

SCALING BACK TRIPS-PLUS: AN ANALYSIS OF INTELLECTUAL PROPERTY PROVISIONS IN TRADE AGREEMENTS AND IMPLICATIONS FOR ASIA AND THE PACIFIC

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I. INTRODUCTION

The rapid transformation of the East Asian developmental states from agricultural to advanced economies in the late twentieth century has served as a case study for development theorists around the world.¹ Studies of the Asian experience have cast doubt on the assumption that rule of law is a prerequisite to economic growth,² and have illustrated that intellec-

1. See, e.g., THE DEVELOPMENTAL STATE, xi (Meredith Woo-Cumings ed., 1999) (aiming “to understand the historical interplay of forces—historical, political, market, security—that have determined the structure of opportunity in East Asia, which situated and launched the different nations of the area in a path-dependent manner”).

2. See, e.g., John K. M. Ohnesorge, *The Rule of Law, Economic Development, and The Developmental States of Northeast Asia*, in LAW AND DEVELOPMENT IN EAST AND SOUTHEAST ASIA 91, 92 (Christoph Antons ed., 2003) (evaluating rule of law and economic growth in post-World War II Northeast Asian coun-

tual property protection may not be appropriate at all levels of development.³ Even in developed countries, laws that afford strong protection to rights-holders require a careful balancing of interests prior to adoption.⁴ In spite of the decidedly divergent priorities and needs of different states, intellectual property laws have become increasingly uniform in content. The World Trade Organization's (WTO) 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) established a uniform baseline for global intellectual property standards.⁵ Over the past ten years, a new trend has developed in which bilateral trade agreements mandate changes to domestic intellectual property laws, resulting in laws that exceed the standards agreed to at the WTO. These agreements are referred to as "TRIPS-plus." Understanding the implications of these provisions is crucial, as they result in significant social and economic costs that reach far beyond the intellectual property industry.

This Note examines TRIPS-plus preferential trade agreements (PTAs)⁶ in the Asia-Pacific region, and argues that these agreements are not an appropriate vehicle for intellectual property lawmaking. Part II briefly introduces the debate on the relationship between intellectual property protection and development and provides background on the present and historical use of trade agreements to raise intellectual property protection around the world. Part III analyzes the TRIPS-plus provisions in agreements signed with Asia-Pacific countries

tries and concluding that "present Rule of Law-economic development rhetoric . . . doesn't reconcile easily with the Northeast Asian experience").

3. *Id.* at 103 (contending that given the experiences of the Developmental States, "it seems absurd to argue that effective [intellectual property rights] protection is intrinsically necessary to economic development").

4. Rochelle C. Dreyfuss, *TRIPS – Round II: Should Users Strike Back?*, 71 U. CHI. L. REV. 21, 22 (2004) [hereinafter Dreyfuss, *TRIPS – Round II*].

5. WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

6. A note on terminology: "Preferential trade agreements" (PTAs) refer generally to any bilateral or regional trade agreements that lower trade barriers between contracting parties. "Free trade agreements" (FTAs) and "economic partnership agreements" (EPAs) are technical terms that describe the preferential trade agreements that have been pursued by the United States and Japan, respectively.

and compares them to the terms found in TRIPS. This analysis is based on a survey of all preferential trade agreements in force in the region as of 2008. It establishes that Asia-Pacific PTAs exceed TRIPS standards in four main areas: accession to international intellectual property agreements, domestic enforcement of intellectual property terms, patenting of pharmaceuticals, and patenting of life forms. This Note demonstrates how TRIPS-plus provisions result in grave economic and social costs to stakeholders who are not represented at the negotiation table. Part IV examines the case of the United States, the most aggressive advocate of TRIPS-plus provisions in bilateral trade negotiations, and argues that it is in the United States' own interest to alter its TRIPS-plus trade strategy.

The Asia-Pacific region was selected as the focus of this Note because it presents a particularly useful setting for studying the implications of TRIPS-plus trade agreements. The region is home to a large number of countries at disparate levels of economic development, possessing a wide range of bargaining power. Intellectual property plays differing roles in each society and economy; some are significant importers of various types of innovations, and others collect sizeable revenues from exports in intellectual property industries. Some rely economically on the counterfeited goods market, and some depend critically on the accessibility of generic pharmaceuticals. Despite these diverse conditions, the intellectual property provisions to which governments have agreed are closely replicated across countries, with only minimal variations responding to the unique circumstances in each country. Furthermore, the robust expansion of many Asian economies and the growth in intellectual property innovation and manufacturing are rapidly changing relationships between these economies and advanced Western economies with respect to trade in intellectual property. These realities highlight the need to revisit the desirability of TRIPS-plus PTAs for all parties.

II. BACKGROUND: INTELLECTUAL PROPERTY AS A TRADE ISSUE AND CONSEQUENCES FOR DEVELOPMENT

A. *The Global Debate on Intellectual Property Protection and Development*

Determining an optimal level of intellectual property protection requires a careful balancing of interests. Protection of intellectual property rights (IPRs) serves the proprietary interests of rights-holders but may also have broader economic and social value. Innovation can be an important source of national income, and the public depends on continuous research and development (R&D) for the advancement of technologies, effective medicines, and dependable food varieties. As R&D is expensive and uncertain, patent laws must provide adequate protection for innovators to recover costs and to incentivize continuous investment in progressive innovations.⁷

The positive correlation between high protection and R&D is not absolute, however. Overprotective terms may actually limit innovation; unless researchers can share data and information, the pace of technological advancement will slow.⁸ As Rochelle Dreyfuss notes, “[k]nowledge production is a cumulative enterprise; the storehouse of information does not grow unless creators have the freedom to learn from, and build on, earlier work.”⁹ Furthermore, high protection of intellectual property creates monopolies that enable rights-holders to keep prices artificially high, greatly limiting public access.¹⁰ Even in advanced economies, intellectual property lawmaking must carefully trade off private and public interests.

7. Grace K. Avedissian, *Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of “Super-Terrorism”*, 18 AM. U. INT’L L. REV. 237, 244-46 (2002).

8. See, e.g., Peter K. Yu, *TRIPS and Its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 382 (2006) [hereinafter Yu, *TRIPS and Its Discontents*] (arguing that “overprotection is just as dangerous as underprotection”).

9. Dreyfuss, *TRIPS – Round II*, *supra* note 4, at 22.

10. CARLOS M. CORREA, IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH 7 (June 2002), available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (commenting that “the patent system is designed to enable patent holders to set prices higher than those that would be obtained in a competitive market” and that these high prices “are part of the grave problems that afflict developing countries and [least developed countries]”).

The role of intellectual property protection in low-income countries is especially contentious.¹¹ Proponents of IPR protection in developing economies argue that such laws are both beneficial and essential to growth.¹² Inclusion of IPRs in trade agreements benefits developing countries by creating an efficient and secure business environment that may encourage foreign direct investment and increase technology transfers.¹³ Yet, there are several grounds for questioning whether the proclaimed benefits of intellectual property protection actually materialize in developing countries, especially as long-term returns are offset by immediate needs to access critical medicines and affordable technologies. First, it is unclear that intellectual property laws have actually resulted in increased investments and technology transfers in developing countries.¹⁴ Relative to the number of studies done on the impact of IPR protection in developed countries, comparatively little empirical data exists on the impact in developing countries,¹⁵ and the studies that have emerged show that the relationship between intellectual property protection and economic development is generally ambiguous.¹⁶ Positive results are especially rare in least developed countries (LDCs), where IPR re-

11. See generally Comm'n on Intell. Prop. Rts., *Integrating Intellectual Property Rights and Development Policy* (Sept. 2002), available at http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf (providing an in-depth discussion of the arguments that higher IPRs do not generally benefit developing countries).

12. See e.g., Kamil Idris, World Intell. Prop. Org., *Intellectual Property – A Powerful Tool for Development* (2003), available at http://www.wipo.int/about-wipo/en/dgo/wipo_pub_888/index_wipo_pub_888.html.

13. See e.g., Peter K. Yu, *From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-First Century*, 50 AM. U. L. REV. 131, 192-93 (2000) (discussing benefits of adequate intellectual property protection in developing countries).

14. Dreyfuss, *TRIPS – Round II*, *supra* note 4, at 29; see also Carsten Fink & Keith E. Maskus, *Why We Study Intellectual Property Rights and What We Have Learned*, in *INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH* 1, 2 (Carsten Fink & Keith E. Maskus eds., 2005), available at <http://siteresources.worldbank.org/INTRANETTRADE/Resources/Pubs/IPRs-book.pdf> (stressing that “many effects of stronger IPR standards are theoretically ambiguous”).

15. Daniel J. Gervais, *The Changing Landscape of International Intellectual Property*, in *INTELLECTUAL PROPERTY & FREE TRADE AGREEMENTS* 49, 62 (Christopher Heath & Anselm Kamperman Sanders eds., 2007) [hereinafter Gervais, *The Changing Landscape*].

16. *Id.* at 63.

forms are often insufficient to compensate for broader institutional deficiencies that create an unattractive business environment.¹⁷ Second, countries that have achieved high levels of growth over the past couple of decades did so in spite of, or even as a result of, low levels of IPR protection.¹⁸ Finally, as this Note seeks to demonstrate, high IPR protection is sometimes detrimental to development due to attendant economic and social costs, especially in areas of public health and agriculture.

B. *The TRIPS Agreement: Introducing Intellectual Property to the Trade Agenda*

The TRIPS Agreement was established at the end of the Uruguay Round of negotiations on the General Agreement on Tariffs and Trade (GATT) in 1994, and brought intellectual property law into the international trading system for the first time.¹⁹ TRIPS was one of the components of the Agreement Establishing the WTO, and as such, it was a part of the package countries had to accept in order to gain membership in the organization.²⁰ Today, the WTO has 153 members, 29 of

17. *Id.* at 63-64 (citing Mark A. Thompson & Francis W. Rushing, *An Empirical Analysis of the Impact of Patent Protection on Economic Growth*, 21 J. ECON. DEV. 61 (1996)).

18. See Anselm Kamperman Sanders, *The Development Agenda for Intellectual Property*, in INTELLECTUAL PROPERTY & FREE TRADE AGREEMENTS 3, 6 (Christopher Heath & Anselm Kamperman Sanders eds., 2007) (“Figures show that countries with weak protection or enforcement of IPR like Brazil and China have been more successful in attracting FDI than many developing countries that have made strong IPR central to their development strategy”) (citing Keith E. Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, in INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH 41, 54 (Carsten Fink & Keith E. Maskus eds., 2005), available at <http://siteresources.worldbank.org/INTRANETTRADE/Resources/Pubs/IPRs-book.pdf>); SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 9 (2003) (“the dramatic expansion of the scope of IP rights embodied in TRIPS reduces the options available to future industrializers by effectively blocking the route that earlier industrializers followed”).

19. World Trade Organization [WTO], Understanding the WTO – Intellectual Property: Protection and Enforcement, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Feb. 15, 2010) [hereinafter WTO, Protection and Enforcement].

20. Gervais, *The Changing Landscape*, *supra* note 15, at 51-53.

whom are located in Asia and the Pacific.²¹ TRIPS sets out minimum standards of intellectual property protection that all WTO member states are required to incorporate into their national laws,²² and as a result, it has radically changed international intellectual property law by standardizing and raising protection.²³

TRIPS contains three main features. First, it lays out substantive requirements in the areas of copyrights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits, and undisclosed information, including trade secrets and test data.²⁴ Members must apply general principles of national treatment²⁵ and most-favored-nation treatment²⁶ in these categories. Second, TRIPS establishes certain enforcement and remedial requirements.²⁷ Third, it subjects WTO members with intellectual property disputes to the mandatory jurisdiction of the WTO's dispute settlement procedures.²⁸ The Agreement embodies a level of protection previously found only in certain advanced developed countries, such as the United States and some European countries.²⁹ Given that IPRs increase prices and developing countries are predominantly *consumers* of intellectual property,

21. WTO, Understanding the WTO – Members and Observers, July 23, 2008, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm; United Nations Economic and Social Commission for Asia and the Pacific [UNESCAP], ESCAP Members and Associate Members and Status of their Membership in WTO as of February 5, 2008, http://www.unescap.org/tid/member_status.pdf.

22. WTO, Protection and Enforcement, *supra* note 19.

23. See Ruth L. Okediji, *Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection*, 1 U. OTTAWA L. TECH. J. 127, 127 (2004) (noting that TRIPS was “regarded by most commentators as the most significant development in international intellectual property”).

24. TRIPS, *supra* note 5, part II.

25. *Id.* art. 3. National treatment under TRIPS obliges member states to afford the same level of intellectual property protection to foreign nationals as it does to its own nationals. *Id.*

26. *Id.* art. 4. Most-favored-nation treatment requires that with few exceptions, members must immediately and unconditionally extend any advantage, favor, privilege, or immunity granted to a national of any other country to the nationals of all other WTO members. *Id.*

27. *Id.* part III.

28. *Id.* part V.

29. See J. Michael Finger, *Introduction and Overview*, in POOR PEOPLE'S KNOWLEDGE: PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES 1, 3 (J. Michael Finger & Philip Schuler eds., 2004); SELL, *supra* note 18, at 2

TRIPS is widely viewed as favoring the interests of net exporters of intellectual property.³⁰

While accounts of the bargaining behind TRIPS vary, the Agreement is commonly viewed as a part of a larger compromise in which developing countries committed themselves to rigorously protecting IPRs in exchange for promises of greater market access in textile and agriculture industries.³¹ Many developing countries believed that implicit in the bargain was an understanding that TRIPS would be a ceiling to U.S. demands.³² Prior to the emergence of the TRIPS Agreement, the United States relied on unilateral trade sanctions under § 301 of the Trade Act of 1974 as an enforcement mechanism if countries did not conform to desired levels of intellectual property protection.³³ TRIPS's mandatory dispute settlement process was seen as a way to protect against the unilateral actions that characterized the previous regime.

Today's turn to TRIPS-plus bilateral agreements amounts to yet another requirement that developing countries must meet in order to gain access to other markets.³⁴ Many scholars attribute the proliferation of bilateral PTAs to net exporters' forum-shopping; exporters have moved negotiations to the bilateral sphere because they can use their bargaining advantages more effectively in a one-on-one setting.³⁵ While TRIPS

(stating that the draft of TRIPS presented to the GATT Secretariat in 1988 was based on industrialized countries' existing laws).

30. See SELL, *supra* note 18, at 9 (suggesting reasons why developing countries, who are mostly net intellectual property importers, chose to sign TRIPS); Dreyfuss, *TRIPS – Round II*, *supra* note 4, at 21 (observing that the GATT negotiators who created TRIPS were focused primarily on welfare gains, and were therefore “not likely to appreciate the social importance . . . of balancing proprietary interests against public access needs”).

31. Yu, *TRIPS and Its Discontents*, *supra* note 8, at 371.

32. *Id.* at 372-73.

33. Trade Act of 1974, Pub. L. No. 93-618, § 301, 88 Stat. 1978, 2041 (codified as amended at 19 U.S.C. § 2411(a) (2006)); SELL, *supra* note 18, at 75; see also Okediji, *supra* note 23, at 134-35 (recounting bilateral measures used by the United States prior to TRIPS).

34. Okediji, *supra* note 23, at 139-40.

35. See *id.* at 141 (stating that “[t]he new bilateralism [of the U.S.] is clearly a tool to effectuate the benefits of forum shifting”); Peter Drahos, *Expanding Intellectual Property's Empire: The Role of FTAs*, at 7 (Nov. 2003) [hereinafter Drahos, *Expanding Intellectual Property's Empire*], available at http://www.grain.org/rights_files/drahos-fta-2003-en.pdf (noting that the European Union and the U.S. use FTAs to bypass dead-end debates at the

has been the target of extensive criticism,³⁶ the Agreement contains provisions that safeguard certain public interests and allow governments to prioritize public health and other public policy concerns.³⁷ For example, Article 8 protects members' rights to adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development.³⁸ These flexibilities have been re-affirmed in the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration)³⁹ and have been highlighted by the work of scholars who have argued for a pro-development interpretation of TRIPS.⁴⁰ TRIPS-plus PTAs eschew these flexibilities.⁴¹

C. *Asia-Pacific Trade Agreements with Intellectual Property Provisions: A Snapshot*

To date, there has been a dearth of legal scholarship examining and evaluating the specific provisions of TRIPS-plus PTAs. This Note seeks to fill this gap by providing a comprehensive picture of the TRIPS-plus PTAs in the Asia-Pacific region and analyzing their impact on economic and social rights. The analysis presents the results of a survey of all PTAs with intellectual property provisions in force in Asia and the Pacific as of 2008.⁴² Of the nearly 100 PTAs in force, approximately forty contained provisions on intellectual property. The vast majority of these were signed after the year 2000. The appearance of intellectual property provisions in PTAs is thus

TRIPS Council and target specific countries in which they have particular interests).

36. Yu, *TRIPS and Its Discontents*, *supra* note 8, at 370 (noting that "many less developed countries have been dissatisfied" with the TRIPS system's failure to "consider [] their needs, interests, and local conditions").

37. Charles T. Collins-Chase, Comment, *The Case Against TRIPS-Plus Protection In Developing Countries Facing AIDS Epidemics*, 29 U. PA. J. INT'L L. 763, 770-71 (2008); Okediji, *supra* note 23, at 1.

38. TRIPS, *supra* note 5, art. 8.

39. WTO, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

40. See, e.g., Yu, *TRIPS and Its Discontents*, *supra* note 8, at 389-92.

41. See generally Okediji, *supra* note 23 (discussing the challenges that bilateralism presents for developing countries).

42. This research relied on data gathered from the UNESCAP Trade and Investment Agreements Database, http://www.unescap.org/tid/aptiad/agg_db.aspx (last visited Feb. 15, 2010).

a recent phenomenon; it began only after TRIPS was agreed upon at the WTO in 1994. More than half of the PTAs that have entered into force since 2000 now include IPR provisions, suggesting a trend towards inclusion of IPRs in PTAs.

IPR provisions in Asia-Pacific trade agreements exceed TRIPS terms in four main areas. First, many PTAs compel accession to, or compliance with, international intellectual property conventions that are not contained in TRIPS. Second, PTAs call for strengthened intellectual property enforcement procedures and penalties. Third, they provide extended protection of pharmaceutical patents and data and restrict policy options for designing domestic intellectual property laws on parallel imports. Finally, they limit the flexibility found in TRIPS with regards to plant patenting. The first two types of provisions require costly investments in legislative reforms and the development of specialized institutions—investments that benefit net exporters while placing burdens on countries with limited resources and pressing budgetary needs. The latter two bind countries to structures that hinder the fulfillment of economic and social rights and limit governments' abilities to respond to public health crises, food shortages, and other public needs.

The PTAs with the most consequential TRIPS-plus provisions are agreements pursued by the United States, Japan, and members of the European Free Trade Association (EFTA).⁴³ It is noteworthy that these parties were the crafters of the GATT draft that eventually resulted in TRIPS,⁴⁴ the agreement that developing countries believed would be the ceiling to externally imposed IPR obligations.⁴⁵ U.S. free trade agree-

43. EFTA is a European trade bloc set up for the promotion of free trade and economic integration. EFTA, <http://www.efta.int/> (last visited Feb. 15, 2010). The four EFTA members are Iceland, Liechtenstein, Norway, and Switzerland. *Id.*

44. *See* SELL, *supra* note 18, at 96-97 (pointing out that the first proposal for TRIPS presented to the GATT Secretariat in 1988 was crafted by the U.S.-based twelve-member Intellectual Property Committee and its counterparts in Europe and Japan).

45. *See* Okediji, *supra* note 23, at 140 (noting that TRIPS-plus FTAs have shattered the hope of developing countries that TRIPS “would diminish the use of bilateralism to secure international intellectual property protection”); Kaitlin Mara, *Stronger IP Enforcement Finds a Home in Bilateral Trade Agreements*, Apr. 21, 2009, <http://www.ip-watch.org/weblog/2009/04/21/stronger-ip-enforcement-finds-home-in-bilateral-trade-agreements/> (citing Henning Gross

ments (FTAs) are most comprehensive in their coverage of intellectual property and frequently contain TRIPS-plus provisions in all of the four categories. These provisions reproduce standards found in U.S. intellectual property law.⁴⁶ While IPR chapters in Japan's PTAs are not nearly as extensive in their coverage, plant patenting is a central feature.⁴⁷ Finally, EFTA's agreements are mainly TRIPS-plus in their inclusion of accession requirements to various intellectual property conventions not contained in TRIPS. On the other hand, PTAs between net importing countries have much more modest intellectual property chapters.⁴⁸ They commonly contain vows to increase cooperation in enforcement and public intellectual property protection campaigns,⁴⁹ but these clauses are not considered TRIPS-plus for the purposes of this Note due to their aspirational and ambiguous nature. The proliferation of TRIPS-plus PTAs is thus driven by net exporters; similar provisions are not found in agreements between importers in the region.⁵⁰

Ruse-Kahn of the Max Planck Institute as arguing that some TRIPS provisions created a mandatory ceiling to intellectual property protection).

46. See, e.g., Carsten Fink & Patrick Reichenmiller, World Bank Group, *Trade Note 20: Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements*, at 4, Feb. 7, 2005, available at <http://siteresources.worldbank.org/INTRANETTRADE/Resources/Pubs/TradeNote20.pdf> (noting that most copyright provisions in U.S. FTAs are based on the U.S. Digital Millennium Copyright Act).

47. See Part III.C, *infra*.

48. Compare Comprehensive Economic Cooperation Agreement between the Republic of India and the Republic of Singapore, India-Sing., ch 11, Jun 29, 2005 [hereinafter India-Singapore CECA], available at http://www.eicindia.org/eic/certificates/FTA_CECA_Agreement.pdf (including only two articles on intellectual property cooperation), with United States – Singapore Free Trade Agreement, U.S.-Sing., ch 16, Jan. 15 2003 [hereinafter U.S.-Singapore FTA], available at http://www.ustr.gov/sites/default/files/uploads/agreements/fta/singapore/asset_upload_file708_4036.pdf (including ten articles on intellectual property rights).

49. For examples of such provisions, see Thailand-Australia Free Trade Agreement, Thail.-Austl., arts. 1304 and 1305, July 5, 2004, available at http://www.thaifta.com/english/fa_thau.pdf and India-Singapore CECA, *supra* note 48, art. 11.2.

50. See Peter Drahos, *Weaving Webs of Influence: The United States, Free Trade Agreements and Dispute Resolution*, 41(1) J. WORLD TRADE 191, 196-97 (2007) [hereinafter Drahos, *Weaving Webs of Influence*] (observing that PTAs “that do not have the United States as a party contain much more modest chapters

Table I below provides a summary of significant TRIPS-plus features found in Asia-Pacific PTAs pursued by the United States, Japan, and EFTA.⁵¹ These TRIPS-plus terms are found in agreements with both developing trade partners (e.g. Vietnam and Laos) and developed trade partners (e.g. Australia and Singapore). Part III analyzes the terms with both types of trade partners but gives special attention to implications for developing countries. The analysis shows that only limited concessions or considerations are given to the partner country's development status, drawing attention to the need for further analysis of TRIPS-plus terms as PTAs expand to include more developing countries and LDCs.

III. COMPARATIVE ANALYSIS OF TRIPS-PLUS PROVISIONS AND THEIR IMPLICATIONS

A. *Accession to International Conventions*

The first type of TRIPS-plus terms mandate accession to international intellectual property conventions that otherwise have voluntary membership. The most commonly referenced conventions raise the level of intellectual property protection in their respective fields. Accession to such agreements should be preceded by a comprehensive national dialogue regarding the costs and benefits of such accession given the state's levels of innovation and economic development. Accession requirements in PTAs have the effect of displacing this evaluative process, which is especially problematic given the costs of such terms for the public at large.

on intellectual property" because net importers "have little to gain from raising the current international standards of protection").

51. This table builds on Carsten Fink and Patrick Reichenmiller's table summarizing "Intellectual Property Provisions of Recent US Bilateral FTAs that Go Beyond TRIPS Standards." Fink & Reichenmiller, *supra* note 46, 5-6, tbl.2.

TABLE I: COMPARISON OF TRIPS-PLUS PREFERENTIAL TRADE AGREEMENTS IN ASIA

A. United States		U.S.-Vietnam (2001)	U.S.-Singapore (2004)	U.S.-Australia (2005)	U.S.-Laos (2005)
<i>TRIPS-Plus Provision</i>					
<i>Accession to International Conventions</i>					
		Prompt effort to accede to Geneva, Berne, Paris, UPOV, and Brussels Conventions if this has not happened by the date of entry into force.	<ul style="list-style-type: none"> - Ratify Brussels Convention, UPOV, WCT, WPPT, PCT; - Give effect to Article I-6 of Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks, Trademark Law Treaty; - Best effort to ratify Hague Agreement, Madrid Protocol. 	<ul style="list-style-type: none"> - Accede to WCT, WPPT by date of entry into force - Best effort to comply with Geneva Agreement, PLT. 	Prompt effort to accede to Geneva, Berne, Paris, UPOV, and Brussels Conventions if this has not happened by the date of entry into force.
<i>Enforcement of IPRs</i>					
<i>Institutional Flexibility in IPR Enforcement</i>					
			Resource constraints cannot be invoked as an excuse for not complying with specific enforcement obligations.		
<i>Border Measures</i>					
		Apply to imported and exported goods.	Apply to imported, exported, and transiting goods.	Apply only to imported goods (similar to TRIPS)	Carve-out for goods in transit.
<i>Civil & Administrative Procedures</i>					
		Obligation to fine infringers of copyright and trademark rights irrespective of the injury suffered by rights holders.		Obligation to fine infringers of copyright and trademark rights irrespective of the injury suffered by rights holders.	Same as TRIPS

<i>Criminal Procedures & Remedies</i>	Similar to TRIPS.	Similar to TRIPS. In addition, criminal procedures apply in cases of willful infringements, not only for a financial gain, and specifically for knowing trafficking in counterfeit labels affixed to certain copy-righted works.	Same as TRIPS
Protection of Patents and Pharmaceutical Data			
<i>Patent Terms</i>	- 20 years from date of filing; - Extensions may be given for delays caused by regulatory approval process.	Extension available for up to 5 years for delays caused by regulatory approval process that exceed 4 years from the filing of the application.	- 20 years from date of filing; - Extensions may be given for delays caused by regulatory approval process.
<i>Second-Use Patents</i>		Patents shall be available for any new uses or methods of using a known product.	
<i>Compulsory Licensing</i>	Limited to national emergencies, as antitrust remedy, and for public non-commercial use.		Same as TRIPS
<i>Drug Marketing Approval</i>		Marketing approval of a generic drug is prohibited during the patent term, unless authorized by the patent owner. Patent holder must be notified of the identity of the generic company requesting marketing approval.	
<i>Test Data Protection</i>	Data exclusivity for a 'reasonable' period, normally not less than 5 years.	Data exclusivity for 5 years. Where drug regulators rely on foreign marketing approvals, data exclusivity applies automatically at home.	Data exclusivity for a 'reasonable' period, normally not less than 5 years.
<i>Parallel Imports/Exhaustion</i>		Patent holders may limit parallel imports through licensing contracts or other means.	

<i>Patenting of Life Forms</i>				
	Japan-Malaysia (2006)	Japan-Thailand (2007)	Japan-Indonesia (2008)	Japan-Philippines (2008)
	Certain plants and animals may not be excluded from patentability.	No general exclusion of plants and animals from patentability.	Exclusions only allowed for moral, health and safety reasons.	No general exclusion of plants and animals from patentability.
B. Japan				
<i>TRIPS-Plus Provision</i>				
<i>Accession to International Conventions</i>				
			Endeavor to become party of Madrid Protocol; Rome Convention; UPOV 1991	
Enforcement of IPRs				
<i>Institutional Flexibility in IPR Enforcement</i>				
<i>Border Measures</i>	Similar to TRIPS.	Similar to TRIPS.	Apply to imported and exported goods.	Similar to TRIPS.
<i>Civil & Administrative Procedures</i>	Same as TRIPS.	Same as TRIPS.	Same as TRIPS.	Same as TRIPS.
<i>Criminal Procedures & Remedies</i>	Similar to TRIPS, in addition parties endeavor to apply to willful infringements of other IPRs.	Similar to TRIPS; in addition, utility models, industrial design, and layout designs.	Similar to TRIPS; in addition, apply to willful commercial infringements of patent rights, utility models, industrial design, and layout designs.	
Protection of Patents and Pharmaceutical Data				
<i>Patent Terms</i>				
<i>Second-Use Patents</i>				
<i>Compulsory Licensing</i>				
<i>Drug Marketing Approval</i>				
<i>Test Data Protection</i>				
<i>Parallel Imports/Exhaustion</i>				

<i>Patenting of Life Forms</i>		Parties endeavor to provide adequate protection of as many genera or species as possible within the shortest period of time in a manner consistent with international standards.	Parties endeavor to provide adequate protection of as many genera or species as possible in a manner based on international standards.	Protection of all plant genera and species consistent with UPOV.	Parties endeavor to increase the number of plant genera and species that can be protected under its laws and regulations.
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C. EFTA

<i>TRIPS-Plus Provision</i>	EFTA-Turkey (1996)	EFTA-Singapore (2003)	EFTA-Korea (2006)
<i>Accession to International Conventions</i>			
	Adherence to Budapest, Rome, UPOV (1961), Madrid by Jan 1, 1999.	Accession to Geneva Act of the Hague Agreement, WCT, WPPT, WIPO joint resolution on Well-Known Marks by Jan 1, 2005.	Accession or implementation of WPPT, WCT, Rome Convention by 2008.
<i>Enforcement of IPRs</i>			
<i>Institutional Flexibility in IPR Enforcement</i>			
<i>Border Measures</i>	Adherence to TRIPS	Adherence to TRIPS	Adherence to TRIPS
<i>Civil & Administrative Procedures</i>	Adherence to TRIPS	Adherence to TRIPS	Adherence to TRIPS
<i>Criminal Procedures & Remedies</i>	Adherence to TRIPS	Adherence to TRIPS	Adherence to TRIPS

<i>Protection of Plant and Pharmaceutical Data</i>			
<i>Patent Terms</i>	- 20 years from date of filing.	- 25 years from date of filing. - Extension given for up to 5 years for delays caused by regulatory approval process exceeding 5 years. May exclude from patentability diagnostic, therapeutic, or surgical methods.	- Compensatory term for up to 5 years for delays caused by regulatory approval process. May exclude from patentability diagnostic, therapeutic, or surgical methods.
<i>Second-Use Patents</i>			
<i>Compulsory Licensing</i>	Granting in line with TRIPS. Licenses granted on the grounds of non-working shall be used only to the extent necessary to satisfy the domestic market on reasonable commercial terms		Granting in line with TRIPS and Doha Declaration.
<i>Drug Marketing Approval</i>			

<i>Test Data Protection</i>			<p>Unless seeking approval for original products, applicants for marketing approval of pharmaceuticals and chemical products shall be prevented for an adequate number of years from relying on undisclosed test data submitted by the first applicant that utilized new chemical entities and was difficult to originate.</p>
<i>Parallel Imports/Exhaustion</i>			
<i>Patenting of Life Forms</i>			
			<p>Plant or animal varieties may be excluded from patentability, plant varieties must be protected under patent or sui generis system, in line with TRIPS.</p>

1. *Overview of International Intellectual Property Treaties*

Prior to the enactment of TRIPS in 1994, the international intellectual property framework consisted of a variety of international treaties and organizations governing numerous areas of intellectual property.⁵² The World Intellectual Property Organization (WIPO), a specialized agency of the United Nations, facilitates international protection through the administration of 24 treaties, including the Paris Convention for the Protection of Industrial Property (the Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (the Berne Convention).⁵³ These principal agreements formed the foundation for TRIPS negotiations.⁵⁴ The text of the TRIPS Agreement incorporates certain substantive provisions found in the Paris Convention and the Berne Convention⁵⁵ and makes these provisions enforceable under the WTO Dispute Settlement Mechanism (DSM).⁵⁶ Hence, WTO members are obliged to comply with the standards found in these conventions regardless of accession to the particular conventions.

WIPO classifies intellectual property conventions into three categories.⁵⁷ First are those agreements that contain substantive intellectual property standards; these include the WIPO Copyright Treaty (WCT), the WIPO Performances and Phonograms Treaty (WPPT),⁵⁸ and the International Convention for the Protection of New Varieties of Plants (hereinafter UPOV Convention).⁵⁹ Accession to the WIPO treaties is less consequential since TRIPS builds on many of the treaties' substantive provisions, whereas accession to the UPOV Conven-

52. DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 5 (2003) [hereinafter GERVAIS, *THE TRIPS AGREEMENT*].

53. World Intellectual Property Organization [WIPO], What is WIPO?, <http://www.wipo.int/about-wipo/en/what/> (last visited Feb. 15, 2010); WIPO, WIPO-Administered Treaties, <http://www.wipo.int/treaties/en/> (last visited Feb. 15, 2010) [hereinafter WIPO-Administered Treaties].

54. GERVAIS, *THE TRIPS AGREEMENT*, *supra* note 52, at 9.

55. TRIPS, *supra* note 5, arts. 2(1), 9.

56. GERVAIS, *THE TRIPS AGREEMENT*, *supra* note 52, at 124.

57. WIPO-Administered Treaties, *supra* note 53.

58. *Id.*

59. International Convention for the Protection of New Varieties of Plants, Dec 2, 1961, 33 U.S.T. 2703, 815 U.N.T.S. 89 [hereinafter UPOV], available at <http://www.upov.int/en/publications/conventions/1991/act1991.htm>.

tion entails conforming national plant variety protection (PVP) laws to a specific system.⁶⁰ The significance of UPOV is discussed further under Patenting of Plants, Part III(d) *infra*. The second category of conventions comprises global protection treaties that ensure that the international registration or filing of intellectual property will have effect in any and all other signatory states.⁶¹ These include the Budapest Treaty, the Hague Agreement, and the Madrid Protocol.⁶² Finally, there are those conventions that create classification systems that organize information concerning the respective types of IPRs, notably the Locarno, Nice, Strasbourg, and Vienna Agreements.⁶³

2. PTAs Require Accession to External Conventions

Nearly all U.S. and EFTA PTAs with Asian partners call for accession to external intellectual property conventions. Japanese PTAs generally do not, with the exception of the Japan-Indonesia Economic Partnership Agreement, which compels accession to UPOV.⁶⁴ Most of the TRIPS-plus accession terms found in Asian agreements relate to conventions in WIPO's substantive category. These conventions generally impose higher protection levels in their respective intellectual property areas than corresponding TRIPS provisions. Table II lists the accession clauses by PTA, and includes a brief description of the convention and the specific language of the clause.

By bundling accession requirements with other IPR terms, PTAs can be used as a platform for pressuring developing countries into joining additional conventions that may otherwise not be in their interest.⁶⁵ U.S. FTAs overwhelmingly require partner countries to accede to conventions of which the United States is already a member. For example, both Singapore and Vietnam have joined several conventions in compliance with their respective U.S. FTAs. Laos is currently under

60. *Id.*

61. WIPO-Administered Treaties, *supra* note 53.

62. *Id.*

63. *Id.*

64. Japan-Indonesia Economic Partnership Agreement, Japan-Indon., art. 106, Aug. 20, 2007 [hereinafter Japan-Indon. FTA], available at <http://www.mofa.go.jp/region/asia-paci/indonesia/epa0708/agreement.pdf>.

65. SANYA REID SMITH, INTELLECTUAL PROPERTY IN FREE TRADE AGREEMENTS 6 (2008).

pressure to follow suit in accordance with the U.S.-Laos FTA.⁶⁶ It is noteworthy that while Laos is not yet a WTO member, it has incurred certain TRIPS obligations vis-à-vis the United States even though it is not bound by TRIPS generally. Table II highlights accessions by countries that have followed the signing of a PTA.

TABLE II: PTA PROVISIONS & ACCESSION TO INTELLECTUAL PROPERTY CONVENTIONS

☐ = Substantive IP Conventions ☐ = Global Protection Systems
 NP = Not party to the convention

* Accession dates in bold denote those countries that acceded to an agreement after the signing of the PTA.

<i>Short Name (Year), Total No. of Parties</i>	<i>IP Area</i>	<i>PTA Accession Provision</i>	<i>Date of Accession</i>
US – Australia (2005)			
WCT (1996), 65	Copyright	Accession or ratification by date of entry into force	US- 2002, AUS – 2007
WPPT (1996), 64	Performances and phonograms		US – 2002, AUS 2007
Hague Agreement (1990 Geneva Act)	Registration of industrial designs	Best effort to comply with	Neither NP (but to HA generally)
PLT (2000)	Patents		US – Signature, AUS – NP
US – Lao P.D.R. (2005)			
Geneva Convention (1971), 76	Phonogram producers	Parties shall make prompt efforts to accede if they have not done so by the date of entry into force.	US – 1974, LAO – NP
Berne (1971), 164	Literary and artistic works		US- 1989, LAO – NP
Paris (1967), 173	Industrial property		US – 1887, LAO – 1998
UPOV (1978 or 1991)	New plant varieties		US — 1999, LAO – NP
Brussels (1974), 32	Program-carrying signals transmitted by satellite		US – 1985, LAO – NP

66. Agreement Between the United States of America and the Lao People’s Democratic Republic on Trade Relations, U.S.-Laos, art 13(2), 2005 [hereinafter U.S.-Laos FTA], *available at* <http://www.laoembassy.com/news/bta.pdf>.

US – Singapore (2004)			
Brussels (1974), 32	Program-carrying signals transmitted by satellite	Parties shall ratify or accede	US – 1985, SGP – 2005
UPOV (1991),	New plant varieties		US – 1999, SGP – 2004
WCT (1996), 65	Copyright		US – 2002, SGP – 2005
WPPT (1996), 64	Performances and phonograms		US – 2002, SGP – 2005
PCT (1984), 139 *	Patent cooperation		US – 1978, SGP – 1995
Trademark Law Treaty, 40	Trademarks		US – 2000, SGP – NP
Hague Agreement (1999)	Registration of industrial design	Parties shall make best effort to ratify or accede	US – NP, SGP – 2005
Madrid Protocol (1989), 76	Registration of marks		US – 2003, SGP – 2000
US – Vietnam (2001)			
Geneva Convention (1971), 76	Phonogram producers	Parties shall make prompt efforts to accede if they have not done so by the date of entry into force.	US – 1974, VNM – 2005
Berne (1971), 164	Literary and artistic works		US – 1989, VNM – 2004
Paris (1967), 173 *	Industrial property		US – 1887, VNM – 1949
UPOV (1978 or 1991)	New plant varieties		US – 1999, VNM – 2006
Brussels (1974)	Programme-carrying signals transmitted by satellite		US – 1985, VNM – 2006
EFTA – Korea (2006)			
WCT (1996), 65	Copyright	Ratify, accede, or apply their substantive standards by 2008.	ISL, NOR – NP, LIE – 2007, CHE – 2008 ; KOR – 2004
WPPT (1996), 64	Performances and phonograms		ISL, NOR – NP, LIE – 2007, CHE – 2008 ; KOR – NP
Rome Convention (1961), 86	Performers, phonogram producers, broadcasters		ISL – 1994 NOR – 1978, LIE – 1999, CHE – 1993; KOR – NP

EFTA – Singapore (2003)			
Hague Agreement (1999 Geneva Act)	Registration of Industrial Designs	Parties undertake to adhere to the conventions on or before 1 January 2005.	
WCT (1996), 65	Copyright		ISL, NOR – NP, LIE – 2007, CHE – 2008; SGP – 2005
WPPT (1996), 64	Performances and phonograms		ISL, NOR – NP, LIE – 2007, CHE – 2008; SGP – 2004
EFTA – Turkey (1992**)			
Budapest Treaty	Deposit of micro-organisms for patent procedure	Parties undertake to adhere to the conventions on or before 1 January 1999.	ISL – 1995, LIE – 1981, NOR – 1986, CHE – 1981; TUR - 1998
Rome Convention (1961), 86	Performers, phonogram producers, broadcasters		ISL – 1994 NOR – 1978, CHE – 1993, LIE – 1999; TUR – 2004
UPOV (1961)	New plant varieties		ISL – 2003 , LIE – NP, NOR – 1993, CHE – 1997; TUR - 2007
Madrid Agreement (1989 Protocol),	Registration of marks		ISL, NOR – NP, LIE – 1933, CHE - 1892; TUR – NP

A complete comparative analysis of each convention and its policy implications is beyond the scope of this Note. It is significant, however, that accession requirements contained in PTAs change the enforcement structure of the conventions by making adherence binding under both the convention agreement itself and the PTA.⁶⁷ If the convention agreement lacks its own dispute settlement body, inclusion in a PTA makes enforcement possible through the dispute settlement procedures established in the PTA,⁶⁸ whereas previously, challenges could only be brought as treaty violation claims at the International

67. Ermias Tekeste Biadgleng & Viviana Munoz Tellez, *The Changing Structure and Governance of Intellectual Property Enforcement* 31 (South Centre, Research Paper No.15, 2008), available at http://www.southcentre.org/index.php?option=com_docman&task=doc_download&gid=714&Itemid=

68. See Drahos, *Weaving Webs of Influence*, *supra* note 50, at 196-200 (outlining the structure of the dispute settlement chapters found in U.S. FTAs).

Court of Justice, where jurisdiction is consent-based.⁶⁹ PTAs thus give significant teeth to intellectual property conventions. While increased enforcement of international treaties is not undesirable *per se*, the bilateralization of enforcement raises some concerns. Dispute settlement chapters of U.S. FTAs contain specific choice-of-forum provisions that allow the complaining party to choose the forum in those situations where an obligation is binding under two or more agreements.⁷⁰ These choice-of-forum clauses disproportionately benefit developed, net-exporting countries which are more likely to bring a violation claim, and which have greater capacity and expertise to take advantage of more sympathetic fora.⁷¹ Bilateral dispute resolution reduces developing countries' opportunities for coalition building, thereby reinforcing structural inequalities.⁷² On a systemic level, bilateral enforcement also undermines the multilateral trade law regime and creates greater uncertainty in rule interpretation.⁷³ Thus, the choice-of-forum clauses create systemic and individual costs that could be avoided by preserving multilateral dispute resolution for PTAs.⁷⁴

B. *Enforcement of IPRs*

The second type of TRIPS-plus provisions concerns IPR enforcement. Prior to TRIPS, enforcement of IPRs was left to individual governments; there were no international obligations that required specific procedures or remedies for IPR vi-

69. Statute of the International Court of Justice, art. 36, June 26, 1945, 59 Stat. 1055, 33 U.N.T.S. 993.

70. Drahos, *Weaving Webs of Influence*, *supra* note 50, at 192, 198-99.

71. *Id.* at 192.

72. *Id.* at 201-02.

73. *Id.* at 199-200; *see also* Mara, *supra* note 45 (arguing that bilateral agreements "may serve to interpret TRIPS negotiations . . . in some cases pre-empting the freedom of transposition of TRIPS" (quoting Jean-Christophe Maur, World Bank Institute)).

74. For example, international arbitration through the International Centre for Settlement of Investment Disputes (ICSID) is a key feature of bilateral investment treaties. *See, e.g.*, Treaty Between United States of America and the Argentine Republic Concerning the Reciprocal Encouragement and Protection of Investment art. VII(3)(a), U.S.-Arg., Nov. 14, 1991, S. Treaty Doc. No. 103-2 (1993).

olations.⁷⁵ Inclusion of enforcement obligations was considered a major TRIPS accomplishment, and as one of the main features of the agreement, TRIPS contains rather extensive terms on enforcement. These terms cover general obligations, specific requirements for border measures, civil and administrative procedures, remedial provisions, and requirements for criminalization of certain violations.⁷⁶ TRIPS-plus enforcement provisions expand the scope of enforcement in one or more of these areas, creating costly obligations for net importers, especially developing countries, whose existing legal institutions are often insufficient to handle complex enforcement procedures. They also omit significant flexibilities found in TRIPS that are aimed at protecting differences in national legal systems.⁷⁷ Notably, the two major concerns of developing countries during the negotiations of the TRIPS enforcement provisions were to maintain respect for their limited resources and for existing differences among legal systems.⁷⁸ These concerns were protected in Article 41(5) and Article 66 of TRIPS. This section sets forth the main differences between TRIPS and TRIPS-plus enforcement provisions, and shows that TRIPS-plus PTAs discard these key safeguards of developing countries' interests. This survey of enforcement provisions brings to light serious concerns about the resource burden that developing countries must take on when they sign onto PTAs.

75. GERVAIS, *THE TRIPS AGREEMENT*, *supra* note 52, at 287 (explaining that aside from general obligations to provide for legal remedies or occasionally seize infringing goods, enforcement was left to national legislation).

76. TRIPS, *supra* note 5, pt. III.

77. Biadgleng & Tellez, *supra* note 67, at 32; TRIPS, *supra* note 5, art. 41(5) ("It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general."); TRIPS, *supra* note 5, art. 66 (recognizing the "economic, financial, and administrative constraints" of least-developed countries and granting a 10-year transition period for the implementation of the TRIPS Agreement).

78. GERVAIS, *THE TRIPS AGREEMENT*, *supra* note 52, at 287.

1. *Border Measures*

Under international and domestic laws, countries may require competent authorities to take *ex officio* action to stop the movement of goods across borders, absent a third-party formal complaint, so long as there is *prima facie* evidence that an IPR has been infringed. TRIPS Article 58 sets out the rights and obligations to be exercised when *ex officio* action is taken by such authorities. Border enforcement measures in PTAs go beyond TRIPS and national laws in many countries by stating that parties *must* provide for *ex officio* enforcement in potential IPR violation cases.⁷⁹ Some PTAs extend the Article 58 measure to apply to exports and sometimes in-transit merchandise⁸⁰ to combat the operation of counterfeiting hubs.

2. *Penalties and Remedies*

Under TRIPS, criminal penalties and procedures must be applied in cases of willful trademark counterfeiting or copyright piracy on a commercial scale.⁸¹ Japan's PTAs either require or encourage parties to also adopt criminal penalties in other types of IPR violations, including willful commercial infringements of patent rights, utility models, industrial design, and layout designs.⁸² PTAs also go beyond TRIPS with regard to civil remedies. PTAs provide that damages should be payable in all infringement cases,⁸³ while TRIPS only requires

79. Biadgleng & Tellez, *supra* note 67, at 32.

80. *See e.g.*, U.S.-Singapore FTA, *supra* note 48, art 16.9; Agreement between the United States of America and the Socialist Republic of Vietnam on Trade Relations, U.S.-Vietnam, ch. 1, arts. 14-15, July 13, 2000 [hereinafter U.S.-Vietnam FTA], *available at* <http://www.usvtc.org/trade/bta/US-VN-BTA.pdf>; Japan-Indon. FTA, *supra* note 64, art. 119.

81. TRIPS, *supra* note 5, art. 61.

82. Japan-Indon. FTA, *supra* note 64, art. 121; Agreement between the Government of Japan and the Government of Malaysia for an Economic Partnership, Japan-Malay., art. 127, Dec. 13, 2005 [hereinafter Japan-Malaysia EPA], *available at* <http://www.mofa.go.jp/region/asia-paci/malaysia/epa/content.pdf>; Agreement between the Government of Japan and the Kingdom of Thailand for an Economic Partnership, Japan-Thail., art. 140, Apr. 3, 2007 [hereinafter Japan-Thailand EPA], *available at* <http://www.mofa.go.jp/region/asia-paci/thailand/epa0704/agreement.pdf>.

83. *See e.g.*, U.S.-Vietnam FTA, *supra* note 80, ch. 2, art. 14.1 ("Each Party shall provide that penalties available include imprisonment or monetary fines, or both, sufficient to provide a deterrent, consistent with the level of penalties applied for crimes of a corresponding gravity.").

members to issue compensatory damages to rights-holders if they suffer monetary losses as a result of a violation.⁸⁴ In the case of copyright and trademark violations, all U.S. FTAs require that punitive fines be imposed regardless of actual injury to the rights-holder.⁸⁵

3. *Implications for Developing Countries*

The TRIPS Agreement recognizes the institutional limitations present in many countries. The Agreement does not “create[] any obligation with respect to the distribution of resources as between enforcement of [IPRs] and the enforcement of law in general,” nor should it be read to require a judicial system for the enforcement of IPRs distinct from the general law enforcement system.⁸⁶ Compliance with TRIPS and, to an even greater extent, TRIPS-plus enforcement provisions requires hefty investments in relevant sectors of law enforcement. It has been estimated that compliance with TRIPS will cost developing countries \$60 billion per year.⁸⁷ As a significant portion of overall TRIPS obligations, enforcement requirements, and to an even greater extent, TRIPS-plus enforcement requirements, place an immense resource burden on developing countries that lack well-established legal systems, and require a redistribution of resources to improve IPR enforcement regardless of language in the agreement indicating otherwise.⁸⁸ Despite the costs of these obligations, the U.S.-Singapore FTA stipulates that resource constraints shall not be an excuse for failure to comply with IPR provisions,⁸⁹

84. TRIPS, *supra* note 5, art. 45(1) (“The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person’s intellectual property right . . .”).

85. United States-Australia Free Trade Agreement, U.S.-Austl., art. 17.11(27), May 18, 2004, 43 I.L.M. 1248 [hereinafter AUSFTA], available at http://www.ustr.gov/sites/default/files/uploads/agreements/fta/australia/asset_upload_file148_5168.pdf; U.S.-Laos FTA, *supra* note 66, art. 25; U.S.-Singapore FTA, *supra* note 48, art. 16.9(21); U.S.-Vietnam FTA, *supra* note 80, art. 14.

86. TRIPS, *supra* note 5, art. 41(5).

87. J. Michael Finger, *The Doha Agenda and Development: A View from the Uruguay Round 9* (Asian Dev. Bank, Econ. & Research Dep’t, Working Paper Series No. 21, 2002).

88. Biadgleng & Tellez, *supra* note 67, at 4.

89. U.S.-Singapore FTA, *supra* note 48, art. 16.9(4).

explicitly eliminating any institutional flexibility. While Singapore has advanced legal institutions and economic resources such that the mandated reforms may be relatively manageable, this clause repudiates the TRIPS protection, and raises concerns about whether resource constraints will be respected in future PTAs with developing countries. Beyond creating complex institutional requirements for customs authorities, extending border measures to goods in transit, as the U.S.-Singapore FTA does, can have public health implications for *third* countries.⁹⁰ In a recent incident, Dutch customs authorities used their in-transit border measure laws to confiscate a generic version of the drug Losartan in transit from India to Brazil.⁹¹ The drug was not subject to patent in either India or Brazil, but was patented by Merck in the Netherlands.⁹² Border measures can thus create barriers to legitimate trade of medicines.

C. *Patenting of Pharmaceuticals*

The third type of TRIPS-plus provision relates to the patenting of pharmaceuticals. Along with the patenting of life forms discussed in the following section, this area of protection have received the strongest opposition from human rights advocates and civil society groups. The consequences of these terms disparately impact society's most vulnerable groups, and have severe implications for the fulfillment of economic and social rights in both developing and developed countries.⁹³ The International Covenant on Economic and Social Rights, for example, recognizes a governmental obligation to ensure

90. See News Statement, World Health Organization [WHO], Access to Medicines (Mar. 13, 2009) [hereinafter WHO, Access to Medicines], available at <http://www.who.int/mediacentre/news/statements/2009/access-medicines-20090313/en/index.html> (noting that "recent events related to the handling of medicines in transit and the potential consequences for the supply of medicines in developing countries are of major concern to the organization").

91. Frederick M. Abbott, *Worst Fears Realized: The Dutch Confiscation of Medicines Bound from India to Brazil*, BRIDGES, Feb.–Mar. 2009, at 13, available at <http://ictsd.org/downloads/bridges/bridges13-1.pdf>.

92. *Id.* at 13-14.

93. See SELL, *supra* note 18, at 139 (discussing civil society opposition to patents on life forms and pharmaceuticals and noting that the social and economic effects of patents were not understood when the intellectual property agreements were signed).

the highest standard of health attainable,⁹⁴ which includes access to affordable medicines for all.⁹⁵

1. *Pharmaceutical Patenting Under TRIPS and Attendant Public Health Concerns*

Patent protection of pharmaceutical products and processes represents one of the most contentious areas of TRIPS.⁹⁶ Under TRIPS, an innovator whose product or process meets the criteria of novelty, inventiveness, and industrial application must be granted patent protection for a period of twenty years.⁹⁷ New drugs are therefore generally subject to patent protection. Prior to TRIPS, over 40 countries did not authorize patents for pharmaceutical products because of their price-elevating effects.⁹⁸ TRIPS has thus significantly altered pharmaceutical protection around the world⁹⁹—a trans-

94. International Covenant on Economic, Social, and Cultural Rights [ICESCR], art 12, Dec. 16, 1966, 993 U.N.T.S. 3, *available at* <http://www2.ohchr.org/english/law/pdf/cescr.pdf>.

95. *See* WHO, Access to Medicines, *supra* note 90 (asserting “equitable access to safe and affordable medicines as vital to the attainment of the highest possible standard of health by all”); Committee on Economic, Social, and Cultural Rights [CESCR], *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Article 12 of ICESCR)*, ¶ 43, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000), *available at* <http://www.unhcr.ch/tbs/doc.nsf/0/40d009901358b0e2c1256915005090be?Opendocument> (confirming that states have a core international human rights law obligation to provide essential drugs).

96. *See* Phil Thorpe, *Study on the Implementation of the TRIPS Agreement by Developing Countries* 16 (Comm’n on Intell. Prop. Rts., Study Paper No. 7, 2002), *available at* http://www.iprcommission.org/papers/pdfs/study_papers/sp7_thorpe_study.pdf (noting that “[o]ne of the more controversial aspects of the [TRIPS] agreement is the requirement to provide product protection for pharmaceuticals”).

97. TRIPS, *supra* note 5, art. 27(1) (“[P]atents shall be available for any inventions . . . provided that they are new, involve an inventive step and are capable of industrial application.”); TRIPS, *supra* note 5, art. 33 (“The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.”).

98. WHO, WTO and the TRIPS Agreement, http://www.who.int/medicines/areas/policy/wto_trips/en/index.html (last visited Feb. 16, 2010).

99. *See* Thorpe, *supra* note 96, at 1 (finding that intellectual property laws in more than 70 developing and least developed countries “have recently been amended to take account of [TRIPS]” and that “very few developing countries are still denying patent protection for pharmaceutical products”).

formation that has been accompanied by grave concerns regarding the Agreement's effect on access to essential medicines and implications for public health policy-making in developing countries.¹⁰⁰

The TRIPS patent protection standards caused alarm in the international public health community. The market exclusivity granted to patent holders eliminates pricing competition, thereby restricting access to affordable drugs. Furthermore, fears emerged that TRIPS might restrict governments' abilities to respond to public health crises through the use of compulsory licenses and parallel importation. As a result, developing countries and advocates began to voice concerns that TRIPS compliance would compromise their ability to implement public health policies meant to improve access to essential medicines.¹⁰¹

In response to these concerns, WTO members adopted the Doha Declaration in 2001.¹⁰² The declaration reaffirmed countries' abilities to take measures to protect public health.¹⁰³ For example, compulsory licensing gives a third party the right to produce a patented good, allowing for the production of generic drugs, and the Declaration emphasizes that each member has the freedom to determine the grounds upon which compulsory licenses are granted, and that these grounds are not limited to the circumstances enumerated in Article 31.¹⁰⁴ Doha also reaffirms governments' rights to adopt laws allowing for parallel importation.¹⁰⁵ In 2004, the World Health Assembly adopted a resolution encouraging World Health Organization (WHO) member states to ensure

100. See CORREA, *supra* note 10, at 1 (noting that growing concerns regarding TRIPS implications for access to drugs prompted the African Group and other developing countries to request that the Council for TRIPS address the relationship between TRIPS and public health, resulting in the Doha Declaration).

101. *Id.* at 2.

102. Doha Declaration, *supra* note 39.

103. *Id.* ¶ 4.

104. See *id.* ¶ 5(b) ("Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.")

105. *Id.* ¶ 5(d) (reaffirming that each member is free to establish its own exhaustion regime). The relationship between exhaustion and parallel importation is further discussed in the section on Parallel Importation, Part III.C(3), *infra*.

that bilateral trade agreements protect the flexibilities contained in TRIPS as recognized by the Doha Declaration.¹⁰⁶ Yet the survey of Asian PTAs reveals the opposite: several PTAs disregard the Doha Declaration and reverse efforts to emphasize public health by tightening patent protection of pharmaceuticals. In the sections that follow, this Note compares PTA provisions that pertain to compulsory licensing, parallel imports, and second use with corresponding TRIPS terms and shows how these provisions reduce governments' abilities to act in the area of public health.

2. *Compulsory Licensing*

TRIPS allows countries to issue compulsory licenses subject to several conditions under Article 31.¹⁰⁷ The license applicant must first attempt to obtain a voluntary license from the patent holder on "reasonable commercial terms,"¹⁰⁸ unless the situation constitutes a national emergency or other circumstance of extreme urgency, or the product is intended for public non-commercial use.¹⁰⁹ In the event that a compulsory license is issued, "adequate remuneration" must still be paid to the patent holder.¹¹⁰ Compulsory licensing must also meet certain additional requirements; in particular, it cannot be given exclusively to the licensee (the patent holder must be allowed to continue to produce), and it must be predominantly limited to supply of the domestic market.¹¹¹ This domestic market provision in Article 31(f) presents a major limitation for developing countries that do not have the ability to produce or manufacture drugs domestically. For these countries, the right to issue compulsory licenses is meaningless if they cannot import generic drugs from manufacturing coun-

106. World Health Assembly, Scaling Up Treatment and Care Within a Coordinated and Comprehensive Response to HIV/AIDS, WHA Res. 57.14 (May 22, 2004), available at http://apps.who.int/gb/ebwha/pdf_files/WHA57/A57_R14-en.pdf.

107. TRIPS, *supra* note <CITE_Ref102405546>, art. 31.

108. *Id.* art. 31(b).

109. *Id.* As stated above, however, the Doha Declaration clarifies that each member has the right to determine what constitutes such situations, and confirms that public health crises qualify as an emergency within the meaning of Article 31. Doha Declaration, *supra* note 39, ¶ 5(c).

110. TRIPS, *supra* note 5, art. 31(h).

111. *Id.* art. 31(d), (f).

tries. At the request of the Doha Declaration, the WTO General Council rendered a decision regarding this issue in August 2003, finding that countries with manufacturing capacities can issue compulsory licenses for pharmaceutical exports to “eligible importing members.”¹¹² This exemption for Article 31(f) is subject to restrictions that limit the use to public health.¹¹³

Notwithstanding these conditions in Article 31, the TRIPS Agreement does not limit the circumstances under which governments can issue compulsory licenses.¹¹⁴ Under U.S. FTAs, however, parties may only grant compulsory licenses in three specific contexts: in emergency situations, as an anti-trust remedy, or if the product is destined for public non-commercial use.¹¹⁵ Grants of compulsory licenses can be challenged on the grounds that a situation did not warrant such granting, greatly restricting the freedom of governments to permit compulsory licensing. These rules are not only TRIPS-plus, but are even more restrictive than U.S. domestic law. Under U.S. law, compulsory licensing is protected in a variety of fields that are far broader than situations of national emergency.¹¹⁶ For example, the Clean Air Act contains compulsory licensing provisions related to air pollution prevention inventions, the Bayh-Dole Act protects march-in rights, and the Atomic Energy Act contains provisions that protect the public interest in energy production.¹¹⁷

112. General Council, *Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Aug. 30, 2003).

113. Ng-Loy Wee Loon, *Parallel Imports of Pharmaceuticals: Doha Versus Free Trade Agreements*, in *INTELLECTUAL PROPERTY AND FREE TRADE AGREEMENTS* 157, 165-66 (Christopher Heath & Anselm Kamperman Sanders eds., 2007).

114. GERVAIS, *THE TRIPS AGREEMENT*, *supra* note 52, at 250.

115. AUSFTA, *supra* note 85, art. 17.9(7); U.S.-Singapore FTA, *supra* note 48, art. 16.7(6); U.S.-Vietnam FTA, *supra* note 80, ch. 2, art. 7(8).

116. Maristela Basso & Edson Beas Rodriguez, Jr., *Free Trade Agreements, UPOV and Plant Varieties*, in *INTELLECTUAL PROPERTY AND FREE TRADE AGREEMENTS* 171, 174 (Christopher Heath & Anselm Kamperman Sanders eds., 2007).

117. *Id.* at 174 n.11 (citing the Clean Air Act, 42 U.S.C. § 7608 (2006), the Bayh-Dole Act, 35 U.S.C. § 203 (2006), and the Atomic Energy Act, 42 U.S.C. § 2183 (2006)).

PTAs negotiated by the United States also contain provisions that limit the effective *use* of compulsory licenses.¹¹⁸ Once a manufacturer of a pharmaceutical product has obtained a compulsory license, it must also obtain regulatory approval to sell the product in its own market. PTAs signed by the United States prevent non-patent holders from gaining market approval for a generic drug without the authorization of the patent holder.¹¹⁹ Thus, if a patent holder refuses to consent to market approval, a compulsory license is insufficient to allow the party to introduce a generic product on its market, rendering the license useless.¹²⁰

Under many countries' laws, drug manufacturers must also submit test data on a drug's safety and efficacy to authorities in order to receive marketing approval. TRIPS requires such test data to be protected against "unfair commercial use" except where necessary to protect the public.¹²¹ In the United States, competing manufacturers are prohibited from relying on test data submitted by the original manufacturer for a period of five years, excluding the possibility of producing generic drugs during this time.¹²² This data exclusivity restriction has been incorporated into all U.S. FTAs with Asia-Pacific partners.¹²³ Even after the expiration of patent terms, patentees may, upon introduction of the drug in a new market, continue to protect their test data for another five year period. This has the effect of extending an exclusive right in drugs that are already in the public domain in other countries.

118. See Fink & Reichenmiller, *supra* note 46, at 2 (surveying all TRIPS-plus U.S. FTAs and finding that all but two include provisions preventing marketing approval for generic drugs).

119. See *e.g.*, AUSFTA, *supra* note 85, art. 17.9(6); U.S.-Singapore FTA, *supra* note 48, art. 16.9(5).

120. Fink & Reichenmiller, *supra* note 46, at 2.

121. TRIPS, *supra* note 5, art. 39(3).

122. Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585. European Union members offer similar protection for a period of up to 10 years, and Japan's laws protect data exclusivity for 4-10 years. Milind Antani & Prashant Iyengar, *Towards a Law on Data Exclusivity*, PHARMABIZ.COM, Jan. 5, 2005, <http://www.pharmabiz.com/article/detnews.asp?articleid=25566§ionid=46>.

123. See, *e.g.*, United States-Republic of Korea Free Trade Agreement, U.S.-S. Korea, art. 18.9.1, June 30, 2007, *available at* http://www.ustr.gov/Trade_Agreements/Bilateral/Republic_of_Korea_FTA/Final_Text/section_index.html; AUSFTA, *supra* note 85, art. 17.10(1)(a); U.S.-Singapore FTA, *supra* note 48 art. 16.8(1).

Since necessary test data is very expensive to produce (one study estimates the average cost for market approval to be \$802 million),¹²⁴ such prohibitions can effectively bar second manufacturers from obtaining market access.

3. *Parallel Importation*

Another key area affecting drug access is parallel importation, the practice of importing a patented product sold abroad without the permission of the patent holder. In an international exhaustion of rights regime, a patentee's rights are exhausted after the patentee has placed the product on the market in any country. Thus, once the patentee has made an initial sale, any party may resell the product in another country at a new market price. Since differential pricing across countries is very common, parallel importation can provide a way for low-income communities to gain access to affordable medicines that are highly priced in their countries.¹²⁵ On the other side of the debate, proponents of national exhaustion argue that banning parallel importation is necessary in order to persuade pharmaceutical companies to implement pro-poor differential pricing of essential medicines, a key strategy advocated for by public health activists. Drug companies may only agree to make drugs available to low-income markets at cheaper prices if they are assured that the lower-priced drugs will not be resold in markets that can afford to pay higher prices.¹²⁶

TRIPS article 6 stipulates that the TRIPS Agreement does not reach the issue of exhaustion of rights.¹²⁷ This wiggle room was intentional, recognizing that there were sharp disagreements in the international community pertaining to the

124. Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003).

125. See CORREA, *supra* note 10, at 17 ("The authorization of parallel imports under an international principle of exhaustion has [] been regarded by developing countries as a key component of a patent system sensitive to public health needs.").

126. Ng-Loy, *supra* note 113, at 169.

127. TRIPS, *supra* note 5, art. 6 ("For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.").

optimality of either system. The Doha Declaration confirms that “[t]he effect of the provisions in the TRIPS Agreement . . . is to leave each member free to establish its own regime for such exhaustion without challenge . . .”¹²⁸

PTAs eradicate the flexibilities found in TRIPS by binding countries to laws that protect patent-holders. This raises questions as to whether such PTA clauses conflict with the spirit and purpose of TRIPS.¹²⁹ U.S. FTAs with Singapore and Australia give patent holders the right to limit parallel imports through licensing contracts.¹³⁰ Thus, patent holders can make contractual stipulations that the distributors may not make the patented product available for exportation without the prior permission of the patent holder. The U.S.-Australia FTA further prohibits importation where the patent-holder has imposed restrictions by means other than inclusion in a contract, such as by indication on the product itself that it is for sale only in a specified country.¹³¹ These FTAs confer substantial powers to the rights holders to contractually prohibit parallel importation.¹³² Implementation of the provisions did not re-

128. Doha Declaration, *supra* note 39, ¶ 5(d).

129. See CORREA, *supra* note 10, at 13 (suggesting that “pressures to impede the use of available flexibilities run counter to the spirit and purpose of the TRIPS Agreement”). Article 7 of TRIPS states as its objectives that “[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.” TRIPS, *supra* note 5, art. 7. Article 8 states that “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.” TRIPS, *supra* note 5, art. 8(1).

130. AUSFTA, *supra* note 85, art. 17.9(4); U.S.-Singapore FTA, *supra* note 48, art. 16.7(2).

131. AUSFTA, *supra* note 85, art. 17.9(4); Ng-Loy, *supra* note 113, at 167 (noting, as an example of such means, labeling a product “Not for Sale Outside Country”).

132. See David Richardson, *Intellectual Property Rights and the Australia-US Free Trade Agreement* (Austl. Dep’t of Parliamentary Serv., Research Paper No. 14 2003-04, 2004), available at <http://www.aph.gov.au/library/Pubs/rp/2003-04/04rp14.htm> (noting that “AUSFTA include[s] provisions to enhance the ability of patent owners to prohibit international exhaustion of patent rights”).

quire substantial reforms to national laws in these cases,¹³³ but the FTAs' terms are significant in that they bind the countries to their current laws, and disable them from taking advantage of the flexibilities found in TRIPS even if a future public health situation should demand it.¹³⁴ TRIPS, as reaffirmed in the Doha Declaration, ensured that members can adopt any parallel importation rule “*without challenge*” (emphasis added); yet as countries sign onto FTAs, they accept treaty obligations to protect the rights of patent-holders with no room for future adjustments.

4. *Second Use*

Patent laws often allow patentees to seek patent protection for new uses of known products. Under such second use patenting, a patentee can obtain multiple patent terms on a drug by coming up with new dosage forms or methods of use.¹³⁵ TRIPS does not require members to provide patents for second use inventions.¹³⁶ Countries are taking advantage of this flexibility. India, for example, is considering barring second use patenting, a decision that would keep present generic drugs from being patented and maintain wide access to medicines.¹³⁷ Some U.S. PTAs, however, mandate that countries must afford protection to second uses.¹³⁸ Even after a patent term ends, a pharmaceutical company can thus pro-

133. See Ng-Loy, *supra* note 113, at 161 (noting that Japan, Taiwan, Hong Kong, and Thailand premise international exhaustion of rights on the consent of the rights-holder whereas South Africa does not).

134. *Id.* at 168.

135. Rochelle C. Dreyfuss, *Creative Lawmaking: A Comment on Lionel Bently, Copyright, Translations, and Relations between Britain and India in the Nineteenth and Early Twentieth Centuries*, 82 CHI.-KENT. L. REV. 1243, 1247 (2007) [hereinafter Dreyfuss, *Creative Lawmaking*].

136. See TRIPS, *supra* note 5, art. 27(1) (requiring an “inventive step” for patentability without defining how inventive the “inventive step” must be in order to require patent availability).

137. Dreyfuss, *Creative Lawmaking*, *supra* note 135, at 1247.

138. See, e.g., AUSFTA, *supra* note 85, art. 17.9(1) (“The Parties confirm that patents shall be available for any new uses or methods of using a known product.”).

long its monopoly by developing second uses, such as by instructing that drugs be used in new combinations.¹³⁹

D. *Patenting of Biodiversity and Plant Life*

One of the central innovations found in TRIPS was the expansion of the IPR regime to include previously unprotected subject matters, including plant varieties, microbiological processes, and biotechnological inventions.¹⁴⁰ As with pharmaceuticals, patenting of plant varieties presents a classic dilemma: the protection of plant breeders' rights incentivizes vital R&D in plant varieties, but it does so by creating monopolies on seeds and raising costs for farmers. Developing countries that rely heavily on agriculture have strongly opposed patenting of plants because of threats to food security and environmental sustainability.¹⁴¹

1. *Plant Patenting under TRIPS*

TRIPS requires WTO members to provide patenting for microorganisms, but leaves flexibility in the area of plant protection.¹⁴² Under Article 27(3)(b), members may exclude plants from patentability, but must provide for the protection of plant varieties either through patents or through a *sui generis* system, or a combination of the two.¹⁴³ A *sui generis* system may entail plant variety protection (PVP) laws that are separate and wholly distinct in structure from a patent system.¹⁴⁴ Many developing countries have chosen to adopt *sui generis* laws in place of a patent regime. In a study of 35 developing countries and LDCs, Philip Thorpe found that 71 percent have adopted legislation that excludes certain types of

139. Jakkrit Kuanpoth, *TRIPS-Plus Rules under Free Trade Agreements: An Asian Perspective*, in *INTELLECTUAL PROPERTY AND FREE TRADE AGREEMENTS* 27, 33 (Christopher Heath & Anselm Kamperman Sanders eds., 2007).

140. Basso & Rodriguez, Jr., *supra* note 116, at 171.

141. SELL, *supra* note 18, at 140.

142. TRIPS, *supra* note 5, art. 27(3)(b); Basso & Rodriguez, Jr., *supra* note 116, at 172.

143. TRIPS, *supra* note 5, art. 27(3)(b).

144. See Basso & Rodriguez, Jr., *supra* note 116, at 191 (noting that under a TRIPS *sui generis* system, states are free to choose the conditions required for protection, the scope, genera, and species that may be protected, exemptions to the exclusive rights, and compulsory licensing provisions).

plants and other life forms from patenting, taking advantage of the flexibility found in TRIPS¹⁴⁵

Article 27(2) of TRIPS also allows countries to exclude from patentability inventions “necessary to protect *ordre public* or morality.”¹⁴⁶ When read in light of Article 8, which states that “members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development,” there are credible arguments for interpreting TRIPS as permitting countries to implement laws and procedures that place limits on plant patenting.¹⁴⁷ Developing countries continue to object to patentability of plants and have lobbied to revise article 27(3)(b) to explicitly exclude plants from patenting.¹⁴⁸ Despite the loud objections to patentability during multilateral negotiations, however, there are no Asia-Pacific PTAs that elect to exempt life forms. On the contrary, many PTAs further restrict the flexibility found in TRIPS by mandating plant patenting or by requiring accession or compliance with the UPOV Convention.

2. *Plant Patenting Provisions in PTAs*

Japan has been particularly committed to including TRIPS-plus terms that require the patenting of plants. In the Japan-Philippines Economic Partnership Agreement (EPA), the parties generally endeavor to increase the scope of plant protection.¹⁴⁹ The Japanese agreements with Malaysia and Thailand go further, as parties commit themselves to providing adequate protection for as many genera or species as at-

145. Thorpe, *supra* note 96, at 17.

146. TRIPS, *supra* note 5, art. 27(2).

147. *Id.* art. 8(1); see also Basso & Rodriguez, Jr., *supra* note 116, at 190 (asserting that “[p]ublic health, nutrition and protection of the general public interests are part of the wide concept of *ordre public*”).

148. MEIR PEREZ PUGATCH, *THE INTERNATIONAL POLITICAL ECONOMY OF INTELLECTUAL PROPERTY RIGHTS* 163 (2004).

149. Agreement between Japan and the Republic of the Philippines for an Economic Partnership, Japan-Phil., art. 127, Sept. 9, 2006, available at <http://www.mofa.go.jp/region/asia-paci/philippine/epa0609/main.pdf> [hereinafter Japan-Philippines EPA].

tainable within the shortest possible time period.¹⁵⁰ While the language is still general, and “adequate” protection may be open to interpretation, the terms provide broad grounds to challenge national policies for insufficient plant protection. Both agreements also contain language that refers to “international “standards” or “internationally harmonized system.” Since the UPOV Convention arguably embodies the international standards for plant variety protection, these parties are in effect pressured to implement UPOV-level protection. The Japan-Indonesia EPA expressly requires protection of all plant genera and species in a manner consistent with UPOV.¹⁵¹

U.S. FTAs with Asian developing countries prohibit exclusion of certain¹⁵² or all¹⁵³ plants and animals from patentability.” FTAs with developed countries provide more, but still limited, flexibility. In the case of U.S.-Australia, exclusions from patentability are permitted in narrow circumstances, when exclusion can be justified based for moral, health, and safety reasons.¹⁵⁴

European PTAs are generally not as restrictive as other TRIPS-plus PTAs. Of the EFTA agreements with Asia-Pacific partners, EFTA-Korea is the only one to contain provisions on plant patenting.¹⁵⁵ It reflects the language in TRIPS and reiterates that plants and animals may be excluded from patenting.¹⁵⁶ While the EFTA agreements do not contain substantive TRIPS-plus provisions, they do compel accession to the UPOV Convention, as discussed in the preceding section.

3. *Plant Variety Protection Under the UPOV Convention*

The UPOV Convention is a *sui generis* system that ensures that breeders of new plant varieties are granted IPRs. As of 2009, the convention had 68 members, all of whom have na-

150. Japan-Malaysia EPA, *supra* note 82, art. 123; Japan-Thailand EPA, *supra* note 82, art. 135(2).

151. Japan-Indon. FTA, *supra* note 64, art. 116.

152. U.S.-Laos FTA *supra* note 66, art. 7(2)(c).

153. U.S.-Vietnam FTA, *supra* note 80, ch. 2, art. 7(2)(c).

154. AUSFTA, *supra* note 85, art. 17.9(2).

155. Free Trade Agreement between the European Free Trade Area States and Republic of Korea, art. 7.2, Dec. 15, 2005, *available at* <http://secretariat.efta.int/~-/media/Documents/legal-texts/free-trade-relations/republic-of-korea/Free%20Trade%20Agreement.ashx>.

156. *Id.*, annex XIII, art. 2.

tional PVP laws that conform to the standards specified in either the 1978 or 1991 Acts of the Convention.¹⁵⁷ There are notable differences between the acts relating to scope, coverage, minimum protection period, and exemptions for farmers.¹⁵⁸ Most notably, the 1991 Act was passed with the purpose of strengthening breeder's rights, and does not exempt farmers from prohibitions on seed saving.¹⁵⁹

By protecting the rights of plant breeders, the UPOV system seeks to attract investment in biotechnology vital to sustainable agricultural and horticultural progress. The UPOV Impact Study (2006) of five member countries, namely Argentina, China, Kenya, Poland, and the Republic of Korea, found economic, health, and social benefits associated with implementation of the UPOV system of protection.¹⁶⁰ These countries also reported an increase in the overall numbers of plant varieties developed after the introduction of the UPOV system.¹⁶¹ Advocates of UPOV have also suggested that adoption of the system ensures compliance with the TRIPS requirement that states adopt an "effective" *sui generis* system.¹⁶² Explicit references to UPOV were rejected in the TRIPS negotiations,¹⁶³ however, and since UPOV compliance leaves less room for national discretion than TRIPS, UPOV can be considered TRIPS-plus. PTA clauses that explicitly require joining the Union¹⁶⁴ or that specify accession to the 1991 Act are considered even further down the TRIPS-plus spectrum, whereas

157. UPOV, Members of the International Union for the Protection of New Varieties of Plants, <http://www.upov.int/export/sites/upov/en/about/members/pdf/pub423.pdf> (last visited Mar. 4, 2010).

158. See Basso & Rodriguez, Jr., *supra* note 116, at 197-203 (outlining key differences between the 1978 and 1991 Acts).

159. BIJAWIT DHAR, SUI GENERIS SYSTEMS FOR PLANT VARIETY PROTECTION: OPTIONS UNDER TRIPS 11-13 (2002).

160. UPOV REPORT ON THE IMPACT OF PLANT VARIETY PROTECTION 12 (2006), available at http://www.upov.int/export/sites/upov/en/publications/pdf/353_upov_report.pdf.

161. *Id.*

162. See Basso & Rodriguez, Jr., *supra* note 116, at 172 (noting that during the GATT Uruguay Round, developed countries asserted that "the UPOV Convention would be the most satisfactory instrument for complying with the obligations enshrined in Article 27(3)(b) TRIPS").

163. *Id.*

164. PTAs that require UPOV membership implicitly require accession to the 1991 Act, since the 1978 Act was closed to further members in 1998.

those that require compliance with standards similar to either Act leave some room for national flexibility.

In spite of the arguments in favor of adoption of UPOV standards, developing countries have voiced fervent objections to the system, maintaining that it is inappropriate and detrimental to less developed, agricultural economies.¹⁶⁵ UPOV is seen as protecting plant breeders' rights at the expense of farmers' rights—a system that hurts farmers' livelihoods, disrupts traditional ways of farming, and reduces profits in the agricultural sector.¹⁶⁶ As one example, farmers' abilities to save seeds for use in the following season may be conditioned on authorization by the rights-holder,¹⁶⁷ illegalizing long-established practice in many agricultural societies. In India, for example, farmers rely heavily on seed saving and this practice is protected under domestic law.¹⁶⁸ For countries in which a large portion of the population relies on farming, promises of new plant varieties do not compensate for these immediate costs. It is noteworthy that for a large proportion of current UPOV members, only a small percentage of their economically active population is engaged in agriculture.¹⁶⁹ Of the original members, most have less than 5 percent of the population engaged in agriculture.¹⁷⁰ These numbers reflect a drastically different economic landscape than that in the countries now being pressured to join UPOV.

4. *UPOV Accession Requirements in PTAs*

Accession to or compliance with the UPOV Convention is perhaps the most common TRIPS-plus provision found across PTAs in the Asia-Pacific region. Most U.S. trade agreements call for UPOV accession and have accordingly resulted in the accession of developing countries with robust agricultural sectors that were previously opposed to the Union. For example, the U.S.-Vietnam FTA entered into force in 2001 with the stip-

165. See, e.g., GRAIN, *UPOV on the War Path*, SEEDLING, June 1999, available at <http://www.grain.org/seedling/?id=67>.

166. Srividhya Ragavan & Jamie Mayer O'Shields, *Has India Addressed Its Farmers' Woes? A Story of Plant Protection Issues*, 20 *Geo. Int'l Envtl. L. Rev.* 97, 98, 110-112 (2008).

167. UPOV, *supra* note 59, art. 15(2).

168. Ragavan & O'Shields, *supra* note 166, at 118-19.

169. DHAR, *supra* note <CITE _Ref104016961">, at 8.

170. *Id.*

ulation that Vietnam would give effect to the substantive economic provisions of the UPOV Convention of either 1978 or 1991.¹⁷¹ Vietnam committed to joining the Convention by the agreement's date of entry into force, or to make every effort to do so without delay, and did in fact become a party to the 1991 Act in December 2006.¹⁷² The U.S.-Laos FTA contains the same language as U.S.-Vietnam,¹⁷³ and Laos is in the process of acceding at the time of this writing. The U.S.-Singapore FTA contains the strictest wording; it requires Singapore to accede to the 1991 Act within six months of entry into force or by the end of 2004.¹⁷⁴ Singapore became a party to the Act in 2004, but this may be less consequential for Singapore than for many other countries due to the small size of their agricultural sector.¹⁷⁵

EFTA agreements with non-Asia Pacific members overwhelmingly contain UPOV accession clauses. South Korea joined UPOV prior to the signing of the EFTA-Korea agreement. Singapore officially joined UPOV one year after the entry into force of the EFTA-Singapore FTA, but the Agreement itself did not contain a UPOV accession clause. As discussed in Part III.A, *supra*, Japan's PTAs do not contain explicit references to UPOV, but in effect also require compliance with UPOV by demanding a similar level of protection.

5. *Plant Patenting and Implications for Food Security*

The soaring prices in food staples associated with the global food crisis of 2008 shook international confidence in food security. The world's poorest nations, already afflicted with chronic hunger and famine, were the hardest hit. But spikes in food prices and population growth have triggered concern about food security in rich, import-dependent nations

171. U.S.-Vietnam FTA, *supra* note 80, ch. 2, art. 1.

172. UPOV Notification No. 100, Accession by the Socialist Republic of Vietnam, http://www.wipo.int/treaties/en/html.jsp?file=/Redocs/notdocs/en/upov/treaty_upov_100.html.

173. U.S.-Laos FTA, *supra* note 66, art. 13(2)(d).

174. U.S.-Singapore FTA, *supra* note 48, art. 16.10.

175. UPOV Notification No. 92, Accession by the Republic of Singapore, http://www.wipo.int/treaties/en/html.jsp?file=/Redocs/notdocs/en/upov/treaty_upov_92.html

as well.¹⁷⁶ Plant patenting exacerbates these concerns by raising the production costs of agriculture, which are reflected in higher grain prices. In the 2008 food crisis, input suppliers and grain traders, not farmers, profited from higher prices.¹⁷⁷ By way of example, the world's largest grain trader, Cargill, reported a 2008 increase in profits of nearly 70 percent over 2007, a 157 percent rise in profits since 2006.¹⁷⁸ The monopolization of seed breeding has also led to market domination by a few commercial varieties.¹⁷⁹ As climate change alters land and weather conditions, crop productivity becomes more volatile, and reliance on just a few varieties could lead to drastic declines in crop yields, creating grave risks to food security.¹⁸⁰ This situation is exacerbated by the agricultural interdependence of countries. Overprotection of plant breeders thus results in monopolies that may in fact create a less sustainable food supply, and FTAs that bind countries to plant patenting further strip governments of flexibility to address food shortages, consequently affecting their ability to meet international human rights obligations related to the right to food.¹⁸¹

176. See SHEPARD DANIEL & ANURADHA MITTAL, *THE GREAT LAND GRAB: RUSH FOR WORLD'S FARMLAND THREATENS FOOD SECURITY FOR THE POOR* 2-5 (2009); Andrew Rice, *Is There Such a Thing as Agro-Imperialism?*, N.Y. TIMES MAG., Nov. 22, 2009, at 46 (discussing food insecurity among developed nations as a major cause of land investment in the Global South).

177. *The Great Global Land Grab*, RED PEPPER, Nov. 7, 2009, available at <http://www.redpepper.org.uk/The-great-global-land-grab>.

178. *Id.*

179. Basso & Rodriguez, Jr., *supra* note 116, at 206-7.

180. Basso & Rodriguez, Jr., *supra* note 116, at 207.

181. Food security is an integral part of the right to food. The "core content of the right to adequate food implies: the availability of food in a quantity and quality sufficient to satisfy the dietary needs of individuals, free from adverse substances, and acceptable within a given culture; the accessibility of such food in ways that are sustainable and that do not interfere with the enjoyment of other human rights." CESCR, *General Comment No. 12: The Right to Adequate Food (Article 11 of ICESCR)*, ¶ 8, U.N. Doc. E/C.12/1999/5 (May 12, 1999), available at <http://www.unhchr.ch/tbs/doc.nsf/0/3d02758c707031d58025677f003b73b9>. Freedom from hunger, as a core principle of the right to food, has been interpreted to be customary international law binding on non-signatories of ICESCR. See, e.g., Smita Narula, *The Right to Food: Holding Global Actors Accountable Under International Law*, 44 COLUM. J. TRANSNAT'L L. 691, 791-96 (2006).

E. *Summary of Findings*

1. *Burdens on Net Importers*

The above sections demonstrate the various ways that TRIPS-plus PTAs place burdens on net importers of intellectual property. These burdens are especially severe for developing countries. In countries where legal institutions are weak, legislative reform and implementation of advanced enforcement mechanisms impose sizeable costs¹⁸²—costs that inevitably divert scarce resources from more foundational programs and institutions. Michael Finger, the former head of the World Bank's trade research department, found that the \$60 billion obligation that developing countries incurred through TRIPS more than offsets the gains they may expect from increased market access in the agriculture and textile industries.¹⁸³ Thus, the market access that justified the TRIPS trade-off¹⁸⁴ does not seem to lead to sufficient capital inflows to outweigh the costs. Secondly, grave social costs result from high levels of patent protection. Writing for the Third World Network, Sanya Reid Smith collected data on the effects of TRIPS-plus terms in a variety of developing and developed countries.¹⁸⁵ For example, under the pending U.S.-Korea FTA, calculations suggest that an extension of patent terms for three years would cost South Korea \$757 million.¹⁸⁶ An implementation of eight years of data exclusivity in Canada would add \$600 million in prescription medicine costs over five years.¹⁸⁷ These burdens are likely to be felt over a long period of time. The WHO predicts that the full impact of U.S. TRIPS-plus provisions on medicine prices may not be felt until 15 years after an FTA enters into force.¹⁸⁸ TRIPS-plus terms lead to the violation of basic economic and social rights, such as the right to health and food,¹⁸⁹ by impacting access to essential medicines, food security, and farmers' livelihoods.

182. Comm'n on Intell. Prop. Rts., *supra* note 11, at 15.

183. SMITH, *supra* note 65, at 2.

184. *See supra* note 31 and accompanying text.

185. SMITH, *supra* note 65, at 14-16.

186. *Id.*

187. *Id.*

188. *Id.* at 14.

189. The rights to food and health are protected in articles 11 and 12, respectively, of ICESCR, *supra* note 94. *See also supra* notes 93-95, 181 and accompanying text.

Yet this trade-off of human rights for increased market access is done through a largely non-participatory process.¹⁹⁰ Closed-door PTA negotiations do not allow for democratic input or comprehensive evaluation of impacts on diverse stakeholders, both of which should precede intellectual property law revisions.¹⁹¹ Moreover, PTAs are a particularly problematic mechanism for raising intellectual property protection since they create obligations that are binding in the international arena.¹⁹² Such international obligations bar future amendments in response to new domestic demands and challenges.¹⁹³ When disputes arise, the agreements are subject to binding interpretations by dispute settlement bodies that lack the institutional competence to engage in complex intellectual property lawmaking and take into account various interests and public needs.¹⁹⁴

A reversal of the TRIPS-plus trend will require two things: first, net importing countries must develop fuller information on the long-term costs of TRIPS-plus standards, and use this information to take a stronger, unified stance against net exporters; second, net exporters must revisit the desirability of their policies in light of their costs. While scholarship is emerging on the impact of FTAs in net importing countries, there is a lack of systemic support for developing countries as they enter into negotiations on bilateral agreements. Much of the information that is available is often non-technical in na-

190. See, e.g., Kamol Hengkietisak, *FTA Negotiations Need Transparency*, BANGKOK POST, Jan. 15, 2006, available at <http://www.biothai.org/cgi-bin/content/news/show.pl?0134> (discussing the lack of transparency in Thai-U.S. FTA negotiations).

191. See, e.g., FTA WATCH, THAILAND'S Free Trade Agreements and Human Rights Obligations, Submission to the 84th Session of the UN Human Rights Committee 5 (2005), available at <http://www.twinside.org.sg/title2/FTAs/General/Thailand%27sFTAsAndHumanRightsObligations.doc> (contending that the secret nature of Thai-U.S. FTA negotiations violate the International Covenant of Civil and Political Rights and Thai constitutional law).

192. See Dreyfuss, *TRIPS – Round II*, *supra* note 4, at 22 (noting that international agreements have the effect of freezing intellectual property laws, limiting abilities to respond to changing creative enterprises).

193. See Biadgleng & Tellez, *supra* note 67, at 30 (“As has been widely noted, binding obligations for higher [IPRs] standards may significantly diminish the flexibility to regulate [IPRs] according to the development priorities of each country.”).

194. Dreyfuss, *TRIPS – Round II*, *supra* note 4, at 23.

ture, and couched in vague and emotional language. The High Commissioner for Human Rights has encouraged States to undertake systematic human rights impact assessments of trade-related rules and policies.¹⁹⁵ Such an approach would not only require participatory methodologies to ensure assessment quality and implementation of the right to participate, but would also evaluate the real and potential impact of trade policies using a range of comprehensive indicators based on internationally recognized civil, cultural, economic, political, and social rights.¹⁹⁶ The second component of a TRIPS-plus reversal relates to net exporting countries. As the United States is the most rigorous advocate for TRIPS-plus PTAs, the final section of this Note reviews TRIPS-plus policies from the U.S. point of view and puts forth three arguments for the United States' reconsideration of its current commitment to TRIPS-plus.

IV. AN EVALUATION OF U.S. TRADE STRATEGY: ARGUMENTS AGAINST TRIPS-PLUS FROM THE AMERICAN POINT OF VIEW

Among the three parties that pursue TRIPS-plus PTAs in Asia and the Pacific, the United States is the most active TRIPS-plus promoter.¹⁹⁷ FTAs negotiated by the United States are a one-way ratchet in that each subsequent FTA contains increasingly stricter TRIPS-plus terms.¹⁹⁸ Over the past decade, the Bush administration sought to “ensur[e] that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law,”¹⁹⁹ a one-size-fits-all approach that has been characterized by a refusal to respond to the unique economic and institutional characteristics of its trading part-

195. High Commissioner for Human Rights, *Analytic Study of the High Commissioner for Human Rights on the Fundamental Principle of Non-Discrimination in the Context of Globalization*, ¶ 55, E/CN.4/2004/40 (Jan. 15, 2004).

196. FTA Watch, *supra* note 191, at 5.

197. See *supra* notes 46-48 and accompanying text.

198. Biadgleng & Tellez, *supra* note 67, at 30.

199. Bipartisan Trade Promotion Authority Act of 2002, Pub. L. No. 107-210, § 2102(b)(4)(A)(i)(II), 116 Stat. 993, 996 (codified at 19 U.S.C. § 3802(b)(4)(A)(i)(II) (2006)).

ners.²⁰⁰ On the domestic front, this approach is justified by arguments that it serves the American economic interest.²⁰¹

This final section presents three arguments why it is actually in the United States' interest to reform its TRIPS-plus trade strategy. First, the TRIPS-plus terms presented by the U.S. Trade Representative (USTR) in trade negotiations reflect industry interests, and the creation of international obligations that protect industry interests conflicts with the American public interest in this case. Second, shifting balances of trade in intellectual property vis-à-vis Asian countries means that the United States must increasingly rely on foreign innovations. Under such a scenario, the provisions for which the United States is currently bargaining will be increasingly harmful to its own public interest. Finally, even if TRIPS-plus did serve the American public interest, an uncompromising trade strategy is not *strategically* optimal as it has led some developing countries to reject intellectual property chapters altogether, occasionally resulting in a complete failure of FTA negotiations.²⁰² A case study of the Thailand-U.S. negotiations exemplifies this outcome, and illustrates that excessive rigidity in intellectual property terms can leave the United States without free market access. For these reasons, the United States should employ a more flexible approach to intellectual property provisions in trade agreements.

A. *TRIPS-Plus Benefits U.S. Industry, Not the Public*

The U.S. government should reconsider its national trade policy because it cannot be justified on the grounds that it serves the domestic public interest. Under U.S. constitutional

200. See Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 *IND. INT'L & COMP. L. REV.* 613, 707 (noting that the United States is seeking to transplant U.S.-style patent protections "even in Africa, at the heart of the AIDS pandemic").

201. See OFFICE OF THE U.S. TRADE REP., *TRADE DELIVERS: OPENING MARKETS FOR GROWTH: THE U.S. FTA AGENDA* (June 2006), available at <http://www.fas.usda.gov/itp/policy/2006-07factsheetopeningmarkets2.pdf> (listing implemented and initiated FTAs and noting that "[t]hese agreements collectively will bring significant benefits to Americans and the American economy as well as to our free trade partners").

202. Roger Kampf, *TRIPS and FTAs: A World of Preferential or Detrimental Relations?*, in *INTELLECTUAL PROPERTY & FREE TRADE AGREEMENTS* 87, 105 n.58 (Christopher Heath & Anselm Kamperman Sanders eds., 2007).

law, the power to negotiate trade agreements rests with the President, who has delegated the authority to the USTR.²⁰³ The USTR's commitment to write the most protective IPR terms into trade agreements could perhaps be justified domestically if these terms were the product of a careful consideration of the U.S. public interest. However, intellectual property lawmaking in the United States is rife with public choice concerns,²⁰⁴ and a number of commentators who have studied the USTR have noted that private interests dominate the agency's agenda.²⁰⁵ Agency capture is problematic for several reasons. Governments have the unique ability and responsibility to engage in long-term planning, to weigh the interests of present generations against future ones, and to create laws that protect the rights of society's underrepresented groups. In stark contrast, private corporations are inherently self-interested and profit-seeking.²⁰⁶ When private interests dominate and effectively replace the democratic process, the outcomes are unlikely to correspond with the public interest. In the case of intellectual property, public interests must be balanced against those of rights-holders.²⁰⁷

1. *U.S. TRIPS-plus Terms Reflect Private Interests*

Susan Sell has documented the ways that the pharmaceutical and entertainment industries have controlled international intellectual property lawmaking for the past few decades.²⁰⁸ Private industry introduced intellectual property as a trade issue, and successfully lobbied both the USTR and foreign governments to make intellectual property enforceable at

203. U.S. CONST. art. 2, § 2, cl. 2; Office of the U.S. Trade Rep., History of the United States Trade Representative, June 2, 2009, <http://www.ustr.gov/about-us/history> (outlining the establishment of the USTR).

204. See Dreyfuss, *TRIPS – Round II*, *supra* note 4, at 26 (noting that right holders have been more successful at getting their demands before legislatures).

205. See, e.g., SELL, *supra* note 18; GREGORY SHAFFER, DEFENDING INTERESTS: PUBLIC-PRIVATE PARTNERSHIPS IN WTO LITIGATION ch. 3 (2003) (tracing the role of private firms in the USTR and their influence on WTO litigation).

206. A.L.I., PRINCIPLES OF CORPORATE GOVERNANCE §2.01(a) (1994) ([A] corporation should have its objective the conduct of business activities with a view to enhancing corporate profit and shareholder gain.)

207. See *supra* notes 7-11 and accompanying text.

208. See SELL, *supra* note 18.

the WTO.²⁰⁹ The American Intellectual Property Committee, a group of twelve chief executive officers from the pharmaceutical, entertainment, and software industries who stood to gain from increased intellectual property protection abroad, prepared the first draft of TRIPS.²¹⁰

The IPR chapters in bilateral agreements are similarly reflective of industry interests.²¹¹ In the process of developing and coordinating government positions on trade issues, the USTR consults with other government agencies through the Trade Policy Review Group (TPRG) and the Trade Policy Staff Committee (TPSC).²¹² An extensive 2007 report on the public health consultation process prepared by the United States Government Accountability Office (GAO) shows that this process does not cure capture concerns.²¹³ GAO found that input from the Department of Health and Human Services did not cover the public health implications of trade agreements, but rather was merely technical in nature, relating primarily to regulatory concerns.²¹⁴ The other major source of input into USTR policymaking is through Industry Trade Advisory Committees, whose purpose is to “ensure that U.S. trade policy and trade negotiation objectives adequately reflect U.S. commercial and economic interests.”²¹⁵ Public health representatives were only added to these committees as of 2007, following NGO lawsuits demanding more representation²¹⁶—and the one public health representative sitting on the Intellectual Property Committee is still significantly outnumbered by the 19 representatives from pharmaceutical and other industry

209. *Id.* at 1-2.

210. *Id.*

211. SELL, *supra* note 18, at 162; *see also* RAYMOND J. AHEARN & WAYNE M. MORRISON, CRS REPORT FOR CONGRESS: U.S.- THAILAND FREE TRADE AGREEMENT NEGOTIATIONS 9 (2006) (reporting the concerns of U.S. IPR stakeholders regarding the Thailand’s IPR enforcement and noting former U.S. Trade Representative Robert Zoellick’s deference to these concerns.)

212. Office of the U.S. Trade Rep, *Mission of the USTR*, Aug. 24, 2009, <http://www.ustr.gov/about-us/mission> [hereinafter *Mission of the USTR*].

213. U.S. GOV’T ACCOUNTABILITY OFFICE, REPORT TO CONGRESSIONAL REQUESTERS: INTELLECTUAL PROPERTY: U.S. TRADE POLICY GUIDANCE ON WTO DECLARATION ON ACCESS TO MEDICINES MAY NEED CLARIFICATION (2007) [hereinafter REPORT TO CONGRESSIONAL REQUESTERS].

214. *Id.* at 52.

215. *Mission of the USTR*, *supra* note 212.

216. REPORT TO CONGRESSIONAL REQUESTERS, *supra* note 213, at 53-54.

sectors.²¹⁷ Furthermore, the introduction of public health representatives on these committees came after the USTR had already concluded nine TRIPS-plus FTAs.²¹⁸

Once a trade agreement has been negotiated, it is submitted to Congress for approval and then to the President for ratification. Most of the agreements discussed in this paper were passed under a “fast track” procedure pursuant to the Trade Promotion Authority Act of 2002,²¹⁹ a process that lacks sufficient opportunity for critical review. It is an expedited procedure through which Congress formally surrenders its ability to condition approval of the agreements on amendments to the negotiated texts, and rather agrees to vote yes or no on the signed and submitted text in exchange for commitment by the President to consult with Congress during the negotiation process.²²⁰ This limits the entire congressional consideration period to a maximum of ninety days.²²¹ While the fast track approach expired in 2007, the numerous FTAs that entered into force through this process have established important momentum and legitimacy for the current template—legitimacy that should be reconsidered in light of procedural deficiencies and long-term consequences for both net-importing and -exporting parties.

2. *The Nature and Content of TRIPS-plus FTAs are Undesirable for the U.S. Public*

Supporters of TRIPS-plus FTAs may argue that because the agreements reflect domestic intellectual property law, their contents have been subject to the democratic process at other stages and therefore do reflect the public interest. Two characteristics of FTAs belie such reassurances. First, there are some instances in which the terms go beyond even domestic law. Second, even where the terms reflect domestic laws, there are inherent problems with writing them into international treaty obligations.

217. *Id.* at 56.

218. *Id.* at 53-54.

219. Trade Promotion Authority Act, 19 U.S.C. § 3803(c), 3804 (2006).

220. FREDERICK M. ABBOTT, INT’L CENTER FOR TRADE AND SUSTAINABLE DEV., ISSUE PAPER NO. 12, INTELLECTUAL PROPERTY PROVISIONS OF BILATERAL AND REGIONAL TRADE AGREEMENTS IN LIGHT OF U.S. FEDERAL LAW 3 (2006).

221. 19 U.S.C. § 3804.

TRIPS-plus FTAs are problematic because, in certain cases, the terms go beyond even domestic law. It is first worth noting that high levels of protection should not be presumed to be optimal even in the United States. Banning parallel imports, for example, has harsh implications for low-income communities in the United States who rely on medicine supplies from Canada. By taking a strong stance against compulsory licensing and signing agreements that limit use of patented medicines to extreme circumstances, the U.S. government is tying its own hands in relation to unanticipated public health crises. Two recent examples illustrate this point. Following the 2001 anthrax attacks, a consensus quickly emerged on the need to ensure sufficient supplies of the standard antibiotic treatment for anthrax exposure: ciprofloxacin (Cipro).²²² Had the Bush Administration not been able to negotiate price reductions with Bayer, the sole producer of Cipro, its only option would have been relying on compulsory licenses. The ongoing H1N1 crisis presents a similar situation, as Tamiflu is patented and produced exclusively by Roche.²²³ While TRIPS-plus PTAs contain emergency exceptions, U.S. domestic law sets the threshold much lower and allows the U.S. government to exercise march-in rights in a variety of circumstances where the President has not yet declared a national emergency.²²⁴ In addition, strong test data protection limits the supply of many significant drugs to a single source, which may cause problems in the face of sudden peaks in demand. Roche's production capacity of 400 million treatments per year raised such concerns and was estimated to be insufficient to cope with the scale of the H1N1 pandemic.²²⁵

To some extent, the United States insulates itself from having to reform domestic laws to comply with TRIPS-plus and "U.S.-plus" FTAs because FTAs are not self-executing under U.S. law.²²⁶ FTAs also have clauses providing that those provi-

222. See Avedissian, *supra* note 7, at 258; SELL, *supra* note 18, at 160.

223. Press Release, Globalization with Equity, CAN-UE Alliance & HAI Latin America and Caribbean, Swine Flu Highlights the Problem of Accepting the Intellectual Property Protections Promoted by the European Union (May 7, 2009), available at http://www.bilaterals.org/spip.php?page=print&id_article=15017.

224. See *supra* notes 116- 117 and accompanying text.

225. Globalization with Equity, *supra* note 223.

226. ABBOTT, *supra* note 220, at 4-5.

sions of the Agreement that are inconsistent with U.S. law shall not have effect.²²⁷ While these are important protections from the U.S. point of view, the United States still incurs international legal obligations by entering into these agreements. Violations of such agreements can be costly on many levels, including soft factors such as damaging diplomatic relations. Furthermore, the IPR terms are subject to binding adjudication and interpretation by an international tribunal whose primary responsibility is to interpret the agreement in light of the text and drafters' intent,²²⁸ a task that is inherently different from drafting intellectual property laws that respond to an evolving public need. As the economic relationship between the United States and its trade partners shifts, and the United States becomes increasingly import-dependent, these concerns will be exacerbated.

B. *TRIPS-Plus Agreements in a Changing Economic Climate*

The primary justification for the United States' firm IPR policies is that they benefit the U.S. economy. The United States profits disproportionately from such heightened standards because it is a major intellectual property exporter. At the time the TRIPS Agreement was signed, the United States was the world's leading exporter of intellectual property,²²⁹ and the United States continues to dominate the business today. As of 2005, U.S. trade in intellectual property produced a surplus of \$32.9 billion.²³⁰

However, it is likely that the balance of trade in intellectual property will shift over the coming decades. In the 19th century, the United States was a net intellectual property importer, a role to which it may eventually return.²³¹ The Ameri-

227. *Id.*

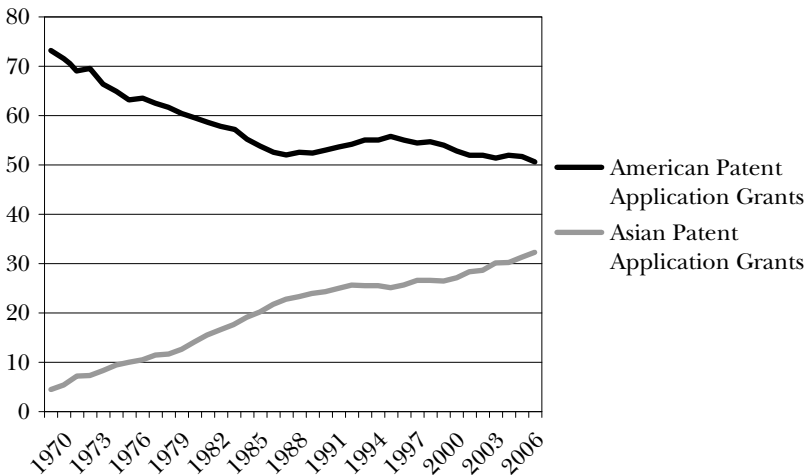
228. The Vienna Convention on the Law of Treaties art. 31 governs interpretation of international agreements and instructs that treaties should be read "in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose." Vienna Convention on the Law of Treaties, art. 31(1), May 23, 1969, 1155 U.N.T.S. 331.

229. Drahos, *Expanding Intellectual Property's Empire*, *supra* note 35, at 2.

230. NAT'L SCI. FOUND., SCIENCE AND ENGINEERING INDICATORS, ch.6 (2008), available at <http://www.nsf.gov/statistics/seind08/c6/c6h.htm>.

231. PAUL GOLDSTEIN, INTELLECTUAL PROPERTY: THE TOUGH NEW REALITIES THAT COULD MAKE OR BREAK YOUR BUSINESS 35-36 (2007).

can surplus today is mostly a result of high profits from copyrights, stemming predominantly from the entertainment industry, but comparative advantages in R&D are causing export centers in certain patent-based industries, such as information technology (IT), to shift to Asia.²³² The emergence of this trend is increasingly evident. An examination of the number of patents granted by the U.S. Patent and Trademark Office (PTO) as distributed by the year of application grant shows a steady decline in the percentage of patent filings by Americans.²³³ The graph below illustrates the increase in the number of patents granted to Asian rights-holders and the corresponding decrease in American patents.²³⁴



The balance of trade between Japan and the United States more precisely illustrates this trend. When viewed as a whole,

232. *Id.*

233. U.S. PATENT AND TRADEMARK OFFICE [USPTO], PATENT TECHNOLOGY MONITORING TEAM, HISTORIC DATA, ALL TECHNOLOGIES (UTILITY PATENTS) REPORT, Part A1 (2008), available at http://www.uspto.gov/go/taf/h_at.htm#PartA1_2.

234. The graph is based on data gathered from USPTO, PATENT TECHNOLOGY MONITORING TEAM, EXTENDED YEAR SET – HISTORIC PATENTS BY STATE, COUNTRY, YEAR (Dec. 2008), available at http://www.uspto.gov/go/taf/cst_utlh.htm.

the balance of trade in royalty payments between the United States and Japan remains in the United States' favor, largely due to U.S. copyright royalties. But when patent industries are viewed in isolation, a certain shift in the balance of trade is apparent. As Ken Jarboe reports, the "royalty balance in industrial property (trademark rights, right of registered designs, utility model rights, and patents) turned to a Japanese surplus in 2002," attributable to growth in the automobile, electrical machinery, and IT industries.²³⁵ Recognizing this shift, some large U.S. businesses, including Microsoft and Cisco, are responding by establishing their business centers in Asia.²³⁶

Even in Asian economies that are less advanced than Japan, the large numbers of engineers turned out each year are combining with rapidly growing populations to contribute to the likelihood of a shift in innovation output. New investments in higher education in places such as India and China have resulted in tremendous increases in the number of engineers; commonly cited statistics suggest that in 2005 more than 600,000 engineers graduated from institutions of higher education in China,²³⁷ while in India the figure was 350,000.²³⁸ In the United States, it was about 70,000.²³⁹ Though the exact accuracy of these numbers has since been called into question, the relative proportions still make the case that centers of innovation are relocating from the United States to Asia.²⁴⁰

Over the coming years, it is thus plausible that the United States will become increasingly dependent on Asian innova-

235. Ken Jarboe, *U.S. Japan Royalty Payments Balance of Trade*, ATHENA ALLIANCE, Oct. 18, 2006, http://www.athenaalliance.org/weblog/archives/2006/10/us_japan_royalt.html.

236. GOLDSTEIN, *supra* note 231, at 36.

237. Geoffrey Colvin, *Is America the World's 97-pound Weakling?*, FORTUNE MAG., July 22, 2005, available at <http://www.mutualofamerica.com/articles/Fortune/July2005/fortune.asp>.

238. *Id.*

239. *Id.*

240. See, e.g., Vivek Wadhwa et al., *Where the Engineers Are*, ISSUES IN SCI. & TECH. (Spring 2007), available at <http://www.issues.org/23.3/wadhwa.html> (noting that these numbers have been referenced by "various articles in the popular media, speeches by policy-makers . . . reports to Congress . . . the National Academies and the U.S. Department of Education"). Wadhwa's own findings differ, but reflect similar proportions.

tions. If such a shift continues and eventually results in a U.S. deficit in industrial property trade, the terms in FTAs that impose strict IPR protection will result in higher costs to U.S. consumers. To protect future generations from bearing the burden of higher prices, the USTR should shift away from negotiating trade agreements that only serve the economic interest of net exporters. While domestic laws can be amended to respond to changing circumstances, international obligations are not easily renegotiated. This is especially salient as Asian economies continue to grow while the United States' comparative bargaining power shrinks. The utilization of international trade agreements to implement high levels of intellectual property protection should be reconsidered, as it may have long-term negative consequences on U.S. users of intellectual property.

C. *Strategic Implications of TRIPS-Plus*

Even if TRIPS-plus PTAs were to serve the best interests of the countries bargaining for them, excessive rigidity is not an optimal strategy for achieving higher intellectual property protection around the world. In net importing countries, governments and civil society movements are increasingly raising their voices in objection to TRIPS-plus provisions that create social costs and undermine basic human rights, such as by limiting access to essential medicines.²⁴¹ Much of the anti-TRIPS-plus movement has focused on provisions that limit compulsory licensing options for developing countries facing severe public health crises. Despite these human rights concerns, and in disregard of the Doha Declaration, the United States has refused to depart from its one-size-fits-all approach and has presented IPR provisions in a "take it or leave it" fashion. Un-

241. Protests and opposition movements surrounding the U.S.-Thailand FTA are a prime example. In Thailand, 10,000 protesters took to the streets during the Chiang Mai round of negotiations in January 2006. Bilaterals.org, US-Thailand, April 2009, http://www.bilaterals.org/rubrique.php?id_rubrique=19. Internationally, 46 international NGOs joined in a solidarity statement to express their opposition to the FTA and its effects on medicines. International NGO Solidarity Statement, US-Thai Free Trade Negotiations Threaten Access to Medicines; Activists Demand Suspension of Negotiations and End to TRIPS-plus IP Provisions (Jan. 9, 2006) *available at* <http://www.cptech.org/ip/health/c/thailand/solidaritystatement01092006.doc>.

ble to negotiate around these terms, developing countries have resorted to rejecting IPR chapters altogether, resulting in chronically stalled and failed negotiations.²⁴²

Opposition to TRIPS-plus has been particularly strong in countries with severe HIV/AIDS problems, where fears that PTAs would hinder the country's ability to supply low-cost antiretroviral drugs (ARVs) have defeated negotiations.²⁴³ Among the public health concerns in the developing world, HIV/AIDS has taken on a central role in the pharmaceutical patenting debate due to the pandemic's soaring infection rates and accompanying disputes over drug pricing.²⁴⁴ UNAIDS estimates that around 33 million people are living with HIV worldwide.²⁴⁵ While ARVs do not cure the disease, they have "dramatically improved rates of mortality and morbidity, prolonged lives, improved the quality of life, revitalized communities and transformed perceptions of HIV/AIDS so that it is seen as a manageable chronic illness rather than as a plague,"²⁴⁶ in the words of the WHO. Due to high costs, however, access to ARVs is greatly limited among the poor.²⁴⁷ The WHO estimates that only 42 percent of those needing ARVs

242. In addition to the Thai case, negotiations between the Southern African Customs Union (South Africa, Botswana, Lesotho and Swaziland) and both the U.S. and EFTA States have failed under similar circumstances. Kampf, *supra* note 202, at fn.58.

243. See Collins-Chase, *supra* note 37, at 780-93 (discussing the costs of FTAs for Thailand and SACU countries in light of their HIV/AIDS problems); Médecins Sans Frontières, *Call for Moratorium on Trade Provisions that Threaten Access to Medicines or Treatment Programmes*, Aug. 17, 2006, http://www.msf.org/msfinternational/invoke.cfm?objectId=1D04D94F-5056-AA77-6CC351A5BE86A965&component=toolkit.article&method=full_html.

244. See Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317, 322 (2005) (noting that "the medicines controversy at the WTO arose out of events surrounding the HIV/AIDS pandemic").

245. Joint United Nations Programme on HIV/AIDS [UNAIDS], *Executive Summary of 2008 Report on the Global AIDS Epidemic* 5 (2008), available at http://data.unaids.org/pub/GlobalReport/2008/JC1511_GR08_ExecutiveSummary_en.pdf.

246. WHO, *Scaling Up Antiretroviral Therapy in Resource-Limited Settings: Guidelines for a Public Health Approach* 19 (June 2002); see also Collins-Chase, *supra* note 37, at 768 (explaining that the gap in access to medicines can be largely attributed to the cost of treatment).

247. See Collins-Chase, *supra* note 37, at 768 ("While many factors contribute to unavailability of medicines, in large part the access gap can be attributed to the cost of treatment.").

worldwide are actually receiving them.²⁴⁸ Availability of generic drugs could transform the HIV/AIDS reality. Patented ARVs cost on average \$15,000 per patient per year, whereas generic versions cost as little as \$99.²⁴⁹ The effects of TRIPS-plus terms that limit access to generics thus have a substantial impact on HIV treatment options.

1. *Example: The Failed Negotiation of a Thailand-U.S. Free Trade Agreement*

While the international community continually recognizes the critical nature of the HIV/AIDS pandemic, TRIPS-plus provisions are inimical to efforts to improve drug access. The United States' unflinching stance in favor of such provisions has drawn significant bad press,²⁵⁰ and has led several countries to walk away from PTA negotiations. The Thailand-U.S. FTA is but one example of such a controversy. Negotiations for a Thailand-U.S. FTA began in 2004.²⁵¹ Inclusion of IPRs in any agreement has been of great importance to the United States, as Thailand is a primary staging point for Asia's counterfeit market. The International Intellectual Property Rights Alliance estimates that IPR piracy in Thailand cost U.S. firms \$160 million in 2002.²⁵² Thailand's high counterfeiting and piracy rates have earned it a spot on the 2008 USTR Priority Watch List, signifying that it is the focus of increased bilateral attention concerning problems in IPR protection, en-

248. WHO, *Towards Universal Access: Scaling Up Priority HIV/AIDS Interventions in the Health Sector, Progress Report 5* (2009) [hereinafter WHO, *Towards Universal Access*], available at http://www.who.int/hiv/pub/tuapr_2009_en.pdf.

249. SMITH, *supra* note 65, at 8 (citing MÉDECINS SANS FRONTIÈRES, UNTANGLING THE WEB OF PRICE REDUCTIONS: A PRICING GUIDE FOR THE PURCHASE OF ARVs FOR DEVELOPING COUNTRIES (10th ed. 2007)).

250. See, e.g., James Love, *Making Enemies – The US/Thai FTA Negotiations are Bitter Medicine*, HUFFINGTON POST, Jan. 11, 2006, available at http://www.huffingtonpost.com/james-love/making-enemies-the-ust_b_13603.html (arguing that the approach to IPRs in the U.S.-Thai FTA negotiations epitomizes the reasons why people dislike the United States); Bilaterals.org, Intellectual Property, http://www.bilaterals.org/rubrique.php?id_rubrique=33 (database of news articles that criticize FTAs).

251. Office of the U.S. Trade Rep., Thailand, Oct. 27, 2009, http://www.ustr.gov/Trade_Agreements/Bilateral/Thail_FTA/Section_Index.html.

252. INT'L INTELL. PROP. RTS. ALLIANCE, 2003 SPECIAL 301 REPORT: THAILAND, at 324 (2003), available at <http://www.iipa.com/rbc/2003/2003SPEC301THAILAND.pdf>.

forcement, or market access.²⁵³ While the United States has cognizable interests in obtaining higher IPR standards in Thailand, certain aspects of the TRIPS-plus patent provisions pushed for by the United States have conflicted with the Thai government's legitimate interests in responding to public health concerns. As a result, the rigid IPR terms proposed by the United States in FTA negotiations have been a source of major controversy.²⁵⁴ Since the opening of talks in 2003, six rounds of negotiations have failed and are currently stalled in large part because of Thai objections to strict patent standards.²⁵⁵

The issues of compulsory licensing and data exclusivity of pharmaceutical patents have been at the center of disagreements between the two countries.²⁵⁶ Thailand struggled with high HIV infection rates in the 1980s and 1990s.²⁵⁷ The Thai government committed to combating the spread of HIV through comprehensive condom distribution awareness programs in 1991,²⁵⁸ and adopted a universal ARV coverage policy

253. OFFICE OF THE U.S. TRADE REP., 2008 SPECIAL 301 REPORT, at 18, 36-37 (2008) [hereinafter USTR, SPECIAL 301 REPORT], available at http://www.ustr.gov/sites/default/files/asset_upload_file553_14869.pdf.

254. See Rungrawee C. Pinyorat, *Thai Civil Groups Want IP Off Trade-Talks Agenda With U.S.*, THE NATION, Oct. 12, 2004, available at http://www.bilaterals.org/article.php?id_article=835 (reporting that in the Thailand-U.S. free trade negotiations, there has been a specific outcry against altering intellectual property laws under the agreement).

255. RAYMOND J. AHEARN & WAYNE M. MORRISON, U.S.-THAILAND FREE TRADE AGREEMENT NEGOTIATIONS (2006) (CRS Report to Congress), available at <http://www.nationalaglawcenter.org/assets/crs/RL32314.pdf>.

256. See Daniel Ten Kate, *Mounting Opposition to FTA Drug Rules*, THAI DAY, Jan. 13, 2006, available at <http://www.biothai.org/cgi-bin/content/news/show.pl?0115>; FTA Watch, *supra* note 191, at 3 (reporting that the biggest threats are in the area of expanded patent protection and protection of undisclosed information concerning medicines.)

257. AVERT, HIV and AIDS in Thailand, <http://www.avert.org/aidsthai.htm> (last visited Feb. 19, 2010) ("Between 1988 and 1989, the HIV prevalence among injecting drug users rose dramatically from almost zero to 40%. The prevalence among sex workers also increased, with studies in Chang Mai suggesting that 44% of sex workers were infected with HIV. The rising level of infection among sex workers led to subsequent waves of the epidemic among the male clients of sex workers, their wives and partners, and their children.").

258. See *id.* (providing a historical overview of rates and responses in Thailand); WHO, Thailand Achieves Sustained Reduction in HIV Infection

in 2003.²⁵⁹ Amid objections from the United States, the Thai government issued a compulsory license for the import and production of a generic version of Efavirenz, a first-line ARV, from India.²⁶⁰ Thailand is now one of only a few countries where access to ARVs among HIV/AIDS patients has surpassed 80 percent.²⁶¹ Following this public health success, Thailand has insisted on retaining the ability to grant compulsory licenses and import generics, and has refused to commit to terms that would prohibit such practices.²⁶²

At the same time, the Thai government has also demonstrated a commitment to improving copyright protection and combating counterfeiting.²⁶³ But the United States has not been willing to budge on the compulsory license issue, leading to calls for exclusion of IPRs from the agreement altogether.²⁶⁴ These disagreements have been a key source of the failure of negotiations thus far.²⁶⁵ Overall, an FTA with Thai-

Rates, <http://www.who.int/inf-new/aids1.htm> (last visited Feb. 19, 2010) (reporting a decline in infection rates resulting from increased condom use).

259. Robert Steinbrook, *Thailand and the Compulsory Licensing of Efavirenz*, 356 NEW ENG. J. MED. 544, 544 (2007).

260. MINISTRY OF PUBLIC HEALTH OF THAILAND, DEPARTMENT OF DISEASE CONTROL, ANNOUNCEMENT ON THE PUBLIC USE OF PATENT FOR PHARMACEUTICAL PRODUCTS (Nov. 29, 2006), available at <http://www.cptech.org/ip/health/c/thailand/thaicl4efavirenz.html>; see also USTR, SPECIAL 301 REPORT, *supra* note 253, at 37 (giving Thailand's decision to issue compulsory licensing as a reason for the country's inclusion on the list); Letter from 40 NGOs and 100 individuals, to Condoleezza Rice, Secretary of State and to Susan Schwab, United States Trade Representative (Dec 21, 2006), available at <http://www.cptech.org/ip/health/c/thailand/riceschwabthailand21dec06.pdf> (requesting that the U.S. government not interfere with the Thai government's decision to grant a compulsory license).

261. WHO, *Towards Universal Access*, *supra* note 248, at 15 tbl.1.

262. On March 7, 2009, the Thai Prime Minister reaffirmed the Thai government's policy on compulsory licensing despite continuing trade pressures from the United States. Surasak Glahan, *Government to Affirm CL Stance in U.S.*, BANGKOK POST, Mar. 7, 2009, available at <http://www.bangkokpost.com/print/12892/govt-to-affirm-cl-stance-in-us>.

263. Edward J. Kelly & David Lyman, *Anti-Counterfeiting Campaigns: Strategies for Thailand*, Oct. 2001, at 7, http://www.tillekeandgibbins.co.th/Publications/pdf/anti_counterfeiting_campaigns.pdf (noting the Thai government's commitment to enforcing IPRs in Thailand).

264. Kampf, *supra* note 202, at n.58.

265. See Third World Network, *Thai Human Rights Commission Attacks FTA with US*, Jan. 24, 2007, <http://www.twinside.org.sg/title2/twninfo492.htm> (quoting a report from the Thai Human Rights Commissioner stating that "[t]he fact that Thailand is on the receiving end with the United States uni-

land could generate significant economic benefits for the United States,²⁶⁶ but the countries' ability to reach an agreement may depend on the United States' willingness to allow flexibility on patent terms.

The Thai example illustrates two points regarding the implications of the U.S. TRIPS-plus strategy. First, the USTR's refusal to be flexible with regards to the legitimate and critical public policies of trading partners has resulted in costly and lengthy negotiation failures. By making concessions in certain areas when it is in the interest of human rights, the United States can secure both higher intellectual property protection in other areas and greater market access to vital economic spheres. Second, the United States' hard-line approach has earned the government an unnecessarily negative reputation both for itself and for free trade. In the trade context, the United States has been portrayed as insensitive to public health and human rights, causing it to lose face in the international community.²⁶⁷ Further, the opposition movements that have grown out of these causes have been highly successful in marring the name of free trade as a whole, which has created costly obstacles to negotiating deals, especially in countries where governments are particularly responsive to public opinion. To date, the Thai case is not unique; similar resistance has been seen in other countries facing severe public health problems. For example, the five members of the Southern African Customs Union have rejected agreements with both the United States and the EFTA states on grounds similar to those in the Thai case. As the global effort to combat infectious diseases such as HIV, tuberculosis, and malaria grows, governments and non-state actors increasingly recognize access to medicines as a basic human right.²⁶⁸ In light of this, it is in the United States' strategic interest to adopt a trading strategy that respects the public health needs of its trading partners.

laterally making a 'take it or leave it' proposal" was the factor most deserving of criticism in the U.S.-Thailand FTA negotiations).

266. Press Release, Office of the U.S. Trade Rep., United States and Thailand Conclude Fifth Round of FTA Talks (Oct. 3, 2005), *available at* http://www.ustr.gov/Document_Library/Press_Releases/2005/October/United_States_Thail_Conclude_Fifth_Round_of_FTA_Talks.html.

267. *See* note 250, *supra*. . .

268. *See, e.g.*, WHO, The 3 by 5 Initiative, <http://www.who.int/3by5/en/> (last visited Feb. 19, 2010); *supra* notes 93-95 and accompanying text.

V. CONCLUSION

Intellectual property protection has social costs and benefits that must be carefully balanced in domestic and international legal frameworks. The TRIPS Agreement states as its objective:

“The protection and enforcement of [IPRs] should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”²⁶⁹

The emergence of bilateral PTAs as a mechanism for raising intellectual property protection past the levels in TRIPS offsets this balance, and is problematic because the terms impose permanent constraints on development, and on the realization of economic and social rights in developing and developed countries alike.

Despite the increasing attention given to the general impact of intellectual property protection on fundamental rights such as access to medicines and food security, there is a lack of literature that analyzes and evaluates the legal and societal implications of specific TRIPS-plus terms. This Note surveyed the TRIPS-plus PTAs in force in Asia and the Pacific. At the outset, the Note questioned whether high levels of intellectual property protection constitute a desirable policy choice for developing countries given that such protections primarily serve the interest of rights-holders, who are predominantly located in developed, net importing countries. Despite promises to the contrary, there is not a clear causal relationship between strong IPRs and higher rates of foreign investment and technology transfers in developing countries. In Part II, the Note traced the history of intellectual property as a trade issue and provided an overview of the increased reliance on bilateral PTAs to push intellectual property protection in net importing countries with traditionally lower levels of protection. Part III analyzed the TRIPS-plus terms in Asia-Pacific PTAs and compared them to the TRIPS Agreement. TRIPS-plus PTAs exceed TRIPS in four main areas: first, PTAs compel accession to, or compliance with, international intellectual property con-

269. TRIPS, *supra* note 5, art. 7.

ventions that are not contained in TRIPS; second, PTAs mandate strengthened intellectual property enforcement procedures and penalties; third, they provide expanded protection of pharmaceutical patents and data, and restrict policy options for designing domestic intellectual property laws on parallel imports; and finally, they limit the flexibility found in TRIPS with regards to plant patenting. Many of these TRIPS-plus terms generate significant economic and social costs for net importing countries—costs that are especially severe for developing countries.

While the TRIPS Agreement has itself raised intellectual property protection around the world in an unprecedented manner, it includes flexibilities and safeguards that have been further omitted from bilateral PTAs. TRIPS explicitly protects governments' abilities to legislate and adopt policies that protect public health and nutrition, and promotes the public interest through its principles and pharmaceutical and plant patenting provisions. TRIPS also respects states' resource constraints by allowing for implementation delays and ensuring that the enforcement of TRIPS does not require the establishment of a separate enforcement system or inhibit the enforcement of a country's own laws. These flexibilities are central to both the letter and spirit of the TRIPS Agreement, and were reaffirmed in the Doha Declaration. In order to ensure that bilateral trade agreements do not infringe on economic and social rights, the intellectual property chapters of PTAs should at a minimum preserve the flexibilities and public policy protections contained in TRIPS.

A scaling back of rigid TRIPS-plus provisions will require a concerted effort by a number of global actors. Net importing countries need fuller information on the long-term impacts of intellectual property terms, and scholars and NGOs can contribute more systematic and scientific studies in this area. Legal professionals can play a critical role in conducting human rights impact assessments and providing legal expertise during the negotiation of intellectual property terms. Net exporting countries must also engage more critically with the justifications for TRIPS-plus terms. These trade policies affect the realization of international human rights obligations in both trade partners' territories and third countries, and also have negative impacts on exporters. In Part IV, this Note argued that it is not in the United States' interest to maintain rigid

TRIPS-plus terms as a cornerstone of its trade policy because such terms serve U.S. industry at the expense of the public, and writing the terms into international trade agreements is unwise given changing international economic relations. While this Note focused on the United States, the arguments presented above are also applicable to other net exporters who pursue TRIPS-plus terms.

The past decade highlighted the new global nature of critical public policy challenges; food insecurity, climate change, and pandemics such as the H1N1 influenza are perils that cross borders irrespective of levels of development. Addressing these challenges will require flexibility and cooperation within the global legal framework. International intellectual property laws are of key relevance to a wide array of these issues, and must therefore maintain a balance that will allow governments to meet the challenges ahead.