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Much Ado About the TPP's Effect on Pharmaceuticals

*Emily Michiko Morris**

ABSTRACT

The many provisions in the Trans-Pacific Partnership Agreement (TPP) that were beneficial to the pharmaceutical industry caused a good deal of controversy. Specifically, critics alleged that the TPP's provisions requiring that member states expand patentable subject matter and adjust pharmaceutical patent terms would have raised drug prices and hindered access to medicines, particularly in developing countries. But closer examination of these provisions, as well as the various ways in which member states can modify or ameliorate the effects of these provisions, suggests that their potential effect on drug prices and access to health care is not nearly so clear.

I. INTRODUCTION

Thanks in part to the secrecy under which it was negotiated, and the U.S. presidential campaigns in which it was debated, the now defunct multinational trade agreement known as the Trans-Pacific Partnership (TPP) has proven to be quite controversial.¹ The agreement contains provisions on a large number of subjects, including human rights, the environment, and labor standards.² Among the most controversial provisions, however, are those addressing pharma-friendly intellectual property (IP) rights, mainly in the form of expanded patent protections, as well as multiple IP-like regulatory protections unique to the pharmaceutical and biotechnology industries.³ These

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1. Steven Seidenberg, *Turmoil in the Pacific: A Controversial Trade Agreement Raises Questions About How Disputes Should Be Resolved Between Governments and Private Corporations*, 102 A.B.A. J. 54, 55–56 (2016); Nick Florko & Valerie Holdford, *Secret TPP Text Unveiled: It's Worse Than We Thought, With Limits on Food Safety and Controversial Investor-State System Expanded, Rollback of Bush-Era Medicine Access and Environmental Terms*, PUBLIC CITIZEN (Nov. 5, 2015), <http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=5724>.
2. David A. Gantz, *The TPP and RCEP: Mega-Trade Agreements for the Pacific Rim*, 33 ARIZ. J. INT'L & COMP. L. 57, 60 (2016).
3. See Jing Luo & Aaron S. Kesselheim, *Protecting Pharmaceutical Patents and Test Data: How the Trans-Pacific Partnership Agreement Could Affect Access*

pharma-friendly provisions go above and beyond the baselines set in The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), signed by World Trade Organization (WTO) member states twenty years ago to set minimum levels for intellectual property rights.⁴ Defenders of the TPP argue that the enhancements on the TRIPS baselines, often referred to as TRIPS-plus provisions, are necessary both to protect the pharmaceutical research and development investments in developed countries and to attract investments in domestic pharmaceutical research and development in less developed countries.⁵ Critics, by contrast, issue warnings that the TPP's pharma-friendly provisions will raise pharmaceutical prices and reduce access to medicines by blocking the availability of lower-cost generic copies, a result that would be particularly harmful to developing countries.⁶ Despite the discourse flowing from both sides on the issue, the actual effect the TPP's pharma-friendly provisions might have had—if it had been ratified—is far from clear.

The TPP, of course, no longer seems to be a viable agreement. Now that the United States has withdrawn from the agreement, the other countries that originally signed are unlikely to move forward with ratification.⁷ The TPP nonetheless provides a useful point of departure for analyzing the potential effect of pharma-friendly trade agreement provisions on drug costs and access to medicine. First, almost all of the pharma-friendly provisions in the

to Medicines in the US and Abroad, 18 *AMA J. ETHICS* 727, 727–35 (2016); Matthew E. Silverman, *The Case for Flexible Intellectual Property Protections in The Trans-Pacific Partnership*, 27 *J.L. & HEALTH* 215, 219 (2014).

4. Mohammed K. El-Said, *TRIPS-Plus, Public Health and Performance-Based Rewards Schemes Options and Supplements for Policy Formation in Developing and Least Developed Countries*, 31 *AM. U. INT'L L. REV.* 373, 408–10 (2016).
5. See, e.g., Press Release, Office of the U.S. Trade Rep., Trade Enhancing Access to Medicines (Sept. 2011), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2011/september/trade-enhancing-access-medicines>; see also KEITH E. MASKUS, *INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY* 186–94 (2000) (analyzing this argument).
6. E.g., El-Said, *supra* note 4; Burcu Kilic et al., *What Is Patentable Under the Trans-Pacific Partnership? An Analysis of the Free Trade Agreement's Patentability Provisions from a Public Health Perspective*, 40 *YALE J. INTL. L. ONLINE* 1, 4–5 (2015); Ruth Lopert & Deborah Gleeson, *The High Price of "Free" Trade: U.S. Trade Agreements and Access to Medicines*, 41 *J.L. MED. & ETHICS* 199, 207–08 (2013); Brook K. Baker, *US Trade-Enhancing Access to Medicines (Access Window) in Its Proposed TPP IP Text is a Sham*, *INFOJUSTICE.ORG* (Oct. 25, 2011), <http://infojustice.org/resource-library/us-trade-enhancing-access-to-medicines-access-window-in-its-proposed-tpp-ip-text-is-a-sham>.
7. *TPP: What Is It and Why Does It Matter?*, BBC NEWS (Jan. 23, 2017), <http://www.bbc.com/news/business-32498715>.

TPP have appeared in some form in previous U.S.-negotiated free trade agreements (FTAs).⁸ Because these earlier agreements are still relatively new, it may be too early to determine with any accuracy exactly what effect they have had on access to medicine⁹—what little evidence available is hotly disputed.¹⁰ Nonetheless, knowing whether and how the signatories to the earlier agreements have implemented the pharma-friendly provisions in the earlier agreements can help reveal the extent to which states have found ways to soften or sidestep the effect of these provisions. Second, depending on the new White House administration's attitude toward trade agreements, the TPP is likely to serve as a model for future trade negotiations between the United States and its trade partners—and perhaps others.¹¹

The analysis below takes a closer look at the most controversial of the TPP's pharma-friendly patent provisions. The TPP's expansion of patentable subject matter to include new uses of known products, including pharmaceuticals, is seen as fostering broader and longer patent exclusivity over drugs, leading to more monopolistic rights and their attendant supracompetitive pricing.¹² Likewise, the TPP's requirement that patent terms be adjusted for unreasonable delays due to patent prosecution or regulatory marketing approval processes also could have the effect of prolonging patent exclusivity over drugs.¹³ Even the TPP's requirement that government

8. Lee Branstetter, *TPP and the Conflict Over Drugs: Incentives for Innovation Versus Access to Medicines*, in 2 THE PETERSON INST. FOR INT'L ECON., ASSESSING THE TRANS-PACIFIC PARTNERSHIP: INNOVATIONS IN TRADE RULES 1, 20, 30 (Jeffrey J. Schott & Cathleen Cimino-Issacs eds., 2016).
9. Amy Kapczynski et al., *The TPP and Drug Prices: Not a Settled Matter*, FOREIGN AFFAIRS (Oct. 28, 2016), <https://www.foreignaffairs.com/articles/2016-10-28/tpp-and-drug-prices>.
10. Compare Gargi Chakrabarti, *Need of Data Exclusivity: Impact on Access to Medicine*, 19 J. INTELL. PROP. RTS. 325, 332 (2014), and Lopert & Gleeson, *supra* note 6, at 202, and Mike Palmedo, *Do Pharmaceutical Firms Invest More Heavily in Countries with Data Exclusivity?*, 21 SUM CURRENTS: INT'L TRADE L.J. 38, 39 (2013), and Ctr. for Econ. Policy and Research, *Prescription Drugs and the Trans-Pacific Partnership: Big Pharma Hit by Skills Shortage*, BEAT THE PRESS (Mar. 26, 2016), <http://cepr.net/blogs/beat-the-press/prescription-drugs-and-the-trans-pacific-partnership-big-pharma-hit-by-skills-shortage>, with Branstetter, *supra* note 8, at 11, and Thomas J. Bollyky, *A Dose of the TPP's Medicine: Why U.S. Trade Deals Haven't Exported U.S. Drug Prices*, FOREIGN AFFAIRS (Mar. 23, 2016), <https://www.foreignaffairs.com/articles/2016-03-23/dose-tpps-medicine>.
11. Lopert & Gleeson, *supra* note 6, at 206–07; Palmedo, *supra* note 10, at 39.
12. Brook K. Baker & Katrina Geddes, *Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines—Eli Lilly v. Canada and the Trans-Pacific Partnership Agreement*, 23 J. INTELL. PROP. L. 1, 33 (2015); Kilic et al., *supra* note 6, at 4–6.
13. Lopert & Gleeson, *supra* note 6, at 201.

regulatory agencies link marketing approval of generic drugs to the patent status of those drugs (so-called patent linkage) is seen as extending patent exclusivities.¹⁴

The implications of the TPP's pharma-friendly patent provisions depend not only on the express text of the provisions themselves, but also on the many explicit and implicit flexibilities TPP signatories have in implementing these provisions. The analysis below looks at the most controversial patent-related provisions in the TPP that could affect pharmaceutical prices and availability. First, is the provision at issue subject to any express or implied exceptions that would allow developing countries to limit exclusive rights over drugs? Second, do signatory countries have flexibility, whether explicitly through what the TPP stipulates or implicitly through what it does not, in how countries can implement the pharma-friendly provision domestically? Third, what flexibilities do signatory countries have, whether express or inferred, in deciding how to incorporate any given provision into domestic law? In looking at the final draft of the TPP, we can see that members of the TPP were surprisingly successful in negotiating for themselves a fair amount of flexibility. Had the TPP been ratified, this flexibility would have given signatories significant leeway to limit the accretion of exclusive rights over pharmaceuticals.

The discussion here is necessarily brief and incomplete as it is intended only as a survey of the TPP's pharma-friendly patent provisions and the flexibilities available to its signatories for implementing those provisions. There are many other provisions in the TPP, other international agreements, and other external elements that are not covered in detail here that, patent exclusivities notwithstanding, could have a huge impact on access to medicines. Chief among these is the TPP's requirement that signatories grant pharmaceutical firms additional, IP-like rights of exclusivity over data used to support regulatory marketing approval.¹⁵ Still, other TPP provisions could have had an even more direct effect on drug price and availability, such as the TPP's provisions on drug price controls, patent exhaustion, and compulsory licensing.¹⁶

On the other hand, countries that have attempted to moderate pharmaceutical prices either directly through measures such as price controls or indirectly through their patent systems have faced possible backlash for their efforts.¹⁷ Such backlash occasionally takes the form of trade sanctions, but more often as dispute settlement proceedings, like those between member

14. D.G. Shah, *Impact of the TPP on the Pharma Industry*, INTELL. PROP. WATCH (Feb. 12, 2015), <http://www.ip-watch.org/2015/12/02/impact-of-the-tpp-on-the-pharma-industry/>.

15. El-Said, *supra* note 4, at 400.

16. *Id.* at 400; *see infra* text accompanying notes 186–200.

17. El-Said, *supra* note 4, at 401–03.

countries under TRIPS.¹⁸ Now, under the TPP and other recently U.S.-negotiated FTAs, signatories face further challenges from private parties through investor-state dispute settlement (ISDS) proceedings.¹⁹ The potential for such reprisals may explain why most of the United States' trade agreement partners historically have not taken full advantage of the flexibilities and workarounds available to them for implementing the IP provisions in those agreements.²⁰ Further, the threat of reprisal could have deterred TPP signatories from making use of the flexibilities and workarounds allowed to them under the TPP. The discussion here merely mentions these additional factors without analyzing them in detail, but they are important aspects of the overall discussion of the potential impact of trade agreements on access to medicines.

II. THE TRANS-PACIFIC PARTNERSHIP AGREEMENT

From what began as an agreement between the “Pacific Four” trade bloc countries of Brunei, Chile, New Zealand, and Singapore, the TPP evolved into a much larger trade agreement that included Australia, Canada, Japan, Malaysia, Mexico, Peru, the United States, and Vietnam as well.²¹ A final draft was signed on February 4, 2016, in Auckland, New Zealand, but for the TPP to take effect, at least six member states comprising at least eighty-five percent of the gross domestic product of the signatory countries would have had to ratify it.²² This became impossible when the newly inaugurated President of the United States immediately signed an executive order withdrawing the United States from the TPP.²³

A wide-ranging and ambitious pact, the TPP has been heavily criticized on many counts, particularly for its provisions on pharmaceuticals. These include the TPP's articles on patentable subject matter, patent term adjustments, patent linkage, and regulatory exclusivities over data submitted for marketing approval—all of which can significantly expand a pharmaceutical

18. *Id.* at 420–32; *see infra* text accompanying notes 206–12.

19. El-Said, *supra* note 5, at 400; *see infra* text accompanying notes 206–12.

20. Richard D. Smith et al., *Trade, TRIPS, and Pharmaceuticals*, 373 LANCET 684, 684 (2009); Peter K. Yu, *Are Developing Countries Playing a Better TRIPS Game?*, 16 UCLA J. INT'L L. & FOREIGN AFF. 311, 339 (2011).

21. 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, 33–34 (2014); Kilic et al., *supra* note 6, at 1 n.5.

22. Seidenberg, *supra* note 1, at 55; *Trans Pacific Partnership Trade Deal Signed in Auckland*, BBC NEWS (Feb. 4, 2016), <http://www.bbc.com/news/business-35480600>.

23. Peter Baker, *Trump Abandons Trans-Pacific Partnership, Obama's Signature Trade Deal*, N.Y. TIMES (Jan. 23, 2017), https://www.nytimes.com/2017/01/23/us/politics/tpp-trump-trade-nafta.html?_r=0.

firm's ability to maintain the firm's monopolistic rights over its drug products by delaying market entry of lower-priced generic versions of the same drugs. Given that pharmaceutical firms in the United States already earn phenomenal returns just from the domestic market alone,²⁴ delaying generic market entry and raising drug prices in other countries that are trading partners with the United States is unnecessary.²⁵ Critics see these provisions as imposing the ideals of the developed Western world on non-Western developing countries and catering to the pharmaceutical industry's greed at the expense of access to medicines.²⁶

The Office of the United States Trade Representative (USTR) and others, by contrast, have characterized the TPP's pharma provisions as a good balance between maintaining incentives for pharmaceutical innovation and safeguarding access to medicines.²⁷ Supporters of the TPP's pharma-friendly provisions point out that pharmaceutical innovation is expensive and that the costs have thus far been borne chiefly by patients in wealthy, developed countries such as the United States.²⁸ At least one economist has argued that as the U.S. population ages and as the rise in health care costs in the United States continues to outstrip income, the pharmaceutical industry will no longer be able to support research and development (R&D) on revenues from the United States alone.²⁹ Pharmaceutical R&D, at least in wealthier, developed countries like the United States, is known to be heavily dependent on patent protections.³⁰ Greater patent and other protections for pharmaceutical innovations abroad may therefore be necessary to maintain adequate resources for research.³¹ In any event, these proponents say that international harmonization of intellectual property rights and marketing approval regulations make it easier for pharma firms to introduce their products to other markets quickly and cheaply.³²

24. Ian Gustafson, *TPP Pharmaceuticals*, COUNCIL ON HEMISPHERIC AFF. (Apr. 11, 2016), <http://www.coha.org/tpp-pharmaceuticals/>.

25. *Id.*

26. Ruth L. Okediji, *Legal Innovation in International Intellectual Property Relations: Revisiting Twenty-One Years of the Trips Agreement*, 36 U. PA. J. INT'L L. 191, 239–40 (2014).

27. Branstetter, *supra* note 8, at 31.

28. *Id.* at 30.

29. *Id.* at 31.

30. *Id.* at 30; Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303, 303 (2008); Silverman, *supra* note 3, at 226.

31. Branstetter, *supra* note 8, at 30.

32. Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1571 (2009).

Regardless of the justifications for the TPP's heightened protections for pharmaceuticals, concerns about the effects of these protections on access to medicines in developing and least-developed countries are understandable. The TPP will not affect the vast majority of drugs, particularly those on the World Health Organization's Model List of Essential Medicines, as the patent and regulatory exclusivities for these drugs have expired or were never available.³³ But, for drugs that are developed in the future, patent and data exclusivities could have a profound impact on pricing and availability, and many have voiced their objection to the TPP on these grounds.³⁴

That being said, the negotiating parties were more successful than many might have expected in pushing to remove and modify several controversial provisions from the final draft of the TPP, as the discussion below explains.³⁵ A number of the TPP member states not only objected to many of the initial proposals that favored the pharma industry, but also floated their own counterproposals.³⁶

The language in many parts of the final draft of the TPP arguably reflects this more liberal tone. For example, Article 18.3 of the TPP's intellectual property chapter stipulates that a signatory country "may, in formulating or amending its laws and regulations, adopt measures necessary to protect public health and nutrition . . . provided that such measures are consistent with the provisions of this Chapter."³⁷ Article 18.6 of the same chapter states that the negotiating parties "affirm their commitment to the Declaration on TRIPS and Public Health," and that

[t]he obligations of this [intellectual property] 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.³⁸

33. Branstetter, *supra* note 8, at 26; Trade Enhancing Access to Medicines, *supra* note 5, at 3.

34. See, e.g., *Trading Away Health: The Trans-Pacific Partnership Agreement (TPP)*, DOCTORS WITHOUT BORDERS (2013), <http://www.doctorswithoutborders.org/news-stories/briefing-document/trading-away-health-trans-pacific-partnership-agreement-tpp>.

35. Branstetter, *supra* note 8, at 28.

36. *Id.* at 20; see, e.g., *infra* text accompanying notes 77–82.

37. Trans-Pacific Partnership, OFFICE OF THE U.S. TRADE REP. art. 18.3, Feb. 4, 2016, <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text> [hereinafter TPP].

38. *Id.* art. 18.6.

These statements provided a background against which the TPP's signatories could interpret its pharma-friendly provisions in a way most conducive to public health and access to medicines.

III. PATENTABLE SUBJECT MATTER

The first of the TPP's pharma-friendly provisions is Article 18.37.2's extension of patentable subject matter to include new uses of known products, including pharmaceuticals.³⁹ This provision is suspected of allowing pharmaceutical companies to "evergreen" their patent rights and extend their patent monopolies by repeatedly filing new patents on alternative uses of already existing drugs.⁴⁰ This expansion of patentable subject matter is argued to lead to sequential patents on "dubious or marginally used" indications for drugs that are used simply to prolong patent monopolies and increase prices with no countervailing benefit to health outcomes.⁴¹ Critics claim that such sequential patenting can prolong patent protections for up to six or seven years after the original patent on the active ingredient itself.⁴² Some countries, such as India, have therefore prohibited such sequential patenting on new uses or new forms of existing drugs, a move that is thought to have helped foster India's sizable generic drug industry.⁴³

It is important to first note that, regardless of whether they ultimately contribute to social welfare, new-use patents on existing drugs are not, as some have suggested, merely *renewals* of the patent on the drug itself.⁴⁴ The concept of evergreening presupposes that the new use or other sequential innovation on which subsequent patent rights are based are not technologically advanced enough to warrant additional patent protection and that subsequent patents on a known drug are broad enough in scope to prevent any meaningful use of the drug while the patent is in effect.⁴⁵ Although incremental in nature, sequential patents on new uses are in fact separate patents

39. Article 18.37.2 of the TPP states:

Subject to paragraphs 3 and 4 and consistent with paragraph 1, each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit those new processes to those that do not claim the use of the product as such.

TPP, *supra* note 37, art. 18.37.2.

40. Gustafson, *supra* note 24; Shah, *supra* note 14.

41. Gustafson, *supra* note 24; Silverman, *supra* note 3, at 228.

42. Luo & Kesselheim, *supra* note 3, at 729.

43. Amy Kapczynski, *The Trans-Pacific Partnership—Is It Bad for Your Health?*, 373 N. ENGL. J. MED. 201, 201–02 (2015).

44. Gustafson, *supra* note 24.

45. Kilic et al., *supra* note 6, at 4–5.

that must satisfy all of the same patentability requirements that active ingredient patents must satisfy, including novelty, nonobviousness, and utility.⁴⁶ Thus, although they may not contribute significantly to general health outcomes, patentable new uses of existing drugs do at least enjoy the presumption of contributing some new advantages.⁴⁷

More importantly, patents on a new use of an existing drug are much narrower in scope than a patent on the active ingredient in the drug itself.⁴⁸ Once the patent on the active ingredient patent expires, it can be used freely for any unpatented use, including the use for which it was originally patented, without fear of infringement liability.⁴⁹ In fact, such new-use patents may be particularly ineffectual because other producers of the underlying drug can merely *carve out* the new use from their labeling for the drug, thereby officially advising purchasers and prescribers that their versions of the drug are indicated only for off-patent or licensed uses.⁵⁰

On that note, it is also interesting to observe what subject matter was ultimately excluded from the patentability requirements of the final draft of Article 18.37. The United States' original proposal would have required that diagnostic, surgical, and therapeutic methods be patentable subject matter,⁵¹ along with new forms of known drugs.⁵² Neither of these proposals remained in the final draft, however,⁵³ and the United States and Australia continue to be the only countries that allow patents on diagnostic, surgical, and therapeutic methods.⁵⁴ The effect of excluding new forms of known drugs could be significant—after Argentina changed its laws in 2012 to exclude new drug

46. Baker & Geddes, *supra* note 12, at 33.

47. *Id.*

48. Henry Grabowski & John Vernon, *Longer Patents for Increased Generic Competition in the US: The Waxman-Hatch Act After One Decade*, 10 PHARMACOECONOMICS 110, 121 (1996); C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 619–20 (2011).

49. John Thomas, *Patent Eligibility*, PHARMACEUTICAL PAT. L. (BNA), pt. II, ch. 2 (3d ed. 2005); Kapczynski, *Harmonization and Its Discontents*, *supra* note 32, at 1591.

50. See 21 U.S.C.A § 355(j)(2)(A)(viii) (Westlaw through Pub. L. No. 115-30).

51. Kilic, *supra* note 21, at 39; Kilic et al., *supra* note 6, at 14–15.

52. Kilic, *supra* note 21, at 39.

53. *Id.* at 40; Kilic et al., *supra* note 6, at 14–15.

54. Kilic, *supra* note 21, at 39. Articles 18.37.3–18.37.4 state that signatories may exclude from patentability “(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) animals other than microorganisms, and essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes,” as well as “plants other than microorganisms,” as long as “patents are available at least for inventions that are derived from plants.” TPP, *supra* note 37, arts. 18.37.3–18.37.4.

forms, the number of pharmaceutical patents granted appeared to drop drastically as compared to other countries in the region.⁵⁵

Moreover, to the extent that sequential patents on new uses under Article 18.37 in its final, more limited form do foster evergreening, individual states can further limit the risk both directly and indirectly through domestic law. Many have focused on the negotiation of the TPP and other FTAs, but have not paid as much heed to the implementation of such agreements, in which some signatories, especially the larger developing countries such as Brazil, India, and South Africa, have had more success in tailoring implementation to suit their own specific needs.⁵⁶

Heightened patentability requirements directly limit the risk of evergreening by limiting the possibility of acquiring further patent rights on known products.⁵⁷ Even if they qualify as patentable subject matter, new uses of known substances often will not meet the requirements for patentability and are particularly vulnerable to validity challenges by generic manufacturers.⁵⁸ Flexibility in heightening the patentability requirements of novelty, nonobviousness (or inventive step), utility (or industrial application), and disclosure may further limit pharma's ability to patent new uses of existing drugs.⁵⁹ The TPP circumscribes flexibility with regard to some of the patentability requirements to a limited degree, but for the most part TPP signatories are ostensibly free to adapt their patentability requirements as they see fit.⁶⁰

Canada and India have employed such tactics by raising their respective patentability requirements in ways that have greatly limited the ability of pharmaceuticals to obtain sequential patents.⁶¹ Section 3(d) of India's Patent Act states that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known

55. GERMÁN VELÁSQUEZ, GUIDELINES ON PATENTABILITY AND ACCESS TO MEDICINES 19 (Mar. 2015), http://www.southcentre.int/wp-content/uploads/2015/03/RP61_Guidelines-on-Patentability-and-A2M_EN.pdf.

56. M. Monirul Azam, *Globalizing Standard of Patent Protection in WTO Law and Policy Options for the LDCs: The Context of Bangladesh*, 13 CHI.-KENT J. INTELL. PROP. 402, 406 (2014); Yu, *Are Developing Countries Playing a Better Trips Game?*, *supra* note 20, at 324.

57. Baker, *Ending Drug Registration Apartheid*, *supra* note 30, at 304.

58. *Id.*

59. CARLOS M. CORREA, GUIDELINES FOR THE EXAMINATION OF PHARMACEUTICAL PATENTS: DEVELOPING A PUBLIC HEALTH PERSPECTIVE 18–20 (2007), <http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/guidelines-for-the-examination-of-patent-applications-relating-t.html>.

60. *Id.*

61. *Id.* at 23–24, 36.

substance” cannot be patented.⁶² Although Section 3(d) is not limited to pharmaceutical inventions, it was enacted with the purpose of promoting access to medicines by reducing the risk of evergreening.⁶³ Section 3(d) therefore not only prohibits patenting of many new drug forms that lack superior efficacy, but also all new uses of known drugs, regardless of their therapeutic value.⁶⁴ India is not a member of the TPP, and most countries do not have such strict patentability standards,⁶⁵ but other countries have already followed India’s lead. The Philippines have recently adopted a provision similar to Section 3(d),⁶⁶ as has Argentina.⁶⁷

Canada’s utility requirement takes a slightly different tack on raising the patentability bar. In recent years Canada has interpreted its patent law as requiring that a patent application must either demonstrate or soundly predict that the covered invention will work for any utility expressed or merely implied in the application.⁶⁸ This “promise doctrine” is designed to prevent patenting until an inventor has conducted adequate research to support patentability⁶⁹ and may be particularly effective with regard to pharmaceutical patents.⁷⁰ Dozens of drug patents have been invalidated under the promise doctrine,⁷¹ although it is not clear how many of these invalidated pharmaceutical patents were evergreening-type sequential patents.

62. Patents Act, No. 15 of 2005, INDIA CODE sec. 3 (2005), <http://indiacode.nic.in>; Kilic et al., *supra* note 6, at 5.
63. Kapczynski, *Harmonization and Its Discontents*, *supra* note 32, at 1590–91; Kilic et al., *supra* note 6, at 5.
64. Kapczynski, *Harmonization and Its Discontents*, *supra* note 32, at 1590.
65. El-Said, *supra* note 4, at 405–08; Kapczynski et al., *supra* note 9.
66. INTELLECTUAL PROPERTY CODE, § 22, as amended by Rep. Act 8293 (Phil.), http://www.jpo.go.jp/shiryuu_e/s_sonota_e/fips_e/pdf/philippines_e/e_tizai.pdf; El-Said, *supra* note 4, at 407.
67. Res. Nos. 118/2012, 546/2012, 107/2012, May 8, 2012 (Arg.), <http://www.wipo.int/wipolex/en/details.jsp?id=13007>; Rajarshi Banerjee, Note, *The Success of, and Response to, India’s Law Against Patent Layering*, 54 HARV. INT’L L.J. 204, 228–29 (2013) (also banning new forms of known drugs even if they demonstrate enhanced efficacy).
68. Cynthia M. Ho, *Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions*, 30 BERKELEY TECH. L.J. 213, 226–27 (2015); Mark D. Penner, *Increased Utility Requirements in Canada? How the “Promise Doctrine” Has Challenged Patentees and What Can Be Done to Address These Challenges*, LAWYERISSUE (July 3, 2015), <http://www.lawyerissue.com/increased-utility-requirements-in-canada-how-the-promise-doctrine-has-challenged-patentees-and-what-can-be-done-to-address-these-challenges/>; Kilic et al., *supra* note 6, at 7–8.
69. Kilic et al., *supra* note 6, at 7–8.
70. Baker & Geddes, *supra* note 12, at 43–44.
71. Ho, *Sovereignty Under Siege*, *supra* note 68, at 236.

India was not a party to the TPP, but both India's and Canada's heightened standards did not go unnoticed during TPP negotiations.⁷² The TPP negotiating parties debated over the utility requirement, and although India's Section 3(d) is technically a patentable subject matter restriction,⁷³ the United States and Japan wanted the TPP to disallow denials of patents on known products "solely on the basis that the product did not result in an enhanced efficacy of the known product," a restriction that would have directly forestalled adoption of analogs to India's Section 3(d).⁷⁴ This proposed language is now conspicuous by its absence, again signaling its likely opposition from other TPP member states.⁷⁵

Earlier drafts of the TPP also contained language that seemed to target more stringent utility standards such as Canada's promise doctrine.⁷⁶ This earlier language would have required patentability for anything that has "specific, substantial, and credible utility,"⁷⁷ the utility standard that U.S. patent law applies.⁷⁸ Although subtle, the difference between the more lenient "specific, substantial, and credible utility" standard and Canada's more demanding "soundly predicted" utility standard was apparently significant.⁷⁹ A majority of the TPP negotiating parties objected to this attempt to restrict their flexibility to set their own patentability standards,⁸⁰ and any reference to "specific, substantial, and credible utility" is also conspicuous by its absence.⁸¹

The final draft of the TPP does somewhat constrain flexibility with regard to the novelty and inventive step (non-obviousness) requirements. Article 18.38 of the final draft stipulates that, in determining both novelty and inventive step, each party "shall disregard at least information contained in public disclosures" if the information was disclosed by or from the patent applicant less than twelve months before the application filing date.⁸² This provision thus cabins the universe of prior art on which each party can rely to disprove an invention's novelty or inventive step, effectively lowering the

72. Kapczynski, *Harmonization and Its Discontents*, *supra* note 32, at 1596–98.

73. CORREA, *supra* note 59, at 12; Kapczynski, *Harmonization and Its Discontents*, *supra* note 32, at 1590.

74. Kilic et al., *supra* note 6, at 6.

75. *Id.* at 6–7.

76. *Id.* at 7–8.

77. *Id.* at 7.

78. Utility Examination Guidelines, 66 Fed. Reg. 1092, *passim* (Jan. 5, 2001).

79. Kilic et al., *supra* note 6, at 7–8.

80. *Id.*

81. *Id.*

82. TPP, *supra* note 37, art. 18.38 (emphasis added).

bar for patentability.⁸³ This may affect the TPP signatories' ability to weed out sequential patents suspected of evergreening exclusivity over pharmaceuticals. That said, there are still a number of flexibilities that signatories can exert in limiting the patentability of pharmaceuticals or other inventions under the novelty and inventive step requirements.

India, for example, has set a high threshold for proving "inventive step" by requiring not only that an invention be nonobvious to a person of ordinary skill in the relevant art, but also that the invention demonstrate some "technical advance" or "economic significance."⁸⁴ The additional requirements of "technical advance" or "economic significance" could be used effectively to limit patentability for many inventions.⁸⁵ China has similarly tightened its non-obviousness standard,⁸⁶ which requires "prominent substantive features and . . . remarkable advancements" over existing technologies.⁸⁷ In fact, at least one commentator has specifically called for application of standards of non-obviousness and inventive step more rigorous than those used in the United States, specifically for pharmaceuticals.⁸⁸ The novelty requirement also allows great leeway.⁸⁹ Individual countries can choose how easily to imply the presence of an invention in the prior art,⁹⁰ whether to rely on a single or multiple prior art references in determining an invention's novelty,⁹¹ or other potential measures for narrowing the boundaries for novelty.

And in addition to the stringency or leniency of a given party's substantive patentability requirements, the rigor of a party's domestic procedural processes for examining and issuing patents could also help curb patents on pharmaceuticals or other technologies. Pre-grant oppositions to patent applications are a procedural mechanism that uses third-party challenges to help

83. Branstetter, *supra* note 8, at 9.

84. Kapczynski, *Harmonization and Its Discontents*, *supra* note 32, at 1593.

85. *Id.*

86. El-Said, *supra* note 4, at 406–07.

87. Patent Law of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Dec. 27, 2008, effective Oct. 1, 2009), art. 22, 2008 P.R.C. Laws (China). Literally translated, Article 22 refers to "creativity" rather than non-obviousness or inventive step.

88. *E.g.*, CORREA, *supra* note 59, at 15–16 (advocating use of a variety of factors, not just prior art references, and use of more than unexpected results from something that one might otherwise be expected to try).

89. Jerome H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11, 30 (1997) ("[T]here is no agreed international standard of absolute novelty, and, within limits, the developing countries may pick and choose from among the different approaches recognized in the domestic patent laws.").

90. CORREA, *supra* note 59, at 13–14 (calling for liberal use of the inherency doctrine).

91. *Id.* at 8.

identify patents and patent claims that should not be issued.⁹² Although patents can be invalidated after issuance, preventing the issuance of weak patent claims, such as those that might be found in sequential new-use patents, avoids the over-deterrence of competitors as well as expensive litigation later in court.⁹³ Of course, pre-grant (and post-grant) oppositions are only effective if interested third parties have adequate access to the information necessary for such challenges,⁹⁴ but pre-grant oppositions have been used quite successfully in India to challenge pharmaceutical patents and protect the robust generic industry.⁹⁵

Previous U.S.-negotiated FTAs have included provisions precluding pre-grant oppositions, including the FTA between the United States and Korea⁹⁶ and the FTAs between the United States and Singapore, Morocco, Bahrain, and Oman.⁹⁷ Unsurprisingly, the United States made a similar proposal during TPP negotiations, but a 2013 counterproposal submitted jointly by Australia, Canada, Chile, Malaysia, New Zealand, and Singapore insisted on maintaining the flexibility to allow either pre-grant or post-grant third-party oppositions.⁹⁸ The United States subsequently withdrew its proposal to bar pre-grant oppositions⁹⁹ and indeed has itself recently ramped up its own administrative procedures for third-party opposition to pending patent applications under the America Invents Act.¹⁰⁰

More indirect methods of limiting evergreening and its effects also can be adopted through specific exemptions to infringement liability. Article 18.40 of the TPP final draft explicitly permits parties to impose “limited exceptions” to patent rights, “provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the

92. Kilic, *supra* note 21, at 42–43; Krista Cox, *TPP Negotiating Parties’ Counterproposal to the US on Medicines Represents a More Flexible Approach*, KNOWLEDGE ECON. INT’L (Nov. 14, 2013), <http://keionline.org/node/1826>.

93. Cox, *supra* note 92; Kilic, *supra* note 21, at 42–43; Kevin Outtersson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL’Y, L. & ETHICS 193, 257–58 (2005) (warning that merely filing a patent application may deter generic market entry in some instances).

94. Azam, *supra* note 56, at 441–42.

95. Cox, *supra* note 92.

96. Lopert & Gleeson, *supra* note 6, at 203.

97. Smith et al., *supra* note 20, at 687.

98. Cox, *supra* note 92.

99. Kilic, *supra* note 21, at 43.

100. Michael A. Carrier, *Post-Grant Opposition: A Proposal and a Comparison to the America Invents Act*, 45 U.C. DAVIS L. REV. 103, 113–15 (2011).

legitimate interests of third parties.”¹⁰¹ One widely accepted example of such an exception is included in the TPP itself. Article 18.49 of the TPP stipulates that each TPP signatory “shall adopt or maintain a regulatory review exception for pharmaceutical patents.”¹⁰² This reference to a “regulatory review exception” refers to what is commonly known in the United States as the “*Bolar* exception,” which exempts from patent infringement liability any pre-market testing of a patented drug for the purpose of obtaining regulatory marketing approval.¹⁰³ This exception expedites market entry by generic drug marketers by authorizing them to prepare for sale of the drug immediately upon patent expiry.¹⁰⁴ It is noteworthy that many of the TPP signatories were again successful in pushing back on proposals to cabin the *Bolar* exception by limiting it to only product patents and to only the territory of the country granting the exception.¹⁰⁵ Article 18.49 uses the term “pharmaceutical patents” rather than “pharmaceutical products” or “product patents,” and a footnote to the Article states that “consistent with Article 18.40 (Exceptions), nothing prevents a Party from providing that regulatory review exceptions apply for purposes of regulatory reviews in that Party, in another country or both.”¹⁰⁶ On the other hand, TPP signatories were not successful in pushing for an even broader experimental-use exception that would also have supported use of a patented invention for determining how the invention works, its scope, its validity, or how to improve on the invention.¹⁰⁷

Analogous exceptions to medical patent rights can be found outside of the TPP as well. Section 287(c) of the Patent Act in the United States, for one, grants fairly broad immunity from patent infringement liability to “medical practitioners” and “related health care entities” who use patented medical procedures.¹⁰⁸ The effect of Section 287(c) is to give medical practitioners and health care entities an immediate, royalty-free, compulsory license to

101. TPP, *supra* note 37, art. 18.40.

102. *Id.* art. 18.49.

103. Okediji, *supra* note 26, at 246–47 (noting that the United States’ statutory *Bolar* exception expressly overrules the United States Federal Circuit court decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, 863 (Fed. Cir. 1984), which held that no such experimental-use exception existed at common law).

104. *Id.*

105. 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, 369 (2014).

106. TPP, *supra* note 37, art. 18.49 n.49.

107. Cox, *supra* note 92.

108. 35 U.S.C.A § 287(c) (Westlaw through Pub. L. No. 115-30); *see also* Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection*, 33 U.C. DAVIS L. REV. 601 (2000) (analyzing Section 287(c) in depth).

such patents, albeit with some important limitations.¹⁰⁹ Although much more bounded in scope, Article 78 of Australia's 1990 Patent Act also provides for patent infringement immunity, specifically singling out patented pharmaceutical substances used for non-therapeutic purposes or in unpatented forms.¹¹⁰ The exemption also applies only during the extended term of the patent if it was granted a term extension under Australian law. The Australian exemption therefore may not be as useful in combatting evergreening-type sequential patents as the Section 287(c) of U.S. patent law.

Another example of an exception that may be of particular benefit to countries such as India, which only relatively recently began granting patents on pharmaceutical substances,¹¹¹ is prior-user rights. To "grandfather" in generic drug manufacturers who were already producing drugs that later were granted patent rights under Indian law, India effectively gave generic manufacturers immediate compulsory licenses to these patents by granting the manufacturers prior-user rights.¹¹² Generic manufacturers who made "significant investment" in producing and marketing a drug, and were in fact doing so prior to January 1, 2005, may continue to do so if they pay a reasonable royalty to the later patent holder.¹¹³ And while India's prior-user rights are thus subject to exceptions, Brazil's prior-user rights are unrestricted and guarantee that prior users are "assured [of] the right to continue the exploitation, without onus, in the same manner and under the same conditions as before."¹¹⁴

IV. PATENT TERM ADJUSTMENTS

Other IP provisions in the TPP that raise similar concerns are those in Articles 18.46 and 18.48, which require patent-term adjustments to compensate for "unreasonable" delays in either the patent prosecution and regulatory marketing approval processes.¹¹⁵ Like the patentable subject matter expansions in Article 18.37, the patent term adjustments under TPP Articles 18.46 and 18.48 have been criticized as unduly prolonging patent monopolies.¹¹⁶ But, like the patentable subject matter provisions, both Articles 18.46 and 18.48 could be limited directly and indirectly through a member state's domestic patent laws. More importantly, nothing in either Article 18.46 or 18.48 specifies what kind of adjustments states must make or for how long.

109. See generally Ho, *Sovereignty Under Siege*, *supra* note 68.

110. El-Said, *supra* note 4, at 426–27.

111. Kapczynski, *Harmonization and Its Discontents*, *supra* note 32, at 1576.

112. Azam, *supra* note 56, at 439–40.

113. *Id.*

114. *Id.* at 439–40 (quoting No. 9.279 art. 45, de 14 de maio de 1996, *Diario Oficial Da Uniao* [D.O.U.] de 15.05.1996. (Port.)).

115. TPP, *supra* note 37, arts. 18.46, 18.48.

116. Lopert & Gleeson, *supra* note 6, at 201.

Indeed, Article 18.48 does not even specify what kind of marketing-approval delays constitute such an “unreasonable curtailment” of patent term that adjustments must be made. Member states therefore retain a fair amount of flexibility in limiting the effects of these provisions on their domestic pharmaceutical markets.

Article 18.46 of the TPP’s intellectual property chapter addresses delays in processing patent applications. The Article first exhorts member states to make “best efforts to process patent applications in an efficient and timely manner” and “to avoid unreasonable or unnecessary delays,”¹¹⁷ but then mandates that, if “unreasonable delays” nonetheless occur, the member “shall provide the means to, and at the request of the patent owner shall, adjust the term of the patent” in compensation.¹¹⁸ Article 18.46 then defines “unreasonable delays” as at least including delays in issuance of more than five years from the date of filing or three years after a request for examination, whichever is later.¹¹⁹ Article 18.48 addresses delays specifically due to regulatory processes to evaluate pharmaceuticals for marketing approval and similarly exhorts member states to make their best efforts to grant marketing approvals in a timely manner, without unreasonable or unnecessary delays.¹²⁰ Like Article 18.46’s provisions on patent prosecution delays, Article 18.48 also mandates patent term adjustment to compensate for “unreasonable curtailment of the effective patent term” of the pharmaceutical resulting from the marketing approval process.¹²¹ Unlike Article 18.46’s provisions on patent prosecution delays, however, Article 18.48, does not define “unreasonable curtailment” or “effective patent term,” and also does allow TPP members to stipulate “conditions and limitations” on patent term adjustments granted for marketing approval delays.¹²²

The justifications for these respective patent term adjustments differ from one another. Adjustments for patent prosecution delays stem from the fact that, in some countries, the administrative process takes longer than patent applicants find acceptable and are aimed primarily at incentivizing more efficient patent prosecution.¹²³ Such administrative delays are apparently inevitable in developing countries such as those in Latin America (Chile, Peru, and Mexico, in TPP’s case), leading to the similar inevitability of calls for

117. TPP, *supra* note 37, art. 18.46.1. For example, member states may implement expedited procedures for patent prosecution. *Id.* art. 18.46.2.

118. *Id.* art. 18.46.3.

119. *Id.* art. 18.46.4.

120. *Id.* art. 18.48.1. Article 18.48.4 also states that member parties may provide for expedited regulatory review. *Id.* art. 18.48.4.

121. *Id.* art. 18.48.2.

122. TPP, *supra* note 37, art. 18.48.3.

123. Ryan Davis, *TPP Aims To Spread US-Style IP Protections Overseas*, LAW360 (Nov. 5, 2015, 10:04 PM), <https://www.law360.com/articles/723789/tpp-aims-to-spread-us-style-ip-protections-overseas>.

term extensions.¹²⁴ The Pharmaceutical Research and Manufacturers of America (PhRMA) similarly have complained about TPP members Canada, Chile, Malaysia, New Zealand, and Vietnam (along with nonmembers Thailand and Turkey) for alleged “backlogs” in patent prosecution.¹²⁵ PhRMA has also criticized India, Brazil, and Thailand for taking six to ten years to examine biopharma patents, with one patent in Thailand reportedly issuing only six weeks before it expired.¹²⁶ Whether patent term extensions are the proper way to remedy administrative backlogs in the patent prosecution process, however, is unclear; the 2013 joint counterproposal did not include term adjustments and merely exhorted member states to improve efficiency and avoid delays.¹²⁷

Term adjustments for marketing approval delays, on the other hand, advert to the fact that the incredibly long period is necessary not only for the pharmaceutical regulatory approval process but also for pre-market product development and clinical trials.¹²⁸ And because pharma firms must typically file patent applications on their active pharmaceutical ingredients very early in the development process to avoid novelty and non-obviousness objections and to establish priority, several years of the term of such active ingredient patents will tick away before the firm even has approval to market the drug.¹²⁹ To enjoy an effective patent term that even approximates that of patents in other technologies then, pharmaceutical firms seek patent term extensions.¹³⁰ PhRMA’s complaints that TPP members and others grant regulatory marketing approvals at rates much slower than international practice¹³¹ therefore may be more compelling.

The patent term adjustment provisions in the TPP have been the object of criticism on a number of counts. First, critics accuse patent term adjustment requirements as furthering evergreening of patent rights and leading to higher drug prices. One report found that patent term extensions in the Republic of Korea under its FTA with the United States could increase national

124. Gustafson, *supra* note 24, at 2.

125. Usdin, *Trans-Pacific Dreams*, BIOCENTURY (Dec. 21, 2015, 2:00 AM), <https://www.biocentury.com/biocentury/politics-policy-law/2015-12-21/how-tpp-deals-ip-provisions-read-wish-list-phrma-biologics>.

126. PHARM. RESEARCH & MFG. OF AM. (PhRMA), SPECIAL 301 SUBMISSION 2016 12 (2016), http://phrma-docs.phrma.org/sites/default/files/pdf/PhRMA_2016_Special_301_Submission.pdf.

127. Cox, *supra* note 92; Kilic, *supra* note 21, at 46.

128. Baker, *Ending Drug Registration Apartheid*, *supra* note 30, at 304; Davis, *supra* note 123.

129. Baker, *Ending Drug Registration Apartheid*, *supra* note 30, at 304; Davis, *supra* note 123.

130. Baker, *Ending Drug Registration Apartheid*, *supra* note 30, at 304; Davis, *supra* note 123.

131. SPECIAL 301 SUBMISSION 2016, *supra* note 126, at 19.

drug expenditures by hundreds of millions of dollars.¹³² Second, patent term adjustment systems can be complex and difficult to administer, leading to uncertainty over patent rights.¹³³ Imposing patent term adjustment systems on the many countries that do not possess such systems could therefore be quite burdensome.¹³⁴ Third, the TPP has been criticized for rolling back many of the policies encouraging access to medicines set forth in the United States' Bipartisan Agreement on Trade Policy (Bipartisan Trade Policy or BTP).¹³⁵ This 2007 agreement set policies for congressional consideration of the FTAs with Peru, Colombia, Panama, and Korea that were negotiated around that time.¹³⁶ Although the TPP appears to embrace most of the BTP's provisions,¹³⁷ the TPP does not adopt the BTP policy that term adjustments should be optional for FTA signatories and instead makes term adjustments mandatory.¹³⁸ Not surprisingly, the pharma industry lobbied heavily against incorporation of the BTP's provisions into the TPP.¹³⁹

The TPP does contain two express, but very narrow, exceptions to both Articles 18.46 and 18.48, which appear in Annex 18-D to the agreement. Under Annex 18-D, Peru—and apparently only Peru—can be exempted from granting patent term adjustments in compensation for either patent office delays or marketing approval delays if, despite Peru's best efforts, it cannot obtain a waiver from Andean Decision 486, Common Industrial Property Regime, and Andean Decision 689, Adequacy of Certain Articles of Decision 486.¹⁴⁰ Andean Decision 486 is a Sub-regional Integration Agreement that grants rights to Andean Community members Bolivia, Colombia, Ecuador, and Peru, to use their domestic laws to strengthen protection of patents, utility models, industrial designs, trademarks, biological and genetic heritage, and traditional knowledge.¹⁴¹ Andean Decision 689 modifies Decision 486 in relevant part to allow member countries to compensate for undue delays in patent issuance attributable to the Patent Office *except in the case of patents*

132. Azam, *supra* note 56, at 443.

133. Kilic, *supra* note 21, at 44.

134. Davis, *supra* note 123.

135. Florco & Holdford, *supra* note 1.

136. USTR, BIPARTISAN AGREEMENT ON TRADE POLICY, BIPARTISAN TRADE DEAL (May 2007), https://ustr.gov/sites/default/files/uploads/factsheets/2007/asset_upload_file127_11319.pdf.

137. *Id.*

138. Silverman, *supra* note 3, at 221.

139. *Id.* at 222.

140. TPP, *supra* note 37, Annex 18-D.

141. Cartagena Agreement, Decision 486, Common Provisions on Industrial Property, Sept. 14, 2000, http://www.wipo.int/wipolex/en/text.jsp?file_id=223717.

for pharmaceutical products and processes.¹⁴² Annex 18-D could therefore have significant implications for pharmaceutical patents in Peru if Peru is not able to obtain a waiver of Decision 689.¹⁴³ What flexibility do other TPP members have, however?

With regard to patent term adjustments under Article 18.46 to compensate for patent office delays, TPP signatories would not seem to have much flexibility. Article 18.46 states that TPP parties “shall” adjust patent terms at the request of the patent holder and must do so under very defined circumstances: if issuance is delayed for more than five years from the date of filing or three years after a request for examination, whichever is later.¹⁴⁴ Nonetheless, TPP signatories retain flexibility on a variety of aspects of patent term adjustment.¹⁴⁵

First, patents can be extended only if a patent has been granted. To the extent that domestic patent systems can limit evergreening through the patentability of pharmaceutical inventions, as discussed above, they also limit evergreening through patent term extensions.¹⁴⁶ Second, Article 18.46.4 states that in making term adjustment determinations, parties may exclude periods “that do not occur during the processing of, or the examination of, the patent application by the granting authority,” “that are not directly attributable to the granting authority,” and “that are attributable to the patent applicant.”¹⁴⁷ None of these terms are defined, leaving a signatory to define what qualifies as “processing” or “examination of” a patent narrowly and define what qualifies as “attributable to the patent applicant” and “not directly attributable to the granting authority broadly.” Signatories could thus make it more difficult for patent applicants to show that they meet the five or three-year minimum under Article 18.46 by excluding delays due to third-party oppositions or other external factors.¹⁴⁸ Third, the TPP also does not specify how long a term adjustment must be, leaving it to individual signatories to decide whether to compensate day-for-day for patent prosecution delays or for just some fraction thereof.

142. José Barreda, *New Andean Decision 689*, IP TANGO (Aug. 20, 2008), <http://iptango.blogspot.com/2008/08/new-andean-decision-689.html>.

143. Annex 18-D does stipulate that, if Peru is unable to obtain a waiver, Peru’s patent system will not discriminate on the basis of technology, place of invention, or importation or local production. “Thus, Peru confirms that the treatment of pharmaceutical patents will be no less favourable than treatment of other patents in respect to the processing and examination of patent applications.” TPP, *supra* note 37, Annex 18-D.

144. *Id.* art. 18.46.4.

145. Davis, *supra* note 123.

146. *See supra* text accompanying notes 102–08.

147. TPP, *supra* note 37, art. 18.46.4.

148. Kilic, *supra* note 21, at 45.

The language of TPP Article 18.48 on patent term adjustments for delays in the regulatory approval process is even more open-ended than that in Article 18.46. Like the term extension provision for patent office delays, Article 18.46 does not specify how much of an adjustment must be given for “unreasonable curtailment” of effective patent life due to the regulatory approval process and in fact does not even define what qualifies as part of the “marketing approval process”—individual member states have the flexibility to decide whether it includes both pre-market testing and the marketing approval process, the marketing approval process only, or just some portion thereof. Unlike Article 18.46, TPP Article 18.48 does not specify what constitutes “unreasonable curtailment” for which an adjustment must be granted, thus allowing TPP parties to be quite parsimonious in how they determine what pharmaceutical patents merit term adjustments.¹⁴⁹

TPP member states also have other avenues for restricting patent term adjustments. For one, member states appear to have carte blanche in deciding whether to limit term adjustments under Article 18.48 to one extension per pharmaceutical product.¹⁵⁰ Article 18.48 allows parties to institute conditions and limitations on term extensions for the purposes of “certainty,” which arguably could include the limitation that only one patent can be extended or, alternatively, that extensions cannot be applied to sequential patents on new uses or forms of known drugs on the premise that the effective patent life of a “pharmaceutical product”¹⁵¹ has not been unreasonably curtailed if it has been effectively extended by sequential patenting. In this way, the TPP’s mandate to extend patent terms to compensate for regulatory approval delays is more limited than in other FTAs. The FTA between the United States and South Korea, for example, specifies that term extensions for regulatory delays should be applied not only to composition patents, but also to patents on methods of using and methods of producing new pharmaceutical products.¹⁵²

Another such avenue can be seen in Australia’s 1990 Act, which lays out three key restrictions on patent term extensions¹⁵³ granted for regulatory delays. First, the above-mentioned Article 78 establishes carve-outs from infringement liability during the extended term of a pharmaceutical patent.¹⁵⁴ Second, Article 78 establishes formal procedures for challenging such exten-

149. Branstetter, *supra* note 8, at 8.

150. Kilic, *supra* note 21, at 46.

151. TPP, *supra* note 37, art. 18.48.2.

152. Free Trade Agreement Between the United States of America and the Republic of Korea, U.S.-S. Kor., art. 18.8.6(b), June 30, 2007, USTR, http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file273_12717.pdf.

153. *Patents Act 1990* (Cth) ch. 6 pt. 3 s 70 sub-divs (2)–(3) (Austl.).

154. *Id.* at 78.

sions.¹⁵⁵ Third, Article 70 of the 1990 Act sets limits on term adjustments, allowing a patent to be extended only if at least five years have elapsed between patent issuance and marketing approval.¹⁵⁶ These limits on patent term extensions due to the regulatory approval process are particularly important, given that regulatory delays are unique to pharmaceutical patents.¹⁵⁷

V. PATENT LINKAGE

A third type of provision in the TPP that could have a major impact on the price and availability of drugs is patent linkage, another patent-related provision unique to the pharmaceutical industry. Article 18.51 of the TPP mandates that no one can obtain regulatory marketing approval for a patented drug unless they either own the patent rights to the drug, or have given the patent holder notice and opportunity to address any potential patent infringement.¹⁵⁸ Patent linkage thus imposes the burden of knowing the patent status of all approved drugs and then policing potential infringement of those patents on the regulatory agency that monitors pharmaceutical marketing, regardless of whether they have any expertise in patent law.¹⁵⁹ As a result, regulatory authorities are left simply to trust in the validity of patents alleged to cover a given drug, despite the fact that this would lead to blocking approval of cheaper generic versions of the drug that may or may not actually infringe the asserted patents.¹⁶⁰

Critics of patent linkage see it as yet further promoting patent evergreening in this regard—as long as a pharmaceutical firm can continue obtaining sequential patent rights to its drugs, it can continue blocking generic market entry for the drug through patent linkage.¹⁶¹ This risk appears to be particularly acute for drugs synthesized through biological process (biologics), as biologics typically are subject to many more patents than other types of drugs.¹⁶² Furthermore, critics ask why patent linkage is even necessary. Pat-

155. *Id.*

156. El-Said, *supra* note 4, at 426–27.

157. Baker, *Ending Drug Registration Apartheid*, *supra* note 30, at 304; Davis, *supra* note 123.

158. TPP, *supra* note 37, art. 18.51.1.

159. FREDERICK M. ABBOTT, THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH AND THE CONTRADICTION TREND IN BILATERAL AND REGIONAL FREE TRADE AGREEMENTS 8 (2004), <http://www.quno.org/sites/default/files/resources/TRIPS-Public-Health-FTAs.pdf>; Kilic, *supra* note 21, at 52.

160. ABBOTT, *supra* note 159, at 8.

161. Michael Grunwald, *Leaked: What's in Obama's Trade Deal*, POLITICO (July 1, 2015), http://www.politico.com/agenda/story/2015/06/tpp-deal-leaked-pharma-000126?hp=t1_r.

162. *Id.*; Eugenia Costanza Laurenza, *The Scope of 'Patent Linkage' in the US-South Korea Free Trade Agreement and the Potential Effects on International*

ent linkage is not required under the TRIPS agreement,¹⁶³ and why should pharmaceutical patent holders benefit from what is effectively agency enforcement of their patent rights?¹⁶⁴

Those who defend patent linkage argue that it protects both those who hold patents on marketed drugs as well as those who seek to offer generic versions of them. Patent linkage saves generic manufacturers from liability for patent infringement damages by stopping them before they incur such liability by going on the market.¹⁶⁵ It also protects pharmaceutical patent holders, not only by blocking generic market entry, but also by preventing premature generic entry from even temporarily lowering drug prices in a one-way ratchet from which it is difficult to raise drug prices.¹⁶⁶ In addition, patent linkage may help provide greater legal certainty and thereby encourage generic market entry.¹⁶⁷ Once patent holders learn that generics are manufacturing versions of the patent holders' drugs, generics are likely to face patent infringement claims regardless of patent linkage. Given this inevitability, perhaps generics would be more likely to apply for marketing approval if they were able to receive earlier notice of what patents stand in their way, and a chance to resolve any potential patent infringement before liability is incurred.

But some critics worry that establishing a patent linkage system could be counterproductive when discovering that the patent status of a particular drug is too difficult.¹⁶⁸ These critics are also concerned that compiling listings of applicable pharmaceutical patents, similar to the Orange Book maintained by the United States Food and Drug Administration, could be difficult for developing countries to organize.¹⁶⁹

This concern overlooks the fact that Article 18.5 of the TPP applies only if pharmaceutical manufacturers must seek regulatory approval to market their drugs. The regulatory authority at issue presumably conditions such approval on some form of application, accompanied by some quantity of supporting information.¹⁷⁰ Given that they must already be in direct contact with

Trade Agreements, 6 EUR. J. RISK REG. 439, 442 (2015); see also David E. Adelman & Christopher M. Holman, *Misplaced Fears in the Legislative Battle Over Affordable Biotech Drugs*, 50 INTELL. PROP. L. REV. 565 (2010) (defining biologics and noting the complexity of patents that protect them).

163. Silverman, *supra* note 3, at 219.

164. Baker, *Ending Drug Registration Apartheid*, *supra* note 30, at 308.

165. Branstetter, *supra* note 8, at 7–8.

166. *Id.*

167. Trade Enhancing Access to Medicines, *supra* note 5, at 1.

168. Chakrabarti, *supra* note 10, at 330.

169. Shah, *supra* note 14.

170. TPP, *supra* note 37, art. 18.51.1. (explaining that under Article 18.51, patent linkage applies only if a member state permits manufacturers to seek marketing

the regulatory authority to submit such information, manufacturers could easily be required to submit information about any relevant patents rights that they believe apply to the drugs for which they are seeking approval, from which a central listing of patents can be constructed. The regulatory authority could then penalize applicants who refuse or fail to submit a list of relevant patents by effectively deeming those applicants to have waived the benefit of blocking subsequent generic applications via patent linkage. Article 18.51 of the TPP requires only that “a system” be put in place to provide notice to patent holders that others are seeking to market their products.¹⁷¹ Article 18.51 does not specify what form that system should take, apparently leaving each TPP member to craft a system for themselves.¹⁷² And while Article 18.51 does call for patent holders to be afforded adequate time and opportunity to seek available remedies before others are granted approval to market their patented drugs, the Article appears to require such opportunities only for those patent holders who have received notice—¹⁷³ i.e., those who participated in the “system” by duly submitting information on any patents to which their drugs are subject.

The need to allow time and opportunity to seek remedies for potential patent infringement can nonetheless unduly delay generic market entry, especially if the patents at issue are ultimately held to be invalid.¹⁷⁴ The TPP does not specify exactly what procedures signatory members should use to resolve disputes over pharmaceutical patents, nor does it demand that any patent disputes be fully resolved before a generic can be granted marketing approval.¹⁷⁵ Nor does Article 18.51 set a minimum for what constitutes “adequate time and opportunity” or require that patent holders be given time to do anything other than “seek” (as opposed to “secure”) available remedies.¹⁷⁶

Perhaps more to the point, patent linkage becomes an issue only to the extent that there is a patent to link regulatory marketing approval to. Patent linkage can unnecessarily delay generic market entry, but so can the *in ter-*

approval of a drug previously approved for marketing by relying in effect on the safety and efficacy data submitted by the previously approved manufacturer (called a “right of reference”), rather than by submitting their own data. Patent holders must have submitted safety and efficacy data before they can enjoy the benefit of patent linkage.).

171. *Id.* art. 18.51.1.a.

172. *See id.* art. 18.51.

173. *Id.* art. 18.51.1.b. (the Article states that TPP members must provide “adequate time and opportunity for *such a patent holder* to seek . . . available remedies,” by which the Article seems to refer to the patent holder providing notice under the system established under 18.51.1.a.) (emphasis added).

174. Baker, *Ending Drug Registration Apartheid*, *supra* note 30, at 308.

175. Branstetter, *supra* note 8, at 8.

176. TPP, *supra* note 37, art. 18.51.1.b.

rorem effect of simply threatening a patent infringement lawsuit—or indeed, simply filing a patent application.¹⁷⁷ Limiting patent rights to pharmaceuticals or other technologies through heightened patentability standards, restrictions on patentable subject matter, exceptions to patent infringement liability, pre-grant oppositions, and so on can reduce the effect not only of patent linkage but also of patent exclusivity itself. To the extent that member states were concerned about how the TPP's patent-related provisions might affect access to medicines, exercising the various levers and flexibilities available to them might have helped weaken the effect these provisions could have had.

VI. OTHER FACTORS AFFECTING ACCESS TO MEDICINES

While patent exclusivity over pharmaceuticals can have a significant impact on drug prices and availability, patents are by no means the only factors with serious repercussions for access to medicines. For example, the data exclusivities that many developed countries grant only to pharmaceuticals may have implications for drug prices by making it more difficult for generic versions of drugs to obtain regulatory marketing approval.¹⁷⁸ The safety and efficacy data generated through clinical trials of drugs is generally quite costly, but generic drug manufacturers can avoid incurring these costs (and avoid passing these costs on to patients through higher drug prices) by asking for a “right of reference” to data previously submitted to the regulatory authority. In effect, data exclusivities delay the time at which generics can rely on rights of reference, thereby delaying the time at which generics can enter the market.¹⁷⁹ Data exclusivities typically run concurrently with any relevant patent protections, but also protect even unpatentable drugs and biologics.¹⁸⁰

Data exclusivities are a common feature of all recent U.S.-negotiated FTAs¹⁸¹ and the TPP is no exception. The TPP includes two different data exclusivities for pharmaceuticals and, for the first time in any trade agreement, extends data exclusivity to biologics as well.¹⁸² Critics argue that imposing data exclusivities on developing countries is unnecessary, particularly when a drug is already protected by data exclusivities in one or more developing countries.¹⁸³ Not surprisingly, developing countries have stepped up

177. Outterson, *supra* note 93, at 257.

178. Baker, *Ending Drug Registration Apartheid*, *supra* note 30, at 308.

179. Gustafson, *supra* note 24, at 2.

180. Baker, *Ending Drug Registration Apartheid*, *supra* note 30, at 306; Chakrabarti, *supra* note 10, at 332; Cox, *supra* note 92.

181. Branstetter, *supra* note 8, at 6.

182. TPP, *supra* note 37, art. 18.52.

183. Peter K. Yu, *The Political Economy of Data Protection*, 84 CHI.-KENT L. REV. 777, 784–85 (2010).

their objections to the imposition of regulatory exclusivities in FTAs.¹⁸⁴ The Annex to the TPP's intellectual property chapter does provide some modifications to its data exclusivity for Malaysia, Peru, and Chile, but these modifications are modest at best.

Enhanced patent or data exclusivities are unlikely to have a significant effect on drug prices in countries that impose drug price controls, as most countries employ some form of price controls for drugs.¹⁸⁵ In countries with national health insurance systems, the government can control drug prices through reference pricing and using its monopsony power to negotiate for lower drug prices.¹⁸⁶ Pharmaceutical firms also price discriminate between countries and voluntarily reduce their drug prices in response to threats of being delisted from national formularies¹⁸⁷ or having their patents subject to compulsory licensing.¹⁸⁸

The TPP does not prohibit such governmental price control strategies, but it does require that decisions regarding drug formulary listing and reimbursement be transparent.¹⁸⁹ Furthermore, the TPP mandates that pricing and listing decisions be reviewable on an applicant's request.¹⁹⁰ It is this latter provision in particular that concerns critics of the TPP, as it gives private pharmaceutical companies a chance to challenge pricing decisions and attempt to compel listings of their drugs at higher prices.¹⁹¹ Whether this review mechanism would have led to higher drug prices is not clear, as the TPP Annex explicitly allows drug pricing based on either a "competitive market" or on "therapeutic significance,"¹⁹² thus allowing TPP signatories to base drug pricing on criteria other than the manufacturer's asked-for price.¹⁹³

The TPP also gives signatories *carte blanche* to choose a patent exhaustion regime that allows parallel importation of lower-priced generic drugs

184. Baker, *Ending Drug Registration Apartheid*, *supra* note 30, at 335–37.

185. Azam, *supra* note 56, at 449.

186. *Id.* at 450; Branstetter, *supra* note 8, at 10; Luo & Kesselheim, *supra* note 3, at 728; Outterson, *supra* note 93, at 205, 214.

187. Bollyky, *supra* note 10.

188. *Id.*; Outterson, *supra* note 93, at 224.

189. TPP, *supra* note 37, Annex 26-A art. 3(c).

190. *Id.*

191. Brook K. Baker, *Trans-Pacific Partnership Provisions in Intellectual Property, Transparency, and Investment Chapters Threaten Access to Medicines in the US and Elsewhere*, 13 PLOS MED. 1, 4 (Mar. 8, 2016); Kapczynski et al., *supra* note 9; Luo & Kesselheim, *supra* note 3, at 728–29.

192. TPP, *supra* note 37, Annex 26-A art. 2(d).

193. *See* Azam, *supra* note 56, at 455–56 (noting that withdrawal of price controls does not always lead to higher drug prices); *see also* Lopert & Gleeson, *supra* note 6, at 204.

manufactured in other countries.¹⁹⁴ Developing countries, for example, can employ an international patent exhaustion rule such that the first sale of a lower-priced pharmaceutical anywhere in the world exhausts any patent right over it, thereby depriving the patent holder of any power to object to export or other disposition of the drug.¹⁹⁵ An international exhaustion rule thus enables the import of drugs from countries where they are being sold at lower prices, enhancing access to medicine in smaller, less wealthy markets.¹⁹⁶

The TPP also preserves signatories' rights to avail themselves of the compulsory licensing provision under Article 31 of TRIPS.¹⁹⁷ Compulsory licensing allows governments to use or grant a license to a private party to use a patented invention without the patent holder's permission and at a rate other than what the patent holder might have demanded.¹⁹⁸ In this way, compulsory licenses can serve to lower patented drug prices below what the patent holder might wish.¹⁹⁹

Finally, the TPP also contains a number of other provisions designed to increase access to medicines and lower drug prices. These provisions include lowering import tariffs, reducing customs barriers, eliminating internal barriers to drug distribution, and minimizing discriminatory and non-transparent (and sometimes corrupt)²⁰⁰ regulatory regimes.²⁰¹

But even if TPP signatories were to take advantage of the flexibilities and workarounds allowed them, they still might find themselves subject to the threat of some form of retaliation.²⁰² Under Section 301 of the U.S. Trade Act,²⁰³ for example, the United States regularly monitors its trade partners to see whether they are providing adequate protections for intellectual property rights or are erecting what the United States perceives as trade barriers to U.S. goods and businesses. Countries that the United States deems to have the most egregiously insufficient IP protections may face trade sanctions, although most offender countries are simply placed on non-statutory "watch lists," most often for failures to provide adequate IP protections for the phar-

194. TPP, *supra* note 37, art. 18.11.

195. Outterson, *supra* note 93, at 209–10.

196. *Id.*; Azam, *supra* note 56, at 426.

197. TPP, *supra* note 37, arts. 18.6 & 18.41.

198. Sarah R. Wasserman Rajec, *Evaluating Flexibility in International Patent Law*, 65 HASTINGS L.J. 153, 162, 180 (2013).

199. *Id.*

200. Baker, *Ending Drug Registration Apartheid*, *supra* note 30, at 310.

201. Trade Enhancing Access to Medicines, *supra* note 5, at 1–2.

202. Smith et al., *supra* note 20, at 688.

203. 19 U.S.C.A § 2242 (Westlaw through Pub. L. No. 115-30) (Section 301 of the Trade Act of 1974 as amended by Section 1303 of the Omnibus Trade and Competitiveness Act of 1988).

maceutical industry.²⁰⁴ The effects of being placed on a Section 301 list are unclear.

Chapter 28 of the TPP also establishes a mechanism for member-to-member complaints to be filed for dispute resolution, much like the similar mechanism that exists under TRIPS.²⁰⁵ Perhaps more worrisome is the dispute mechanism established under the TPP—the investor-state dispute settlement process (ISDS), found in the investment chapter of the TPP.²⁰⁶ Unlike the separate inter-governmental dispute resolution mechanism under Chapter 28, ISDS permits foreign—but not domestic—private investors to bring arbitration claims against countries that allegedly impair “investments” such as intellectual property rights.²⁰⁷ The ISDS mechanism thus could have deterred TPP signatories from exercising any available flexibilities to rein in patent rights over pharmaceuticals.²⁰⁸ And while for political reasons national governments may be loath to bring complaints for dispute settlement, private firms may not be so unwilling, and are increasingly using ISDS mechanisms in other trade agreements to file complaints against foreign laws.²⁰⁹ The ISDS mechanism was particularly controversial and threatened to stall TPP negotiations.²¹⁰ But the negotiating parties did manage to institute a number of provisions for dismissing frivolous claims, emphasizing the rights of governments to legislate in their citizens’ interest, carving out disputes over compulsory licenses, drug listing, pricing decisions, and other safeguards.²¹¹

One final category of factors that may pose the most formidable obstacle to access to medicines is, of course, lack of resources. Developing countries often lack the resources to establish distribution networks for medicine through investments in transportation, hospitals, public health programs, and healthcare professionals.²¹² As the United States Trade Representative’s white paper during the TPP negotiations noted, trade policy alone cannot solve challenges hindering access to medicines.²¹³ Foreign assistance and development programs, work on domestic public health issues, and many other

204. Kilic, *supra* note 21, at 26; Outterson, *supra* note 93, at 257.

205. *See infra* text accompanying note 20.

206. TPP, *supra* note 37, ch. 9, § B.

207. Baker, *Trans-Pacific Partnership Provisions in Intellectual Property*, *supra* note 191, at 4; Ho, *Sovereignty Under Siege*, *supra* note 68, at 215.

208. Baker, *Trans-Pacific Partnership Provisions in Intellectual Property*, *supra* note 191, at 4–5; Ho, *Sovereignty Under Siege*, *supra* note 68, *passim*.

209. Ho, *Sovereignty Under Siege*, *supra* note 68, at 219, 283–85.

210. *Id.* at 221.

211. TPP, *supra* note 37, arts. 9.8, 9.10, & 9.16.

212. Trade Enhancing Access to Medicines, *supra* note 5, at 3.

213. *Id.* at 2.

initiatives are necessary to address guaranteed access to medicines on a meaningful level.²¹⁴

VII. CONCLUSION

Other authors have written extensively about the flexibilities that trade agreement signatory countries have in implementing agreements such as the TPP.²¹⁵ This article is not the first to mention the fact that, despite the historic lack of push back against the demands of the United States and other developed countries in proposing such agreements, there are increasing instances of developing and least-developed countries resisting these proposals and countering them with proposals of their own. The TPP negotiating parties appear to have been surprisingly successful in their efforts to soften many of the patent-related provisions in the TPP and to preserve a fair amount of flexibility in the way that they would have implemented those provisions. Whether this success was due to the multilateral nature of the TPP—allowing negotiating parties to form more powerful blocs with sufficient net economic power to influence negotiations—is unclear. Now that the TPP is a dead letter, however, we cannot know how much use, and to what effect, the flexibilities under the agreement would have had.

214. *Id.*

215. See, e.g., Rajec, *supra* note 198, at 153; Yu, *Are Developing Countries Playing a Better Trips Game?*, *supra* note 20.