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# Exploring the Trans-Pacific Partnership's Complexities Through the Lens of Its Intellectual Property Rights Chapter

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# EXPLORING THE TRANS-PACIFIC PARTNERSHIP'S COMPLEXITIES THROUGH THE LENS OF ITS INTELLECTUAL PROPERTY RIGHTS CHAPTER


## ABSTRACT

*The Trans-Pacific Partnership (TPP) is a multilateral trade agreement negotiated between twelve Pacific-Rim countries, including the United States. Despite receiving significant criticism, the agreement ultimately represents a delicate balance of concessions intended to promote global economic stability and increase cooperation between member nations. One way in which the TPP increases cooperation is by harmonizing intellectual property rights across member nations. In doing so, the TPP also establishes a sensible regulatory regime for biologic medicines that provides strong incentives to innovate while safeguarding access to affordable medicines. Unfortunately, in light of an executive order issued by President Donald Trump, it appears likely that the United States may withdraw from the agreement. This Comment urges U.S. lawmakers on both sides of the aisle to press the Trump Administration to reconsider withdrawal. Ultimately, this Comment argues that the U.S. Congress should vote in favor of implementing the TPP, should such an opportunity arise.*


## INTRODUCTION

The Trans-Pacific Partnership (TPP) is a multilateral trade agreement between the United States and eleven other Pacific Rim countries[1] that proponents claim will rewrite the rules of international trade.[2] In addition to reducing tariffs, the TPP addresses issues related to intellectual property, competition, and investment.[3] Negotiated largely in secret, the TPP has received

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[1] The TPP is an expansion of the Trans-Pacific Strategic Economic Partnership Agreement (P4) between Brunei, Chile, New Zealand, and Singapore, which came into force in 2006. *Trans-Pacific Strategic Economic Partnership (P4) Agreement*, NEW ZEALAND FOREIGN AFF. & TRADE, http://www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/Trans-Pacific/2-P4.php (last visited Jan. 31, 2017). The other TPP Parties include Australia, Canada, Japan, Malaysia, Mexico, Peru, and Vietnam. *See The Trans-Pacific Partnership*, OFFICE OF U.S. TRADE REP., https://ustr.gov/tpp/ (last visited Oct. 18, 2016) (original copy of U.S. webpage about TPP on file with the *Emory International Law Review*) [hereinafter *The Trans-Pacific Partnership*].

[2] *See, e.g.*, *The Trans-Pacific Partnership*, *supra* note 1 (stating that the TPP "writes the rules for global trade").

[3] *Id.*

significant criticism, particularly for its attempt to harmonize intellectual property rights across member states.[4] Moreover, the agreement has faced opposition from lawmakers both in the United States and abroad.[5] However, after a protracted negotiation process lasting nearly six years, an agreement was finally reached in Atlanta, Georgia on October 5, 2015.[6]

Critics have come out in opposition to the agreement's provisions regulating pharmaceutical products, particularly biologic medicines,[7] fearing that the agreement will lead to increased healthcare costs in member nations.[8] Others argue that the agreement provides inadequate protection to incentivize medical innovation.[9] More alarmist voices around the globe see the TPP as simply an imperial quest by the United States for foreign markets, arguing that the U.S. delegation used its superior negotiation power to secure favorable trading positions to the detriment of its trading partners.[10]

While some of these aforementioned concerns are reasonable, it may not be time to sound the alarm over the TPP just yet. Far too often, discussions over its various provisions seem to devolve into a set of reductive platitudes. However, many important aspects of the deal still need to be explored and analyzed. Luckily, that opportunity is finally here—the official text of the TPP has at last

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[4] Press Release, WikiLeaks, TPP Treaty: Intellectual Property Rights Chapter – 5 October 2015 (Oct. 9, 2015), http://wikileaks.org/tpp-ip3/press.html [hereinafter October WikiLeaks Press Release]; *The Trans-Pacific Partnership Agreement*, ELECTRONIC FRONTIER FOUND., https://www.eff.org/issues/tpp (last visited Jan. 31, 2017) (referring to the secretive nature of negotiations).

[5] *See, e.g.*, Letter from Ten U.S. Representatives, to Ambassador Ron Kirk, U.S. Trade Rep. (Aug. 2, 2011), http://infojustice.org/wp-content/uploads/2011/08/Ten-Representatives-on-TPP-08022011.pdf.

[6] Jackie Calmes, *Trans-Pacific Partnership Is Reached, but Faces Scrutiny in Congress*, N.Y. TIMES (Oct. 5, 2015), http://www.nytimes.com/2015/10/06/business/trans-pacific-partnership-trade-deal-is-reached.html?r=0.

[7] For a discussion of biologics, see *infra* Part II.C.

[8] As of November 2016, notable critics include U.S. Senator and Democratic presidential candidate Bernie Sanders and WikiLeaks founder Julian Assange. *See* Letter from Bernard Sanders, U.S. Senator, to Ambassador Ron Kirk, U.S. Trade Rep. (Dec. 1, 2011), http://keionline.org/sites/default/files/Sen_Sanders_letter_to_USTR_TPP_negotiations_12-1-2011.pdf; Press Release, WikiLeaks, Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter (Nov. 13, 2013), http://wikileaks.org/tpp/ [hereinafter November WikiLeaks Press Release].

[9] *See, e.g.*, THE TRANS-PACIFIC PARTNERSHIP AND INNOVATION IN THE BIOECONOMY: THE NEED FOR 12 YEARS OF DATA PROTECTION, BIO 37 (July 18, 2013, 11:02 AM), https://www.bio.org/sites/default/files/TPP%20White%20Paper%20_2_.pdf [hereinafter THE NEED FOR 12 YEARS OF DATA PROTECTION]. The Biotechnology Industry Organization (BIO), a "trade association representing more than 1,100 companies, universities, research institutions, investors, and other entities in the field of biotechnology," has been critical of the shorter data exclusivity periods for biologics and other TPP provisions concerning pharmaceuticals. *Id.* at 6.

[10] Joseph Stiglitz & Adam Hersh, *Don't Let TPP Jeopardise Malaysia's Future*, MALAYSIAN INSIDER (Oct. 2, 2015, 6:46 AM), https://www8.gsb.columbia.edu/faculty/jstiglitz/sites/jstiglitz/files/2015%20TPP%20Malaysia.pdf. Nobel laureate Joseph Stiglitz stated that the TPP favors corporate interests, increasing profits "at the expense of everyone else." *Id.*

been released to the public,[11] providing an opportunity for a more meaningful analysis of the deal's text and its potential implications. Ultimately, this Comment argues that the final text of the TPP represents a delicate balance of concessions intended to promote global economic stability and peace by lowering trade barriers and increasing cooperation. Thus, it may be time for the media, scholars, and politicians alike to temper their attitudes towards the deal. Moreover, this Comment will provide an analysis of the TPP's provisions regarding biologic medicines and discuss the potential impact these provisions will have on competition within the pharmaceutical industry and public access to medicines. This Comment will also address the concerns raised over the procedural aspects of negotiating large-scale, multilateral free trade agreements, and the extent to which these concerns are legitimate. This Comment will conclude by arguing that the U.S. Congress should ratify the TPP, as the agreement provides the United States with an opportunity to reestablish a foothold in Asia and create a level playing field in the region in the face of an ascendant China. The TPP will not only advance U.S. interests by opening new markets and establishing economic stability, but it will also improve labor standards, address concerns over the environment, and balance incentives to innovate with access to affordable medicine across the Pacific Rim.

## I. THE TRANS-PACIFIC PARTNERSHIP

### *A. What Is the Trans-Pacific Partnership?*

The TPP is a multilateral trade agreement between twelve Pacific Rim countries, including Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam.[12] Delegates from the twelve countries—who together account for about forty percent of global GDP—negotiated the treaty over the course of almost six years.[13]

The agreement itself is unlike any other traditional free trade agreement (FTA) because it is a comprehensive plan to coordinate national economic policies.[14] The TPP does more than liberalize Asian economies through

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[11] *See TPP Full Text*, OFFICE OF U.S. TRADE REP., https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text (last visited Jan. 31, 2017).

[12] *Id.*

[13] Raj Bhala, *Trans-Pacific Partnership or Trampling Poor Partners? A Tentative Critical Review*, 11 MANCHESTER J. INT'L ECON. L. 2, 8 (2014).

[14] Stefano Barazza, *The Draft Trans-Pacific Partnership Agreement and its Implications for Public Health and Access to Medicines: The UNITAID Report*, 5 EUR. J. RISK REG. 366, 366 (2014).

comprehensive tariff reduction; it addresses issues related to intellectual property, competition, and investment.[15] The chapter covering intellectual property rights has garnered much controversy and disagreement, in particular the provisions regulating biologics and other pharmaceutical products.[16]

The Obama Administration heralded the TPP as an opportunity to rewrite the rules of global trade—rules that would increase U.S. exports, grow the U.S. economy, and strengthen the U.S. middle class.[17] Under the Obama Administration, the Office of the United States Trade Representative (USTR) projected that the TPP would lower trade barriers on U.S. products across the twelve countries.[18] Many critics see the TPP as just another opportunity for the United States to impose its pro-business (and in the opinion of some, anti-competitive) policies on its trading partners.[19] It is worth noting that U.S. government rhetoric somewhat reinforces this notion; according to the USTR, "[t]he rules of the road are up for grabs in Asia," and the United States must "write those rules" in order to save "American jobs" and maintain a position of leadership in Asia.[20] According to the USTR, the TPP is a "landmark trade agreement that reflects America's values and gives workers the fair shot at success they deserve."[21] The TPP is considered the forerunner to the "equally secret[ive]" Transatlantic Trade and Investment Partnership (TTIP), which the United States and the European Union are currently negotiating.[22] In fact, the TPP is just the first of three U.S.-backed economic treaties, the third being the Trade In Services Agreement (TISA), which is set to cover fifty-two countries worldwide.[23]

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[15] Roma Patel, *A Public Health Imperative: The Need for Meaningful Change in the Trans-Pacific Partnership's Intellectual Property Chapter*, MINN. J.L. SCI. & TECH. 477, 480–81 (2015).

[16] October WikiLeaks Press Release, *supra* note 4.

[17] *The Trans-Pacific Partnership*, *supra* note 1.

[18] *Id.*

[19] *See, e.g.*, Stiglitz & Hersh, *supra* note 10; Tom Sullivan, *WikiLeaks: Big Pharma Measures in TPP Will Raise Drug Prices*, WUFYS (June 10, 2015), http://wakeupfromyourslumber.com/wikileaks-big-pharma-measures-in-tpp-will-raise-drug-prices/.

[20] *The Trans-Pacific Partnership*, *supra* note 1.

[21] *What They're Saying: Completion of Trans-Pacific Partnership (TPP) Negotiations*, TRADEWINDS: OFFICIAL BLOG OF U.S. TRADE REP. (Oct. 5, 2015), https://ustr.gov/about-us/policy-offices/press-office/blog/2015/october/what-they're-saying-completion-trans-pacific.

[22] *Translantic Trade and Investment Partnership*, OFFICE OF U.S. TRADE REP., https://ustr.gov/ttip (last visited Jan. 31, 2017); November WikiLeaks Press Release, *supra* note 8. TTIP is predicted to mirror the text of TPP. *Id.* President Obama initiated negotiations with the EU in January of 2013. *Id*.

[23] October WikiLeaks Press Release, *supra* note 4.

### *B. Ratifying the Trans-Pacific Partnership in the United States*

On February 4, 2016, U.S. Trade Representative Michael Froman formally signed the TPP in New Zealand.[24] However, under U.S. law, trade agreements such as the TPP are not self-executing.[25] Rather, because the TPP was negotiated pursuant to a congressional-executive agreement, it must be enacted through "implementing legislation."[26] Ultimately, passage will depend on whether the Trump Administration has the desire to reverse course and push for ratification.[27] Previously, President Obama was reticent to submit any implementing legislation, believing he lacked sufficient votes in Congress to ensure passage.[28]

The Obama Administration negotiated the TPP pursuant to Trade Promotion Authority granted by Congress, which allows the President to negotiate international agreements that Congress can either approve or disapprove but not amend.[29] This authority is a temporary power granted to the President by Congress. Though this move can often be controversial, it is not unusual for Congress to grant such authority before negotiation of major trade agreements.[30] In 2013, the Obama Administration began seeking renewal of the authority.[31] In June 2015, TPA passed Congress and was signed by President Obama.[32] The final approval to legislation granted President Obama this "enhanced power to

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[24] Rebecca Howard, *Trans-Pacific Partnership Trade Deal Signed, but Years of Negotiations Still to Come*, REUTERS (Feb. 4, 2016), http://www.reuters.com/article/us-trade-tpp-idUSKCN0VD08S.

[25] CONG. RES. SERV., R44360, U.S. WITHDRAWAL FROM FREE TRADE AGREEMENTS: FREQUENTLY ASKED LEGAL QUESTIONS 3 (2016); *see also* Joseph A. Laroski, Jr. & Bonnie B. Byers, *Trans-Pacific Partnership IP Provisions Remain at Forefront as Scrutiny of Text*, LEXOLOGY (Dec. 30, 2015), http://www.lexology.com/library/detail.aspx?g=ea70c59b-6b45-48f0-b790-6154c422032e.

[26] *Id.* Trade agreements such as NAFTA and TPP are voted on as congressional-executive agreements. *See* James J. Varellas, *The Constitutional Political Economy of Free Trade: Reexamining NAFTA-Style Congressional-Executive Agreements*, 49 SANTA CLARA L. REV. 717, 720 (2009).

[27] On January 23, 2017, President Trump issued an executive order formally withdrawing the United States from the TPP. Yian Q. Mui, *President Trump Signs Order to Withdraw From Trans-Pacific Partnership*, WASH. POST (Jan. 23, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/01/23/president-trump-signs-order-to-withdraw-from-transpacific-partnership/?utm_term=.3aaae2605ae3.

[28] Don Lee, *Signing of Trans-Pacific Partnership Trade Deal Opens Up Tough Battle in U.S.*, L.A. TIMES (Feb. 4, 2016, 8:39 AM), http://www.latimes.com/business/la-fi-pacific-trade-agreement-signed-20160204-story.html.

[29] U.S. Trade Representative, *Trade Promotion Authority*, OFFICE OF U.S. TRADE REP., https://ustr.gov/trade-topics/trade-promotion-authority (last visited Jan. 31, 2017).

[30] IAN F. FERGUSSON, CONG. RES. SERV., RL33743, TRADE PROMOTION AUTHORITY (TPA) AND THE ROLE OF CONGRESS IN TRADE POLICY 2, 6 (2015).

[31] *Id.* at 2.

[32] Jonathan Weisman, *Trade Authority Bill Wins Final Approval in Senate*, N.Y. TIMES (June 24, 2015), http://www.nytimes.com/2015/06/25/business/trade-pact-senate-vote-obama.html?_r=0.

negotiate major trade agreements [such as the TPP, TISA, and TTIP] with potential Asian and European trading partners."[33]

For the TPP to pass, the Trump Administration would have to convince enough Republicans and Democrats in both chambers to support the trade bill. Chairman of the Senate Finance Committee, Orrin Hatch, will likely play a crucial role in passing the TPP.[34] However, Senator Hatch has expressed concern over the exclusivity period for intellectual property protection of biologics, stating that he will push to renegotiate these provisions.[35] Regardless, further negotiation is highly unlikely—the Obama White House advised that any attempt at renegotiation would likely kill the deal.[36] As it stands, it remains unclear whether the TPP will ever be implemented by Congress, due to President Trump's intent to withdraw the United States from the TPP.[37]

### *C. Criticisms and Concerns*

From the start of negotiations, the TPP drafting process has been marked by extraordinary secrecy, and officials continually guarded drafts from access by the general public.[38] Even U.S. lawmakers were denied opportunities to view drafts and other treaty-related documents.[39] Meanwhile, so-called "trade advisers" were frequently given access to major parts of the agreement's text.[40] According to WikiLeaks, these "trade advisers" were simply lobbyists representing the interests of U.S. corporations.[41] Moreover, a "majority of Congress [was] kept in the dark as to the substance of the TPP negotiations, while representatives of U.S. Corporations . . . [were] being consulted and made privy to details of the agreement."[42]

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[33] *Id.*

[34] Laroski & Byers, *supra* note 25.

[35] *Id*; William Mauldin, *House Passes Trade Component, but Trans-Pacific Partnership Still in Doubt*, WALL STREET J. (Dec. 11, 2015, 3:30 PM), http://www.wsj.com/articles/house-passes-trade-component-but-trans-pacific-partnership-still-in-doubt-1449863100.

[36] Laroski & Byers, *supra* note 25.

[37] *See* Mui, *supra* note 27.

[38] November WikiLeaks Press Release, *supra* note 8.

[39] *Id.* Members of Congress have "only been able to view selected portions of treaty-related documents . . . under strict supervision." *Id.*

[40] *Id.*

[41] *Id.*

[42] Nile Bowie, *The Trans-Pacific Partnership (TPP), An Oppressive US-Led Free Trade Agreement, A Corporate Power-Tool of the 1%*, GLOBAL RES. (Apr. 2, 2013), http://www.globalresearch.ca/the-trans-pacific-partnership-tpp-an-oppressive-us-led-free-trade-agreement-a-corporate-power-tool-of-the-1/5329497.

Additionally, the TPP seeks to strengthen intellectual property rights, adopting a higher standard of protection than that endorsed by the World Trade Organization (WTO).[43] These provisions in particular have attracted significant criticism.[44] The U.S. delegation introduced many of these provisions with the objective of promoting innovation.[45] However, the Generic Pharmaceutical Association (GPhA) wrote a letter to President Obama expressing concern about elements of the trade agreement that, in the view of the GPhA, would restrict access to lower-cost generic and biosimilar products in the United States and around the world.[46] Even among U.S. politicians, these provisions have proven controversial.[47]

Furthermore, scholars have lambasted the TPP as "a blatant and shameful attempt to place intellectual property rights above human rights,"[48] claiming that it "will set a precedent" that "global citizens[] cannot afford to support."[49] They argue against ratification, claiming that once effective, the TPP will have a resounding and negative impact on the global economy."[50] Scholars have also argued that the intellectual property chapter proposed by the USTR "includes measures harmful to access to affordable medicines," the likes of which have never before been seen in previous free trade agreements.[51] For instance, Burcu Kilic has argued that the USTR's demands would "lengthen pharmaceutical monopolies," and be "especially dangerous for access to affordable medicines" in the Asia-Pacific region, flying in the face of the Doha Declaration.[52] These

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[43] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 320 (1999), 1869 U.N.T.S. 229, 33 I.L.M 1197 [hereinafter TRIPS].

[44] *See, e.g.*, Andrew D. Mitchell et al., *Public Health and the Trans-Pacific Partnership Agreement*, 5 ASIAN J. INT'L L. 279, 281–82 (2015).

[45] *Trans-Pacific Partnership: Summary of U.S. Objectives*, OFFICE OF U.S. TRADE REP., http://www.ustr.gov/tpp/Summary-of-US-objectives (last visited Jan. 31, 2017).

[46] *Letter to the President from GPhA and Biosimilars Council Regarding TPP*, GENERIC PHARMACEUTICAL ASS'N, http://www.gphaonline.org/media/cms/GPhA6624_GPhA_Wash_Post_PRINT_AD_12X21_Mech_5_FINAL.pdf (last visited Jan. 31, 2017); Michael Johnson, *GPhA Argues That Trans-Pacific Partnership Agreement Will Impede Generic Utilization*, DRUG STORE NEWS (Dec. 17, 2014), http://www.drugstorenews.com/article/gpha-argues-trans-pacific-partnership-agreement-will-impede-generic-utilization.

[47] *See, e.g.*, Barazza, *supra* note 14, at 367.

[48] Patel, *supra* note 15, at 508.

[49] *Id.*

[50] *Id.* at 490.

[51] Burcu Kilic, *Defending the Spirit of the Doha Declaration in Free Trade Agreements: Trans-Pacific Partnership and Access to Affordable Medicines*, 12 LOY. U. CHI. INT'L L. REV. 23, 25 (2014).

[52] *Id.*

critics argue that, in effect, developing nations are being coerced into trading away access to affordable medicines.[53]

## II. THE INTELLECTUAL PROPERTY RIGHTS CHAPTER

### *A. The Evolution of the Intellectual Property Rights Chapter*

The Intellectual Property Rights Chapter (IPR Chapter) of the TPP covers the agreed upon obligations and enforcement mechanisms for copyright, trademark, and patent law.[54] The Obama Administration stated that the IPR Chapter would "promote high standards of protection, safeguard U.S. exports and consumers against intellectual property infringement, and provide fair access to legal systems in the region to enforce those rights."[55] Due to a series of leaks,[56] the public had an opportunity to scrutinize the text of the IPR Chapter.

The last document to be leaked, the so-called "final" text of the IPR Chapter, was released on October 9, 2015.[57] These leaks, in combination with the recently released official text of the agreement,[58] provide an interesting opportunity to examine the evolution of the IPR Chapter over the course of the heavily protracted negotiating process. The evolution of the IPR Chapter serves as a microcosm for the negotiation process as a whole, shedding light on the evolving negotiating dynamic between member states.

#### *1. The 2013 Leak*

The first leak of the Intellectual Property Rights Chapter (the 2013 IPR Chapter) came ahead of negotiations set to take place in Salt Lake City, Utah.[59] Much of the Chapter's text was bracketed, indicating that an agreement had yet

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53 *Id.* at 31.

54 *See Intellectual Property Rights*, OFFICE OF U.S. TRADE REP., https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-chapter-chapter-negotiating-9 (last visited Jan. 31, 2017).

55 *See The Trans-Pacific Partnership*, *supra* note 1.

56 WikiLeaks released three such drafts. *See Secret TPP Treaty: Advanced Intellectual Property Chapter for All 12 Nations with Negotiating Positions*, WIKILEAKS (Nov. 13, 2013), http://wikileaks.org/tpp/static/pdf/Wikileaks-secret-TPP-treaty-IP-chapter.pdf [hereinafter *The 2013 Leak*]; *Secret TPP Treaty: Intellectual Property Chapter Working Document for All 12 Nations with Negotiating Positions*, WIKILEAKS (Oct. 16, 2014), http://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf [hereinafter *The 2014 Leak*]; *TPP Treaty: Intellectual Property Rights Chapter, Consolidated Text (October, 5 2015)*, WIKILEAKS (Oct. 9, 2015), http://wikileaks.org/tpp-ip3/WikiLeaks-TPP-IP-Chapter/WikiLeaks-TPP-IP-Chapter-051015.pdf [hereinafter *The 2015 Leak*]. To download the texts of these drafts see November WikiLeaks Press Release, *supra* note 8.

57 *Id.*

58 *See The Trans-Pacific Partnership*, *supra* note 1.

59 *The 2013 Leak*, *supra* note 56; November WikiLeaks Press Release, *supra* note 8.

to be reached regarding specific provisions.[60] The text also included annotations detailing each party's position.[61] The draft included ninety-five pages of text establishing a "far-reaching, transnational legal and enforcement regime, modifying or replacing existing laws in TPP member states."[62] This first draft provided for "supranational litigation tribunals to which sovereign national courts [were] expected to defer."[63] Some have insinuated that these tribunals will "conduct hearings with secret evidence" and will provide no "human rights safeguards."[64] The annotations detailing each party's position revealed that Australia was the nation most inclined to support the "hardline position" of the United States, while Vietnam, Chile, and Malaysia stood in opposition.[65]

The 2013 IPR Chapter sought to strengthen intellectual property rights, adopting a higher standard of protection than the standard endorsed by the WTO.[66] These provisions were introduced by the United States, with the objective of promoting innovation.[67] The December 9, 2013 leak of excerpts of internal government commentary indicated that the United States was exerting great pressure on opposing nations to acquiesce to its position on intellectual property rights.[68] At the time of its release, some scholars were of the belief that the intellectual property chapter proposed by the USTR "include[d] measures harmful to access to affordable medicines," the likes of which "ha[d] not been seen before in previous [free trade agreements]."[69]

### *2. The 2014 Leak*

WikiLeaks released an updated version of the IPR Chapter (the 2014 IPR Chapter) ahead of two rounds of negotiations set to take place in Australia.[70] This updated version was leaked after negotiations in Ho Chi Minh City.[71]

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[60] WikiLeaks obtained the text after the August 2013 summit in Brunei. November WikiLeaks Press Release, *supra* note 8.

[61] *Id.*

[62] *Id.*

[63] *Id.*

[64] *Id.*

[65] Julian Assange et al., *US, Australia Isolated in TPP Negotiations*, WIKILEAKS (Nov. 15, 2013), http://wikileaks.org/US-Australia-isolated-in-TPP.html.

[66] TRIPS, *supra* note 43.

[67] *Trans-Pacific Partnership: Summary of U.S. Objectives*, *supra* note 45.

[68] *Second Release of Secret Trans-Pacific Partnership Agreement Documents*, WIKILEAKS (Dec. 9, 2013, 6:51 PM), https://wikileaks.org/Second-release-of-secret-Trans.html.

[69] Kilic, *supra* note 51, at 24.

[70] Press Release, WikiLeaks, Updated Secret Trans-Pacific Partnership Agreement (TPP) – IP Chapter (Second Publication) (Oct. 16, 2014), http://wikileaks.org/tpp-ip2/pressrelease/.

[71] *Id.*

Despite multiple rounds of negotiations, there were few changes to the text, reflecting the contentious nature of the negotiations.[72] Many provisions in the Chapter were "very much on the table" heading into negotiations in Australia.[73] Significant additions included a transition period for developing nations[74] and tentative provisions for establishing a biologic data protection regime.[75] However, the drafters had not yet defined the period of data exclusivity, and the text indicates that there was serious disagreement over what the term should be.[76]

Addendum II of the 2014 IPR Chapter categorized parties for the purpose of establishing transition periods with respect to pharmaceutical patent provisions, with the most developed nations occupying Category A and poorer countries occupying Categories B and C.[77] Those in Category A would be required to comply with specific pharmaceutical patent provisions (*e.g.*, market exclusivity and patent linkage) within two years of the TPP's entry into force.[78] Categories B and C would have longer than two years, but the length of time had not yet been settled.[79]

### *3. The 2015 Leak*

On October 9, 2015, WikiLeaks released what has been termed the "final negotiated text" of the Chapter (2015 IPR Chapter).[80] The document was dated October 5, the same day it was announced in Atlanta, GA that member states had finally reached an agreement.[81] The text lacked "negotiating brackets," implying that a deal was essentially done and that the included provisions were no longer up for debate.[82] Although it was subject to a "legal scrub," the leaked text was thought to represent the final negotiated text of the TPP IPR Chapter, as no more negotiations were set to take place.[83] This was in fact the case, and

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72 *Id.*
73 *Id.*
74 *The 2014 Leak*, *supra* note 56, add. II, art. QQ.A.X.
75 *Id.* arts. QQ.E.16, QQ.E.20.
76 *Id.* art. QQ.E.20. The bracketed proposals indicate that zero, five, eight, and twelve years of pharmaceutical data protection were all on the table going into the final rounds of negotiation. *See id.*
77 *Id.* add. II, art. QQ.A.X.
78 *Id.*
79 *Id.*
80 October WikiLeaks Press Release, *supra* note 4.
81 *Id.*
82 *Id.*
83 *Id.*

the intellectual property rights provisions contained in the 2015 leak are identical to those in the "final text," discussed in the following section.

### *B. The Final Text of the Intellectual Property Rights Chapter*

The official final text of the TPP, including the IPR Chapter, was released on November 5, 2015.[84] The following subsections here will provide a discussion of the IPR Chapter's provisions regarding patents, enforcement of intellectual property rights, and regulation of pharmaceutical products.

#### *1. Patents*

With respect to patents, TPP member nations have committed to establishing a one-year grace period during which certain public disclosures of an invention will not preclude patent protection.[85] Such a provision would bring TPP member nations in line with the United States with respect to the one-year grace period. The parties also agreed to facilitate the processing of patent applications across multiple jurisdictions by minimizing duplication efforts,[86] and adjusted patent terms for pharmaceutical products experiencing unreasonable delays in marketing approval.[87] The TPP deviates from the Trade-Related Aspects of Intellectual Property Rights (TRIPS), which explicitly states that member states may exclude medical procedure patents. Again, this provision brings member nations into line with the United States and Australia.[88] However, the TPP did not include a provision proposed by the United States and Japan that would prohibit member nations from "deny[ing] a patent solely on the basis that the product did not result in enhanced efficacy,"[89] potentially precluding "evergreening."[90]

Patent linkage is a regulatory mechanism that links regulatory approval to patent status.[91] With patent linkage, regulatory authorities are required to deny

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84 *The Trans-Pacific Partnership*, *supra* note 1.

85 *TPP Full Text*, *supra* note 11, art. 18.38.

86 *Id.* art. 18.14.

87 Laroski & Byers, *supra* note 25; *TPP Full Text*, *supra* note 11, arts. 18.14, 18.48.

88 TRIPS, *supra* note 43.

89 *See TPP Full Text*, *supra* note 11, art. 18.37; *cf. The 2014 Leak*, *supra* note 56, art. QQ.E.1.

90 "Evergreening" is a term used to describe various strategies to extend the length of market exclusivity beyond a patent term. U.N. DEV. PROGRAMME, U.N. AIDS, USING TRIPS FLEXIBILITIES TO IMPROVE ACCESS TO HIV TREATMENT: POLICY BRIEF 2–3, 8 (2011), http://www.undp.org/content/dam/undp/library/hivaids/Using%20TRIPS%20Flexibility%20to%20improve%20access%20to%20HIV%20treatment.pdf.

91 Ravikant Bhardwaj, K D Raju & M Padmavati, *The Impact of Patent Linkage on Marketing of Generic Drugs*, 18 J. INTELL. PROP. RTS. 316, 316 (2013).

marketing approval of a generic if there is a patent covering the reference product.[92] Such provisions are routinely incorporated into U.S. FTAs.[93] Under the TPP, patent linkage is mandatory.[94] However, member states can choose one of two options—"hard" or "soft" patent linkage.[95] Hard patent linkage requires coordination between a country's patent office and regulatory agency and automatically prohibits regulatory approval of a generic—the patent holder need not seek private enforcement of rights to bar approval. Under soft patent linkage, a patent holder must be notified of prior approval and have adequate time to seek remedies. Many argue that patent linkage provides patent holders with a perverse incentive to file frivolous lawsuits in order to delay marketing approval of a competitor's product.[96] Though the Chapter's provisions concerning patent linkage have raised concerns that even spurious patents could bar generic approval,[97] it is worth noting that the text provides member nations the option to adopt a soft patent linkage regime, free of the automatic bar on regulatory approval.[98]

### *2. Enforcement*

Nominally, the IPR Chapter sets up an enforcement regime.[99] However, it is a far cry from the "supranational litigation tribunals" bemoaned by critics of earlier drafts.[100] Instead, the final text requires TPP member states to ensure that enforcement procedures are specified under each state's domestic law, and "permit effective action against any act of infringement of intellectual property rights covered" by the IPR Chapter.[101] Enforcement measures include border measures, civil remedies, and even criminal enforcement—individuals may be

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92 *Id.*; *Trans-Pacific Partnership Agreement: Harmful Provisions for Access to Medicines*, PUB. CITIZEN, https://www.citizen.org/documents/specific%20provisions%20final%20draft%20w.o.pdf (last visited Jan. 31, 2017).

93 *Comparative Table of Patent Linkage Provisions in U.S. Free Trade Agreements and the U.S. Proposal to the Trans-Pacific Partnership (TPP) Agreement*, PUB. CITIZEN, http://www.citizen.org/documents/patentlinkagetablewclauses.pdf (last visited Jan. 31, 2017) (stating patent linkage provisions have been included in FTAs between the United States and Singapore, Chile, Australia, and Peru).

94 *See TPP Full Text*, *supra* note 11, art. 18.51 (describing measures relating to patent linkage).

95 *Id.*

96 Patel, *supra* note 15, at 501.

97 Burcu Kilic, Peter Maybarduk & Sanya Smith Reid, *What's New in the TPP Intellectual Property Text?*, WIKILEAKS (Oct. 9, 2015), https://wikileaks.org/tpp-ip3/pharmaceutical/Pharmaceutical%20Provisions%20in%20the%20TPP.pdf.

98 *See TPP Full Text*, *supra* note 11, art. 18.51.

99 *Id.* art. 18.71 (covering enforcement obligations).

100 November WikiLeaks Press Release, *supra* note 8.

101 *TPP Full Text*, *supra* note 11, art. 18.71.

exposed to criminal liability for trademark and copyright infringement, but not for patent infringement.[102]

### *3. Data Exclusivity*

Data exclusivity is a mechanism that supplements patent protection by prohibiting generic manufacturers from relying on an originator's clinical data to demonstrate the safety and efficacy of generic drugs.[103] The IPR Chapter protects undisclosed test data and other information generated to obtain marketing approval of pharmaceutical products.[104] The final text provides for a minimum of five years (or eight years for biologics) of data exclusivity for new pharmaceutical products.[105] This provision was perceived as a blow to the U.S. pharmaceutical industry, which sought the inclusion of a twelve-year data exclusivity period for biologic medicines as is currently provided for under U.S. law.[106] Regardless, these provisions have important implications for Brunei, Malaysia, Mexico, Peru, and Vietnam, which would be required to change their laws regarding data exclusivity.[107]

Many are critical of such exclusivity provisions that "empower rights holders to negate a state's ability to authorize marketing approval of equivalent drugs for a period from five to ten years,"[108] arguing that long exclusivity periods result in needless replication of data, "allow[ing] the pharmaceutical industry to use unconscionable tactics to keep generic competitors out of the market."[109] However, those in the biotechnology industry favor even longer exclusivity periods of up to twelve years.[110] And although the final text does effectively delay regulatory approval of generics by restricting access to originator test data, the agreement only requires members to provide five years of pharmaceutical data protection.[111] Moreover, parties *can* accept generic applications during that

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[102] *Id.*

[103] Jerome H. Reichman, *Undisclosed Clinical Trial Data Under the TRIPS Agreement and Its Progeny: A Broader Perspective*, IPRSONLIINE.ORG (2004), http://www.iprsonline.org/unctadictsd/bellagio/docs/Reichman_Bellagio4.pdf.

[104] *TPP Full Text*, *supra* note 11, art. 18.50

[105] *Id.* art 18.52, Annex 18-F, ¶ 53.

[106] *See generally* THE NEED FOR 12 YEARS OF DATA PROTECTION, *supra* note 9. For a detailed discussion of biologic products, see *infra* Part II.C.

[107] Laroski & Byers, *supra* note 25, at 2.

[108] Reichman, *supra* note 103, at 2–3.

[109] Patel, *supra* note 15, at 504.

[110] *See generally* THE NEED FOR 12 YEARS OF DATA PROTECTION, *supra* note 9, at 3, 5.

[111] *The 2015 Leak*, supra note 56, art. QQ.E.16.

five-year period, and the scope of protection is limited to undisclosed test data only.[112]

### *4. Transition Periods and Other Provisions for Enhancing Access to Medicine*

The final text included variable transition periods for the agreement to enter into force.[113] In Section K of the IPR Chapter, member nations are categorized based on wealth, with smaller, less developed countries (*e.g.*, Brunei, Malaysia, and Vietnam) enjoying longer transition periods before provisions related to pharmaceutical patents and test data enter into force.[114] These transition periods apply generally to provisions relating to: (1) patent term adjustment, (2) marketing approval, (3) patent linkage, and (4) biologics.[115] These concessions give developing nations adequate time to implement legislation in compliance with the TPP's pharmaceutical regulatory regime.

The agreement text also includes provisions meant to enhance access to affordable medicines in smaller, developing nations, including Brunei, Malaysia, and Peru. For instance, Peru can choose to start the "exclusivity clock" based on approval of a pharmaceutical product in any TPP member nation.[116] In addition, Peru, Malaysia, and Brunei can require originators to establish an "access window" during which an originator would be required to seek marketing approval "or otherwise forfeit biologic exclusivity."[117] These provisions incentivize manufacturers to quickly bring new small molecule and biologic medicines to market in countries with smaller populations.

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112 *Id*; Kilic, Maybarduk & Reid, *supra* note 97.

113 *TPP Full Text*, *supra* note 11, art. 18.83.

114 *Id.*

115 *Id*.

116 Sanya Smith Reid & Burcu Kilic, *Ambiguity Leads to Fallacy: Biologics Exclusivity in the Trans-Pacific Partnership*, WIKILEAKS (Oct. 9, 2015), https://wikileaks.org/tpp-ip3/biologics/Ambiguity%20Leads%20to%20Fallacy%20(Biologics).pdf.

117 *Id.*

## *C. Biologic Regulation*

### *1. Biologics and Their Increasing Importance in Healthcare*

Biologics are medicinal products derived from biological sources such as animals and microorganisms.[118] Unlike traditional pharmaceutical products,[119] biologics are generally large, complex molecules, such as monoclonal antibodies[120] and recombinant proteins,[121] manufactured using cutting-edge biotechnological techniques. Biologics are increasingly important for healthcare, as they have a much lower clinical failure relative to traditional small molecules.[122] Moreover, biologics are often the only life-saving treatments for the most severe diseases.[123]

Unfortunately, biologics are often expensive, and many people are unable to afford them.[124] Scholars, politicians, and lobbying groups argue that the high cost of these medicines is the direct result of limited competition, with some advocating for the exclusion of pharmaceutical patents altogether.[125] More moderate voices call for abbreviated approval pathways that allow manufacturers to bring follow-on biologics (biosimilars) to market without performing expensive and time-consuming clinical trial.[126] A biosimilar is a biologic medicine that is "highly similar" to or "interchangeable" with a

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118 *What Are "Biologics" Questions and Answers*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm (last updated Aug. 5, 2015).

119 *Id.* Traditional pharmaceutical products are generally uniform compositions of synthetic small molecules whose structures are well-characterized. *Id.* In contrast, biologics are often heterogeneous mixtures of compounds that are not well-characterized. *Id.*

120 Adalimumab, a monoclonal antibody (mAb) approved for the treatment of rheumatoid arthritis, is marketed as Humira in the United States by AbbVie, Inc. *See, e.g.*, *HUMIRA (adalimumab): The Biography Video Transcript*, HUMIRA, https://www.humira.com/psoriasis/how-humira-works-video-transcript/humira-story (last visited Jan. 31, 2017).

121 Epoetin alfa is a human erythropoietin produced using recombinant DNA (rDNA) approved for the treatment of anemia. *See, e.g.*, *Epogen Label*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/103234s5199lbl.pdf (last visited Jan. 31, 2017).

122 David Meininger, *IP Policy Forum: The Increasing Importance of Biologics-Based Drugs in Pharmaceutical Pipelines*, 18 MARQ. INTELL. PROP. L. REV. 19, 19 (2014).

123 *Biosimilars*, GPHA, http://www.gphaonline.org/issues/biosimilars (last visited Jan. 31, 2017).

124 Lacie Glover, *Why Are Biologic Drugs So Costly?*, U.S. NEWS & WORLD REP. (Feb. 6, 2015, 12:30 PM), http://health.usnews.com/health-news/health-wellness/articles/2015/02/06/why-are-biologic-drugs-so-costly.

125 *See* Michele Boldrin & David K. Levine, *The Case Against Patents*, 27 J. ECON. PERSP. 3, 20 (2013).

126 *See* Patel, *supra* note 15, at 501–03.

previously approved biologic.[127] Follow-on biologics are analogous to generic versions of traditional pharmaceuticals.[128]

### *2. Biologic Regulation in the United States*

The recently enacted Biologics Price Competition and Innovation Act (BPCIA) is an attempt by Congress to bring down the cost of biologics.[129] The BPCIA provides for an abbreviated approval pathway for follow-on biologics.[130] The BPCIA also seeks to incentivize innovation by providing the reference product sponsor (RPS) a period of market exclusivity.[131] Advocates say biologic data exclusivity is necessary to incentivize innovation,[132] while critics say such exclusivity presents significant hurdles to competition within the industry.[133] Under the BPCIA, the originator is entitled to four years of test data exclusivity and twelve years of market exclusivity.[134] The BPCIA also establishes a patent dispute resolution regime, amending the Patent Act to create an artificial act of infringement to allow infringement suits based on a biosimilar application prior to FDA approval and prior to marketing of the biosimilar.[135]

Under the BPCIA, a biologic may be deemed "biosimilar" if data show that, *inter alia*, the product is "highly similar" to an FDA-approved reference product.[136] In order to show biosimilarity, an applicant must show that the product has no clinically meaningful difference in terms of safety and efficacy from the reference product—"[o]nly minor differences in clinically inactive components are allowable in biosimilar products."[137] Biosimilars can also

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[127] *Biosimilar Medicinal Products*, EUR. MED. AGENCY, http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2011/03/WC500104228.pdf (last visited Jan. 31, 2017).

[128] *Biosimilars*, GENERIC PHARM. ASS'N, http://www.gphaonline.org/issues/biosimilars (last visited Jan. 31, 2017).

[129] H.R. Res. 3590-686 111th Cong. (2009) (enacted).

[130] *Id.*

[131] *Id.*

[132] The biotechnology industry is research-intensive, spending billions of dollars each year to develop biological treatment options for patients. *See* THE NEED FOR 12 YEARS OF DATA PROTECTION, *supra* note 9, at 2.

[133] Neil Lesser et al., *In the Face of Uncertainty: A Challenging Future for Biopharmaceutical Innovation*, DELOITTE (2004), https://www2.deloitte.com/content/dam/Deloitte/lu/Documents/life-sciences-health-care/us_consulting_Inthefaceofuncertainty_040614.pdf.

[134] H.R. Res. 3590-686, 111th Cong. (2009) (enacted).

[135] *Id.*

[136] *Information on Biosimilars*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ (last updated May 10, 2016).

[137] *Id.*

qualify as "interchangeable biological products" if they meet certain additional standards.[138] Products that meet these interchangeability standards "may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product."[139] To date, the FDA has only approved four biosimilar products.[140] Moreover, pending litigation will have a significant impact on how the BPCIA functions in practice.[141]

### *3. Biologic Regulation Under the Trans-Pacific Partnership*

The first draft of the IPR Chapter mirrored the BPCIA, including a proposed twelve-year data exclusivity period for originator test data.[142] However, the final text of the TPP leaves member nations with two options regarding biologics—countries can either provide: (1) eight years of market exclusivity counting from the date the biologic is approved in the country concerned;[143] or (2) five years of market exclusivity counting from the date the biologic is approved in the country concerned *and* other measures to deliver a comparable market outcome.[144] Some TPP member nations "have already stated that this does not require them to change their existing system of 5 years of biologic exclusivity."[145]

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138 *Id.*

139 *Id.*

140 Press Release, Food & Drug Admin., FDA Approves First Biosimilar Product Zarxio (Mar. 6, 2015), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm; Press Release, Food & Drug Admin., FDA Approves Inflectra, a Biosimilar to Remicade (Apr. 5, 2016), http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm494227.htm; Press Release, Food & Drug Admin., FDA Approves Erelzi, a Biosimilar to Enbrel (Aug. 30, 2016), http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm518639.htm; Press Release, Food & Drug Admin., FDA Approves Amjevita, a Biosimilar to Humira (Sept. 23, 2016), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm522243.htm.

141 *See* Amgen Inc. v. Sandoz Inc., 794 F.3d 1347 (Fed. Cir. 2015).

142 Kilic, *supra* note 51, at 50–51.

143 *The 2015 Leak*, *supra* note 56, art. QQ.E.20.1.a.

144 *Id.* art. QQ.E.20.1.b.

145 Reid & Kilic, *supra* note 116. The Australian government stated that under the final text of the IPR Chapter it will not be required to change existing law regarding biologic regulation. *See Trans-Pacific Partnership Agreement: Outcomes: Biologics*, AUSTL. GOV'T DEP'T FOREIGN AFF. & TRADE, http://dfat.gov.au/trade/agreements/tpp/outcomes-documents/Pages/outcomes-biologics.aspx (last visited Jan. 31, 2017). New Zealand has expressed a similar sentiment. *See The Trans-Pacific Partnership: Intellectual Property*, N.Z. FOREIGN AFF. & TRADE, http://tpp.mfat.govt.nz/assets/docs/TPP_factsheet_Intellectual-Property.PDF (last visited Jan. 31, 2017).

## III. ADDRESSING CRITICISMS AND CONCERNS SURROUNDING THE TRANS-PACIFIC PARTNERSHIP

### *A. Procedural Dynamics*

Several groups have voiced significant concern over the procedural dynamics that led to the TPP. For example, critics cite disparities in the bargaining power between prospective TPP member nations.[146] Some have even gone so far as to suggest that developed nations, in particular the United States, have coerced developing nations into bargaining away the rights of their citizens in exchange for favorable trading positions.[147] However, the procedural dynamics that led to this agreement may not raise as many concerns as its critics claim. In fact, some of these criticisms may be somewhat insulting to smaller member nations. For instance, the negotiating process was long-drawn, and the text of the agreement was substantially revised on several occasions. In particular, the provisions covering intellectual property rights and biologic regulation underwent significant evolution during the course of negotiations. The evolution of the IPR chapter serves as a microcosm indicative of the intense negotiation process that led to the final text of the document.

As mentioned above, critics of the TPP also argue that the agreement is simply an imperial quest by the United States for foreign markets, claiming that the U.S. delegation has sought to secure favorable trading positions to the detriment of its trading partners through its superior negotiating position.[148] However, this interpretation does not stand up to scrutiny. The TPP is a complex and heavily nuanced agreement that has been painstakingly negotiated by disparate nations, each seeking to advance important interests. With careful analysis, this Comment shows that the TPP is not simply an instrument of U.S. imperialism or a boon for big business. Moreover, these critiques suggesting that

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[146] *E.g.*, Wan Fayhsal, *The Geopolitics of the Trans-Pacific Partnership Agreement, A US Imperial Strategy*, GLOBAL RES. (Jan. 15, 2016), http://www.globalresearch.ca/the-geopolitics-of-the-trans-pacific-partnership-agreement-tppa-a-us-imperial-strategy/5501558; Carlos Furche, *Chile and the TPP Negotiations: Analysis of the Economic and Political Impact*, ONG DERECHOS DIGITALES (May 2013), https://www.derechosdigitales.org/wp-content/uploads/TPP-furche-EN.pdf.

[147] *E.g.*, Shiro Armstrong, *The Race to a Risky Trans-Pacific Partnership Deal*, E. ASIA F. (July 26, 2015), http://www.eastasiaforum.org/2015/07/26/the-race-to-a-risky-trans-pacific-partnership-deal/; Dan Gillmor, *Thanks to WikiLeaks, We See Just How Bad TPP Trade Deal Is for Regular People*, GUARDIAN (Nov. 13, 2013), https://www.theguardian.com/commentisfree/2013/nov/13/trans-pacific-paternership-intellectual-property.

[148] *See WikiLeaks Releases IP Chapter of TPP, Stokes Generic Drug Fears*, MALAYSIAN INSIDER (Oct. 9, 2015), *reprinted in* YAHOO! NEWS (Oct. 10, 2015), https://sg.news.yahoo.com/wikileaks-releases-ip-chapter-tpp-011624961.html. Nobel laureate Joseph Stiglitz states that the TPP favors corporate interests, increasing profits "at the expense of everyone else." Stiglitz & Hersh, *supra* note 10.

the governments of Brunei and Malaysia were willing to sacrifice the rights of their people[149] are somewhat insulting. Examining the TPP through the lens of the IPR Chapter reveals that these smaller, seemingly unsophisticated nations were able to gain leverage over trade representatives from the United States and Canada. For instance, the addition of addendums delaying the implementation of certain intellectual property provisions for certain nations and other substantive safeguards[150] are evidence of pushback against developed nations such as the United States and Japan. It is also clear that despite their best lobbying efforts, pharmaceutical companies are not getting everything they want (*e.g.*, twelve years of data exclusivity for biologics).[151] Thus, the final text of the TPP IPR Chapter is the result of multilateral negotiation and indicates that developing nations were able to push back on the United States in order to secure a better deal for their citizens.

### *B. Substantive Concerns: Public Health and Access to Medicine*

Scholars have argued that the IPR Chapter "includes measures harmful to access to affordable medicines"[152] that run counter to the standards set by the WTO.[153] These critics argue that, in effect, developing nations are being coerced into trading away their public health.[154] However, it is important to realize that TPP member nations remain committed to upholding the standards set forth in TRIPS[155] and the Doha Declaration.[156] Specifically, the TPP includes public health safeguards similar to those found in TRIPS and the Doha Declaration.[157] Moreover, these public health exceptions apply to all exclusivity provisions, including those for biologics.[158] Despite their ambiguity, these exceptions

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149 *See* Rick Rowden, *9 Ways the TPP Is Bad for Developing Countries*, FOREIGN POL'Y (July 7, 2015, 12:58 PM), http://foreignpolicy.com/2015/07/07/9-ways-the-tpp-is-bad-for-developing-countries/.

150 *See Secret TPP Treaty: Intellectual Property Chapter Working Document for All 12 Nations With Negotiating Positions*, WIKILEAKS (Oct. 16, 2014), http://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf.

151 Mauldin, *supra* note 35.

152 Kilic, *supra* note 51, at 24.

153 *Id.* at 25; AMFAR, TRANS-PACIFIC PARTNERSHIP: CURBING ACCESS TO MEDICINES NOW AND IN THE FUTURE 1, 1 (2015), http://www.amfar.org/uploadedFiles/_amfarorg/Articles/On_The_Hill/2015/IB_TPP_Brief_RC_050615.pdf.

154 *Id.*

155 *See infra* Part III.B.1.

156 *See Chapter 18 Intellectual Property: Chapter Summary*, OFFICE OF U.S. TRADE REP., https://ustr.gov/sites/default/files/TPP-Chapter-Summary-Intellectual-Property.pdf (last visited Jan. 31, 2017). According to the USTR, the IPR Chapter "defines a robust standard for patentability, consistent with international norms drawn from the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as well as other international best practices, including relevant exclusions." *Id.*

157 *The 2015 Leak*, *supra* note 56, art. QQ.E.16.3.

158 *Id.*

provide a significant safety valve for protecting public health and patient access to medicine.

### *1. The Trade-Related Aspects of Intellectual Property Rights Agreement*

Before the conception of the Trans-Pacific Partnership, the TRIPS Agreement was the most comprehensive international agreement on intellectual property.[159] TRIPS requires member nations to abide by minimum standards for the protection and enforcement of intellectual property rights (*e.g.*, twenty years of patent protection).[160] TRIPS also establishes standards for the use of patents, intellectual property enforcement, and dispute resolution.[161] Another key aspect of the TRIPS Agreement is the provision requiring WTO member states to grant patents on pharmaceutical products.[162] Prior to the introduction of TRIPS, countries could exclude pharmaceutical patents and allow markets to dictate the price of drugs. Many feared that pharmaceutical patent protection would provide large drug manufacturers with a global monopoly on important medicines.[163]

To address these concerns, TRIPS attempts to strike a balance between the rights of pharmaceutical patent holders and international public health needs. These so-called "TRIPS flexibilities" allow countries to safeguard access to medicines.[164] For example, under TRIPS, countries can apply rigorous patentability standards and issue compulsory licenses, permitting a government to allow the sale and/or manufacture of patented medicines without the patent holder's consent.[165] Moreover, in 2001, the WTO adopted the Doha Declaration on the TRIPS Agreement and Public Health, requiring the TRIPS Agreement to be interpreted in a manner that supports public health.[166] The Doha Declaration allows members to choose how to deal with drug patents terms in order to fit "domestic policy objectives."[167] However, many member nations have yet to

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159 The TRIPS Agreement is Annex 1C of the Marrakesh Agreement that established the WTO. *TRIPS Material on the WTO Website*, WORLD TRADE ORG., http://www.wto.org/trips (last visited Jan. 31, 2017).

160 *Intellectual Property: Protection and Enforcement*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Jan. 31, 2017).

161 *Id.*

162 TRIPS, *supra* note 43, art. 30.

163 P. Boulet et al., *Pharmaceuticals and the WTO TRIPS Agreement: Questions and Answers*, WORLD HEALTH ORG. (2000), http://apps.who.int/medicinedocs/pdf/whozip18e/whozip18e.pdf.

164 Patel, *supra* note 15, at 479.

165 *Id.* at 486.

166 *The Doha Declaration Explained*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm (last visited Jan. 31, 2017).

167 *TRIPS and Pharmaceutical Patents: Obligations and Exceptions*, WORLD TRADE ORG. (Sept. 2006), https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.

amend laws to reflect TRIPS flexibilities; a United Nations Development Program study from 2007 found that only six countries had done so,[168] and in 2010 the World Intellectual Property Organization stated that uniform incorporation of TRIPS flexibilities had not yet been realized.[169]

### *2. The Trans-Pacific Partnership Will Not Derogate Public Health Safeguards Guaranteed Under the TRIPS Agreement*

Article 18.6, entitled "Understandings Regarding Certain Public Health Measures" in the final draft of the IPR Chapter reaffirms commitments made under TRIPS and the Doha Declaration.[170] This articles provides that:

> [t]he obligations of [the IPR Chapter] do not and should not prevent a Party from taking measures to protect public health. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all. Each Party has the right to 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.[171]

### *3. The Trans-Pacific Partnership Will Not Stymie Access to Affordable Medicines*

Despite what its detractors claim, the final text of the Agreement includes provisions that enhance access to medicine. For example, like TRIPS,[172] the final text of the Chapter includes two important exceptions to patent rights for pharmaceutical products. First, under Article 18.40, "a Party may provide

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[168] U.N. DEV. PROGRAMME, U.N. AIDS, USING TRIPS FLEXIBILITIES TO IMPROVE ACCESS TO HIV TREATMENT: POLICY BRIEF 2–3, 8 (2011), http://www.undp.org/content/dam/undp/library/hivaids/Using%20TRIPS%20Flexibility%20to%20improve%20access%20to%20HIV%20treatment.pdf.

[169] World Intell. Property Org. [WIPO], Secretariat of the Comm. on Development and Intellectual Property, *Patent Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels*, CDIP/5/4 (Apr. 26–30, 2010), http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=131629.

[170] *TPP Full Text*, *supra* note 11, art. 18.6.

[171] *Id.*

[172] Article 30 of TRIPS allows "[m]embers to provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owner, taking account of the legitimate interest of third parties." TRIPS, *supra* note 43, art. 30.

limited exceptions to the exclusive rights conferred by a patent."[173] Second, Article 18.49 provides a more specific regulatory review exception, stating that "each Party shall adopt or maintain a regulatory review exception for pharmaceutical products."[174] These so-called "Bolar exceptions" allow generic manufacturers to produce small batches of a patented pharmaceutical product without fear of infringement liability.[175] This provides an incentive for generic manufacturers to market products in other member nations by allowing small batches to be submitted for regulatory review both domestically and abroad.[176]

### *C. The Trans-Pacific Partnership Establishes a Sensible Biologic Regulatory Regime*

Biologics are fundamentally different from traditional small molecules.[177] Recognizing this fact, the TPP takes a measured approach to biologic regulation, one that carefully balances access to medicine and incentives to innovate.[178] Moreover, TPP member nations remain committed to reevaluating the effect of these provisions—Article 18.52(3) provides:

> Recognising that international and domestic regulation of new pharmaceutical products that are or contain a biologic is in a formative stage and that market circumstances may evolve over time, the Parties shall consult after 10 years from the date of entry into force of this Agreement, or as otherwise decided by the Commission, to review the period of exclusivity . . . with a 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, and to ensuring that the scope of application remains consistent with international developments regarding approval of additional categories of new pharmaceutical products that are or contain a biologic.[179]

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173 *TPP Full Text*, *supra* note 11, art. 18.40.

174 *Id.* art. 18.49.

175 Kilic, Maybarduk & Reid, *supra* note 97.

176 *Id.*

177 *What Are "Biologics" Questions and Answers*, *supra* note 118.

178 *See* Editorial Board, *Critics' Concerns About the Trans-Pacific Partnership Are Overblown*, WASH. POST (Feb. 4, 2015), https://www.washingtonpost.com/opinions/critics-concerns-about-the-trans-pacific-partnership-are-overblown/2015/02/04/91dd4df2-abdc-11e4-9c91-e9d2f9fde644_story.html?utm_term=.316a4c09e7ba.

179 *TPP Full Text*, *supra* note 11, art. 18.52.

Bringing a biologic product to market requires considerable time and huge investments in cutting edge technology and talent.[180] Therefore, robust data exclusivity provisions for biologics is "essential to the future" of these medicines.[181] These provisions prohibit competing firms from using an originator's proprietary clinical test data to seek marketing approval for a generic version for a specified period of time following the marketing approval of the originator's product.[182] Competing firms seeking regulatory approval of a biosimilar are required to independently generate clinical data, or in the alternative, wait for a predefined period of time before utilizing the originator's test data in an abbreviated regulatory approval process.[183] These provisions recognize that producing and compiling safety and efficacy data is time intensive and expensive.[184] Thus, data exclusivity essentially functions to provide innovators with a period of protection for its investment in data collection, regardless of the length of time required to bring the drug to market.[185]

Ultimately, data exclusivity seeks to achieve the same goal of the patent system to incentivize innovation. However, the two regimes achieve this goal in distinct but complementary ways.[186] U.S. and foreign patent systems protect inventions that meet standards of patentability, *i.e.*, those inventions that are useful, new, and nonobvious,[187] while data exclusivity protects the "tremendous investments of time, talent, and financial resources required to establish a new therapy as safe and effective."[188] Data exclusivity is crucial because the length of time required to develop biologic pharmaceutical products and achieve regulatory approval often exceeds ten years.[189] For this reason, patents covering these products often expire soon after marketing approval. Data exclusivity is not simply an extension of patent rights. Thus, a competing firm is not precluded

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180 Kristina M. Lybecker, *Essay: When Patents Aren't Enough: Why Biologics Necessitate Data Exclusivity Protection*, 40 WM. MITCHELL L. REV 1427, 1431 (2014). The typical cost of bringing a biologic to market is $1.2 billion. *Id.* A major reason biologics take so long to get to market is because of the time required to achieve regulatory approval. *Id.*

181 *Id.* at 1428.

182 *See id.* at 1428–29.

183 THE NEED FOR 12 YEARS OF DATA PROTECTION, *supra* note 9, at 14; Lybecker, *supra* note 180, at 1429.

184 *See* Lybecker, *supra* note 180, at 1429.

185 THE NEED FOR 12 YEARS OF DATA PROTECTION, *supra* note 9, at 13; Lybecker, *supra* note 180, at 1429.

186 Lybecker, *supra* note 180, at 1438.

187 *Id. See, e.g.*, 35 U.S.C. §§ 101–103 (2012). These sections of the U.S. Code set forth the statutory requirements of patentability in the United States. *Id.* The patent system is essentially designed to incentivize innovation by granting inventors a limited monopoly to practice their invention in exchange for disclosing the invention to the public. Lybecker, *supra* note 180, at 1431.

188 Lybecker, *supra* note 180, at 1428.

189 *Id.* at 1431; THE NEED FOR 12 YEARS OF DATA PROTECTION, *supra* note 9, at 2.

from introducing a generic version of a drug (or in the case of a biologic, a biosimilar), so long as the originator's clinical data is not used to secure regulatory approval.[190] By preventing competitors from free riding on the efforts of originators to establish safety and efficacy, data exclusivity provisions incentivize biopharmaceutical companies to invest in the development of novel biologic products.[191] These provisions also promote competition in the pharmaceutical industry, because upon the expiration of data exclusivity periods, competing firms can rely on originator test data to reduce development costs for biosimilars or other types of generics.[192] Therefore, this system strikes a balance between incentivizing innovation and promoting competition.

## CONCLUSION

The TPP is an important agreement that has the potential to substantially increase trade and raise the GDP of member countries.[193] The agreement is particularly important for the United States because it provides a unique opportunity to increase U.S. exports and grow the U.S. economy in an otherwise uncertain macroeconomic environment.[194] More importantly, the TPP provides the United States with an opportunity to reestablish a foothold in Asia and create a level playing field in the region in the face of China's growing influence. As many economists have detailed, U.S. manufacturers have been investing heavily in China.[195] This has led to high levels of interdependence between the United States and China, with the unfortunate side effect of "granting the Chinese Politburo ever-increasing leverage of America's economic and political life."[196] With this leverage, the Beijing government can decide to cut access to its markets and its sources of labor at will. Thus, the United States would be wise to enter into free trade agreements with other willing partners. This would provide the United States with access to foreign markets, labor, and investment opportunities across the Pacific Rim. In addition, the TPP would harmonize

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190 THE NEED FOR 12 YEARS OF DATA PROTECTION, *supra* note 9, at 15.

191 Lybecker, *supra* note 180, at 1429.

192 *Id.* at 1428–29.

193 Csilla Lakatos et al., *Potential Macroeconomic Implications of the Trans-Pacific Partnership*, GLOBAL ECON. PROSPECTS (Jan. 2016), http://pubdocs.worldbank.org/en/287761451945044333/Global-Economic-Prospects-January-2016-Highlights-Trans-Pacific-Partnership.pdf. The TPP could raise the GDP of member nations by an average of 1.1% and increase member nations' trade by eleven percent by 2030. *Id.*

194 The TPP is estimated to boost annual real income for Americans by $131 billion by 2030. Lee, *supra* note 28.

195 Barry C. Lynn, *The New China Syndrome: How Beijing Shakes Down Foreign Businesses*, HARPER'S MAG., 31, 32–33 (2015).

196 *Id.* at 33.

intellectual property rights throughout its member states, providing strong incentives to innovate while also providing public health safeguards and ensuring access to affordable medicines.

Unfortunately, due to significant criticism from the public and backlash from lawmakers, even before the election of Donald Trump, the fate of the TPP remains unclear.[197] Seemingly, the desire to criticize substantive aspects of the agreement arises more so from concerns over the procedural aspects of negotiating the agreement and the potential for abuse and coercion. However, in light of the agreement's final text, many of these substantive critiques appear exceptionally pessimistic. For instance, the TPP actually endeavors to implement a progressive and sensible regime for the protection of intellectual property rights.

In addition, the more legitimate concerns over the inherent power imbalance that exists when negotiating such an agreement seem somewhat overblown. An analysis of the IPR Chapter and the circumstances of its negotiation indicate that the final text of the agreement was the result of legitimate compromise. Moreover, parties such as Brunei and Malaysia were able to exert an appreciable level of influence over the negotiating process, despite the appearance of having less bargaining power.[198] In fact, these smaller, less developed nations were able to push back against the United States in order to secure a better deal.[199] For example, the 2013 IPR Chapter merely included a placeholder for provisions detailing biologic regulation, because several delegations were unwilling to accept the U.S. proposal to impose a mandatory twelve-year data exclusivity period for biologic test data.[200] In addition, the 2013 IPR Chapter contained annotations indicating opposition to proposals by the United States and Japan, suggesting that there was a realignment of member nations around key portions of the text (*e.g.*, Australia ended up more closely aligned with New Zealand than with the United States, its primary ally when negotiations began).[201] Moreover, the inclusion of transition periods for developing nations and other substantive

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197 *See e.g.*, Bernie Sanders, *Democrats Must Fight to Defeat the Trans-Pacific Partnership*, HUFFINGTON POST: BLOG, (July 8, 2016, 2:08 PM), http://www.huffingtonpost.com/bernie-sanders/democrats-must-fight-to-d_b_10890466.html.

198 *See* Gabriel J. Michael, *Visualizing Negotiating Positions in the TPP IP Chapter*, WORDPRESS: TO PROMOTE THE PROGRESS? (Nov. 17, 2013), https://topromotetheprogress.wordpress.com/2013/11/17/visualizing-negotiating-positions-in-the-tpp-ip-chapter/.

199 *See id.*

200 *The 2013 Leak*, *supra* note 56, art. QQ.E.20.

201 Julian Assange & Sarah Harrison, *US and Japan Lead Attack on Affordable Cancer Treatments*, WIKILEAKS (Oct. 16, 2014), https://wikileaks.org/tpp-ip2/attack-on-affordable-cancer-treatments.html.

safeguards is evidence of the influence developing nations were able to exert even in the face of pressures from developed nations such as the United States and Japan.

Thus, the final text of the agreement represents a delicate balance of concessions intended to promote global economic stability and increased cooperation in addition to lowering trade barriers. Therefore, there should be less concern over the procedural dynamics involved in negotiating large-scale trade agreements such as the forthcoming Transatlantic Trade and Investment Partnership and Trade in Services Agreement. Moreover, many of the fears over substantive aspects of the TPP's IPR Chapter can be put to rest. Because of the agreement's commitment to upholding TRIPS flexibilities and the Doha Declaration, it is incorrect to assume that the TPP will have disastrous consequences on access to affordable medicines. While it can be argued that the negotiation process could have been more transparent, the compromises reached by negotiating parties led to reasonable outcomes, at least with regard to pharmaceutical regulation. Thus, Democrats and Republicans in both chambers of Congress should ultimately vote in favor of the TPP's implementing legislation, should such an opportunity arise.

With the fate of the TPP in serious doubt, U.S. politicians on both sides of the aisle have expressed concern that U.S. withdrawal from the TPP will allow China to expand its influence in Asia and beyond.[202] Republican Senator John McCain called the decision "a serious mistake" that "will send a troubling signal of American disengagement in the Asia-Pacific region."[203] Though an ambitious proposal, this Comment encourages Republican lawmakers to push the Trump Administration to recommit to the deal. Alternatively, this Comment urges the Trump Administration to incorporate the TPP's provisions on biologics into future trade deals, such as a renegotiated version of NAFTA. The TPP's biologic provisions include both strong incentives for biopharmaceutical innovation and important safeguards for access to medicine. Finally, and at the very least, this

[202] Peter Baker, *Trump Abandons Trans-Pacific Partnership, Obama's Signature Trade Deal*, N.Y. TIMES (Jan. 23, 2017), https://nyti.ms/2jQSDwo.

[203] *Id.*

Comment implores the Trump Administration to be more open-minded towards global trade in the future.

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