pew Charitable Trusts found that the US pharmaceutical industry spent \$27 billion in 2012 on drug promotion. The Pew Charitable Trusts (2013) "Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patents," <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients> [accessed June 12, 2016]. "Pharmaceutical and biotechnology companies in the S&P 1500 earn an average net profit margin of 16% compared with an average of about 7% for all companies in the Index, according to S&P Capital IQ," Whalen, Jane, "Why the U.S. Pays more than Other Countries for Drugs," *Wall Street Journal*, Dec. 1, 2015.

⁷³ <https://www.hillaryclinton.com/briefing/factsheets/2015/09/21/hillary-clinton-plan-for-lowering-prescription-drug-costs/> [accessed June 12, 2016].

⁷⁴ Haddon, Heather, "Trump Vows to Take on 'Powerful' Drug Companies, Drive down Costs," *Wall Street Journal*, Feb. 4, 2016 <http://blogs.wsj.com/washwire/2016/02/04/trump-vows-to-take-on-powerful-drug-companies-drive-down-prices/> [accessed June 12, 2016].

⁷⁵ <https://www.donaldjtrump.com/positions/healthcare-reform> [accessed June 12, 2016].

III. Key trends in the global and regional pharmaceutical industry

The IMS Institute for Health Informatics forecasts that global spending on medicines will reach nearly \$1.3 trillion by 2018, an increase of about 30% over the 2013 level. The United States remains the largest market, representing over one-third of the global total, and is expected to grow at a compound annual growth rate of 5-8% through 2018. In the last five years, the value of small molecule products facing loss of exclusivity in developed markets totalled \$154 billion, however patent expiries peaked in 2011-2012 and will moderate through 2018. A further \$48 billion of spending for biologic medicines will lose exclusivity in the next five years, but the gradual evolution of biosimilar regulations and competition will result in less impact on brands than is typically seen with small molecules (IMS (2014)). The USFTC report stated that follow-on biologic entry would be likely only in biologic drug markets larger than \$250 million in annual sales. It also found that only two or three biosimilar manufacturers were likely to attempt entry for a given pioneer biologic product and they were unlikely to introduce their drugs at discounts any larger than between 10 and 30 percent of the pioneer product's price (USFTC (2009), pp. iv). Generics are the largest driver of growth in spending on medicines globally as well as the largest growth contributor in Latin America and smallest contributor in North America. In 2014, generics represented 86% of the total volume of medicines consumed. Specialty medicines are larger drivers of spending growth in developed regions such as North America and Europe, than in developing countries (IMS (2014)). The global market potential for biologics is estimated to reach \$250 billion globally by 2020, of which \$11-25 billion for biosimilars and non-original biologics (Rickwood and Di Biase 2013). Seven of the top ten pharmaceutical companies in biologics are US multinationals, based on 2014 sales.⁷⁶

⁷⁶ PMGroup, "Top 15 Pharma Companies by Biologic Sales," compiled from GlobalData's pharmaceutical revenue figures, which are based on sales of prescription medicines in 2014. The top 10 biologics companies are Roche (\$30.1 billion), Amgen (\$17.6 billion), Novo Nordisk (\$14.2 billion), AbbVie (\$13.9 billion), Sanofi (\$13.9 billion), Johnson & Johnson (\$11.4 billion), Pfizer (\$11.3 billion), Merck & Co. (\$9 billion), Lilly (\$7 billion), and Biogen Idec (\$6 billion) http://www.pmlive.com/top_pharma_list/biologic_revenues [accessed June 12, 2016].

Not only is the United States the world's largest market for pharmaceuticals, it is the world leader in biopharmaceutical research. According to PhRMA, U.S. firms conduct the majority of the world's research and development (R&D) in pharmaceuticals, produced more than half of the world's new molecules in the last decade, and hold the IPRs on most new medicines.⁷⁷ PhRMA companies invested \$51 billion in R&D in 2014; the biopharmaceutical industry invests more than 18% of sales generated in further R&D.⁷⁸ But pharmaceutical innovation is also the product of public investment, with the U.S. National Institutes of Health (NIH) taken together funding about \$31 billion annually in biomedical research.⁷⁹

Research and development for new medicines are costly. Citing researchers at Tufts University, the US Chamber of Commerce has stated that it takes on average \$2.6 billion and 10 or more years to research and develop a successful new treatment; the FDA approves only 12% of potential medicines that enter clinical trials.⁸⁰ And biosimilars are more costly than developing generic versions of traditional small molecule medicines due to the complexity of biopharmaceuticals (WHO, WIPO, and WTO (2013) p. 52). The USFTC calculated that follow-on biologics products were likely to take eight to ten years to develop, and their development would likely cost between \$100 and \$200 million. These amounts differ substantially from the product development costs for small-molecule generic drugs, which the FTC said typically take three to five years to develop and cost between \$1 and \$5 million (USFTC (2009), p. iii). Entry into the US biosimilar market also requires establishing manufacturing facilities that meet FDA requirements regarding good manufacturing practices that may cost \$250 million. Moreover, because biosimilars are not identical to the reference originator drug and because of the risk of immunogenicity arising from introducing a foreign biological substance into the human body, at least some clinical trials will likely be required.⁸¹ The biopharmaceutical pipeline has over 7,000 new medicines currently in development around the world with approximately 3,400 compounds currently being studied in the U.S. —more than in any other region around the world. Biologics account for a quarter of all new drugs in clinical trials or awaiting FDA approval.⁸²

The pharmaceutical industry is heavily dependent on the development of new molecules to replace the revenue stream of older drugs that come to the expiration of their patent terms. Several large multinationals produce the majority of innovative pharmaceuticals globally but have come to rely more heavily on research performed by industry partners, including smaller, innovative manufacturers and academic institutions.⁸³

This research is either acquired by large companies that can bring the products to commercialization or independently financed. Major pharmaceutical companies continue to diversify into biologics through acquisitions of biotechnology companies, in-licensing of products, and research and development alliances. Some biotech firms have chosen to license their products through joint

⁷⁷ USDOC *supra* note 6, and PhRMA (2016) “Special 301 Submission 2016,” p.2.

⁷⁸ PhRMA *supra* note 40, but *see* also the Pew Charitable Trusts, *supra* note 70.

⁷⁹ Public Citizen, “Comments to the United States International Trade Commission Re: Investigation No. 332-543, Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy,” which was submitted as part of Public Citizen’s submissions to the Special 301 Committee, available along with all submissions at www.regulations.gov, docket number USTR-2014-0025.

⁸⁰ <http://www.theglobalipcenter.com/access-to-medicines-and-the-tpp/> [accessed June 12, 2016].

⁸¹ Blackstone, Erwin A. and Fuhr, Joseph P. “Biologics & Biosimilars: The Possibility of Encouraging Innovation and Competition,” *The SciTech Lawyer*, Spring 2015.

⁸² USDOC *supra* note 6 and PhRMA *supra* note 40.

⁸³ There are claims that PhRMA has “de-commissioned” itself from high-risk R&D and that “roughly 75 percent of so-called new molecular entities with priority rating (the most innovative drugs) trace their existence to NIH funding, while companies spend more on ‘me too’ drugs (slight variations of existing ones).” Mazzucato, Mariana, “Big Pharma Owes a Debt to Society,” *Providence Journal*, Nov. 3, 2015.

ventures with multinational pharmaceutical partners, while reserving rights to the domestic market. Many generic drugs manufacturers are also producers of biosimilars.⁸⁴

Global mergers hit a record \$4.7 trillion in 2015, of which healthcare mergers reached \$ 723.7 billion, according to Dealogic data. The largest deal involved the merger approved by the boards of Pfizer and Allergan worth more than \$160 billion, now since canceled.⁸⁵ Combining the two companies would have displaced Johnson & Johnson as the world's largest maker of drugs and medical devices. At the time, the main attractions for Pfizer were to minimize its US tax bill by moving its headquarters to Ireland, and to add shareholder value.⁸⁶ Since the cost of developing new pharmaceutical products is exceptionally high, one way for pharmaceutical companies to seek to extend their product range is simply to buy another firm.⁸⁷

According to the WTO, global imports of pharmaceutical products exceeded half a trillion dollars in 2014. Trade in electro-medical apparatus —such as ultrasound and MRI equipment—exceeded 100 billion dollars. Implementing the WTO's Trade Facilitation Agreement would help expedite the movement of goods across borders, reducing trade costs by an average of 14.5%. This would have a big impact across the board—including for access to medicines; for example, the Agreement contains provisions for the expedited handling of perishable goods, which is vital in the cold chain management and transportation of medicine, such as vaccines.⁸⁸

The Biotechnology Innovation Organization (BIO) estimates that U.S. exports of biopharmaceuticals to TPP countries in 2014 were valued at about \$8 billion and that biologics accounted for about 28 percent of that total (or \$2.3 billion). The top three markets for biopharmaceuticals in 2014 were Canada, Mexico, and Australia (USITC (2016), p. 288 note 166). The U.S. International Trade Commission (USITC) estimates that U.S. exports of chemical products, including pharmaceuticals, would be 0.7 percent higher (\$1.9 billion) under the TPP than baseline estimates, and that U.S. imports would be 1.3 percent higher (\$5.3 billion) than the baseline, due in part to tariff reductions. This could result in a 0.3 percent decline in output, relative to the baseline, by 2032. Much of TPP's impact on trade is expected to center on the new US FTA partners; i.e., Brunei Darussalam, Malaysia, and Viet Nam (USITC (2016), p. 33).

⁸⁴ *Id.*

⁸⁵ “The Biggest Mergers and Acquisitions of 2015” <http://www.cnn.com/2015/12/23/the-biggest-merger-deals-of-2015.html> [accessed June 12, 2016] and Evans, Melanie “Dealmaking Keeps Heady Pace (Jan. 23, 2016) <http://www.modernhealthcare.com/article/20160123/MAGAZINE/301239984/dealmaking-keeps-up-heady-pace> [accessed March 6, 2016]. According to CNBC, the Pfizer-Allergan deal is worth as much as \$191 billion. According to *The Economist*, the value of global takeovers in the healthcare industry amounted to \$673 billion in 2015, still a record high. *The Economist* (Jan. 16, 2016), “Golden Years,” p. 9.

⁸⁶ Reuters (Oct. 29, 2015), “Pfizer needs a big deal, analysts say; Allergan 'makes sense’” <http://www.reuters.com/article/2015/10/29/us-allergan-m-a-pfizer-analysts-idUSKCN0SN1ET20151029#MjI1LVgiF7PByqcZ.97> [accessed June 12, 2016]. See also Abelson, Reed (Oct. 29, 2015), “Health Care Companies in Merger Frenzy” <http://www.nytimes.com/2015/10/30/business/dealbook/health-care-companies-in-merger-frenzy.html?smprod=nytcore-iphone&smid=nytcore-iphone-share> [accessed June 12, 2016], and de la Merced, Michael G. (Nov. 22, 2015), “Pfizer and Allergan Near \$150 Billion Merger Deal,” <http://www.nytimes.com/2015/11/23/business/dealbook/pfizer-and-allergan-near-150-billion-merger-deal.html?ribbon-ad-idx=4&rref=business/dealbook&module=Ribbon&version=context®ion=Header&action=click&contentCollection=DealBook&pgtype=article> [accessed June 12, 2016].

⁸⁷ *The Economist* (Oct. 29, 2015) “Pfizer and Allergan may make a medical monster,” <http://www.economist.com/news/business/21677349-biggest-example-yet-how-deal-hungry-pharmaceutical-firms-are-pfizer-and-allergan-may-make> [accessed June 12, 2016].

⁸⁸ WTO Director-General Roberto Azevêdo (Oct. 28, 2015), opening remarks at the Joint Technical Symposium by the WHO WIPO and WTO on “Public Health, Intellectual Property, and TRIPS at 20: Innovation and Access to Medicines; Learning from the Past, Illuminating the Future,” Geneva https://www.wto.org/english/news_e/spra_e/spra93_e.htm [accessed June 12, 2016].

IV. Key TPPA provisions affecting pharmaceutical products

Table A.4 showed a certain natural progression in the patent and data exclusivity provisions in terms of generally expanding protection with respect to pharmaceutical products, from the NAFTA, US-Chile, DR-CAFTA to the more recent US FTAs with Peru, Colombia and Panama. The TPPA continues this trend.

A. TPPA features different from previous U.S. FTAs with western hemisphere countries

But the TPPA does differ in some of the following ways from the more recent US FTAs with Western Hemisphere countries. Chief among these is that the TPPA is the first US FTA, indeed the first international trade agreement to include specific provisions for extended regulatory data protection for biologics.

Patent Cooperation and Transparency

- The TPPA has extensive provisions encouraging: coordination, training and information exchange between and among IP offices of the TPP Parties, covering several specific IP areas, including technical assistance for developing countries (TPPA Art. 18.13); patent cooperation and sharing of search and examination work, including to reduce differences in the procedures and processes of patent offices (TPPA Art. 18.14); and cooperation on traditional knowledge associated with genetic resources, including in determining prior art and in examining patent applications (TPPA Art. 18.16). Cooperation activities are on a best endeavors basis, subject to the availability of resources, and on request and mutually agreed terms between and among the Parties involved (TPPA Art. 18.17).
- The TPPA commits the Parties to endeavor to publish unpublished pending patent applications promptly or as soon as practicable (TPPA 18.44).
- The TPPA specifies the minimal information that Parties must make available to the public relating to published patent applications and granted patents, such as search and examination results, non-confidential communications from applicants, and literature citations submitted (TPPA 18.45).

Patent Process

- The TPP Parties confirm that patents are available for at least one of the following: new uses of a known product, new methods of using a known process or new processes of using a known product (TPPA Art. 18.37.2). This provision has been said to support incremental innovation, but it only goes so far. A Party does not have to make available patents for all three of these subject matter categories, but at least for one of them. Moreover, if it allows new processes to be patentable, a Party may still limit those new processes to those that do not claim the use of the product as such. Whatever new uses, methods or processes a Party deems patentable must still meet the requirements of novelty, inventive step, and industrial application. A Party may still exclude inventions from patentability that are necessary to protect *ordre public* or morality, exclude diagnostic, therapeutic and surgical methods of treatment of humans or animals and biological and microbiological processes, and other exclusions broadly in line with TRIPS Art. 27.2 and 27.3 (see para. 2.9).
- Where there are separate applications of an invention made independently by more than one inventor, the TPPA sets out the priority rules each TPP Party shall follow in granting the patent (TPPA Art. 18.42);
- The TPPA provides that each TPP Party shall make best efforts to process patent applications in an efficient and timely manner to avoid unreasonable or unnecessary delays. (TPPA Art. 18.46.1). US FTAs with Peru, Colombia, and Panama contain a similar provision but use the term “expeditiously,” rather than “efficient and timely manner.” The latter term used under the TPPA may be clearer and less ambiguous that the goal is to have effective and not just expedient processing of applications. The 3 FTAs also provide that the Parties shall cooperate and assist one another in these efforts; the above-mentioned TPPA provisions for enhanced cooperation and sharing of search and examination work among patent offices of the TPP Parties may help in making patent application and issuance processes more efficient and timely.
- The TPPA newly provides that a Party may provide procedures for a patent applicant to request to expedite the examination of its patent application (TPPA Art. 18.46.2). By its own terms such provision is optional, and does not commit a Party to respond to an applicant’s request any faster, than would normally apply through best efforts to process the application in an efficient and timely manner.
- The TPPA requires a Party to adjust the patent term at the patent owner’s request, to compensate for unreasonable delays (of > 5 years from the application filing date in the Party or 3 years after a request for application examination, whichever later) by authorities in the issuance of a patent (TPPA Art. 18.46.3 and 4). The TPPA does not specify a minimum or maximum length of time required as compensation to extend the patent term beyond its original 20 years. This requirement exists under the US FTA with Chile and DR-CAFTA. It is optional under the US FTAs with Peru, Colombia and Panama in the case of unreasonable delays in patent issuance for pharmaceutical products. Note the exception that Peru has negotiated to seek a waiver from the Andean Community that would allow it to meet this TPPA obligation on pharmaceutical products (para. 5.6).
- The TPPA limits the scope for patent term adjustments/extensions due to patent office delays, by allowing TPP Parties to discount periods of time not directly attributable to the granting authority in determining what constitutes “unreasonable delays” in issuing a patent (TPPA Art. 18.46.3). Such a provision exists under the US FTAs with Chile, Peru, Colombia and Panama and DR-CAFTA.

- Similar to patent applications, the TPPA also provides that each TPP Party shall make best efforts to process marketing approval applications for pharmaceutical products in an efficient and timely manner to avoid unreasonable or unnecessary delays (TPPA Art. 18.48.1). As with patent applications, the US FTAs with Peru, Colombia, and Panama use the term “expeditiously” rather than “in an efficient and timely manner” with respect to making best efforts to process pharmaceutical marketing approval applications.
- With respect to a pharmaceutical product that is subject to a patent, the TPPA requires a Party to adjust/restore the patent term “to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process” (TPPA Art. 18.48.3). Such a requirement exists under DR-CAFTA, but not under the US-Chile FTA. Under the US FTAs with Peru, Colombia, and Panama, it is optional rather than obligatory for a Party to make pharmaceutical patent term restoration available. As noted below, Peru has negotiated an exception under the TPPA to seek a waiver from the Andean Community to meet this TPPA obligation. The TPPA does open the door for a TPP Party to apply conditions and limitations in implementing this obligation provided it continues to give effect to this Article. (TPPA Art. 18.48.3).
- The TPPA newly provides that a TPP Party may adopt or maintain procedures that expedite the processing of marketing approval applications with a view to avoiding unreasonable curtailment of the effective patent term (TPPA Art. 18.48.4). By its own terms, provision of such expedited processing is optional.

Regulatory data protection for biologics and other pharmaceutical products

- With respect to undisclosed test or other data concerning the safety and/or efficacy of “a new pharmaceutical product,” the TPPA provides that a Party may not permit a third party to rely on “that information” or the marketing approval granted to the person that submitted that information without the latter’s consent, to market the “same or a similar” product, for at least 5 years from the date of approval in that Party (TPPA Art. 18.50.1(a)), or in the case of marketing approval “in another territory,” from the date of approval in “that Party” (18.50.1(b)). It would appear that the reference to “that Party” used here refers to the TPP Party that is requiring the submission of safety and efficacy data in order to grant the marketing approval for a new pharmaceutical product in its territory. The exclusivity period would not run from the earlier date of approval in the other territory or market where the referenced information was submitted (but note the exception for Peru in this respect, paras. 5.7 and 5.8). The TPPA does not specify that the “other territory” has to be that of another TPP Party, so it could be of a non-TPP Party. In footnote 52, a pharmaceutical product is defined as “similar” if the request for marketing approval is based on the safety and efficacy data or prior approval of the previously approved product. Previous US FTAs with Western Hemisphere countries and the TRIPS Agreement do not use the terms “same or similar” product or “that information.” These terms as used in the TPPA may serve to provide greater clarity about what it is to be covered, and may not necessarily expand the scope of regulatory data protection in practice.
- The TPPA newly provides for data protection for incremental innovation that builds upon previously approved pharmaceutical products, but just as with patenting of new uses or processes, this only goes so far. A TPP Party shall apply at least 3 years data exclusivity for new clinical information submitted for the marketing approval of a previously approved pharmaceutical product covering a new indication, a new formulation or a new method of administration (TPPA Art. 18.50.2(a). This may allow data exclusivity protection to be extended for changes in the methods of administration that do not necessarily enhance the safety or efficacy of a previously approved product. Alternatively,” the TPPA provides for a minimum 5 years of data exclusivity for new pharmaceutical products that contain a chemical entity not previously approved in the

Party (TPPA Art. 18.50.2(b)). The use of the term “alternatively” indicates that a Party may provide data exclusivity either for 3 years for a new indication, a new formulation or a new method of administration of a previously approved pharmaceutical, or for 5 years for a combination with a chemical entity not previously approved, but does not have to apply both kinds of data protection. They are options. Moreover footnote 55 exempts a TPP Party from having to apply either of these provisions, if it provides at least 8 years of data protection of a pharmaceutical product other than a biologic.

- The TPPA newly requires that a Party provide a “period of at least 8 years” of “effective market protection” “from the date of first marketing approval of a [new biologic] in that Party” for the undisclosed safety and efficacy information submitted to obtain marketing approval of the product (TPPA Art. 18.51.1(a)). Alternatively, a Party may provide “effective market protection to deliver a “comparable outcome in the market” through at least 5 years of data protection from the date of the first marketing approval in the Party, “through other measures” and “recognizing that market circumstances also contribute to effective market protection” (TPPA Art. 18.51.1(b)). The terms “comparable outcome in the market,” “other measures,” and “market circumstances” are not defined. One point of contention with respect to this alternative is, or will be, whether the combination of 5 years of data protection plus other measures plus market circumstances must provide a minimum of 8 years of data protection, or whether a Party can meet its obligation by delivering a “comparable outcome” of protection that is less than 8 years. TPPA Art. 18.51.1(b) does not specifically provide that the protection outcome be “8 years,” only that it be “comparable,” which may be interpreted to mean “similar” or “close to” and not the “same” as 8 years. Canada and Japan already provide 8-year regulatory data exclusivity periods, and the US 12 years for biologics. As noted, some members of Congress and pharmaceutical associations are displeased that US negotiators failed to secure 12 years of data protection for biologics under the TPPA. Under pressure from Congress, US negotiators will seek to clarify via side letters with the other TPPA Parties what “other measures” they will apply or how “conditions” in their markets will contribute to meeting their respective obligations under TPPA Art. 18.51.1(b). Australia, Chile, and New Zealand have stated that they do not plan on changing their current 5-year data protection laws.
- The TPPA defines a biologic, for purposes of regulatory data protection, as a “product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human being for the prevention, treatment or cure of a disease or condition” (TPPA Art. 18.51.2). This definition thus excludes non-protein biologics from data protection, e.g., those composed of nucleic acids.
- The TPPA bars a Party from cutting short the data exclusivity period it provides in the event that the patent protection terminates beforehand (TPPA Art. 18.54). This provision also exists in the US FTAs with Peru, Colombia, and Panama.
- The TPPA provides that the Parties will review the exclusivity periods and scope of application in relation to biologics in 10 years after the entry into force on the TPPA, or as decided by the Parties, with a view to providing effective incentives for biologics and ensuring that the scope of applications remains consistent with international developments regarding additional categories that are or contain a biologic (TPPA Art. 18.54).

TRIPS and public health flexibilities

- Notwithstanding the provisions relating to the protection of undisclosed test data for new pharmaceutical products and biologics (TPPA Arts. 18.50.1, 18.50.2, and 18.51), the TPPA explicitly recognizes (as did the US FTAs with Peru, Colombia, and Panama) that a TPP Party may take measures to protect public health in accordance with the Doha Declaration on TRIPS and Public Health, any waiver of the TRIPS Agreement granted in

accordance with the WTO Agreement to implement the Declaration, or any amendment of the TRIPS Agreement to implement the Declaration that comes into force (TPPA 18.50.3). These WTO instruments refer *inter alia* to compulsory licenses, and do not specifically mention undisclosed test data, so it is not clear to what extent the TPPA would allow a TPP Party to deviate from its data exclusivity obligations on the basis of the public health flexibilities encompassed in these WTO instruments, in the event of a national emergency or public health crisis. That being said and as noted below, Chile has negotiated an exception under the TPPA that explicitly allows it to continue to be able to terminate regulatory data protection for justified grounds of public health, national security, noncommercial public use, national emergency or other extremely urgent circumstances or where the pharmaceutical product becomes subject to compulsory licensing.

- The TPPA newly commits each Party to notify the WTO of its acceptance of the *Protocol Amending the TRIPS Agreement*, if it has not already done so; *i.e.*, Peru and Viet Nam (TPPA Art. 18.6).
- The TPPA reserves the right of TPP Parties to have a national or international exhaustion system of IPRs, thus preserving the possibility of parallel importation (TPPA Art. 18.11).

Patent Linkage

- The TPPA requires a Party, if it permits a third party to rely on the safety and efficacy information of a pharmaceutical product previously approved in the Party or abroad in another territory, to have a system of notice to the patent holder prior to the marketing of the product that a third person is seeking to market the product during the patent term. The Party is also required to provide the holder with adequate time and opportunity to seek, prior to the marketing of an allegedly infringing product, available remedies, such as judicial or administrative procedures, and expeditious remedies, such as preliminary injunctions, for the timely resolution of patent validity or infringement disputes (TPPA Art. 18.53.1). Alternatively, a TPP Party may elect to adopt or maintain a patent linkage system that precludes the issuance of a marketing approval to any third person seeking to market a patented pharmaceutical product without the holder's consent. This system would be based on patent-related information submitted to the marketing approval authority by a patent holder or the approval applicant, or based on direct coordination between that authority and the patent office (TPPA Art. 18.53.2). An alternative patent linkage system was also provided as an option under the US FTAs with Peru, Colombia, and Panama, with the additional provision for effective rewards for a successful patent challenge. DR-CAFTA required the Parties to implement measures in its marketing approval process to prevent third persons from marketing a pharmaceutical product covered by a patent, and to provide notice to the patent holder of the request and identity of any third person requesting entry into the market during the patent term.

B. Exceptions to the TPPA IP Chapter

There is an Annex to the intellectual property chapter of the TPPA, which includes a general exception to or understanding on the provisions relating to legal remedies and safe harbors for the enforcement of copyright on the Internet. There are also specific exceptions for New Zealand on the protection of plant species, as well as exceptions for Chile, Malaysia and Peru in relation to the pharmaceutical patent and data-related provisions.

Under TPPA Annex 18-B, it is stated that nothing in TPPA Arts. 18.50.1, 18.50.2 (Protection of Undisclosed Test or Other Data) or 18.51 (Biologics) prevents Chile from maintaining or applying Art. 91 of its Law No. 19.039 on Industrial Property.⁸⁹ This exception for Chile was deemed necessary because the exceptions to regulatory data protection under Chilean law are broader than allowed under the TPPA; *e.g.*, Chile does not provide data protection where the pharmaceutical product has not been marketed in its national territory within a year from the grant of marketing approval in Chile, or where the marketing approval application is filed in Chile more than 12 months after approval was granted abroad for the product.

Under TPPA Annex 18-D Part 1, Peru commits to making its best efforts to obtain a waiver from Andean Decisions 486 and 689 to allow it to adjust/restore the patent term for patent office delays in issuing patents for pharmaceutical products or for unreasonable curtailment of the patent term as a result of delays in the marketing approval process, in compliance with TPPA Arts. 18.46.3 and 18.48.2. Art. 1(d) of Decision 689 (referencing Chapter V of Decision 486) authorizes Andean member countries to restore a patent term to compensate for unreasonable delays (of >5 years from the filing date or > 3 years from the request for application examination, whichever later) in patent issuance only with respect to non-pharmaceutical products.⁹⁰ The TPPA Annex further provides that if Peru demonstrates that despite its best efforts, the Andean Community withheld approval of Peru's waiver request, Peru will continue to ensure that it will not discriminate as to availability or enjoyment of patent rights. Peru thus confirms that it will not treat pharmaceutical products less favorably in processing patent applications.

Under paragraph 1 of TPPA Annex 18-D, Part 2, it is stated that if Peru relies on the **marketing approval granted in another territory** of a new pharmaceutical product (TPPA Art. 18.50.1(b)) or a biologic (18.51.1(b)(i)), and grants its own marketing approval within six months of an application, Peru may count the undisclosed test data exclusivity period as running from the date of **“the first marketing approval relied on.”** This exception allows Peru to count the period of data exclusivity as running from the date of the first marketing approval abroad, rather than the later date of marketing approval in Peru. Peru may also apply in such cases, the period of data exclusivity protection provided under Art. 16.10.2(b) of the **US-Peru FTA**; *i.e.*, **“a reasonable period of time, which shall normally mean 5 years.”** Thus Peru may apply a shorter exclusivity of “normally

⁸⁹ Article 91.—Protection under this paragraph shall not apply where:

- (a) the holder of the information providing proof indicated in Article 89 has engaged in conduct or practices declared anticompetitive, directly related to the use or exploitation of such information, according to a final or binding decision by the Antitrust Tribunal;
- (b) on justified grounds of public health, national security, noncommercial public use, national emergency or other extremely urgent circumstances declared so by the competent authority, the protection set out in Article 89 may be terminated;
- (c) the pharmaceutical product or agricultural chemical is the subject of a compulsory license pursuant to the stipulations in this Law;
- (d) the pharmaceutical product or agricultural chemical has not been marketed within the national territory by the end of a 12month period beginning from the date of the health registration or authorization granted in Chile;
- (e) the application for registration or health authorization of the pharmaceutical product or agricultural chemical that is filed in Chile 12 months after the first registration or health authorization has been obtained abroad.

⁹⁰ Artículo 1.- Los Países Miembros, a través de su normativa interna, estarán facultados, en los términos que se indican expresamente en los literales de a) a j), para desarrollar y profundizar únicamente las siguientes disposiciones de la Decisión 486:

... d) En el Capítulo V, Título II (Patentes de Invención): **Con excepción de patentes farmacéuticas**, establecer los medios para compensar al titular de la patente por los retrasos irrazonables de la Oficina Nacional en la expedición de la misma, restaurando el término o los derechos de la patente. Los Países Miembros considerarán como irrazonables los retrasos superiores a 5 años desde la fecha de presentación de la solicitud de patente o de 3 años desde el pedido de examen de patentabilidad, el que fuera posterior, siempre que los períodos atribuibles a las acciones del solicitante de la patente no se incluyan en la determinación de dichos retrasos.

5 years” from the date of the first marketing approval outside of Peru rather than “at least 5 years” from the later date of marketing approval in Peru, which should apply (TPPA Art. 18.50.1(b) and 18.51.1(b)(i)).

There is similar language used in paragraph 2 of TPPA Annex 18-D, Part 2, that allows Peru to apply a data protection period of “normally” 5 years as of the date of marketing approval abroad for pharmaceutical combinations of a previously approved pharmaceutical product rather than “at least 5 years” from the later date of marketing approval in Peru that should apply (TPPA Art. 18.50.2(b)).

C. Transition periods

Table A.3 (see Annex) shows the transition periods established for Brunei Darussalam, Malaysia, Mexico, Peru, and Viet Nam, in relation to implementing certain patent and data provisions for pharmaceutical products under the TPPA. Additionally, New Zealand has a transition period in relation to certain copyright provisions. The other 5 TPP Parties, Australia, Canada, Chile, Japan, Singapore, and the United States are expected to implement the obligations under the intellectual property chapter of the TPPA as of the date of entry into force for these Parties, respectively.

What this table signifies, *inter alia*, is that 5 TPP Parties, including Mexico and Peru, have determined that they require changes to their laws and regulations to implement and comply with the provisions relating to regulatory data exclusivity for pharmaceutical products (5 years for Mexico and Peru) and biologics (5 and 10 years, respectively) (TPPA Art. 18.83 (c) (iv) and (v) and (e) (i) and (ii)). It is not known how these countries will implement their respective obligations under the TPPA regulatory data provisions. Additionally, Mexico has a transition period of 4.5 years to implement pharmaceutical patent restoration to adjust for delays in its marketing approval process (TPPA Art. 18.83 (c) (iii)). Mexico has also reserved the possibility to consult with TPP partner countries on measures to incentivize the timely initiation of the filing of marketing approval applications for new pharmaceutical products.

D. Other non-IP TPPA provisions

Although not the focus of this study, it should be noted that many of the TPPA provisions besides those related to intellectual property, and specifically to patents and exclusivity, may be just as important for access to medicines, if not more so. These include: the schedules for tariff liberalization of goods, including medicines and medical devices as well inputs in their manufacturing; the schedules for services liberalization, including for medical personnel; the provisions on investment and investor-state dispute settlement, including for foreign direct investment in the pharmaceutical and healthcare sectors; the provisions on regulatory transparency, anti-corruption, and due process, particularly for procedural fairness in the listing of new pharmaceuticals and medical devices for reimbursement operated by national health care authorities; the provisions on government procurement that are also important for ensuring that medicines are procured by health-related agencies in a competitive and transparent process; and the competition provisions —of particular interest given the pace of mergers and acquisitions in the healthcare sector. Viewed from another perspective, the IP provisions for expeditious adjudication of patent infringement disputes or for efficient and timely processing of patent applications and marketing approvals, for example, may have positive spillover effects for good governance and the economy as a whole for TPP Parties.

V. Conclusions on striking the appropriate balance between ensuring incentives for innovation and access to medicine

When we consider the balance between incentives to innovate and access to medicine under trade agreements and the recent TPPA, there is really a spectrum of elements that are difficult to weigh against one another and to isolate from external factors and market conditions. Many factors affect access to medicine other than intellectual property protection and trade. These include domestic factors like health plan coverage and payment policies, drug regulatory institutions, public health infrastructures, financing, consumption patterns, and market size, as well as global partnership programs and tiered-pricing schemes (WHO and WTO, 2002; Taubman, Wager, and Watal, 2012). Even with respect to trade agreements, provisions other than those covering IPRs may also impact on access to medicine, such as tariff concessions on pharmaceutical goods and manufacturing inputs, healthcare services liberalization commitments, and rules on regulatory transparency, investment, competition, and government procurement policies.

It is undeniable, however, that IPR provisions in trade agreements, particularly those committing the State parties to grant, enforce, and extend patent monopoly rights on pharmaceuticals, do affect the competitive conditions and commercial opportunities in markets for originator brands as well as generic and biosimilar pharmaceuticals. By definition, a patent gives the patent owner the right to exclude any third person from making, using, offering for sale, selling, or importing, the patented product or process for at least 20 years. Pharmaceutical patents may therefore affect the availability of and access to different medicines and suppliers in a party's territory.

IPRs help deliver the expectation of accruing economic reward from monopoly rent in the marketplace, and logically should spur innovation and development; a medicine must be developed and manufactured in the first place in order for there to be the possibility of access to that medicine. There is, however, little concordance in the empirical literature on the role of patent systems in encouraging pharmaceutical innovation and technology transfer (WHO, WIPO, and WTO, 2013; Smith *et al.*, 2015). Nevertheless, surveys of the US pharmaceutical industry show that these participants consider product and process patent protection as critical for incentivizing pharmaceutical and biotechnological research and development, and obtaining funding (USDOC, 2012; BIO, 2014). As patents are vulnerable to challenge that the product or process claimed by the patent is not sufficiently new, non-obvious, or useful, the pharmaceutical industry also looks to clinical data exclusivity to protect against competition and maximize rents.

The US is the world leader in biopharmaceutical research and the world's largest market for pharmaceuticals. PhRMA firms invested \$51 billion in R&D in 2014 and hold the IPRs on most new medicines (PhRMA, 2016). The pharmaceutical industry supported nearly 3.4 million jobs in the U.S. in 2012. The US exported over \$52 billion in biopharmaceuticals in 2014. US biopharmaceutical innovation has been calculated as generating \$97 billion in 2014 in economic value, with a total impact of \$790 billion annually (PhRMA, 2016). As a leading federal campaign contributor and the top industry lobbying spender, the US pharmaceutical and health products industry wields political influence, particularly with Congressional lawmakers responsible for shaping legislation on patents and trade (The Center for Responsive Politics, 2016).

Under Section 301 of the US Trade and Tariff Act of 1974 and subsequent trade legislation, Congress has required the US administration to go after foreign barriers to US exports and has authorized the right to retaliate against “unreasonable” foreign trade practices, including practices that deny adequate and effective protection of IPRs. In its most recent grant of fast-track authority under TPA, Congress set as a goal “ensuring that the provisions of any trade agreement governing IPRs that is entered into by the United States reflect a standard of protection similar to that found in United States law.” By its terms, the TPPA will not enter into force unless ratified by both Japan and the US. US domestic law—the standard against which the TPPA will be judged by Congress—strikes a certain balance between IPRs and access to medicine by providing *inter alia* for: abbreviated marketing approval for generics based on bioequivalence, a regulatory review (Bolar) exception, patent extensions for regulatory delays, patent linkages, 5-year exclusivity for new drug applications for products containing a new chemical entity, 3-year exclusivity for new clinical information, and 180-day marketing exclusivity for successful generic challengers of patents. With respect to biologics, on which much attention has been focused in the TPPA negotiations, US law provides for: 4-year exclusivity for licensed biologics against submissions of biosimilar applications, 12-year data exclusivity for biologics, 12 to 42-month marketing exclusivity for the first licensed biosimilar, and no exclusivity for changes in administration or delivery of a biologic that do not improve safety or potency (evergreening).

The US sees its IP-intensive industries as crucial for its economy and international competitiveness, and has been the main driver for high IP standards in trade agreements since before the Uruguay Round. Part of the balance negotiated under the TRIPS Agreement on the side of IPRs includes national and m-f-n treatment obligations, broad subject matter patentability—including for pharmaceutical products and agricultural chemicals—regulatory data protection against unfair commercial use, domestic remedies against patent infringement, and enforceability of IPR commitments through the WTO dispute settlement system. The other part of the TRIPS balance towards access to medicine includes requirements for inventors to disclose their inventions, as well as provisions allowing limited exceptions to the exclusive rights conferred by patents and other carve-outs for patent use without the holder's authorization, such as to meet a national emergency or other circumstances of extreme urgency or public non-commercial use. Additionally there are provisions for transitional arrangements and technical cooperation. Subsequent decisions taken by the WTO membership affirmed the right of governments to take measures like compulsory licensing to advance public health goals and meet national emergencies as they determine. The WTO has also continued to exempt its least-developed country members like Haiti from applying the pharmaceutical patent and regulatory data obligations under the TRIPS Agreement, most recently until 2030 or until they cease to be least-developed. WTO jurisprudence has affirmed the right of members to provide regulatory review exceptions allowing producers of generic drugs to use a patented invention without the patent owner's consent during the patent term for purposes of obtaining marketing approval, which would facilitate sales of generic drugs upon the patent's expiration. GATT/WTO case law has also developed an “effective equality of opportunities” test for judging whether internal laws (like judicial procedures applicable on allegedly IP-infringing goods) treat imported goods less favorably than domestic goods, or whether a WTO member is according to other WTO nationals treatment no less favorable than that it accords its own nationals with regard to IPR protection.

The TRIPS Agreement does not provide for patent term extensions, abbreviated marketing approval procedures based on bioequivalence, patent linkage or other special procedures for

adjudicating pharmaceutical patent infringement disputes. The Agreement does require a WTO member to protect against unfair commercial use, undisclosed test data for pharmaceuticals and agricultural chemicals, which was submitted for marketing approval, and which was generated with considerable effort. But the TRIPS Agreement also provides for exceptions to the non-disclosure of this regulatory data where necessary to protect the public, and where other (undefined) steps have been taken to protect against unfair commercial use (Table A.4). Thus under the TRIPS Agreement, WTO member governments have leeway on how to implement regulatory data exclusivity for pharmaceutical products, and for how long.

The subsequent US FTAs in force with 10 Latin American countries (Chile, Central America and the Dominican Republic, Peru, Colombia and Panama), already provide for more extensive TRIPS-Plus protection for pharmaceutical patents and test data (Table A.4). For example, the parties under some of these existing US FTAs are obligated to extend a pharmaceutical patent term to compensate for unreasonable regulatory delays in issuing a patent (US-Chile FTA and DR-CAFTA), or for “unreasonable curtailment” of the effective patent term due to the marketing approval process (DR-CAFTA; pharmaceutical patent extensions for delays in patent issuance and regulatory approval delays are optional under the US FTAs with Peru, Colombia, and Panama, consistent with the Bipartisan Trade Deal). With respect to data exclusivity, the parties under all these US FTAs are required to bar a third person from relying on the undisclosed safety and efficacy data submitted by, or the marketing approval grant to, another person for its product, without the latter’s consent, to support a pharmaceutical product approval application, for at least 5 years from the date of the submitter’s approval grant (US-Chile FTA, DR-CAFTA; under US FTAs with Peru, Colombia, and Panama, the exclusivity is for a reasonable period of time “which normally shall mean 5 years” and does not apply to a product combination that includes a chemical entity previously approved). The FTA parties shall not reduce the data exclusivity period for a product when the patent on it expires (US FTAs with Peru, Colombia, and Panama). An FTA Party shall also implement measures in its marketing approval process preventing third persons from marketing a product covered by a patent during its patent term (patent linkage) and shall also provide that the patent owner be informed of the request and identity of any third person seeking marketing approval for a product covered by a patent (DR-CAFTA; patent linkage is optional under US FTAs with Peru, Colombia, and Panama).

There are also TRIPS-Plus pro-access to medicine provisions in the recent US FTAs with Latin American countries, such as for patent revocation, regulatory review exception, best efforts to expedite patent marketing approval applications, and an affirmation that the parties may take measures consistent with public health flexibilities under the TRIPS and subsequent WTO decisions. There is a 12-month grace period allowing inventors to disclose research findings without forfeiting the ability to obtain patent protection. The recent FTAs also provide for the expeditious adjudication of patent infringement disputes, which may favor patent holders but also competitors if a patent is successfully invalidated.

The TPPA continues the trend in TRIPS-Plus provisions favoring access to medicine; e.g., abbreviated approval of pharmaceutical products based on bioequivalence and bioavailability studies, patent revocation for fraud or lack of novelty, and best efforts for timely and efficient processing of patent and pharmaceutical marketing applications. There is also an affirmation that WTO public health flexibilities are available; the TPPA commits the only TPP Parties, Peru and Viet Nam, who have not yet ratified the Protocol amending the TRIPS Agreement in this respect, to do so.⁹¹

The TPPA also continues the trend in TRIPS-Plus protection of pharmaceutical patents and test data; e.g., patent term extensions for regulatory delays in granting patents and marketing approvals, no cutting short the data exclusivity period for a product covered by a patent that expires, and notification to a patent holder that a competitor is seeking marketing approval of a pharmaceutical

⁹¹ *Supra* notes 32-33.

during the patent term. It should be noted in relation to patent extensions, that Mexico has a 4.5 year transition period from the entry into force of the TPPA for Mexico to implement pharmaceutical patent term restoration—which is not required under NAFTA. Also Peru commits to seeking a waiver from the Andean Community to allow it to extend pharmaceutical patent terms for patent issuance and regulatory delays (TPPA Annex 18-D) to comply with the TPPA (TPPA Arts. 18.46 and 18.48), which it may or may not be successful in obtaining.

The TPPA has new TRIPS-plus features said to be supportive of incremental innovation. This includes provision for patenting: “new uses of a known product [or] new methods of using a known product or new processes of using a known product.” But a TPP Party is required to make available patents for only one of these 3 subject matters, and it can limit patentable new processes to those that do not claim the use of the product as such (TPPA Art. 18.37).

Further supportive of incremental innovation that builds on previously discovered products are the provisions for 3-year data protection for new clinical information covering a new indication, new formulation or new method of administration of a previously approved pharmaceutical (TPPA Art. 18.50.2(a)), or alternatively for 5-year data protection for combinations that include a chemical entity not previously approved (TPPA Art. 18.50.2(b)). But a TPP Party is required to provide data protection for only one of these alternatives, and a Party that already provides 8 year data exclusivity for pharmaceutical products (other than for biologics) does not have to apply this additional data protection for new indications or combinations. Peru will have 5 years from the TPPA’s entry into force for it to implement either option, more likely the 5-year data protection for combinations. Mexico will also have a 5 year transition to implement regulatory data protection more generally for pharmaceutical products, including for new indications or combinations (TPPA Art. 18.50), and for biologics (TPPA Art. 18.51). It reserves the right to adopt measures to incentivize the timely initiation of marketing approval filings (Table A.3).

The most noteworthy and controversial TRIPS-plus requirement of the TPPA is the new minimum 8-year data exclusivity period for undisclosed safety and efficacy information submitted for the first marketing approval of a new pharmaceutical product that is or contains a (protein-based) biologic (TPPA Art. 18.51.1(a)). This is a higher IPR standard than exists under any other trade agreement, and may become the new regional and global norm, if the TPPA comes into force. However, the potential impact of the minimum 8 year data protection period for biologics set by the TPPA, particularly as regards competition from biosimilars, is attenuated in several ways. First, data protection periods of 8 or more years for biologics already apply in the 3 largest TPP markets by GDP (Canada and Japan, 8 years; US 12 years). Of course, subscribing to a TPP commitment of at least 8 years of data protection means that a TPP Party may not lower its national standard to below 8 years,⁹² without running the risk of retaliation from its TPP partners. Secondly, the TPPA provides alternatively that a Party may reach a “comparable” but not necessarily the same outcome of “effective market protection” for regulatory data, through a minimum 5 year period from the date of the first marketing approval of the biologic in the Party plus “other measures” and “market circumstances” that “also contribute to effective market protection” (TPPA Art. 18.51.1(b)). US negotiators will seek to clarify these “other measures” and “market circumstances” via side letters with those TPPA Parties that provide less than 8 years of data exclusivity by law, such as Australia, Chile, and New Zealand, which have said they need not change their respective 5-year data protection laws to comply with the TPPA. Thirdly, 5 TPP Parties, Brunei Darussalam, Malaysia, Mexico, Peru, and Viet Nam have transition periods from 4 to 10+ years from the entry into force of the TPPA for each respectively, to implement the data exclusivity obligation on biologics (Table A.3). Fourth, Peru has the benefit of an exception under the TPPA (TPPA Annex 18-D, Part 2) that allows Peru to apply

⁹² For example, reducing the regulatory data exclusivity period for biologics under U.S. law from 12 to 7 years as the Obama administration has proposed unsuccessfully to Congress. See para. 3.18 and note 68.

a shorter data exclusivity period than the TPPA imposes. Peru may apply a reasonable period of “normally 5 years” from the earlier date of marketing approval abroad. This is instead of at least 8 (or comparable 5+) years for biologics, or at least 5 years for other pharmaceutical products, from the later date of marketing approval in Peru (TPPA Arts. 18.50.1(b), 18.50.2, and 18.51.1(b)). Thus there is considerable doubt as to how the regulatory data exclusivity provisions will be implemented and their impact on innovation and access to medicine.

The TPPA also contains important new TRIPS-Plus pro-access to medicine provisions in relation to cooperation and information exchanges among IP offices, including on traditional knowledge associated with genetic resources, and information to the public about patent applications and grants. Assuming sufficient budgetary resources are allocated, this has the potential to improve and streamline patent search and examination work, reduce differences among patent procedures and processes on a regional basis, facilitate knowledge-sharing with researchers and the public and technology transfer, and cut down on unnecessary regulatory delays in making life-saving new medicine available.

Finally, the litmus test for proponents and opponents alike of the TPPA in judging whether it strikes the right balance between encouraging innovation and access to life-saving medicines, or skews it to the detriment of consumers, has come down to the Agreement’s regulatory data exclusivity provisions, particularly with respect to biologics. This new-generation class of medicines has the market potential to reach \$250 billion globally by 2020 (Rickwood and Di Biase 2013). As discussed above, newly-established regulatory data exclusivity periods and patent extensions can delay the market entry for (and competition from) follow-on biologics or biosimilars, which seek to piggyback on, rather than duplicate, the costly clinical data of originator firms. Significantly, the TPPA does not change the fact that biosimilars are more costly than developing generic versions of traditional small molecule medicines due to the complex nature of biopharmaceuticals (WHO, WIPO, and WTO, 2013), and there will be a limited number of firms that can develop and manufacture a biosimilar with the necessary economy of scale to break even. It has been estimated that it can take eight to ten years to develop a biosimilar at a cost between \$100 and \$200 million, as opposed to three to five years to develop small-molecule generic drugs at a cost between \$1 and \$5 million (USFTC, 2009). Other barriers to entry include additional good manufacturing practice costs, and the slowness with which healthcare systems and patients may accept biosimilars as substitutes.⁹³ One must also consider that the technology and market conditions of producing biosimilars will change in the next 10-15 years, including within new TPP production networks and within the middle income TPP countries as a result of more efficient IPR processes, among other things. TPP Parties have committed to review the data protection period and scope of application for biologics 10 years after the Agreement’s entry into force or at any time they so decide, “with the view to providing effective incentives for the development of new pharmaceutical products that are or contain a biologic, as well as with a view to facilitating the timely availability of follow-on biosimilars” (TPPA Art. 18.51.3). Assuming the TPPA enters into force, the Parties will have much to discuss in this respect.

⁹³ “Biologics are hard to make and at present difficult to take. They must be injected, infused or inhaled, as they are destroyed in the stomach when swallowed. This may discourage doctors from prescribing them in some cases.....A study published in November [2014] by the RAND Corporation, a research institute, said that on current assumptions about how the FDA’s regulations will develop, biosimilars could save America’s health system a total of \$44 billion over the coming decade. That would be a useful sum, but the overall savings from biosimilars will not be as dramatic as those from replacing branded conventional drugs with generic versions. First biosimilars will also be costly to make. Second, since they will not be identical copies, doctors and patients may be slow to accept them as substitutes. All this will be good news for those drugmakers who create successful biologics, for it will allow them to continue selling at higher prices for longer. They may thus find that the ‘patent cliff’ slump in revenues they have been suffering as older remedies lose patent protection, is not as steep as feared.” *The Economist* “Going Large,” Jan. 3, 2015.

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Annex

Table A.1
International applications filed under the Patent Cooperation Treaty (PCT) from TPP States

Origin	2013	2014
Australia	1 604	1 726
Brunei Darussalam	0	0
Canada	2 845	3 089
Chile	142	144
Japan	43 771	42 459
Malaysia	308	314
Mexico	233	284
New Zealand	320	346
Peru	13	12
Singapore	838	944
United States	57 441	61 492
Viet Nam	17	7
Total TPP States	107 515	110 810
Total International Applications	205 272	214 500

Source: Compiled from World Intellectual Property Organization (WIPO) (2015 and 2014) PCT Yearly Review.

Table A.2
International applications filed under the PCT
from western hemisphere (OAS Member) States

Origin	2013	2014
Antigua and Barbuda	0	0
Argentina	26	33
Bahamas	10	20
Barbados	149	175
Belize	3	4
Bolivia	1	0
Brazil	657	581
Chile	142	144
Colombia	82	102
Costa Rica	12	9
Cuba	9	4
Dominica	0	0
Dominican Republic	7	3
Ecuador	19	7
El Salvador	0	3
Grenada	0	0
Guatemala	2	1
Guyana	NA	NA
Haiti	NA	NA
Honduras	0	0
Jamaica	0	2
Mexico	233	284
Nicaragua	2	0
Panama	18	16
Paraguay	0	0
Peru	13	12
St. Kitts and Nevis	2	2
St. Lucia	0	0
St. Vincent and the Grenadines	2	1
Suriname	NA	NA
Trinidad and Tobago	0	1
Uruguay	4	6
Venezuela	1	1
Total Latin America and Caribbean States	1 385	1 411
Canada	2 845	3 089
United States	57 441	61 492
Total Western Hemisphere States	61 671	65 992

Source: Compiled from WIPO (2015 and 2014) PCT Yearly Review.

Note: NA = not applicable as not a PCT contracting state.

Table A.3
Transition periods for implementing certain (TRIPS-Plus)
patent and data provisions for pharmaceutical products
under the TPPA^a

Relevant TPPA Provisions	Brunei Darussalam	Malaysia	Mexico	Peru	Viet nam
Art. 18.46.3 and 18.46.4 Patent Term Extension for Unreasonable Regulatory Delays in Patent Issuance					3 years + 1 year extension
Art. 18.48.2 Pharmaceutical Patent Term Restoration for Unreasonable Curtailment of Patent Term due to Marketing Approval Process		4.5 years	4.5 years		5 years
Art. 18.50 Regulatory Data Exclusivity for Pharmaceutical Products	4 years ^b		5 years ^b	18.50.2 (new clinical information or combinations) 5 years	10 years + 2 year extension + additional 1 year extension ^b
Art. 18.51 Regulatory Data Exclusivity for Biologics	4 years ^b	5 years	5 years ^b	10 years	10 years + 2 year extension + additional 1 year extension ^b
18.53 Pharmaceutical Patent Linkage	2 years	4.5 years			3 years

Source: Elaborated by the author on the basis of legal text of trade agreements.

^aAs provided under Art. 18.83.4 (Final Provisions). The transition periods begin on the date of entry into force of the TPPA for the five Parties listed above, respectively. For the seven TPP Parties not listed above (i.e., Australia, Canada, Chile, Japan, New Zealand, Singapore, United States), they shall give effect to these and other patent provisions as of the date of entry into force for these Parties respectively.

^b If there are unreasonable delays in the Party in the initiation of the filing of marketing approval applications for new pharmaceutical products after implementation, the Party may adopt measures to incentivize timely initiation following consultations with the other Parties.

Table A.4
Evolution of certain patent and data protection provisions for pharmaceutical products in US trade agreements

Agreement ^a	TRIPS	US-Chile	US-DR-CAFTA	US-Peru	US-Colombia	US-Panama
Entry into force	1 Jan 1995	1 Jan 2004	1 Mar 2006- 1 Jan 2009 ^b	1 Feb 2009	15 May 2012	31 Oct 2012
Relevant article(s)	Part II Section 5: Patents Section 7: Protection against undisclosed information	17.09 Patents 17.10 Measures Related to Certain Regulated Products	15.09 Patents 15.10 Measures Related to Certain Regulated Products	16.09 Patents 16.10 Measures Related to Certain Regulated Products	16.09 Patents 16.10 Measures Related to Certain Regulated Products	15.09 Patents 15.10 Measures Related to Certain Regulated Products
Disregard of public disclosure info in determining novelty or inventive step		If the public disclosure was made or authorized by the patent applicant within 12 months of patent filing date.	If the public disclosure was made or authorized by the patent applicant within 12 months of patent filing date.	If the public disclosure was made or authorized by the patent applicant within 12 months of patent filing date.	If the public disclosure was made or authorized by the patent applicant within 12 months of patent filing date.	If the public disclosure was made or authorized by the patent applicant within 12 months of patent filing date.
Patent revocation	Only when grounds exist as would have justified refusing a patent grant; or the grant of a compulsory license hasn't remedied lack of patent exploitation	Only when grounds exist as would have justified refusing a patent grant; fraud in obtaining a patent may constitute grounds	Only when grounds exist as would have justified refusing a patent grant; a Party may also provide for fraud, misrepresentation or inequitable conduct as basis for revoking, cancelling or holding patent unenforceable	Only when grounds exist as would have justified refusing a patent grant; a Party may also provide for fraud, misrepresentation or inequitable conduct as basis for revoking, cancelling or holding patent unenforceable	Only when grounds exist as would have justified refusing a patent grant; a Party may also provide for fraud, misrepresentation or inequitable conduct as basis for revoking, cancelling or holding patent unenforceable	Only when grounds exist as would have justified refusing a patent grant, a Party may also provide for fraud, misrepresentation or inequitable conduct as basis for revoking, cancelling or holding patent unenforceable

Agreement ^a	NAFTA	TRIPS	US-Chile	US-DR-CAFTA	US-Peru	US-Colombia	US-Panama
Regulatory review ("Bolar") exception	-	[Panel ruling that WTO-consistent]	If Party permits 3d party use of the subject matter of a subsisting patent to support an application for marketing approval or sanitary permit of a pharmaceutical product, it shall not be made, used or sold in the Party's territory other than for meeting market approval or sanitary permit requirements; if export is permitted, product shall be exported only to meet requirements for issuing marketing approval or sanitary permits in the exporting Party.	If Party permits 3d party use of the subject matter of a subsisting patent to support an application for marketing approval of a pharmaceutical or agricultural chemical product, it shall not be made, used or sold in the Party's territory other than to generate information to meet requirements for approval to market the product once the patent expires; if export is permitted, product shall be exported only to meet marketing approval requirements in that Party.	If Party permits 3d party use of the subject matter of a subsisting patent to support an application for marketing approval of a pharmaceutical or agricultural chemical product, it shall not be made, used, sold, offered for sale, or imported in the Party's territory other than to generate information to meet requirements for approval to market the product once the patent expires; if export is permitted, product shall be exported only to meet marketing approval requirements in that Party.	If Party permits 3d party use of the subject matter of a subsisting patent to support an application for marketing approval of a pharmaceutical or agricultural chemical product, it shall not be made, used, sold, offered for sale, or imported in the Party's territory other than to generate information to meet requirements for approval to market the product once the patent expires; if export is permitted, product shall be exported only to meet marketing approval requirements in that Party.	If Party permits 3d party use of the subject matter of a subsisting patent to generate information to support an application for marketing approval of a pharmaceutical or agricultural chemical product, it shall not be made, used or sold in the Party's territory other than to generate information to meet requirements for approval to market the product once the patent expires; if export is permitted, product shall be exported only to meet marketing approval requirements in that Party.
Best efforts to expedite patent applications & marketing approvals	-	-	-	-	Each Party shall make best efforts to process patent applications and marketing approval applications expeditiously with a view to avoiding unreasonable delays. Parties shall cooperate and provide assistance to one another to achieve these objectives.	Each Party shall make best efforts to process patent applications and marketing approval applications expeditiously with a view to avoiding unreasonable delays. Parties shall cooperate and provide assistance to one another to achieve these objectives.	Each Party shall make best efforts to process patent applications and marketing approval applications expeditiously with a view to avoiding unreasonable delays. Parties shall cooperate and provide assistance to one another to achieve these objectives.

Agreement ^a	NAFTA	TRIPS	US-Chile	US-DR-CAFTA	US-Peru	US-Colombia	US-Panama
Patent term extension for regulatory delays in patent issuance	A Party may extend patent term protection in appropriate cases to compensate for delays caused by regulatory approval processes	-	Each Party shall provide for the adjustment of the patent term, at the patent owner's request, to compensate for unreasonable delays in patent issuance of > 5 years from filing date in the Party, or > 3 years from application examination request, whichever later, but time attributable to applicant need not be included in determining such delays	Each Party shall adjust the patent term, at patent owner's request, to compensate for unreasonable delays in patent grant of > 5 years from filing date or > 3 years from application examination request, whichever later, but time attributable to applicant need not be included in determining delays	Each Party shall provide the means to and shall, at the patent owner's request, restore patent term or patent rights, to compensate for unreasonable delays in patent issuance for non-pharmaceutical products of > 5 years from filing date or > 3 years from application examination request, whichever later, but time attributable to applicant need not be included in determining delays. Restoration shall confer all exclusive rights subject to the same limitations and exceptions as the original patent.	Each Party shall provide the means to and shall, at the patent owner's request, restore patent term or patent rights to compensate for unreasonable delays in patent issuance for non-pharmaceutical products of > 5 years from filing date or > 3 years from application examination request, whichever later, but time attributable to applicant need not be included in determining delays. Restoration shall confer all exclusive rights subject to the same limitations and exceptions as the original patent.	Each Party shall adjust a patent term, at the patent owner's request, to compensate for unreasonable delays in patent issuance for non-pharmaceutical products of > 5 years from filing date or > 3 years from examination request, whichever later, but time attributable to applicant need not be included in determining delays

Agreement*	NAFTA	TRIPS	US-Chile	US-DR-CAFTA	US-Peru	US-Colombia	US-Panama
Pharmaceutical patent term restoration				<p>For a pharmaceutical product covered by a patent, each Party shall make a restoration of the patent term available to compensate for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial marketing of the product in the Party</p>	<p>At a patent owner's request, each Party may make available a restoration of the patent term or patent rights to compensate for unreasonable delays in patent issuance for a pharmaceutical product of > 5 years from filing date or > 3 years from application examination request, whichever later, but time attributable to applicant need not be included in determining delays in the patent issuance. For a pharmaceutical product covered by patent, the patent term or patent rights may be restored to compensate for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial marketing of the product in the Party. Restoration shall confer all exclusive rights subject to the same limitations and exceptions as the original patent.</p>	<p>At a patent owner's request, each Party may make available a restoration of the patent term or patent rights to compensate for unreasonable delays in patent issuance for a pharmaceutical product of > 5 years from filing date or > 3 years from application examination request, whichever later, but time attributable to applicant need not be included in determining delays in the patent issuance. For a pharmaceutical product covered by patent, the patent term may be restored to compensate for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial marketing of the product in the Party.</p>	<p>At a patent owner's request, each Party may make available a restoration of the patent term for a pharmaceutical product to compensate for unreasonable delays in patent grant of > 5 years from filing date or > 3 years from application examination request, whichever later, but time attributable to applicant need not be included in determining delays. For a pharmaceutical product covered by a patent, the patent term may be restored to compensate for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial marketing of the product in the Party</p>
Public health flexibilities for compulsory licensing		<p>Doha Declaration on TRIPS & Public Health 2001; Council decision / waiver implementing para. 6 of Declaration 2003; and Amendment of TRIPS</p>					
					<p>[Notwithstanding provisions on data exclusivity for pharmaceutical products.] Parties may take measures in accordance with Doha Declaration on TRIPS & Public Health 2001; Council decision / waiver implementing para. 6 of Declaration 2003; and any amendment of TRIPS to implement Declaration</p>	<p>[Notwithstanding provisions on data exclusivity for pharmaceutical products.] Parties may take measures in accordance with Doha Declaration on TRIPS & Public Health 2001; Council decision / waiver implementing para. 6 of Declaration 2003; and any amendment of TRIPS to implement Declaration</p>	<p>[Notwithstanding provisions on data exclusivity for pharmaceutical products.] Parties may take measures in accordance with Doha Declaration on TRIPS & Public Health 2001; Council decision / waiver implementing para. 6 of Declaration 2003; and any amendment of TRIPS to implement Declaration</p>

Agreement*	NAFTA	TRIPS	US-Chile	US-DR-CAFTA	US-Peru	US-Colombia	US-Panama
<p>Regulatory data protection/ exclusivity for pharmaceutical products</p>	<p>If a Party requires for the marketing approval of a pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origin of such data involves considerable effort, except where the disclosure of such data is necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use. Each Party shall provide that for data so submitted, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission, which shall normally mean 5 years from the date the Party granted marketing approval to the person producing the data, taking into account the nature of the data and person's efforts and expenditures in producing them.</p>	<p>Members when requiring for marketing approval of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data, the origin of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use. Each Party shall provide that for data so submitted, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission, which shall normally mean 5 years from the date the Party granted marketing approval to the person producing the data, taking into account the nature of the data and person's efforts and expenditures in producing them.</p>	<p>If a Party requires for the marketing approval of a new pharmaceutical or agricultural chemical product (that does not contain a chemical entity previously approved in the Party's territory), the submission of undisclosed data concerning safety or efficacy, the Party shall not permit 3d persons without the consent of the person who provided the information, to market a product on the basis of (1) the information, or (2) the approval granted to the person who submitted the information for ≥ 5 years for pharmaceutical products and ≥ 10 years for agricultural products, from the date of approval in the Party. Each Party shall protect such undisclosed information against disclosure except where necessary to protect the public. No Party may consider information in the public domain as undisclosed data. If any undisclosed information concerning safety and efficacy submitted to a Party or to an entity acting on behalf of a Party, for marketing approval is disclosed by such entity, the Party is still required to protect against unfair commercial use.</p>	<p>If a Party requires for the marketing approval of a pharmaceutical product that utilizes a new chemical entity, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origin of such data involves considerable effort, except where the disclosure is necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use. Each Party shall provide that no person other than the person that submitted such data may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission, which shall normally mean 5 years from the date on which the Party granted approval to the person that produced the data and person's efforts and expenditures in producing them.</p>	<p>If a Party requires for the marketing approval of a pharmaceutical product that utilizes a new chemical entity, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origin of such data involves considerable effort, except where the disclosure is necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use. Each Party shall provide that no person other than the person that submitted such data may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission, which shall normally mean 5 years from the date on which the Party granted approval to the person that produced the data and person's efforts and expenditures in producing them.</p>	<p>If a Party requires for the marketing approval of a pharmaceutical product that utilizes a new chemical entity, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origin of such data involves considerable effort, except where the disclosure is necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use. Each Party shall provide that no person other than the person that submitted such data may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission, which shall normally mean 5 years from the date on which the Party granted approval to the person that produced the data and person's efforts and expenditures in producing them.</p>	<p>If a Party requires for the marketing approval of a pharmaceutical product that utilizes a new chemical entity, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origin of such data involves considerable effort, except where the disclosure is necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use. Each Party shall provide that no person other than the person that submitted such data may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission, which shall normally mean 5 years from the date on which the Party granted approval to the person that produced the data and person's efforts and expenditures in producing them.</p>

Agreement*	NAFTA	TRIPS	US-Chile	US-DR-CAFTA	US-Peru	US-Colombia	US-Panama
Data exclusivity period for pharmaceutical products when marketing approval in another party is relied on	Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.	-	-	If a Party permits for marketing approval of a new pharmaceutical or agricultural product, 3d persons to submit evidence concerning safety or efficacy previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit 3d persons without the consent of the person who provided the information, to market a product on the basis of (1) evidence of prior marketing approval in the other territory, or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in the other territory for ≥ 5 years for pharmaceutical products and ≥ 10 years for agricultural chemical products, from the date of approval in the Party's territory to the person who received approval in the other territory. A Party may require that the person providing the information in the other territory to seek approval in the Party's territory within 5 years after obtaining approval in the other territory.	Where a Party relies on a marketing approval granted by the other Party, and grants approval within 6 months of the filing of a complete application for marketing approval filed in the Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on. A Party need not apply the above provisions with respect to a pharmaceutical product that contains a chemical entity that has been previously approved in the Party's territory for use in a pharmaceutical product.	Where a Party relies on a marketing approval granted by the other Party, and grants approval within 6 months of the filing of a complete application for marketing approval filed in the Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on. A Party need not apply the above provisions with respect to a pharmaceutical product that contains a chemical entity that has been previously approved in the Party's territory for use in a pharmaceutical product.	Where a Party relies on a marketing approval granted by the other Party, and grants approval within 6 months of the filing of a complete application for marketing approval filed in the Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on. A Party need not apply the above provisions with respect to a pharmaceutical product that contains a chemical entity that has been previously approved in the Party's territory for use in a pharmaceutical product.
Abbreviated approval based on bioequivalence	[Subject to the data exclusivity provisions on pharmaceutical or agricultural chemical products subject to marketing approval] there shall be no limitation on a Party to implement abbreviated approval procedures for such products based on bioequivalence and bioavailability studies.	-	-	[Subject to the data exclusivity provisions on pharmaceutical or agricultural chemical products subject to marketing approval] there shall be no limitation on a Party to implement abbreviated approval procedures for such products based on bioequivalence and bioavailability studies.	[Subject to the data exclusivity provisions on pharmaceutical or agricultural chemical products subject to marketing approval] there shall be no limitation on a Party to implement abbreviated approval procedures for such products based on bioequivalence and bioavailability studies.	[Subject to the data exclusivity provisions on pharmaceutical or agricultural chemical products subject to marketing approval] there shall be no limitation on a Party to implement abbreviated approval procedures for such products based on bioequivalence and bioavailability studies.	[Subject to the data exclusivity provisions on pharmaceutical or agricultural chemical products subject to marketing approval] there shall be no limitation on a Party to implement abbreviated approval procedures for such products based on bioequivalence and bioavailability studies.

Agreement ^a	NAFTA	TRIPS	US-Chile	US-DR-CAFTA	US-Peru	US-Colombia	US-Panama
<p>Requirement to notify patent owner of 3d party requesting marketing approval of pharmaceutical product during patent term (patent linkage) & other special procedures for adjudication of pharmaceutical patent infringement disputes</p>	<p>-</p>	<p>-</p>	<p>-</p>	<p>Where a Party permits for marketing approval of a pharmaceutical product, persons other than the person originally submitting safety or efficacy information, to rely on such evidence or information for a product that was previously approved, such as evidence of prior marketing approval in a Party's territory or in another country, that Party:</p> <ul style="list-style-type: none"> (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved method of use during the term of that patent, unless by consent or (b) shall provide that the patent owner shall be informed of the request and the identity of any such other person who requests approval to enter the market during the term of a patent identified, as claiming the approved product or its approved use. 	<p>Each Party shall provide:</p> <ul style="list-style-type: none"> (a) procedures, such as judicial or administrative proceedings, and remedies, such as preliminary injunctions or equivalent effective provisional measures, for the expeditious adjudication of disputes concerning the validity or infringement of a patent with respect to patent claims that cover an approved pharmaceutical product or its approved method of use; (b) a transparent system to provide notice to a patent holder that another person is seeking to market an approved pharmaceutical product during the term of a patent covering the product or its approved method of use; and (c) sufficient time and opportunity for a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies for an infringing product. <p>Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory, the Party may implement the [above] provisions by:</p> <ul style="list-style-type: none"> (a) implementing measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved method of use during the term of that patent, unless by consent or 	<p>Each Party shall provide:</p> <ul style="list-style-type: none"> (a) procedures, such as judicial or administrative proceedings, and remedies, such as preliminary injunctions or equivalent effective provisional measures, for the expeditious adjudication of disputes concerning the validity or infringement of a patent with respect to patent claims that cover an approved pharmaceutical product or its approved method of use; (b) a transparent system to provide notice to a patent holder that another person is seeking to market an approved pharmaceutical product during the term of a patent covering the product or its approved method of use; and (c) sufficient time and opportunity for a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies for an infringing product. <p>Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory, the Party may implement the [above] provisions by:</p> <ul style="list-style-type: none"> (a) implementing measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved method of use during the term of that patent, unless by consent or 	<p>Each Party shall provide:</p> <ul style="list-style-type: none"> (a) procedures, such as judicial or administrative proceedings, and remedies, such as preliminary injunctions or equivalent effective provisional measures, for the expeditious adjudication of disputes concerning the validity or infringement of a patent with respect to patent claims that cover an approved pharmaceutical product or its approved method of use; (b) a transparent system to provide notice to a patent holder that another person is seeking to market an approved pharmaceutical product during the term of a patent covering the product or its approved method of use; and (c) sufficient time and opportunity for a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies for an infringing product. <p>Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory, the Party may implement the [above] provisions by:</p> <ul style="list-style-type: none"> (a) implementing measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved method of use during the term of that patent, unless by consent or

<p>unless by consent or acquiescence of the patent owner, and</p> <p>(b) providing that the patent owner shall be informed of the identity of any such other person who requests marketing approval to enter the market during the term of a patent identified to the approving authority as covering that product; provided that the Party also provides:</p> <p>(c) an expeditious administrative or judicial procedure in which the person requesting marketing approval can challenge the validity or applicability of the identified patent; and</p> <p>(d) effective rewards for a successful challenge of the validity or applicability of the patent.</p>	<p>acquiescence of the patent owner; and</p> <p>(b) providing that the patent owner shall be informed of the identity of any such other person who requests marketing approval to enter the market during the term of a patent identified to the approving authority as covering that product; provided that the Party also provides:</p> <p>(c) an expeditious administrative or judicial procedure in which the person requesting marketing approval can challenge the validity or applicability of the identified patent; and</p> <p>(d) effective rewards for a successful challenge of the validity or applicability of the patent.</p>	<p>the Party may implement the [above] provisions by:</p> <p>(a) implementing measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the previously approved product or its approved method of use during the term of that patent, unless by consent or acquiescence of the patent owner; and</p> <p>(b) providing that the patent owner shall be informed of the request and the identity of any such other person who requests approval to enter the market during the term of a patent identified as claiming the approved product or its approved use;</p> <p>provided that the Party also provides:</p> <p>(c) an expeditious administrative or judicial procedure in which the person requesting marketing approval can challenge the validity or applicability of the identified patent; and</p> <p>(d) effective rewards for a successful challenge of the validity or applicability of the patent.</p>
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Agreement ^a	NAFTA	TRIPS	US-Chile	US-DR-CAFTA	US-Peru	US-Colombia	US-Panama
Data exclusivity period continues after patent term expiration	-	-	-	-	[Subject to TRIPS public health flexibilities,] when a pharmaceutical product is subject to a marketing approval system in a Party's territory and is also covered by a patent in the Party's territory, the Party shall not alter the term of [data exclusivity] protection that it provides in the event that the patent protection terminates on a date earlier than the end of the term of [data exclusivity] protection.	[Subject to TRIPS public health flexibilities,] when a pharmaceutical product is subject to a marketing approval system in a Party's territory and is also covered by a patent in the Party's territory, the Party shall not alter the term of [data exclusivity] protection that it provides in the event that the patent protection terminates on a date earlier than the end of the term of [data exclusivity] protection.	[Subject to TRIPS public health flexibilities,] when a pharmaceutical product is subject to a marketing approval system in a Party's territory and is also covered by a patent in the Party's territory, the Party shall not alter the term of [data exclusivity] protection that it provides in the event that the patent protection terminates on a date earlier than the end of the term of [data exclusivity] protection.

Source: Compiled on the basis of the texts of the Agreements posted on http://www.sice.oas.org/agreements_e.asp. [accessed Jan. 10. 2016].

Note: "-" = no such provision in an agreement as described in column 1.

^a The titles of the Agreements are respectively: North American Free Trade Agreement, WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, Free Trade Agreement Between the Government of the United States of America and the Government of the Republic of Chile, Dominican Republic-Central America-United States Free Trade Agreement, United States – Peru Trade Promotion Agreement, United States – Colombia Trade Promotion Agreement, and United States – Panama Trade Promotion Agreement.

^b Dates of entry into force of US-DR-CAFTA: for U.S. and El Salvador (1 March 2006); Honduras and Nicaragua (1 April 2006); Guatemala (1 July 2006); Dominican Republic (1 March 2007); Costa Rica (1 Jan 2009).

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