

## **Access to medicines and incentives for innovation**

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

Raquel Artecona  
Rosine M. Plank-Brumback



UNITED NATIONS

**E C L A C**

**STUDIES AND  
PERSPECTIVES****ECLAC OFFICE  
IN WASHINGTON, D.C.****Access to medicines and incentives  
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**ECLAC**

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## Abstract

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Achieving the right balance between incentives to innovate and access to medicine is among the most sensitive and contentious issues in the negotiation of trade agreements, particularly their intellectual property rights (IPR) chapter. Many factors affect access to medicine other than intellectual property protection and trade. These include, among others, domestic factors like health plan coverage and payment policies as well as global factors like global partnership programs. Even with respect to trade agreements, provisions other than those covering IPRs may also impact access to medicine, including tariff concessions on pharmaceutical goods and manufacturing inputs, healthcare services liberalization commitments, and government procurement policies. It is undeniable, however, that IPR provisions in trade agreements, particularly those intended to grant, enforce, and extend patent monopoly rights on pharmaceuticals, do affect market competitive conditions for originator brands as well as generic and biosimilar pharmaceuticals.

This study addresses the balance struck under the Trans-Pacific Partnership Agreement (TPPA) between the right to health and access to medicines and the need to maintain the economic incentives to spur innovation and research and development through intellectual property protection. The analysis focuses on the patent and data-related intellectual property protection provisions of the TPPA, specifically regarding pharmaceutical (small-molecule and biologic) products, including on patent duration, linkage and term extensions as well as clinical test data protection and market exclusivity. Special attention is paid to the United States and its negotiating position with respect to those aspects of intellectual property rights, as it has been and remains the world's principal demandeur for high intellectual property rights (IPR) standards in trade agreements, including the TPPA.

The study concludes by finding that many of the TPP patent and data exclusivity-related provisions for pharmaceutical products cement the U.S.'s increasingly steep intellectual property protections observed in each of the existing U.S. free trade agreements (FTAs) with Latin American countries. This is attenuated by various factors including the transition periods granted to those Trans-Pacific Partnership (TPP) Parties that do not already apply these standards, specific exceptions provided to individual TPP Parties, and the ambiguity surrounding how some provisions, particularly on data exclusivity, will be interpreted and implemented.



## Introduction

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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 Western Hemisphere have signed.

Achieving the right balance between incentives to innovate and access to medicine is among the most sensitive and contentious issues in the negotiation of trade agreements, particularly their intellectual property rights (IPR) chapter. 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 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. Likewise, data exclusivity for pharmaceuticals, by preventing the use of regulatory data of the referenced product for the duration of the exclusivity by competitors, effectively delays the entrance of generics and biosimilars due to the high cost for them of producing their own set of clinical data to prove efficacy and safety.



The U.S. 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. The most recent free trade agreement signed by the U.S., the Trans-Pacific Partnership Agreement (TPPA) is no exception. 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. By its terms, the TPPA will not enter into force unless ratified by both Japan and the U.S.<sup>1 2</sup>

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, expand the area of influence of the TPPA's IP protection standards far beyond its original member countries. 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). In practice, this means 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.

This study addresses 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 the economic incentives to spur innovation and research and development. The analysis focuses on the patent and data-related

<sup>1</sup> 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 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].

<sup>2</sup> 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.

intellectual property protection provisions of the TPPA, specifically regarding pharmaceutical (small-molecule and biologic) products, including on patent duration, linkage and term extensions as well as clinical test data protection and market exclusivity. Special attention is paid to the United States and its negotiating position with respect to those aspects of intellectual property rights, as it has been and remains the world's principal demandeur for high intellectual property rights (IPR) standards in trade agreements, including the TPPA.

The paper is organized as follows. After this introduction, Section II presents key trends in the pharmaceutical industry and describes the significance of IP-intensive industries in the U.S. economy, the U.S. leadership in pharmaceutical research and the importance of the TPP market for the U.S. pharmaceutical industry. Section III compares some of the key pharmaceutical provisions in the TRIPS agreement with those in U.S. free trade agreements (FTAs) with Western Hemisphere countries and in the TPPA. Section IV presents the relevant U.S. domestic law against which the IP provisions of the TPPA will be judged if and when it is debated in Congress. The study concludes by finding that many of the TPP patent and data exclusivity-related provisions for pharmaceutical products cement the U.S.'s increasingly steep intellectual property protections observed in each of the existing U.S. 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., Mexico and Peru), specific exceptions provided to individual TPP Parties (e.g., Chile and Peru), and the ambiguity surrounding how some provisions, particularly on data 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. Key trends in the global, regional and U.S. pharmaceutical industries**

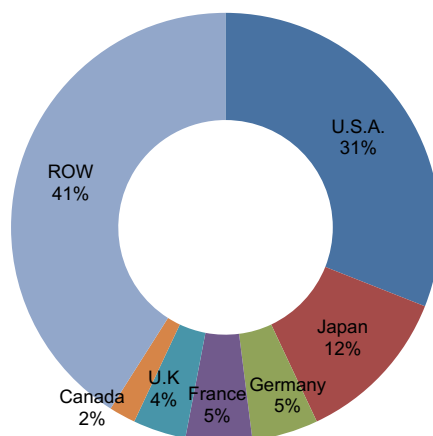
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### **A. Global trends**

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.

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).

**Figure 1**  
**Share of Global Pharmaceutical Revenue, 2011**  
*(Percentage of sales)*



Source: PWC Report on the basis of Business Monitor International.

## B. Pharmaceutical trade among TPP countries

Trade in pharmaceutical products among TPP countries amounted to US\$32.3billion in 2014 (COMTRADE Database).

On average, about half of the TPP trade in pharmaceutical products occurs among TPP member countries. However, the significance of TPP trade flows in pharmaceuticals varies by countries –i.e. 92% of Brunei’s pharmaceutical imports are sourced in TPP countries while only about 10% of U.S.’s come from other TPP partners; the rest of the countries import between one fifth and one third of their pharmaceuticals from other TPP countries.

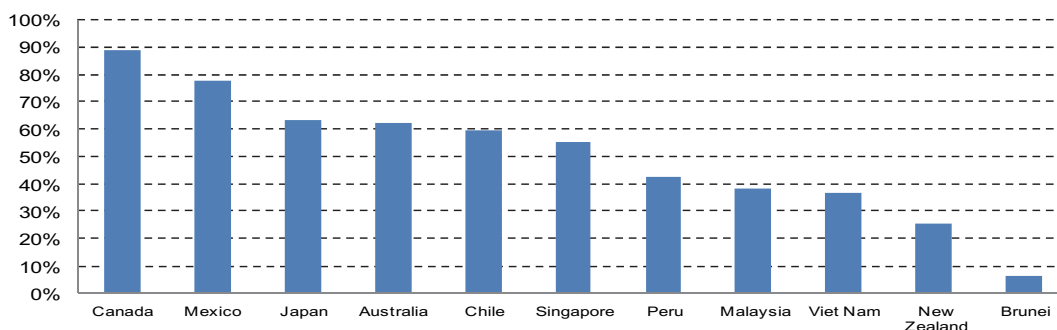
For the U.S., the TPP region is a relatively more significant market as a destination for its pharmaceutical products. About one third of its pharmaceutical exports go to other TPP countries. Likewise, for Canada TPP represents 71% of its export market for pharmaceuticals, 55% for Brunei and 51% for Singapore.

**Figure 2**  
**Share of intra TPP trade in global trade: pharmaceutical products, 2014**  
*(Percentages)*



Source: Elaborated by the authors on the basis of COMTRADE Database.

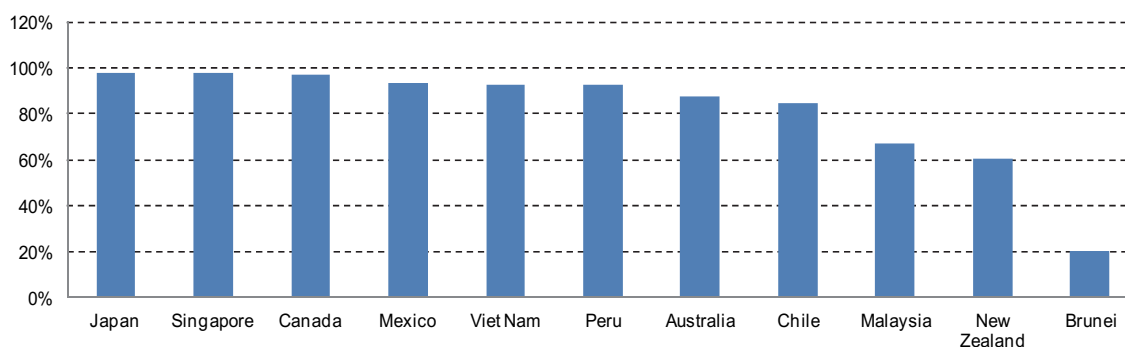
**Figure 3**  
**Share of imports from U.S. in total TPP imports, small molecule products, 2014**  
*(Percentages)*



Source: Elaborated by authors on the basis of COMTRADE Database.

Canada, Mexico, Japan and Australia already import more than two-thirds and up to 90% of their pharmaceuticals from the U.S. At the other extreme, Brunei sources its pharmaceuticals from the TPP area almost entirely (92%) but only imports 6% from the U.S. Interestingly, Peru only imports 42% from the U.S. Its other main suppliers of pharmaceuticals within the TPP are Mexico (29%) and Chile (22%). 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).

**Figure 4**  
**Percentage of biologic imports from the U.S. in total TPP imports, 2014**



Source: Elaborated by authors on the basis of COMTRADE Database.

Figure 4 shows that the U.S. is the main, almost sole, supplier of biologics to countries such as Japan, Singapore, Canada, Viet Nam and Peru where more than 90% of the countries' imports of biologics from the TPP come from the U.S. That means that TPP is a very significant market for biologics for the U.S. Since Japan, Singapore and Canada all import about one-third of their pharmaceutical imports from TPP countries, the U.S. has a market share in all these three countries of about 30%. Protecting the share of those markets seems very relevant to the U.S. pharmaceutical industry.

## C. The U.S. IP-intensive industries, including the pharmaceutical industry and trade

The U.S. is a leader in innovation and R&D spending. Industries that are strongly dependent on patent, copyright, or trademark protection—including the pharmaceutical industry—play an important role in the U.S. economy and U.S. competitiveness. The United States is the world’s leading exporter of ideas, with licensing revenue generated by U.S. intellectual property overseas exceeding \$130 billion in 2014 and a surplus of trade in ideas of \$88 billion (Schott and Cimino-Isaacs, 2016)<sup>3</sup>. The United States 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 and hold the IPRs on most new medicines.<sup>4</sup> PhRMA companies invested \$51 billion in R&D in 2014; the biopharmaceutical industry invests more than 18% of sales generated in further R&D.<sup>5</sup> 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.<sup>6</sup>

Research and development for new medicines are costly. Citing researchers at Tufts University, the U.S. 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. 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 U.S. Federal Trade Commission (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 according to the FTC typically take three to five years to develop and cost between \$1 and \$5 million (USFTC (2009), p. iii). 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. 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.

Thus, it should come as no surprise that the U.S. 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. Since the enactment

<sup>3</sup> Branstetter, Lee, “TPP and the Conflict over Drugs Incentives for Innovation Versus Access to Medicines,” (Schott and Cimino-Isaacs, 2016, p. 29). The study is based on USDOC statistics.

<sup>4</sup> USDOC, “The Pharmaceutical and Biotech Industries in the United States” <https://www.selectusa.gov/pharmaceutical-and-biotech-industries-united-states> [accessed June 12, 2016]. 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.” 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.

<sup>5</sup> 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.”, but see also the 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].

<sup>6</sup> 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](http://www.regulations.gov), docket number USTR-2014-0025.

of the Trade and Tariff Act of 1974 and its Section 301, as expanded by subsequent trade legislation, Congress has required the U.S. administration to attempt to remove foreign barriers to U.S. 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.

According to the U.S. Department of Commerce (USDOC), U.S. industries that depend heavily on intellectual property protection<sup>7</sup> accounted for about \$5.06 trillion in value added or 34.8 percent of U.S. GDP, and supported directly or indirectly 40 million or 30 percent of all jobs in the U.S. in 2010. In addition, goods from these IP-intensive industries accounted for 61% of all U.S. merchandise exports, and merchandise imports by these industries stood at 70% of total U.S. merchandise imports in 2010 (USDOC, 2012, pp. vi-viii).

Among these U.S. 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). 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. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), the U.S. exported over \$52 billion in biopharmaceuticals in 2014; U.S. biopharmaceutical innovation generated \$97 billion in 2014 in economic value, with a total impact of \$790 billion annually.

Moreover, U.S. exports of pharmaceutical products have been growing continuously over the last decade. Between 2005 and 2014, the U.S. pharmaceutical exports increased by 205% (see Figure 5), 184% in small molecule pharmaceuticals and 300% in biologics, reaching a total of US\$39 billion in 2014 —US\$24 billion corresponding to small molecule pharmaceuticals and US\$15 billion to biologics. Although U.S. exports of pharmaceutical products accounted for only 3.3% of total U.S. exports in 2014, pharmaceutical exports are about 3.61 times higher than those of the average industry.

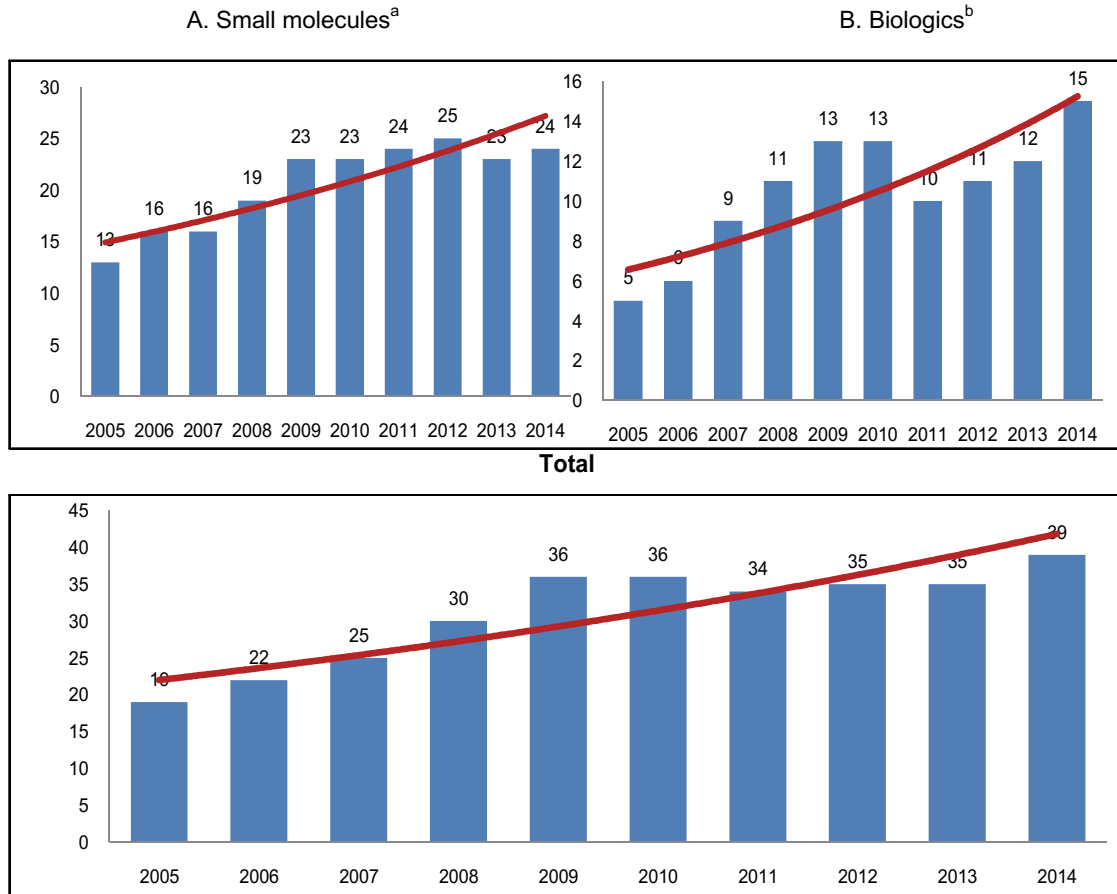
Europe is the main market for U.S. pharmaceutical exports, six of the top 10 export partners are European countries. Among the TPP countries, only Canada, Japan and Mexico make the top 10 list that is completed by China (see table 1). These top 10 export partners account for almost 70% of total U.S. exports of pharmaceuticals.

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<sup>7</sup> 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.



**Figure 5**  
**U.S. Pharmaceutical exports, 2005-2014**  
*(In billion dollars)*



Source: Elaborated by authors on the basis of USITC Database

<sup>a</sup> Small molecules refers to harmonized tariff schedule (HTS) code 3004: Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale.

<sup>b</sup> Biologics refers to Harmonized tariff schedule (HTS) code 3002: Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products.

**Table 1**  
**Top U.S. partners in pharmaceutical trade, 2014**  
*(In billion dollars)*

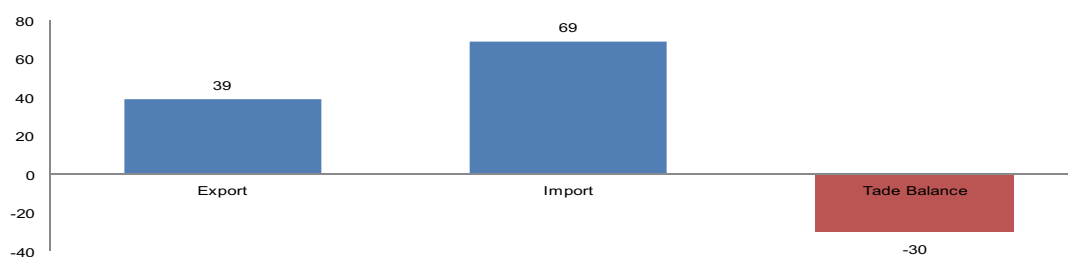
Top 10 Export Partners		Top 10 Import Partners	
Country	Value in Billion Dollars	Country	Value in billion dollars
Belgium	5.3	Germany	13.4
Netherlands	3.9	Ireland	10.2
Canada	3.7	Switzerland	9.4
Japan	3.2	India	4.9
UK	2.4	Israel	4.4
Germany	2.0	Canada	4.2
Switzerland	2.0	UK	3.6
Spain	1.7	Belgium	3.3
China	1.5	Denmark	3.0
Mexico	1.4	France, Monaco	2.2
<b>Grand Total</b>	<b>27.1</b>	<b>Grand Total</b>	<b>58.6</b>
Total global export	39	Total global import	69
Share of U.S. total export	69%	Share of U.S. total import	85%

Source: Elaborated by authors on the basis of COMTRADE Database.

The U.S. is also a large importer of pharmaceutical products. In 2014, the U.S. imported US\$58.6 billion of pharmaceutical products. Although U.S.'s providers are mostly European countries, the U.S. also imports from India, Israel, and Canada.

The market for imports is even more concentrated than that of exports, with 85% originating in one of the U.S.'s top 10 import partners. In 2014, U.S. imports of pharmaceuticals reached US\$69 billion and the U.S. ran a trade deficit of US\$30 billion in pharmaceuticals (see figure 6).

**Figure 6**  
**U.S. Global Pharmaceutical Trade, 2014**  
*(In billion dollars)*



Source: Elaborated by authors on the basis of COMTRADE Database.

## D. International patent filings by the U.S., TPP, and Western Hemisphere Countries

U.S. leadership in research and development is also evident in its intensive use of the international patent filing system under the Patent Cooperation Treaty (PCT). The PCT provides a unified procedure for filing patent applications to protect inventions in each of the states which are parties to the treaty<sup>8</sup>. As of 23 June 2016, there were 150 countries parties to the PCT, including all of the major industrialized countries and all of the TPP member countries<sup>9</sup>.

The U.S. 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 2, applicants from the U.S. 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). Canada and Australia are at a distant third and fourth among TPP countries with 3,089 and 1,726 applications, respectively.

**Table 2**  
**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 3 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.

Pharmaceutical patents represented the seventh largest technological field among PCT filings in 2014, 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 U.S. pharmaceutical company headquartered in New Jersey, was the largest pharmaceutical patent filer with 171 applications, followed by Novartis AG (141), F. Hoffmann-La Roche AG (135) and the University of California (111) in 2014 (WIPO, 2015).

<sup>8</sup> A PCT application, however, does not itself result in the grant of a patent, since there is no such thing as an international patent and the grant of patent is a prerogative of each national or regional authority.

<sup>9</sup> [http://www.wipo.int/pct/en/pct\\_contracting\\_states.html](http://www.wipo.int/pct/en/pct_contracting_states.html) (accessed June 23, 2016).

**Table 3**  
**International applications filed under the PCT from Western Hemisphere States**

Origin	2013	2014
Antigua and Barbuda	0	0
Argentina	26	33
Bahamas	10	20
Barbados	149	175
Belize	3	4
Bolivia (Plurinational State of)	1	0
Brazil	657	581
<b>Chile</b>	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
<b>Mexico</b>	233	284
Nicaragua	2	0
Panama	18	16
Paraguay	0	0
<b>Peru</b>	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 (Bolivarian Republic of)	1	1
<b>Total Latin America and Caribbean States</b>	1 385	1 411
<b>Canada</b>	2 845	3 089
<b>United States</b>	57 441	61 492
<b>Total Western Hemisphere States</b>	61 671	65 992

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

NA = not applicable as not a PCT contracting state.



## II. Patent and regulatory data-related protection on pharmaceutical products in TPP

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The patent and regulatory data-related IP standards provided under the TPPA and other free trade area (FTA) agreements entered into by the U.S. are built upon the multilateral trade rules, which serve as the reference point for comparison of FTA protection levels and policy flexibilities.

The WTO 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 on the side of IPRs includes national and most favored nation (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<sup>10</sup> 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.

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<sup>10</sup> When a government allows someone other than the rights holder to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the TRIPS Agreement ([https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_fa\\_q\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_fa_q_e.htm)). The patent owner still has rights over the patent, including a right to be paid for the authorized copies of the products. Certain conditions need to be met for the government to be able to issue a compulsory license.

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 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 applies independently of whether the pharmaceutical or agricultural chemical products are covered by patents (Section 7, Art. 39, TRIPS). TRIPS 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. However, TRIPS does not specify how long a time period the data should be protected.

There are differing views among members on how to implement these provisions of the TRIPS Agreement and different approaches to data protection against unfair commercial use, a term the agreement does not define. 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.<sup>11</sup>

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 A1). Thus under the TRIPS Agreement, WTO member governments have leeway on how to implement regulatory data exclusivity for pharmaceutical products, and for how long.

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<sup>11</sup> "U.S. 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).

Table A1 in annex 2 compares the relevant patent and data protection provisions for pharmaceutical products in U.S. FTAs with Western Hemisphere countries and the TRIPS Agreement.

It shows 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, U.S.-Chile, DR-CAFTA to the more recent U.S. FTAs with Peru, Colombia and Panama<sup>12</sup>. The TPPA continues this trend.

The following subsections discuss some of the key pharmaceutical patent and data protection provisions in the TPPA. The first subsection addresses the protection of incremental innovation. The TPPA has been criticized for protecting incremental innovation and with it potentially promoting evergreening. The following subsection refers to patent extensions. The TPPA rolls back the flexibilities granted in some of the previous FTAs with Western Hemisphere countries, making them mandatory rather than optional. The third subsection addresses the period of regulatory data protection for biologics, which is one of the most contentious aspects of the TPPA and still an outstanding issue for ratification by the U.S. Congress: the U.S. had pushed for 12 years and the TPPA requires 8 years at most. Although less than what the U.S. had advocated for, this still enhances significantly data protection in many of the TPP countries where data protection is non-existent or far shorter, effectively increasing the IPRs protection for biologics. The fourth subsection describes patent linkages, an aspect where the TPPA provides more flexibility than in previous U.S. FTAs with the region. The rest of the subsections discuss provisions where the TPPA seeks to enhance broader access to medicines: public health flexibilities, transition periods, patent cooperation and transparency, and exceptions.

## A. Patent process

TRIPS Agreement (Art. 271.1) 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 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/manufacture domestically a product within the country granting the patent within a certain time period.

In the TPPA, patents are also made 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.

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). U.S. 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.

<sup>12</sup> The so called "May 10, 2007" agreement between the U.S. Congress and the Administration sought to break down this trend of imposing increasingly stricter IP protections in trade agreements and provide greater flexibilities with the goal of improving access to medicines, in particular, in developing countries.



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.

## **B. Patent extensions**

Under TRIPS, patent terms last 20 years from the date of filing. This means that any delays in finally granting the patent reduce the effective period of patent protection by the amount of time between the filing and the granting of the patent right, something that is outside the control of the inventor. The TRIPS Agreement does not require patent extensions, but the TRIPS-plus provisions in subsequent U.S. 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.

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 U.S. FTAs 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.

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.

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.

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 U.S. 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 provide for 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.

## C. Regulatory data protection

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, Section II.H). 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 U.S. 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 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” of the data that delivers 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 necessarily the “same” as 8 years. Canada and Japan already provide 8-year data exclusivity periods, and the U.S. 12 years for biologics. U.S. negotiators under pressure from Congress 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 their meeting their respective obligations under

TPPA Art. 18.51(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).

## **D. Linkage between patents and marketing approval**

If a TPPA member country 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, it is required to have a system of notice to the patent holder prior to the marketing of 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 U.S. 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.

## **E. TPPA and public health flexibilities**

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 (see Box 1) on TRIPS and Public Health (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.

### Box 1 The WTO TRIPS Agreement, Doha Declaration and Public Health

Concerns about the possible interpretation under WTO dispute settlement of the scope of the flexibilities offered in the TRIPS Agreement in support of public health, particularly as regards compulsory licensing and parallel imports 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)<sup>a</sup> 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 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 through 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 member.<sup>b</sup>

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 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<sup>c</sup>; more acceptances are needed to meet the threshold amount for entry into force by the latest extended deadline of Dec. 31, 2017<sup>d</sup>.

Source: Elaborated by authors.

<sup>a</sup> 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.

<sup>b</sup> 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.

<sup>c</sup> 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](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.

<sup>d</sup> "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.

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).

## F. 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).

## G. Transition periods

The TPPA includes a number of transition periods and other special provisions for specific Parties. Table 4 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 those 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.

**Table 4**  
**Transition periods for implementing certain (TRIPS-PLUS)**  
**patent and data provisions for pharmaceutical products under the TPPA<sup>a</sup>**

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 <sup>b</sup>		5 years <sup>b</sup>	18.50.2 (new clinical information or combinations) 5 years	10 years + 2 year extension + additional 1 year extension <sup>b</sup>
Art. 18.51 Regulatory Data Exclusivity for Biologics	4 years <sup>b</sup>	5 years	5 years <sup>b</sup>	10 years	10 years + 2 year extension + additional 1 year extension <sup>b</sup>
18.53 Pharmaceutical Patent Linkage	2 years	4.5 years			3 years

Source: Elaborated by the authors.

<sup>a</sup>As 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.

<sup>b</sup> 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.

## H. Exceptions

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.<sup>13</sup> This exception for Chile was deemed necessary because the exceptions to regulatory data protection under Chilean law are broader than allowed under

<sup>13</sup> 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 anti-competitive, 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.

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.<sup>14</sup> 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 TPPA Annex 18-D, Part 2, para. 1, 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 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 under TPPA Art. 18.50.1(b) and 18.51.1(b)(i).

There is similar language used under TPPA Annex 18-D, Part 2, para. 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)).

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<sup>14</sup> Article 1. – The Member Countries, through their internal regulations, shall be authorized, under the terms expressly provided in subparagraphs a)through j), to develop and deepen the following provisions only of Decision 486:

(d) In Chapter V, Title II (Patents): With the exception of pharmaceutical patents, establish the means to compensate the patent owner for unreasonable delays by the National Office in the issuance of the patent, by restoring the patent term or patent rights. Member Countries shall deem as unreasonable delays, delays of more than 5 years from the date of filing the patent application or three years from the request for examination of patentability, whichever is later, provided that periods attributable to actions of the patent applicant need not be included in the determination of such delays."

### III. Congressional mandates on intellectual property protection on pharmaceutical products<sup>15</sup>

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Under U.S. law, trade agreements must be approved by both chambers of Congress and signed into law by the President through implementing legislation. Ratification of the TPPA--or more precisely written notification of the completion of applicable legal procedures--by the United States (and Japan) is needed for the agreement to enter into force<sup>16</sup>. TPPA advocates are hoping for the passage by the U.S. Congress of legislation to implement the TPPA before the new U.S. President assumes office on January 20, 2017. Congress voted to give Trade Promotion Authority (TPA) to the U.S. President in 2015, putting the TPPA on “fast track”, and therefore eliminating the possibility of amendments and requiring just 51 votes in the Senate, as opposed to 60.

#### A. Special Section 301

Since the enactment of the Trade and Tariff Act of 1974 and its Section 301, as expanded by subsequent trade legislation<sup>17</sup>, Congress has required the U.S. administration to attempt to remove foreign barriers to U.S. exports and has authorized the right to retaliate against unreasonable foreign trade practices. Congress has made such unreasonable foreign practices--including lack of proper intellectual property protection--actionable for retaliation against foreign countries, like withdrawing GSP eligibility. Viewed in a benign light, Section 301 aims to ensure executive due diligence and responsiveness to trade

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<sup>15</sup> 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).

<sup>16</sup> *Supra* note 2

<sup>17</sup> 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).



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 U.S. unilateral demands and by access to medicine advocates.

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 U.S. 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, 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 U.S., and to monitor Colombia's implementation of its National Development Plan. Countries that were flagged for particular U.S. concern in relation to pharmaceutical IPRs were: Argentina, Brazil, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Guatemala, Peru, and Venezuela.<sup>18 19</sup> The TPPA negotiations

<sup>18</sup> 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-U.S. 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; U.S. 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.)

<sup>19</sup> 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 36, 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/#!search?Results;rpp=25;po=0;s=docket%252Bnumber%252BUSTR-2015-0022;det=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.

offered an opportunity for United States Trade Representative to show Congress that it was addressing some longstanding complaints by the U.S. biopharmaceutical industry on alleged deficiencies in IPR protection by TPP partner countries, such as on patent processing and regulatory protection.

## B. TPA: U.S. domestic intellectual property law as the standard for evaluating the TPPA

The principal negotiating objectives for the United States as established by Congress in its recent grant of fast track authority (TPA) 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.”<sup>20</sup> Thus, the standard against which the IP provisions of the TPPA are 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<sup>21</sup>. 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

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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 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 maintains its 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).

<sup>20</sup> 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).

<sup>21</sup> "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.

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);
- 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 moiety<sup>22</sup> 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.<sup>23</sup>

As regards biologics, the relevant U.S. 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.<sup>24</sup> 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.<sup>25</sup> The BPCI Act includes, inter alia:

<sup>22</sup> “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].

<sup>23</sup> FDA *supra* note 44 and USPTO <http://www.uspto.gov/web/offices/pac/mpep/s2750.html> [accessed June 12, 2016].

<sup>24</sup> 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.”

<sup>25</sup> 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).

The above U.S. law baseline against which the TPPA will be judged by Congress entails 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 negotiations<sup>26</sup>.

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.<sup>27</sup>

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

<sup>26</sup> “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).

<sup>27</sup> 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].

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.<sup>28</sup> 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.<sup>29</sup> On March 6, 2015, the FDA approved the first biosimilar product to be approved in the U.S.<sup>30</sup>

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<sup>28</sup> 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.

<sup>29</sup> <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.

<sup>30</sup> 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].

## IV. Conclusions

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It is difficult to assess whether the (patent and regulatory data-related) intellectual property provisions of the TPPA achieve the appropriate balance between spurring innovation in pharmaceutical products and assuring access to medicine, due *inter alia* to the existence of exceptions and transition periods that obscure the macro picture of the balance struck over different points of time. This is compounded by the uncertainty as to when the TPPA will come into force and for which countries as well as on how the TPPA will be implemented.

All things considered, regulatory data exclusivity would delay market entry for biosimilars which piggyback on the data of originator firms, however, unlike generics there will be a more limited number of firms that can come in with biosimilars due to the necessary economy of scale required to break even.<sup>31</sup> The concern is with the delay in the availability of generic and biosimilar competition that could drive the price of life saving medicines down. On the other hand, provision for improved patent registration and marketing approval processes and greater transparency is a plus for speedier access to medicines

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.

The TPPA also continues the trend in TRIP-Plus protection of pharmaceutical patents and test data; e.g., patent term extensions for regulatory delays in granting patents and marketing approvals, no

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<sup>31</sup> “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’ the 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.

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 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.

Notwithstanding the flexibilities incorporated with respect to pharmaceutical IPR provisions, the IP chapter in the TPPA represents an augmentation of IPR protection for pharmaceutical products compared to the IP chapters in previous U.S. FTAs with Latin American countries. 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 three 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 (see table 4).

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 exclusivity period for biologics set by the TPPA, particularly as regards competition from biosimilars, is uncertain in several ways. First, data exclusivity periods of 8 or more years for biologics already apply in the 3 largest TPP markets by GDP (Canada and Japan, 8 years; U.S. 12 years). Of course, subscribing to a TPP commitment of at least 8 years of data exclusivity means that a TPP Party may not lower its national data exclusivity standard to below 8 years, 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 the minimum 8-year 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)). U.S. 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 (see table 4). Fourth, Peru has the benefit of an exception under the TPPA (TPPA Annex 18-D, Part 2) that allows Peru to apply a shorter data exclusivity period than the 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. 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.





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## **Annexes**

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## Annex 1

### Glossary

**Biologics:** 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 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].

**Biosimilars:** 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).

**Bolar exception:** The Bolar or regulatory review exception that many countries include in their laws “allows generic competitors to make limited use of a patented invention before the patent expires to obtain marketing approval of a competitor product” (WHO, WIPO, WTO, 2013, pp. 61 and 174). It is called the “Bolar” exception after the U.S. court decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (1984) that had considered this type of use to be patent infringement, leading to U.S. legislation, the Hatch-Waxman Act, that defined this type of use as a permissible exception to the patent right (*Roche Products v Bolar Pharmaceuticals*, 733 F.2d. 858 (Fed. Cir. 1984) (*Id.*, note 65)). 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. Likewise, Canada allows generic competitors to manufacture patented goods for six months before the 20-year patent term expires; and Brazil, Chile, Colombia, Dominican Republic, Peru and Uruguay have put in place Bolar exemptions as well. (Tridico, Anthony, Jeffrey Jacobstein, and Leythem Wall, “Facilitating Generic Drug Manufacturing: Bolar Exemptions Worldwide,” *WIPO Magazine*, June 2014).

**Compulsory licensing:** Compulsory licensing allows the exploitation of a patent during the patent term without the consent of the patent holder, but with the authorization of competent national authorities. This authorization may be given to a third party, or, in the case of government use, to a government agency or to a third party authorized to act on the government’s behalf. The term “compulsory licensing” is often used to refer to both forms of authorization, although they can have important operational distinctions (WHO, WIPO, WTO, 2013, p.174) It is one of the flexibilities on patent protection included in the TRIPS Agreement. The patent owner still has rights over the patent, including a right to be paid for the authorized copies of the products. Certain conditions need to be met for the government to be able to issue a compulsory license. ([https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm)) [accessed June 12, 2016].

**Data exclusivity:** Data exclusivity and data protection are often used interchangeably. “Technically, data protection refers to a period during which generic firms are forbidden from using data submitted by a branded firm’s original drug to obtain regulatory approval for a competing product, whereas data exclusivity refers to the period during which generic companies are forbidden from

marketing a product based on that data” (Schott and Cimino-Isaacs, 2016, p. 22, note 7). In principle, the generic drug company could enter by conducting its own clinical trials to demonstrate safety and effectiveness, but that would be extremely expensive and time consuming, and generic companies do not pursue that pathway (*Id.*, note 8).

**Evergreening:** Evergreening is 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).

**Exhaustion:** 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. In other words, the rights of commercial exploitation for a given product end with the product's first sale unless otherwise specified by law, and therefore any subsequent act of resale, rental, lending or other forms of commercial use can no longer be controlled by the right holder. 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 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. (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](http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm) [accessed June 12, 2016].

**Parallel imports:** 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 (Taubman, Wager and Watal, 2012, p. 148).

# Annex 2

**Table A1**  
**Evolution of certain patent and data protection provisions in U.S. trade agreements**

Agreement <sup>a</sup>	NAFTA	TRIPS	US-Chile	US-DR-CAFTA	US-Peru	US-Colombia	US-Panama
Entry into force	1 Jan 1994	1 Jan 1995	1 Jan 2004	1 Mar 2006 <sup>b</sup> 1 Jan 2009 <sup>b</sup>	1 Feb 2009	15 May 2012	31 Oct 2012
Relevant article(s)	17.09 Patents 17.11 Trade Secrets	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	Opportunity for judicial review of decision to revoke or forfeit a patent must be available	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, according to its laws; 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, according to its laws; 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 <sup>8</sup>	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 marketing requirements for issuing sanitary permits in the exporting 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.	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.	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 <sup>a</sup>	NAFTA	TRIPS	US-Chile	US-DR-CAFTA	US-Petu	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 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	Each Party shall adjust a patent term, at the patent owner's request, to compensate for unreasonable delays in 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
Pharmaceutical patent term restoration				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 product in the Party	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.	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.	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 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

Agreement <sup>a</sup>	NAFTA	TRIPS	US-Chile	US-DR-CAFTA	US-Penu	US-Colombia	US-Panama
Public health flexibilities for compulsory licensing		Doha Declaration on TRIPS & Public Health 2001; Council decision / waiver implementing para. 6 of Declaration 2003; and Amendment of TRIPS			[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	[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	[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
Regulatory data protection/ exclusivity for pharmaceutical products	If a Party requires for the marketing approval of a pharmaceutical or agricultural chemical products that utilize 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 such data except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is 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, 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.	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 is 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, 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.	If a Party requires the submission of undisclosed information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product that utilizes a new chemical entity and that has not been previously approved, to grant a marketing approval or sanitary permit for such a product, the Party shall not permit 3d parties not having the consent of the person providing the information, to market a product based on this new chemical entity, on the basis of the approval granted to the party submitting such information. A Party shall maintain this prohibition for ≥ 5 years from the date of approval for a pharmaceutical product and 10 years from the date of approval for an agricultural chemical product. Each Party shall protect such information against disclosure except where necessary to protect the public.	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 chemical 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.	[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	[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	[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
					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 origination 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 for approval to market its product, taking account of the nature of the data and person's efforts and expenditures in producing them.	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 origination 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 for approval to market its product, taking account of the nature of the data and person's efforts and expenditures in producing them.	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 origination 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 for approval to market its product, taking account of the nature of the data and person's efforts and expenditures in producing them.

Agreement <sup>a</sup>	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 shall begin with the date of the first marketing approval relied on.	-	-	If a Party permits for pharmaceutical or agricultural chemical product. 3d persons to submit evidence concerning safety or efficacy of a product that was 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 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 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 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 <sup>a</sup>	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) &amp; other special procedures for adjudication of pharmaceutical patent infringement disputes</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 of 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> <p>(a) shall implement 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; and</p> <p>(b) shall 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</p> <p>(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> <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> <p>(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>	<p>Each Party shall provide:</p> <p>(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;</p> <p>(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</p> <p>(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> <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> <p>(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>	<p>Each Party shall provide:</p> <p>(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;</p> <p>(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</p> <p>(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> <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> <p>(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>	<p>Each Party shall provide:</p> <p>(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;</p> <p>(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</p> <p>(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> <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 a Party or in another country, 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 product or its approved method of use during the term of that patent, unless by consent or</p>

Agreement <sup>a</sup>	NAFTA	TRIPS	US-Chile	US-DR-CAFTA	US-Peru	US-Colombia	US-Panama			
Data exclusivity period continues after patent term expiration	-	-	-	-	<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>or its approved method of use during the term of that patent, unless by consent or 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; 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>[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.</p>	<p>[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.</p>	<p>[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.</p>

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

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

<sup>a</sup> 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.

<sup>b</sup> 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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