

Intellectual Property in the Trans-Pacific Partnership

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ON 4 FEBRUARY 2016, THE largest trade agreement since the Uruguay Round launched the WTO in 1994 was signed by 12 nations, constituting 40 percent of global GDP and nearly one-third of world trade among 800 million people.¹ The Trans-Pacific Partnership (TPP) is, as President Obama has labeled it, a “twenty-first century trade deal.”² By this he means that it reaches beyond traditional trade issues—tariffs, quotas, investment, services, and intellectual property. The TPP negotiation addresses issues fundamental to effective integration of the global economy, such as how to handle state-owned enterprises and building regulatory coherence and administrative transparency. It reaches into issues supporting the growing global supply chains that characterize modern commerce, including harmonization of industrial standards, rules of origin, and efficient customs procedures. More importantly, if approved, the TPP would create a blueprint for rules that support even greater commercial integration across member economies and provide a roadmap for future trade deals.

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The TPP is an ambitious endeavor, but not because of any measurable economic growth it may engender. Competing models of the economic impact

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of the TPP differ on whether it will increase or deter economic growth for the United States. Even economic models incorporating the agreement find that U.S. growth will not be particularly large. The most prominent estimates, by Petri and Plummer, project annual GDP growth of 0.5 percent by 2030 when the agreement is fully implemented.³ Though this growth would be valuable, it is modest considering the agreement is phased in over 15 years.

More important for global development is the legal, regulatory, and institutional framework the TPP sets out across the broad scope of commercial activity that constitutes the integrated global economy. The TPP has reached deeper into established areas of trade agreements, by opening stubbornly closed agriculture markets, more aggressively liberalizing services (the so-called negative list), and adding new requirements on intellectual property, as well as moving into new and important areas including regulatory measures and restrictions on conduct of state-owned enterprises. Undoubtedly, if approved, the TPP will set the standard for the next cycle of economic integration agreements, including the Trans-Atlantic Trade and Investment Partnership (TTIP), the Trade in Services Agreement (TiSA), the ongoing China-U.S. Bilateral Trade (BIT) Negotiation, and a possible future U.S.-China free trade agreement (FTA).⁴

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In perhaps no area is the advancement of the TPP more complex, controversial, and potentially more important than in intellectual property (IP). IP is relatively new to trade agreements, introduced into the Uruguay Round with much dispute and polemics, resulting in the Trade-Related Aspects of Intellectual Property Rights (TRIPS). Many—particularly left-of-center commenters, less developed nations, and most civil society organizations—have challenged it or called for it to be removed entirely from trade agreements.⁵ These arguments have come out particularly fiercely in response to the TPP because it has pushed the TRIPS agenda further than any previous agreement—what has been called TRIPS-plus.⁶

The United States, like the rest of the TPP partners, has held high expectations for this negotiation. It intended to include 97 percent of the more than 10,000 tariff lines into which all imported products are allocated for product definition for statistical accounting purposes and, of course, duty collection. It seeks to set more rigorous enforcement of labor and environmental standards and to level the playing field for state-owned enterprises. Of particular interest to the United States, especially the business community, is greater regulatory and administrative transparency and public participation in the regulatory process by the businesses, consumers, and other interested parties who will be affected by the regulations. The United States is also interested in protecting trade secrets,

promoting an open Internet that protects e-commerce and unencumbered digital trade, and ensuring fair market access for U.S. goods and investments. Ironically, despite the success of U.S. negotiators in getting an outcome so close to the broad U.S. agenda, the failure to get one last concession in the IP chapter may be the straw that breaks the camel's back because of a strong rejection by Republicans in Congress. Indeed, one of the U.S. Senate's most dependable proponents of trade liberalization has set up a major roadblock to approval of the Agreement if a more stringent IP protection is not included. Senator Orrin Hatch of Utah, president pro tempore of the Senate and chairman of the Finance Committee, joined with U.S. drugmakers to insist on the U.S. standard of 12 years of data exclusivity for biologics as a precondition

for the TPP's approval. Taking the contrary view, Nobel Prize-winning economist Joseph Stiglitz has decried imposing strict U.S. standards on medicines because it could result in "thousands and thousands of people who will die and thousands and thousands of people who will have a different quality of life" because they would be unable to obtain access to affordable medicine as a result.⁷ The outcome of this debate clearly matters.

The negotiation over the length of data exclusivity has complicated the TPP negotiations for nearly six years. The compromise reached in the final TPP Agreement establishes a baseline of five years' protection for the drugs, with language that could eventually, as expected by U.S. negotiators, bring the protection period up to at least eight years.⁸

While this particular compromise has risen to the level of brinksmanship, it is just the most prominent of a number of issues in the IP Agreement that symbolize the complicated and controversial nature of the advances made in setting international standards for IP through trade agreements.⁹ It is the aim of this paper to examine the nature of the progress of IP in the TPP. I cannot review in depth the many details of the Agreement, which are far too extensive to describe within this essay. The goal here is to consider the policy problems and consequences from such an ambitious application of a U.S.-level IP regime on the diverse membership of the TPP. A sophisticated IP system in any nation comes from a long evolutionary struggle to design the legislation, regulatory implementation, and adjudicatory processes necessary to tailor the law and its enforcement to commercial realities and to resolve disputes. It has no end point, but is a constant ongoing process conducted in a highly political arena.

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To impose this moving target on a diverse set of nations, some with neither a history of IP protection nor the infrastructure to implement it, is a challenging task for both demanding and responding nations. Effective IP protection—that which best balances the social benefits to costs—will be different in each country. Imposing a one-size-fits-all IP protection scheme as part of a trade agreement must compromise effectiveness to practicality in a way that makes the compact both logically and politically challenging for every nation. In the United States, for instance, the domestic power struggle for certain IP laws and the resulting internal conflict over U.S. compromises in the TPP agreement may derail the trade agreement.

THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY PROTECTION

IP protection is a policy intended to promote economic growth through innovation and designed to balance the incentive to innovate against the societal gains of diffusion of innovation.¹⁰ Specifically, it creates monopolies for innovators to capture high profits in order to encourage more innovation. Society limits the duration of these monopolies to encourage diffusion of new discoveries and engender the competition that makes the fruits of innovation accessible at lower prices and better quality. This benefits both industry and consumers generally, who realize lower prices as a result of greater competition among firms able to use the more broadly diffused, unprotected technology. While the concept is simple, its application is extremely difficult.

IP policy is designed, constructed, and implemented in a messy world of politics, rent-seeking, and litigation.¹¹ There are huge profits to be made or lost depending on how strongly IP is protected, how long protections last, and what

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requirements society imposes on if and how IP is mandatorily licensed. Benefits can shift massively depending on how courts interpret these laws. How these laws are finally structured in a democracy will often be determined by

the most influential lobby. With rapid globalization and numerous trade agreements, IP policies and regulatory regimes are increasingly determined by the most effective negotiators in complex trade agreements. As a result, even the best policy prescriptions are unlikely to maximize overall gains to society.

Moreover, socially optimal IP protection is a dynamic target. First, the balance between permitting monopoly and encouraging diffusion that maximizes the overall benefits to society is different depending on where a nation's economy stands along its development path. For knowledge-based economies like the United States, rewarding innovators with substantial monopoly grants pays off handsomely in new technology that can quickly be capitalized. For developing economies like Vietnam, on the other hand, rapid diffusion of the fruits of innovation offers greater benefit than protecting innovators' monopoly profits, even ignoring the hundreds of millions of dollars required to set up and administer even a crude IP protection system. The logic is straightforward: Developing countries like Vietnam do not yet have the industrial, academic, or innovative infrastructures to produce much IP or to utilize it to the same extent that they can commercially exploit others' IP. They are developmentally structured to need to be able to take economic advantage of others' patented technologies, industrial designs, protected software, and more sophisticated but undisclosed manufacturing processes. As a result, developing economies tend to benefit more from the diffusion of IP than from protection of indigenous IP, at least until they begin producing a sufficient amount of their own IP to change that balance. This social calculation changes over time. First, developing countries realize they need at least rudimentary protection of IP to encourage foreign direct investment critical to economic growth. Vietnam is entering this stage. Eventually countries reach a point (such as Japan in the late 1970s and China today) where indigenous innovation is sufficient (or sufficiently desirable) to warrant more robust IP protection.

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Furthermore, the appropriate policy depends on the industry. For instance, while it may be optimal to grant U.S. pharmaceutical manufacturers 20 years of patent protection, it is not at all clear that economic welfare is best served by the same patent protection in advanced electronics. In modern electronics or software, the production life cycle is limited to months, and technologies are typically bundled in pools with scores of potentially patented or patentable technologies and designs all intimately related. These relationships vary across different industries.¹²

In addition, as knowledge-based economies become increasingly creative, the most appropriate IP protection becomes even more difficult to define. It has become harder to predict its direction, more complicated to implement, and more valuable to individual companies who gain it. For example, among the most active patent seekers in the United States today are banks and financial intermediaries, who find themselves aggressively competing with Silicon Valley

entrepreneurs entering digital finance. Big U.S. banks and payment networks are applying for more patents than ever before on everything from mobile wallets to blockchain ledgers like those used for the digital currency Bitcoin.¹³ A court ruling in 1998 opened the door to business method and software patents, including theretofore disallowed finance patents. Bank of America now holds a portfolio that includes patents on blockchains, a wearable financial indicator, and automated teller machines that can be operated by a smartphone. MasterCard applied for 500 patents last year, up from 50 in 2010.¹⁴ Financial institutions were awarded nearly 1,200 patents over the past three years, up 36 percent from the previous three years, after they faced a lawsuit challenging the way banks and payment networks encode and transmit data related to billions of transactions every day. These were practices that had historically been maintained simply as closely held internal processes. Dozens of lawsuits followed, forcing banks, like the tech companies that invaded the financial market, to become serious about IP protections for all phases of their business.

Moreover, innovators have become increasingly demanding about appropriating the value of their creations. This has led to an expansion of claims for IP “rights” that is remarkable for its creative breadth. Keith Maskus catalogues a number of troubling, if often amusing, cases that make this point. An NBA basketball coach holds the trademark to the phrase “three-peat” (referring to winning the NBA three times in a row; he did not); an NFL team claims trade-

mark protection for the question “Who Dat?”; only T-Mobile can use a certain shade of pink in its advertisements and packaging. The Soloflex Company owns exclusive rights to market exercise equipment and related goods under the phrase “exercise and eat

right.” When Mickey Mouse was reaching the 50 year limit to his trademark protection, Congress upped it to 70 years, which, of course, is now the rule pushed into the TPP.¹⁵

For these reasons, a functioning IP protection system is becoming harder and more expensive to create and administer. The number of petitions for patents, copyrights, and trademarks is exploding. The World Intellectual Property Organization (WIPO) reports that for 2014, 2.7 million patents were granted worldwide—a fifth straight year of growth. More than 10 million are outstanding, and trademarks have doubled since 2000. Plant variety applications

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hit record levels.¹⁶ Institutional structures cannot handle the rapidly growing demand even in well-established, sophisticated systems like that of the United States. As a result, many patents and trademarks that are granted have questionable validity. Consumer rights advocacy group Public Citizen, using data from the U.S. Patent Office, finds that 78 percent of reexamined patents have serious problems with their original claims.¹⁷ Often, invalidity is established only after litigation, which is a rapidly growing, expensive, and disruptive form of dispute resolution—increasing in the United States by 25 percent from 2012 to 2013.¹⁸ Such litigation will grow rapidly in any country with a functioning IP regime. In a developing economy, nascent institutions and processes, overzealous patenting, and growing levels of litigation could result in substantially greater costs than benefits. For the TPP's IP ambitions to have a hope of helping the developing economies, the advanced economies demanding these reforms will have to provide significant and ongoing capacity-building support.

GLOBALIZING A MODERN IP PROTECTION REGIME

It is difficult enough, as the previous discussion shows, to create a competent IP protection regime within a single country. The problems compound quickly when trying to impose a unified regime across nations as different as the TPP members. Trade agreements imposing broad IP protections across diverse economies and political systems are unlikely ever to approach optimal policy in any country. In addition, FTAs like the TPP are integrating these diverse economies by, for example, opening financial services, e-commerce and digital services trade, and the services supporting supply chains from Hanoi to New York.

The TRIPS Agreement was completed before the Internet and before the explosion of e-commerce and global value chains. The TPP IP chapter is a detailed legal construction three-times longer than TRIPS that commits members to a substantially more rigorous compact. A significant component of the TPP's "New Features" touted by the U.S. Trade Representative (USTR) is more extensive and demanding enforcement of IP law, including broadening criminal liability.

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levels of protection that each government has to give to the IP of other WTO members. More rigorous enforcement can be imposed, but not less. The TRIPS agreement details standards concerning the availability, scope, and use of intellectual property rights, covering (1) copyright and related rights trademarks, (2) geographical indications, (3) industrial designs, (4) patents, (5) layout designs (topographies) of integrated circuits, (6) protection of undisclosed information, and (7) control of anti-competitive practices in contractual licenses. In addition, it set out requirements for the enforcement of intellectual property rights with (1) civil and administrative procedures and remedies, (2) provisional measures to prevent infringement by keeping violating goods out of the stream of commerce, (3) special requirements related to border measures, and (4) the incorporation of criminal procedures applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. The TRIPS agreement sets out a basic policy structure required for comprehensive IP protection and calls for, but does not specify in detail, a regulatory and adjudicatory system to implement it. The more powerful dispute settlement mechanism created within the WTO provides an avenue for members to punish violators of IP, creating a unique vehicle to ensure compliance.¹⁹

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The TPP moves further—pushing an ambitious agenda to create a global trading environment more secure for high-technology exports. Among the new features in TPP touted enthusiastically by the USTR are (1) criminal penalties for trade secret theft, including hacking and (2) measures to ensure that state-owned enterprises (SOEs) are covered, notably regarding protection of trade secrets.²⁰ U.S. FTAs established criminal penalties against trademark counterfeiting and copyright piracy consistent with U.S. law. The TPP breaks new ground by addressing cross-border supply chains of counterfeit and pirated goods, including activities that threaten health and safety. The TPP also expands enforcement of IP to online commerce and digital products. It ensures that the existing systems, such as those upon which rights holders, Internet service providers, and consumers have come to rely for digital trade, can stay in place. It ensures copyright exceptions and limitations to permit use of copyrighted materials (“fair use”) for comment, news reporting, teaching, scholarship, and research. It prevents domain name cybersquatting in connection with a member’s country-code top-level domain name registration system. Cybersquatting (also known as domain squatting), according to the U.S. federal law known as the Anticybersquatting Consumer Protection Act, is “registering, trafficking in, or using an Internet domain name with bad faith intent to profit from the goodwill of a trademark belonging to someone else.”²¹ Appropriate remedies are available

in cases of bad faith registration of domain names that are confusingly similar to registered trademarks.

The TPP supports greater cooperation activities especially targeting (1) issues relevant to small and medium-sized enterprises, (2) technical assistance for developing countries, and (3) the exchange of information on patent office search and examination results. The TPP will enhance discipline on the overly expansive use of geographical indications as protection against imports, especially in agriculture. More controversial are specific rules related to biologic medicines. The TPP provides a minimum standard of eight years of data protection (exclusivity), but with an option to deliver a comparable outcome through a combination of at least five years of data protection measures and a somewhat unclear provision to use a country's "other measures" (e.g., regulatory procedures or administrative actions) for an additional three years of protection.

The highly contentious issue of biologics and data exclusivity provides a valuable case study in the difficulty of complex trade agreements setting international rules across diverse nations. Not only did data exclusivity make IP a particularly difficult negotiation, but it also remains a deeply contentious issue in the political process in several capitals as the TPP grinds toward approval.

Biologics, at the cutting-edge of biomedical research, are biological medicines produced from living organisms (natural human, animal, or microorganism sources), such as vaccines, blood components, gene therapy products, living cells and tissues, and recombinant therapeutic proteins.²² Biologics are controversial because they present a difficult free rider problem. In contrast to most drugs that are chemically synthesized with a known chemical structure, and therefore relatively easy to replicate, most biologics are complex mixtures that require intense research and development. In order to reduce costs, manufacturers of follow-on versions (biosimilars) may seek to direct a regulator to data submitted by the originator of a biologic to support the marketing approval of their product. The data to satisfy regulatory scrutiny are extremely expensive to produce. If follow-on producers can use this data without cost—classic free riders—they have a distinct and arguably unfair advantage over the firm that had to produce the data originally.

Data exclusivity refers to the period during which data submitted to regulatory agencies cannot be used by the agency to evaluate applications for marketing approval by follow-on medicine manufacturers. The period starts when marketing approval is granted to the submitting product. It is not a patent, nor is a patent necessary in the issue of data exclusivity. As a result, any new rivals must compile their own record and clinical trial data supporting claims of safety

and efficacy. They cannot simply demonstrate equivalence to products already registered with the agency and refer to the research for those registered products. On the one hand, having to produce one's own data represents a significant cost of entry for manufacturers. On the other hand, not enforcing data exclusivity provides a significant free rider problem for first movers who bear the burden of costly research to show safety and efficacy. The difficult negotiation addresses the question of proper balance across the 12 partner nations.

In reality, domestic laws surrounding data exclusivity differ widely across the 12 partners. Some countries have no such protection. Others have varying degrees of protection. In each case, the level of protection is determined by

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the relative power of special interests in the domestic political process. For instance, Australian law currently provides for five years of data exclusivity for medicines, including biologics (except where the active component

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of the medicine has previously been included in a registered medicine).²³ U.S. law grants 12 years. President Obama has pushed on many occasions to reduce data exclusivity in U.S. law to seven years. Many consumer advocacy groups have supported this effort in a hard-fought political contest in Washington. The industries benefitting from the longer periods of protection have prevailed so far in Congress. The TPP Agreement brought home by President Obama is a clear compromise from the position Congress has laid out in U.S. law. While U.S. law will still prevail in the United States (the TPP sets minimum requirements), advocates of the 12-year exclusivity period want it imposed on all TPP partners.

From an initial negotiating position demanding 12 years of data exclusivity, the U.S. negotiators settled for eight years. Senator Hatch has made it clear that he will oppose the TPP if it does not establish a 12-year exclusivity period. Australian and Chilean negotiators, among others, have adamantly opposed such a measure. Indeed, it will already be difficult for these countries to adjust their laws to incorporate the additional three years that has been negotiated. A 12-year exclusivity period appears impossible.²⁴

Losing the support of a Republican leader in the Senate, who has traditionally been a keen supporter of trade, may be a death knell for the TPP, which already faces significant hurdles. The leading presidential candidates for both parties are strongly opposed to the TPP for many reasons. Senator Mitch Mc-

Connell, majority leader of the Senate, calls for “intense scrutiny” of the TPP, and Senator Robert Portman, former USTR, demands stronger tools to fight currency manipulation.²⁵

CONCLUSION

The IP Chapter of the TPP could make an important contribution to a more robust international IP system by pushing the TRIPS-plus agenda to an important group of trading nations. It was hard to negotiate; it may prove even harder to push through the political process in most of the capitals of the TPP members. For the advanced nations, more rigorous and more closely harmonized IP systems should prove valuable in reducing transaction costs to firms and promoting innovation.

The TPP will be extremely difficult to implement and administer in those countries at which it was primarily aimed: those without established and sophisticated IP protection. A modern IP protection system requires competent patent and trademark administration. Competency means substantial science and engineering educational capability to train officials to properly evaluate innovation. It requires competent administration of the bureaus conducting the evaluations. It will require a sophisticated adjudicatory system to handle the inevitable disputes, including judges and attorneys trained in both the science and law critical to proper IP adjudication.

While a TRIPS-plus agreement, in theory, has great potential to promote innovation and development, it will certainly impose costs: building the enforcement and regulatory infrastructure necessary to implement an IP system; retarding valuable diffusion of innovation and technology; imposing transaction costs on economic activity; and creating new opportunities for rent-seeking. To make this a welfare-enhancing endeavor will require the developed countries to devote a substantial amount of time, expertise, and funding to build competent capacity in the partners for whom these WTO-plus requirements will have the largest impact. 

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NOTES

1. The Uruguay Round was the eighth in the series of multilateral negotiations since the Bretton Woods Agreement launched the General Agreement in Tariffs and Trade (GATT) in 1947. The first seven focused on reducing tariffs and quotas on industrial goods. Agriculture and Textiles were too politically sensitive to even be included. The Uruguay Round Agreement (URA), however, brought these two industries into the negotiation, created the WTO, and laid the foundation for the modern rules-based trading system. The URA includes the Trade Related Intellectual Property Agreement, the General Agreement in Trade in

Services, an Agricultural Agreement, along with the complementary Sanitary and Phyto-Sanitary Agreement, the Textiles Agreement, Agreement on Subsidies and Countervailing Measures, and a substantially more rigorous Dispute Settlement Understanding, as well as a regularly scheduled mandatory peer review monitoring process, mandatory biennial Ministers meetings and other important agreements.

2. "The TransPacific Partnership: What's at Stake," The White House.

3. Two studies recently have provided contradictory results. Peter Petri and Michael Plummer, "The Economic Effects of the Trans-Pacific Partnership: New Estimates" (Working Paper Series, 16-2, Peterson Institute for International Economics, January 2016) finds that the TPP will increase annual real incomes in the United States by \$131 billion, or 0.5 percent of GDP, and annual exports by \$357 billion, or 9.1 percent of exports, over baseline projections by 2030. Annual incomes gains by 2030 will be \$492 billion. Less sanguine results are found by: Jerome Capaldo et al., "Trading Down: Unemployment, Inequality and Other Risks of the Trans-Pacific Partnership" (Global Development and Environment Institute, Tufts University, Working Paper No. 16-01, January 2016). Allowing for changes in employment and income distribution, the authors find that the benefits to economic growth from the TPP are even smaller than those projected with full-employment models, and are negative for Japan and the United States. More importantly, they find that the TPP will likely lead to losses in employment and increases in inequality.

4. The TTIP is the ongoing negotiation between the United States and the European Union. Because trade is broadly open between these two markets, the negotiations are focused on cooperation and synchronizing regulatory systems. The TiSA is a group of WTO members frustrated by the slow pace of Services negotiations in the Doha Round who have created their own separate Services negotiations. The United States and China are negotiating a BIT. This is a negotiation common among nations to agree on the rules for dealing with private investment across the two nations. It is often a preliminary agreement leading to a Free Trade Agreement negotiation.

5. For instance, see: "Trade Watch," Public Citizen.

6. The TRIPS agreement in the URA broke entirely new ground by bringing a broad range of intellectual property under WTO discipline. Copyright covers artistic and literary works and computer software and data bases, including related rights for performers, phonogram producers, and broadcasters. Industrial property was defined and protected, including Trademarks, Geographical indications, Industrial designs, Patents, Plant varieties protection, Topographies of integrated circuits, and Undisclosed information (e.g., trade secrets and test data). It specified levels of protections (e.g., patents for 20 years), enforcement requirements, and timing of requirements for enforcement (varied by level of economic development).

7. "Stiglitz Urges Other TPP Parties Not To Cave To U.S. Demands on Drug IP," *Inside U.S. Trade's China Trade Extra*, January, 30, 2015. Stiglitz argues as well that imposing the U.S. standard will not create new jobs but rather restrict output, and hence jobs, while only improving profits for producers holding the government enforced monopoly.

8. Doug Palmer, "Orrin Hatch holds cards to trade deal," *Politico*, October 19, 2015.

9. "A Very Big Mistake": Joseph Stiglitz Slams Obama for Pushing the TPP," interview by Amy Goodman, *Democracy Now*, November 12, 2015.

10. For brevity, I will use the term *innovate* to capture the broad range of innovation and creativity that is captured in modern IP protection found in trade agreements. The TRIPS agreement covers patents and copyright rights—covering content producers including performers, producers of sound recordings, and broadcasting organizations—to geographical indications, industrial designs, integrated circuit layout-design, new plant varieties, trademarks, trade dress, and undisclosed or confidential information.

11. "Rent-seeking" is the act or process of using one's assets and resources to increase one's share of existing wealth, often through advocating for favorable laws or regulations, without creating new wealth. See: Keith Maskus, *Private Rights and Public Problems: The Global Economics of Intellectual Property in the 21st Century* (Washington, DC: Peterson Institute, 2012) and bibliographical cites therein; Eli Dourado and Alex Tabarrok, "Public Choice Perspectives on Intellectual Property," *Public Choice* 163, no. 1 (2014): 129–51.

12. Bruce Lehman, *The Pharmaceutical Industry and the Patent System* (International Intellectual Property Institute, 2003).

13. Susan Dexter and Elizabeth Dekheimer, "Wall Street is Trying to Beat Silicon Valley at its Own Game," *Businessweek*, February 11, 2016; "Can You Patent This?," *Businessweek*, February 9, 2016.

14. Ibid.

15. Maskus, *Private Rights and Public Problems*, 5. Japan, for instance, will have to update its patent and copyright laws so that they align with TPP standards. Japan currently limits copyright protection to 50 years after the author's death. The TPP requires 70 years. Opposition groups claim that the longer protections will adversely impact certain materials, such as those that are freely usable because the current 50-year copyright has expired. These may have to be retroactively restricted. Japanese officials are also debating whether to allow regulators to investigate and charge offenders of intellectual property rules if the author of the property did not file a complaint. Owners of material that has been misused will also be able to seek damages from the offenders. See: "Japan to Strengthen Copyright Protections in Light of TPP," *Japan Times*, November 15, 2015, <http://www.japantimes.co.jp/news/2015/11/15/business/japan-strengthen-copyright-protections-light-tppt/#.VxWPHJMrLBI>.

16. World Intellectual Property Organization, "Global Patent Filings Rise in 2014 for Fifth Straight Year: China Driving Growth," press release, December 14, 2015, http://www.wipo.int/pressroom/en/articles/2015/article_0016.html.

17. "Trans-Pacific Agreement: Harmful provisions for access to medicines," Public Citizen.

18. Chris Barry et al., *2014 Patent Litigation Study: As case volume leaps, damages continue general decline* (PricewaterhouseCoopers, 2014), 2. The median time to trial in the United States is 2.5 years: Cohen Pontani Lieberman & Pavane LLP, "US—Litigation: Cost and duration of patent litigation," *Managing Intellectual Property*, 2009. "The average patent litigation lasts about two years and costs about \$3 million. An appeal can add another \$2 million and one year to that estimate." See also: "IP Litigation Costs," Special Edition, *WIPO Magazine*, February 2010, http://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2010/wipo_pub_121_2010_01.pdf.

19. TRIPS is built on the long-standing obligations of the Paris Convention for the Protection of Industrial Property (patents, trademarks, industrial designs) formed in 1883 and the Berne Convention for the Protection of Literary and Artistic Works (copyrights) in 1886. These two conventions combined in 1893 to form the Bureaux for the Protection of International Property, known as BIRPI, which was recast as the WIPO in 1970 and joined the United Nations in 1974. By the 1980s, rapid globalization and growing reliance on IP by industries in advanced economies created the impetus to push trade negotiators to seek a more rigorous and enforceable IP protection. The key innovative enforcement feature that makes including IP in trade agreements so powerful is the dispute settlement agreement, which permits a nation falling victim to a lack of IP enforcement by another member to impose trade sanctions, such as a punishing tariff on a strategically selected set of imports from the violating country. The TPP provides a panel process for dispute resolution. This is substantially less rigorous than the WTO Dispute Settlement Understanding, which provides for a three-judge panel and an appeal process to the WTO Appellate Board. Final determinations are automatically imposed and permit the victim nation to impose costly trade sanctions.

20. This list is adapted from USTR's discussion of the IP Chapter. U.S. Trade Representative, "The Trans-Pacific Partnership," *Medium*, <https://medium.com/the-trans-pacific-partnership/intellectual-property-3479efdc7adf#.y4f8cfvni>.

21. U.S. Congress, Senate, *The Anticybersquatting Consumer Protection Act*, August 5, 1995, 106th Cong., 1st sess., Senate Report 106-140.

22. Patent protection is up to 25 years in Australia for pharmaceutical products. Baker & McKenzie, *Trans-Pacific Partnership (TPP) and data exclusivity for biologics* (Baker & McKenzie, August 19, 2015), <http://tpp.bakermckenzie.com/wp-content/uploads/2015/10/Trans-Pacific-Partnership-and-data-exclusivity-for-biologics-17-Aug-2015.pdf>.

23. Section 25A of the *Therapeutic Goods Act* (TGA).

24. In both Chile and Australia, the political decision, reflected in their laws, has determined that the shorter exclusivity period is appropriate. To change that would require both a difficult political battle and legal and regulatory changes to implement it, which neither country appears willing to undertake. Increasing the data exclusivity period by three years in Australia, for instance, will require an amendment to the TGA, which would need to pass through the House of Representatives and the Senate. If the Australian Government (along with the other parties) agrees to the TPP, it would be required to implement its terms. While there are a number of permutations, the likely procedure is as follows. The TPP text must be tabled

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in Federal Parliament. The Joint Standing Committee on Treaties then conducts an inquiry into the TPP and will table a report in Parliament that will recommend whether Australia should take action to be bound by the TPP terms. Amendments to law would then need to be passed by Parliament (including expected amendments to the TGA) before Australia could confirm with the other TPP members that the TPP had entered into force. The Australian government would face embarrassment if it agreed to the TPP but, due to Parliamentary opposition, could not fully implement the TPP. For a more thorough description, see: Baker & McKenzie, "Trans-Pacific Partnership."

25. Jordain Carney, "McConnell vows 'intense scrutiny' of trade deal," *The Hill*, October 5, 2015; Rob Portman, "Portman Urges Obama Administration to Stand Up for Ohio Workers, Address Currency Manipulation Before TPP Vote," news release, Rob Portman, January 25, 2016.