Global Business & Development Law Journal

Volume 26 | Issue 1 Article 11

2-1-2013

Responsible Patent Protections: Preserving Public Health Objectives in the Trans-Pacific Partnership Agreement

Christina Bucci

Responsible Patent Protections: Preserving Public Health Objectives in the Trans-Pacific Partnership Agreement

*Christina Bucci**

TABLE OF CONTENTS

* J.D., University of the Pacific, McGeorge School of Law, to be conferred May 2013; B.A., Communication, specialization in Media Studies, San Diego State University, 2008. I would like to extend special thanks and gratitude to Professor Mike Mireles for his guidance in this project; his comments and suggestions on earlier drafts were invaluable. I also thank my family and friends for their endless support and encouragement.

I. INTRODUCTION

Patent protection, as a part of the larger package of intellectual property protection, plays a prominent role in today's free trade agreement negotiations.[1] As the business of pharmaceuticals increases internationally, the degree of protection nations incorporate into these agreements has a direct effect on access to medicine around the world.[2] As a matter of intellectual property, the premier governing document is the Agreement on Trade-Related Aspects of Intellectual Property ("TRIPS").[3] TRIPS creates, at a minimum, floors which signatory countries must implement into their respective domestic policies.[4] In a post-TRIPS world, however, we see countries increasingly relying on bilateral agreements to achieve higher standards of intellectual property rights.[5] These higher standards have a particularly debilitating effect on how lower income countries provide their citizens access to life-saving medication.[6]

Scientific innovation in the area of anti-retroviral drugs has turned an HIV-positive diagnosis into something that is manageable, where just twenty years ago it may have well been a death sentence.[7] However, HIV/AIDS very much remains an epidemic, especially in lesser-developed countries where access to anti-retrovirals is a problem.[8] Providing treatment for HIV/AIDS is about much more than improving quality of life for those infected, it is about curbing the rapid spread of the virus.[9] Access to these medicines, however, remains a problem for middle to low-income countries.[10] In 2010, for example, UNAIDS

1. *See* Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 CHI. J. INT'L L. 47, 47 (2002).

2. *See id.* at 58-59.

3. *See* GRAEME B. DINWOODIE ET AL., INTERNATIONAL AND COMPARATIVE PATENT LAW 231-32 (2002).

4. Annette Kur & Henning Grosse Ruse-Khan, *Enough is Enough—The Notion of Binding Ceilings in International Intellectual Property Protection* 9 (Max Planck Inst. for Intellectual Prop., Competition & Tax Law Research Paper Series No. 09-01, 2008), *available at* http://ssrn.com/abstract=1326429; *see also* Henning Grosse Ruse-Khan, *The International Law Relation Between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding Flexibilities?*, 18 J. INTELL. PROP. L. 325, 328-29 (2011) (discussing whether treaty interpretation norms allow the policy flexibilities found in TRIPS to be preserved despite higher protections in TRIPS-plus agreements).

5. *See infra* Part III.

6. *See* Ruse-Kahn, *supra* note 4, at 329-30.

7. *See* UNAIDS, OUTLOOK REPORT OF JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS 64-71 (2011), *available at* http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/20110607_jc2069_30outlook_en.pdf (tracking the progress of treatments developed for HIV/AIDS over the last thirty years); Miles D. White, *Drug Patents Are Good for Our Health*, PHRMA.ORG, http://www.phrma.org/drug-patents-are-good-our-health (last visited Jan. 11, 2012).

8. *See generally* MÉDECINS SANS FRONTIÈRES, UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS (14th ed. 2011), *available at* apps.who.int/medicinedocs/documents/s18716en/s18716en.pdf.

9. *Id.*

10. Horace E. Anderson, Jr., *We Can Work it Out: Co-Op Compulsory Licensing as the Way Forward in Improving Access to Anti-Retroviral Drugs*, 16 B.U. J. SCI. & TECH. L. 167, 171 (2010).

reported that the adult HIV prevalence was five percent in Sub-Saharan Africa; globally, 2.5 million children under the age of fifteen are living with HIV.[11] In contrast to those numbers, only twenty-eight percent of patients outside of North America have access to anti-retroviral therapy.[12]

"Access" in this context means much more than physical access; in many cases, the drugs exist but are priced far out of reach. Existing free trade agreements, and new agreements that are being negotiated, such as the Trans-Pacific Partnership Agreement ("TPPA"), affect a country's intellectual property scheme which, in turn, affects how quickly new drugs become available in both the physical and pricing sense.[13] As such, the humanitarian and public health voice can be heard loud and clear amidst today's trade negotiations dealing with international intellectual property protections.[14] This voice sees access to health as a fundamental human right not to be ignored.[15]

Also prominent is the voice of the "market fundamentalist," urging higher patent protection, the absence of which, they argue, would stifle further innovation by lowering incentives.[16] Pharmaceuticals are unique in that many research and development endeavors end in failure.[17] Furthermore, the costs of research and development are a significant portion of the total production cost.[18] In turn, even the smallest return on investment from a successful product keeps the incentive for more research and development alive.[19] In the context of AIDS medication, Abbot Pharmaceuticals' CEO poses a question: AIDS "is a disease that is always new—due to the constant evolution of the virus—and requires new solutions. Where will these come from if we hobble the patent system that drives innovation?"[20] Given the foregoing, this argument makes sense. However, what if, on a global scale, intellectual property rights become so extreme that they begin to discourage

11 UNAIDS, GLOBAL REPORT FACT SHEET 1 (2010), *available at* www.unaids.org/documents/20101123_FS_Global_em_en.pdf.

12. *Id*. at 2.

13. *See infra* Part IV for a discussion on intellectual property rights-related negotiations for the Trans-Pacific Partnership Agreement.

14. *See, e.g.*, JOSEPH BRENNER & ELLEN R. SHAFFER, CTR. FOR POLICY ANALYSIS ON TRADE & HEALTH, COMMENTS CONCERNING PROPOSED UNITED STATES-TRANS-PACIFIC PARTNERSHIP TRADE AGREEMENT 17 (2010), *available at* http://www.cpath.org/sitebuildercontent/sitebuilderfiles/p-cpathontpp1-25-2010.pdf (recommending that the TPPA not contain any TRIPS-plus provisions).

15. Anderson, Jr., *supra* note 10, at 176-77; *see also* Ellen 't Hoen, *Report of the Commission on Intellectual Property Rights, Innovation and Public Health: A Call to Governments*, 84 BULL. WORLD HEALTH ORG. 421, 422 (2006), *available at* www.who.int/bulletin/volumes/84/5/421.pdf. The World Health Organization uses framework set forth by the United Nations to define the "right to health": availability, acceptability, accessibility and quality. *See id*. This Comment deals with intellectual property policy that affects accessibility by keeping medicines priced out of reach for many.

16. Anderson, Jr., *supra* note 10, at 177-79; *see* Sykes, *supra* note 1, at 60-62.

17. Sykes, *supra* note 1, at 61.

18. *Id*. at 60.

19. *See id.*

20. White, *supra* note 7.

pharmaceutical innovation and competition, all the while stifling access to life-saving drugs? This result is not good for either side of the debate.

In Part II, this Comment lays out the provisions of TRIPS and the changes made by the Doha Declaration on Public Health ("DOHA Declaration"). This is a necessary foundation to any discussion about intellectual property rights and public health. Part III will examine TRIPS-plus intellectual property rights: data exclusivity, parallel importation, and patent/registration linkage. It will focus on the effects these higher protections have on access to essential medicines, such as anti-retrovirals, in developing countries. In addition, Part III will discuss how to reconcile these intellectual property rights with the DOHA Declaration, and explore the Central American Free Trade Agreement ("CAFTA") as an example of a TRIPS-plus agreement. Finally, Part IV will examine negotiations and proposed text for the Trans-Pacific Partnership Agreement.

This Comment will conclude with a recommendation that a socially responsible Trans-Pacific Partnership Agreement should not include the extensive TRIPS-plus protections seen in recent bilateral trade agreements. While still in negotiations, even a potential Trans-Pacific Partnership Agreement that incorporates unconditional data exclusivity,[21] patent/ registration linkage,[22] and a prohibition of parallel importation[23] can only serve to pad the monetary interests of the already-thriving pharmaceutical industry.[24] At the same time, it would further stifle access to life-saving drugs in already-struggling, lesser-developed countries. Lastly, it is not enough to provide a textual acknowledgement to TRIPS flexibilities and the DOHA Declaration on Public Health if the actual provisions do not allow for public health improvements through access in the poorest corners of the world.[25]

II. THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS AND THE DOHA DECLARATION ON PUBLIC HEALTH

A. The Agreement on Trade-Related Aspects of Intellectual Property

Before 1995, a comprehensive agreement did not exist to provide international intellectual property protection.[26] This being the case, nations were

21. *See infra* Part III.A.

22. *See infra* Part III.C.

23. *See infra* Part III.B.

24. Press Release, Jerry Carey, Univ. of Med. & Dentistry of N.J., Authors Dispute "Innovation Crisis" among Pharmaceutical Companies (Aug. 8, 2012), *available at* http://www.umdnj.edu/cgi-bin/cgiwrap/hpappweb/newsroom.cgi?month=08&day=08&year=12&headline=Authors+Dispute++Innovation+Crisis++among+Pharmaceutical+Companies.

25. Bryan Mercurio, *Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines,* 5 NW. U. J. INT'L HUM. RTS. 1, 7 (2006).

26. Frederick M. Abbot & Jerome H. Rechman, *The Doha Round's Public Health Legacy: Strategies for*

free to fashion their own patent system, some excluding pharmaceuticals from patent protection altogether.[27] TRIPS was a landmark attempt to remedy this gap in the body of international trade law by providing minimum levels of intellectual property protection.[28] TRIPS is a supplemental agreement to that which created the World Trade Organization ("WTO") in 1994,[29] and adherence to TRIPS is a requirement of WTO membership.[30] This relationship forced countries to evaluate the value of WTO membership as a whole, despite "any detriment from providing protection to foreign intellectual property."[31] By including sweeping intellectual property mandates in agreements with broad subject-matter coverage (like potentially the Trans-Pacific Partnership Agreement), developing countries may accede because the trade benefits carry greater weight than the potential harm of the chapter on intellectual property.[32] The likely compromise in this situation is built-in exceptions. As is true with negotiations of today's free-trade agreements, the disparate intellectual property policies and concerns of developed versus developing countries resulted in TRIPS containing certain exemptions to the patent provisions of TRIPS, often referred to as "flexibilities."[33]

TRIPS mandates that member countries provide patents for "any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application."[34] Patents must provide the holder with exclusive rights to prevent development, use, sale, and importation by others without consent of the patent holder.[35] Article 31 provides a major exception, or flexibility, to these baseline requirements: compulsory licensing.[36]

the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions, 10 J. INT'L ECON. L. 921, 927 (2007).

27. *Id.*

28. *See* Donald Harris, *TRIPS After Fifteen Years: Success or Failure, As Measured By Compulsory Licensing*, 18 J. INTELL. PROP. L. 367, 369 (2011).

29. DINWOODIE ET AL., *supra* note 3, at 231-32.

30. DANIEL C.K. CHOW & EDWARD LEE, INTERNATIONAL INTELLECTUAL PROPERTY 25-26 (2006).

31. DINWOODIE ET AL., *supra* note 3.

32. CHOW & LEE, *supra* note 30.

33. Sykes, *supra* note 1, at 50-55. In addition to the flexibilities, TRIPS members also operate on different deadlines for implementing treaty provisions to account for the many countries which are at a lesser stage of economic development. CHOW & LEE, *supra* note 30.

34. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, § 1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1896 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

35. *Id.*

36. *Id.* at art. 31.

B. Compulsory Licensing Under TRIPS

Compulsory licensing remains a controversial public-health resource.[37] The basic tenet of compulsory licensing is that it allows a government or government-approved third party, usually a generic manufacturer, to obtain limited use rights for a drug without the patent owner's consent.[38] TRIPS provides conditions that must be met before a compulsory license may be issued. It prescribes, in pertinent part, that a proposed user must first make efforts to negotiate authorization on "reasonable commercial terms and conditions."[39] If, after a "reasonable period of time" these negotiations have failed, a compulsory license may be granted.[40] However, the subsection also provides exceptions, providing for waiver of the negotiation period in cases of national emergency, extreme urgency, non-commercial use by the government, or to remedy anti-competitive practices.[41] Once granted, a compulsory license does not come with the same exclusivity rights as a patent.[42] Just as compulsory licenses may only be issued in limited situations, the rights associated with the license are equally limited.[43] Especially relevant to this discussion is the requirement that the use "be authorized predominantly for the supply of the domestic market."[44] In practice, this provision highlights one of TRIPS' shortcomings, at least from the vantage point of developing countries and humanitarians.[45] Many of the least-developed countries lack the manufacturing capability to produce drugs domestically under a compulsory license.[46] It follows that many of the countries for which this flexibility was intended would be unable to utilize the flexibility.[47]

In 2001, faced with a growing HIV/AIDS crisis, South Africa enacted a piece of legislation that issued a compulsory license to produce AIDS medicines to

37. *See e.g.*, Harris, *supra* note 28, at 383-96 (evaluating the success or failure of the TRIPS agreement measure by the various usage of compulsory licensing by members to the agreement and restrictions on the licensing in subsequent agreements).

38. *Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Jan. 11, 2012).

39. TRIPS, *supra* note 34, at art. 31(b).

40. *Id.*

41. *Id*. at art. 31(b)-(k). The 2001 Doha Declaration makes clear that member countries have "the right to determine what constitutes a national emergency or other circumstances of extreme urgency" and explicitly categorizes a crisis related to HIV/AIDS as one such circumstance. World Trade Organization, Ministerial Declaration of 14 November 2001 on the TRIPS Agreement and Public Health, para. 1, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration].

42. TRIPS, *supra* note 34, at art. 31(b)-(k)

43. *Id*. The terms and conditions in Article 31 "weakened compulsory licensing as an access tool by, among other things, requiring negotiations with the patent holder…limiting the scope and duration…, and limiting compulsory licensing to use in supplying the domestic (non-export) market." Anderson, Jr., *supra* note 10.

44. TRIPS, *supra* note 34, at art. 31(f).

45. Harris, *supra* note 28, at 386.

46. *Id.* at 384-86.

47. *Id.* at 387.

local manufacturers.[48] However, the new law also allowed the country to import the drugs from countries that produced it at a lower cost than the patent owner.[49] In response, the patent owners filed suit, claiming that the legislation violated TRIPS because the law "allowed the South African health minister to act unilaterally without first having to prove a drug manufacturer abused its patent," and issued compulsory licenses without first obtaining the patent owners' consent.[50] The suit was eventually dismissed but it was this landscape that gave rise to the DOHA Declaration on Public Health and the subsequent TRIPS amendment.[51]

C. The DOHA Declaration on Public Health

In 2001, the World Trade Organization released the Declaration on the TRIPS Agreement and Public Health.[52] Though it is not a legally binding amendment to TRIPS, the Declaration is persuasive authority for interpretation of what TRIPS requires, especially regarding compulsory licensing.[53] The Declaration lends public health-oriented interpretative guidance to TRIPS provisions by highlighting the "gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS . . . ."[54] Further, the Declaration expressly asserts that TRIPS "can and should be interpreted in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[55]

While the Declaration clarified that HIV/AIDS satisfied the national emergency requirement, it also expressly declined to address the issue of parallel imports,[56] leaving it open for individual Member regulation.[57] The Declaration also urged the TRIPS Council to find an "expeditious solution" to the problem posed in countries, like South Africa, with "insufficient or no manufacturing capacities in the pharmaceutical sector."[58] The solution, first implemented through an interim waiver and now in a proposed amendment,[59] allows a country

48. *Id.* at 384-86.

49. *Id.* This concept is called *parallel importation* and is discussed, *infra*, Part III.B.

50. *Id.* at 384-85.

51. *Id.* at 384-86; *see infra* Part II.C.

52. Doha Declaration, *supra* note 41.

53. Sykes, *supra* note 1, at 54.

54. Doha Declaration, *supra* note 41, at para. 1.

55. *Id.*

56. *See infra* Part III.B (discussing parallel importation of drugs).

57. Doha Declaration, *supra* note 41, at para. 5(d).

58. *Id.*

59. Laura Chung, *Use of Paragraph 6 System for Access to Medicine*, 36 N.C. J. INT'L L. & COM. REG. 137, 143 (2010). To amend TRIPS permanently, the amendment must be ratified by two-thirds of WTO members. Though less than a third of member countries have formally accepted the amendment, the interim waiver will continue to apply until ratification is complete. The deadline for ratification has been extended a

that is incapable of manufacturing generics under a compulsory license to legally import generics from countries that do possess the manufacturing capacity.[60]

III. COMMON FEATURES OF A TRIPS-PLUS AGREEMENT

This Part will discuss those TRIPS-plus intellectual property rights that have been proposed by the United States in Trans-Pacific Partnership Agreement negotiations. It will conclude with brief discussion of the Central American Free Trade Agreement as an example of an agreement that contains these provisions.

A. Data Exclusivity

TRIPS requires member countries to take measures to protect data (e.g. testing data) against "unfair commercial usage," production of which "involves a considerable effort," if data submission is a condition to market approval of products containing a new chemical entity.[61] The United States and European Union, in implementing TRIPS into their respective laws, provide for data exclusivity.[62] The United States, for example, provides for five years of test data (and marketing) exclusivity for new chemical entities.[63] This means that a generic drug application containing the same new chemical entity may not be registered until the end of the fifth year.[64] However, because it takes, on average, eighteen months for the generic drug to be approved, the brand drug effectively enjoys marketing exclusivity longer than five years.[65] In contrast, EU patent holders enjoy eight years of data exclusivity plus an additional two years of marketing

third time to December 31, 2013. *Members Accepting Amendment of the TRIPS Agreement*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last updated May 29, 2012).

60. Harris, *supra* note 28, at 386. This waiver, however, has only been used once, between Canada as the exporter and Rwanda as the importer. Harris argues that the lack of use of the amendment is due to the process for utilizing it being complicated and disjointed, fear of retaliation, and bilateral trade restrictions. *See id.* at 391-94.

61. TRIPS, *supra* note 34, at art. 39.3. As the language used in this provision is broad, there is a debate over whether Article 39.3 really requires data exclusivity by its language or whether protection below the level of exclusivity would suffice. *See* Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPS Agreement*, 45 HARV. INT'L L.J. 443, 446-65, 499 (2004) (examining the language of Article 39.3 and advocating for a solution that preserves incentives to create via trade secret protection without impeding access to medicines in developing countries).

62. Fellmeth, *supra* note 61, at 447-48.

63. 21 U.S.C. § 355(c)(3)(E)(ii) (2001). A "new chemical entity" is a drug in which the molecule or ion responsible for the drug's physiological or pharmacological action has not been approved by the Federal Drug Administration in any other application. 21 C.F.R. § 314.108(a) (2011).

64. 21 C.F.R. § 314.108(b)(2).

65. MARTIN A. VOET, THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA & PHARMACEUTICAL LIFE-CYCLE MANAGEMENT 59 (2005); Fiona M. Scott Morton, *Barriers to Entry, Brand Advertising, and Generic Entry in the US Pharmaceutical Industry*, 18 INT'L J. OF INDUS. ORG. 1085, 1090 (2000).

exclusivity.[66] In effect, a generic application may not be registered until the end of the data exclusivity period and may not be launched into the market until after marketing exclusivity has lapsed.[67]

In bilateral trade agreements subsequent to TRIPS, the United States has pushed for, and achieved, data *exclusivity* provisions, as opposed to the lower threshold of simple data *protection*.[68] This is not a surprising move, given the position of United States that TRIPS requires a period of exclusivity for marketing data:

> The Office of the U.S. Trade Representative (USTR) has interpreted Article 39.3 of the TRIPS Agreement to mean that "the data will not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time . . . . Any other definition of this term would be inconsistent with logic and the negotiating history of the provision."[69]

Construing Article 39.3 this strictly is probably above the minimum standard that TRIPS creates.[70] Professor Brook K. Baker argues that the language used in Article 39.3 does not support mandating data exclusivity as the only logical interpretation.[71]

Notwithstanding compulsory licensing schemes, data exclusivity generally delays the availability of generic medicines,[72] which are typically sold at more affordable prices than their branded counterparts.[73] The potential delay is caused by two implications of a data exclusivity scheme.[74] The first is that a generics manufacturer, in lieu of waiting for the exclusivity period to expire, would need

66. EUROPEAN COMM'N, PHARMACEUTICAL SECTOR INQUIRY PRELIMINARY REPORT 107-08 (Nov. 28, 2008) (DG Competition Staff Working Paper), *available at* http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf.

67. *Id.* at 108.

68. Peter K. Yu, *The Political Economy of Data Protection*, 84 CHI.-KENT L. REV. 777, 783-84 (2010).

69. CARLOS MARIA CORREA, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING STANDARDS OF THE TRIPS AGREEMENT 47 (2002) (quoting the Office of the U.S. Trade Representative interpreting Article 39.3 of the TRIPS agreement in an unattributed paper for submission in bilateral discussions with Australia in May, 1995).

70. *See id.* at 48.

71. Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303, 315 (2008).

72. *Access to Medicines: Data Exclusivity and Other "TRIPS-Plus" Measures*, WORLD HEALTH ORG. (Mar. 2006), http://www.searo.who.int/LinkFiles/Global_Trade_and_Health_GTH_No3.pdf [hereinafter *Access to Medicines*]; *see also* Yu, *supra* note 68, at 78 ("Such delay, along with the reduced price competition, is likely to prolong, or even exacerbate, the massive public health crises in less developed countries. It is also wasteful and highly undesirable to require duplicative testing in countries that have very limited economic resources.").

73. David W. Freeman, *Prescription Drug Prices Set to Fall as Patents Expire*, CBS NEWS (July 25, 2011, 11:37 AM), http://www.cbsnews.com/8301-504763_162-20082918-10391704.html.

74. *Access to Medicines*, *supra* note 72.

to repeat clinical trials for and produce their own data.[75] Second, in a more common scenario, a generics manufacturer would need to wait until the exclusivity period is over to launch their product.[76]

B. Parallel Importation

Parallel importation is one way that a country can reduce drug costs by procuring the drug at a price lower than what is available locally, assuming that the savings are passed on to the consumer.[77] Under this scheme, once a drug has been sold with the consent of the patent owner anywhere in the world, the rights are said to be exhausted and the owner may not protest importation into a different country.[78] Allowing parallel importation "favors consumer interests and access to medicine, because countries are free to import products from the country where they are legitimately sold for the lowest possible price."[79] On the other hand, pharmaceutical business models rely on price differentials for different markets.[80] Allowing parallel imports means these differentials would be moot, as the consumer would be able to find and then import the drug at its cheapest.[81] As TRIPS is silent on this issue[82] and the DOHA Declaration expressly leaves resolution of the issue up to each member country,[83] the parallel import restrictions are on the table in today's trade negotiations. Because restrictions on parallel trade affect pricing differentials, the World Health Organization notes that it may be beneficial for developed countries to include restrictions in their domestic laws to preserve lower pricing in developing countries.[84] On the other hand, developing countries may benefit from less restriction on parallel imports.[85]

There are, of course, moral implications of allowing parallel imports for some markets but not others.[86] The first is the temptation to divert drugs intended for a developing country into a high-income, developed country.[87] The second is

75. *Id.*

76. *Id.*

77. WORLD HEALTH ORG., PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS 123 (2006), *available at* http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealth Report.pdf.

78. Cynthia M. Ho, *A New World Order for Addressing Patent Rights and Public Health*, 82 CHI.-KENT L. REV. 1469, 1501 n.147 (2007).

79. *Id*. at 1501.

80. *Id.*

81. *Id.*

82. TRIPS, *supra* note 34.

83. Doha Declaration, *supra* note 41.

84. WORLD HEALTH ORG., *supra* note 77, at 124.

85. *See id.*

86. *See* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in Inte-rnational Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193, 265-68 (2005).

87. *See id.* at 266-67.

the temptation for a market consumer with the means to pay for the drug to substitute it with drugs imported at a cheaper cost, which are intended for poorer populations.[88] One remedy is a ban on parallel importing and reliance on pricing differentials.[89] However, the better remedy is for developed countries to monitor borders and criminalize diversion practices.[90] Kevin Outterson suggests that this can be combined with persuasive appeals to the consumer's morals: if you are a high-income patient who takes a pill clearly intended for the impoverished, you are stealing from the poor.[91] Furthermore, he argues, the burden of anti-diversion measures should fall on high-income markets because that is where the necessary resources and infrastructure for implementation exist.[92]

In the context of trade-negotiations, the concept of parallel imports and necessary considerations illustrate that a one-size-fits-all approach will not work when negotiating an agreement between countries of disparate development and income levels.[93] Thus, in a potential agreement like the Trans-Pacific Partnership Agreement, regulation of parallel importation should be left to individual countries.[94]

C. Patent/Registration Linkage

Patent/registration linkage is a relatively new patent concept, first appearing in the domestic policies of the United States and Canada about twenty-five years ago.[95] Traditionally, the regulatory body governing drug registration and approval functions independently from the patent system.[96] With a linkage regulatory system, however, the two processes are "linked" and the drug regulatory body becomes a patent enforcer.[97]

88. *See id.* at 266.

89. *EU Commission Extends Ban on Parallel Imports*, PHARM. INDUS. NEWS (Oct. 16, 1995), http://www.thepharmaletter.com/file/68996/eu-commission-extends-ban-on-parallel-imports.html.

90. *See* Outterson, *supra* note 86, at 266-67.

91. *See id.* at 266

92. *See id.* at 265-66 (The European Union, which practices community exhaustion, permits parallel trade within the European Economic Area. To identify products for the poor, all pharmaceuticals exported from the European Union bear a distinguishing logo).

93. *See One Size Fits All Will Not Work in Trade Negotiations: Kamal Nath—Inequitous System Will Hit Trade Flows from Developed Countries,* CARNEGIE ENDOWMENT (Mar. 12, 2007), http://www.carnegieendowment.org/files/pressrelease.pdf.

94. *See Intellectual Licensing—Structuring Deals Worldwide*, LADAS & PARRY LLP, http://www.ladas.com/IPProperty/GrayMarket/GrayMa02.html (last visited Nov. 11, 2012).

95. *See* Ron A. Bouchard, *I'm Still Your Baby: Canada's Continuing Support of U.S. Linkage Regulation for Pharmaceuticals*, 15 MARQ. INTELL. PROP. L. REV. 71, 134 (2011) (The United States implemented a linkage regime with passage of the Hatch-Waxman Act in 1984).

96. Laba Karki, NEIFELD IP LAW, P.C., *Review of FDA Law Related to Pharmaceuticals: The Hatch-Waxman Act, Regulatory Amendments and Implications for Drug Patent Enforcement*, at 1-2, http://www.neifeld.com/pubs/reviewoffdalawrelatedtopharm.pdf (last visited Nov. 11, 2012).

97. Baker, *supra* note 71, at 307.

The Hatch-Waxman Act[98] in the United States illustrates how linkage works in regards to a generics application.[99] When generics producers want to file an equivalent of an already-registered drug with the Food and Drug Administration, they must first certify that "there were no competing patents, that all patents had expired, that the registration would not become final until patent expiration, or that the alleged patent was invalid or would not be infringed."[100] In the case where the filer is certifying invalidity or non-infringement, notice must be provided to the patent holder, who then has forty-five days to bring an action for infringement.[101] This results in an influx of costly litigation and further delay of generics, despite the fact that oftentimes the outcome of the litigation is invalidation of the registered patent.[102] Further, this is inappropriate because a legal presumption of validity is established for the registered patent on the health regulation end, despite a generic meeting the technical requirements to register.[103]

In contrast, EU "[h]ealth authorities have no legal capacity to look into [intellectual property rights] issues and deny approval to an application that conforms to the relevant technical standards, even if there [was a patent] infringement . . . ."[104] It should be noted, however, that some EU member nations have attempted to implement linkage regimes despite it being a prohibited practice.[105] Furthermore, recent free trade agreements ("FTAs") have addressed patent/registration linkage by either strongly encouraging implementation[106] or mandating it.[107]

To understand the serious implications of a linkage regime, it is important to recognize that the vast majority of new patents are for drugs *other than* new chemical entities.[108] Most patents obtained are for the same drug in a different product by patenting a different pharmaceutical formulation (different administration form of the same active ingredient), or a combination of known drugs.[109] This allows an experienced pharmaceutical company to layer their patents with little innovative efforts, effectively extending the patent term via the cumulative impact of multiple patents.[110] Not only does this hurt pharmaceutical

98. *See* 21 U.S.C. § 355(j) (2006) (abbreviated new drug applications).

99. Baker*, supra* note 71, at 307.

100. *Id.*; *see also* 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(IV).

101. Baker, s*upra* note 71, at 307.

102. Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating The WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79, 91 (2004).

103. *Id.*

104. *Id.* at 90.

105. Ron A. Bouchard et al., *Structure-Function Analysis of Global Pharmaceutical Linkage Regulations*, 12 MINN. J.L. SCI. & TECH. 391 (2011).

106. Baker, *supra* note 71, at 340.

107. *See supra* Part III.D. (discussing CAFTA as an example of a linkage-mandating FTA).

108. Correa, *supra* note 102, at 89.

109. *Id.* at 89 nn.37-38.

110. Bouchard, *supra* note 95, at 105 (highlighting Dr. Stephen Schondelmeyer's assertion that

innovation, it also causes extraordinary market-entry delay for the generic competitor.[111] More troublesome is that TRIPS flexibilities are not equipped to deal with this kind of restriction, and thus a loophole is created.[112] When combined with data exclusivity, granting a compulsory license is rendered especially illusory, "as prospective compulsory licensees are unlikely to have sufficient incentives to replicate test data, and governments cannot normally wait until a new set . . . has been developed."[113]

D. Reconciling the DOHA Declaration and TRIPS Flexibilities in TRIPS-Plus Agreements

Some scholarship suggests that while TRIPS certainly created a minimum standard for intellectual property protection, there may also be binding "ceilings" in place imposed by TRIPS and other sources of international law.[114] Explicit in TRIPS is the right, but not obligation, of signatories to provide higher intellectual property protection than required, "provided that such protection does not contravene the provisions" of TRIPS.[115] Without more specific language, subsequent FTAs that limit TRIPS flexibilities would likely be upheld as consistent with the tradition of TRIPS being a floor and not a ceiling.[116]

Including language that preserves the flexibility found in TRIPS is important because that language carries a great deal of interpretive power. The most important flexibilities in regard to public health are found in the DOHA Declaration; the best way to uphold these flexibilities in subsequent FTAs is to incorporate similar or identical language, rather than language that is "ambiguous" or "open-textured."[117] According to Henning Grosse Ruse-Khan, "the more specifically or demandingly a clause refers to the DOHA Declaration, the more effective it is in safeguarding TRIPS flexibilities . . . ."[118] To the extent that the DOHA Declaration continues to have legal significance, the members of the Trans-Pacific Partnership are obligated to incorporate such specific language in order to

assessment of the impact made by Canada's linkage regime must take into consideration the effect of multiple patents).

111. *Id.* at 105.

112. Harris, *supra* note 28, at 394.

113. Correa, *supra* note 102, at 92.

114. Kur & Ruse-Khan, *supra* note 4, at 9; *see also* Ruse-Khan, *supra* note 4, at 350-64 (discussing whether treaty interpretation norms allow the policy flexibilities found in TRIPS to be preserved despite higher protections in TRIPS-plus agreements).

115. TRIPS, *supra* note 34, at art. 1:1.

116. Ruse-Khan, *supra* note 4, at 364.

117. *Id.*

118. *Id.* at 358.

incorporate with certainty the public health-related aims embodied in the DOHA Declaration.[119]

CAFTA, to which the United States is a party, is a prime example of one such agreement that contains significantly higher intellectual property protection than what is required by TRIPS.[120] While it does not place restrictions on parallel importation, CAFTA requires data exclusivity[121] and patent/registration linkage[122] of its member states. However, it also includes an affirmation of existing rights and obligations under TRIPS.[123] In addition, the parties to CAFTA released an "understanding" regarding public health and creating access to medicines.[124] This release specifically acknowledges that CAFTA does not interfere with a member state's ability to address epidemics, including HIV/AIDS, and in "circumstances of extreme urgency or national emergency."[125] This language, which reflects provisions found in the DOHA Declaration, coupled with language affirming specific TRIPS-flexibilities, is a good example of what is urged *supra* as a necessary component of the Trans-Pacific Partnership Agreement.[126] However, even the most specific affirmation of public-health policy cannot remedy the practical effects of an agreement that incorporates every major intellectual property protection available (data-exclusivity, patent extensions, patent/registration linkage, and restrictions on parallel importation), and it appears that the Trans-Pacific Partnership Agreement is headed toward a similar fate.

V. THE TRANS-PACIFIC PARTNERSHIP AGREEMENT

A. Background

This Part will examine negotiations between the United States and eight other Asia-Pacific partners.[127] Throughout the negotiation process, there has been

119. *See id*. at 353-54. Most signatories to FTAs include references in their agreements to further the goals of the Doha Declaration.

120. Correa, *supra* note 102, at 82.

121. CAFTA provides five-year exclusivity for marketing data of a patented product. During this time, third parties (for example, a generics manufacturer) may not "market a product on the basis of (1) the information, or (2) the approval granted to the person who submitted the information . . ." Dominican Republic-Central America Free Trade Agreement art. 15.10.1(a), Aug. 5, 2004, 43 I.L.M. 514 [hereinafter CAFTA]. This is in-line with the data exclusivity that the United States affords to patent holders. 21 U.S.C. § 335(c)(3)(E)(ii) (2001); *see also* Fellmeth, *supra* note 61, at 447-48 (comparing data exclusivity systems in the United States and European Union with practices in developing countries).

122. CAFTA, *supra* note 121, at art. 15.10.2.

123. *Id.* at art. 15.1.7.

124. *See Understanding Regarding Certain Public Health Measures*, OFF. OF THE U.S. TRADE REPRESENTATIVE (Aug. 5, 2004),
http://www.ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file697_3975.pdf.

125. *Id.*

126. *See supra* Part III.D.

127. *The United States in the Trans-Pacific Partnership*, OFF. OF THE U.S. TRADE REPRESENTATIVE,

considerable concern expressed by all participating countries with respect to the proposed intellectual property provisions, probably in light of the fact that these are agreements between developed countries with a strong pharmaceutical presence and developing countries with little to none.[128]

The TPPA is a developing agreement between the United States, Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam.[129] In October 2011, Japan began evaluating whether they would join the negotiations as well.[130] In November, at the Asia-Pacific Economic Cooperation summit, Mexico, Canada, and the Philippines also expressed interest,[131] though as of October 2011, these countries had not begun the formal accession process.[132] Negotiations began for the TPPA in March 2010, and since then negotiations have gone through several subsequent rounds.[133]

The TPPA is unlike any other trade agreement in that it departs from the bilateral model and attempts to harmonize the hundreds of "overlapping and inconsistent [free trade agreements] proliferating the globe."[134] The end goal is a "living" agreement with comprehensive coverage and eventual expansion of the agreement to include more Asia-Pacific economies in the future.[135] To achieve the

http://www.ustr.gov/about-us/press-office/fact-sheets/2011/november/united-states-trans-pacific-partnership (last visited July 15, 2012).

128. *See e.g.*, Krista Cox, *KEI Notes From Eighth Round of TPPA Negotiations* (Sep. 18, 2011, 4:22 PM), KNOWLEDGE ECOLOGY INT'L, http://keionline.org/node/1263 ("As a whole, it appears that there is growing and vocal opposition to USTR's aggressive IP positions."); *EU-India Free Trade Agreement: Generic Medications Under Threat, Says UN Health Expert*, UNITED NATIONS HUM. RTS. (Dec. 10, 2010), http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=10592&LangID=E%22%3Enews%20release (commenting that "[t]he EU-India draft FTA, as it stands, places trade interests over human rights. . . .").

129. *Trans-Pacific Partnership*, OFF. OF THE U.S. TRADE REPRESENTATIVE, http://www.ustr. gov/tpp (last visited Oct. 23, 2011).

130. Press Release, Deputy Chief James P. Zumwalt, U.S. Embassy, Japan, DCM Zumwalt Welcomes Discussion of Trans-Pacific Partnership Agreement (Oct. 7, 2011), *available at* http://japan.usembassy.gov/e/p/tp-20111014-01.html. The addition of Japan to the TPPA would be significant because the policies of Japan and the United States are similar and there is a history of policy-sharing and collaboration between the two countries. *See* Toshiko Takenaka, *The Current Status of U.S.-Japan IPR Systems: Convergence, Cooperation, and Conflict*, CTR. ON JAPANESE ECON. & BUS., COLUM. UNIV. BUS. SCH., 3 (Feb. 15, 2002), http://academiccommons.columbia.edu/catalog/ac:113290.

131. Pablo Garibian & Rachelle Younglai, *Canada, Mexico Ask to Join Pan-Pacific Trade Talks*, REUTERS (Nov. 13, 2011), http://www.reuters.com/article/2011/11/14/us-apec-canada-tpp-idUSTRE7 AC12 B20111114.

132. Krista Cox, *KEI Notes from the Ninth Round of TPPA Negotiations*, KNOWLEDGE ECOLOGY INT'L (Oct. 28, 2011, 11:51 AM), http://keionline.org/node/1306.

133. *Trans-Pacific Partnership*, *supra* note 129.

134. Meredith Kolsky Lewis, *The Trans-Pacific Partnership: New Paradigm or Wolf in Sheep's Clothing*, 34 B.C. INT'L & COMP. L. REV. 27, 28, 39-40 (2011).

135. *Id.*; *Trans-Pacific Partnership Leaders' Statement*, OFF. OF THE U.S. TRADE REPRESENTATIVE (Nov. 12, 2011), http://www.ustr.gov/about-us/press-office/press-releases/2011/november/trans-pacific-partner ship-leaders-statement; *The Trans-Pacific Partnership (TPP) Trade Ministers' Report to Leaders*, OFF. OF THE U.S. TRADE REPRESENTATIVE (Nov. 12, 2011), http://www.ustr.gov/about-us/press-office/press-releases/ 2011/november/trans-pacific-partnership-tpp-trade-ministers'-re.

type of expansion the leaders seek, the agreement must be one that attracts other participants. However, Meredith Kolsky Lewis warns, "[the] more TPP[A] looks like a series of bilateral U.S. FTAs with exclusions for products the United States considers sensitive, the less likely the TPP[A] will attract other countries to accede."[136] This warning is particularly applicable in light of the United States' stated objective "to negotiate trade agreements in terms of [intellectual property rights] that 'reflect a standard of protection similar to that found in U.S. law,'"[137] meaning, a push for TRIPS-plus provisions. As is true in past U.S. FTA negotiations, intellectual property rights are proving to be a "sticking points" in TPPA negotiations.[138]

Negotiations of the TPPA have been notoriously secretive.[139] This has created concerns, in the United States and elsewhere, about accountability of government officials.[140] In addition, the concern stems from the trend of private interests having a heavy influence on public international lawmaking.[141] Though private industry actors may not sit in the negotiations, it is clear that they have omnipresence, "closely monitoring and critiquing the state of play."[142]

This concern was exacerbated when two drafts of the intellectual property rights chapter were leaked, one in February 2011 and one in September 2011.[143] Both drafts, which are indicators of what has been negotiated, contained a cover note saying that it would not be declassified until four years after entry into the TPPA.[144] Secret negotiations can lead to an unbalanced final agreement. For example, a recently negotiated intellectual property treaty, the Anti-Counterfeiting Trade Agreement ("ACTA"), also shrouded its negotiations in secrecy; the end result is a text resembling the entertainment industry's wish list.[145] Peter K. Yu identifies four public-interest concerns about ACTA's secret

136. Lewis, *supra* note 134, at 52.

137. IAN F. FERGUSSON & BRUCE VAUGHN, CONG. RESEARCH SERV., R40502, THE TRANS-PACIFIC PARTNERSHIP AGREEMENT 11 (2010).

138. *Id.*

139. Jane Kelsey, *Trans-Pacific Partnership Papers Remain Secret for Four Years After Deal*, TPP WATCH (Oct. 16, 2011), http://tppwatch.org/2011/10/16/trans-pacific-partnership-papers-remain-secret-for-four-years-after-deal/.

140. *Id.* In New Zealand, for example, the secrecy of the negotiations prompted a response from citizens. A sign-on letter was drafted addressing the Prime Minister of New Zealand, urging that TPP texts be released. *Open Letter 'Release the TPPA Text' Sign-on Letter*, TPP WATCH (Feb. 10, 2011), http://tppwatch.org/what-is-tppa/release-the-text/.

141. Paul B. Stephan, *Privatizing International Law*, 97 VA. L. REV. 1573, 1595-99 (2011).

142. *Id.*

143. Kelsey, *supra* note 139; *The Complete Feb. 10, 2011 Text of the US Proposal for the TPP IPR Chapter*, KNOWLEDGE ECOLOGY INT'L (Mar. 10, 2011), http://keionline.org/node/1091 (positing that U.S. drafts should be available to the public especially when copies are distributed to all the negotiating states).

144. *Trans-Pacific Partnership Intellectual Property Rights Chapter Draft*, art. 8.6(c)-(e) (Sept. 2011), *available at* http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf (leaked text).

145. Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAs, ACTA, and TPP*, 18 J. INTELL. PROP. L. 447, 464 (2011); Peter K. Yu, *Six Secret (and Now Open) Fears of ACTA*, 64 SMU L. REV. 975, 977 n.4 (2011).

negotiations: "(1) lack of transparency; (2) very limited public, non-industry participation; (3) a huge democratic deficit; and (4) virtually no domestic or global accountability."[146] These same concerns are applicable to TPPA negotiations. Using ACTA as an indicator of what secret negotiations can produce, the end text of the TPPA has the potential to be a reiteration of the pharmaceutical industry's wish list.[147]

B. Trade Enhancing Access to Medicines and the September 2011 Leaked TPPA Text

Round Eight of TPPA negotiations, held in Chicago, concluded on September 15, 2011.[148] During these negotiations, the Office of the United States Trade Representative ("USTR") released a white paper[149] outlining a new strategic initiative: Trade Enhancing Access to Medicines ("TEAM").[150] According to the paper, as part of implementing TEAM, the United States has made trade proposals during TPPA negotiations "that are aimed at promoting access to medicines in [TPPA] partner markets."[151] Listed as one of the goals for the TPPA is the reaffirming commitment to the DOHA Declaration and to "[i]ncorporate important understandings on the availability of public health measures, based on the DOHA Declaration . . . ."[152] While acknowledgement of the DOHA Declaration in TPPA is important in terms of preserving TRIPS flexibilities,[153] the general language used in this white paper frustrated many, especially in light of the fact that so little is known about what actually is going on in the negotiations.[154] Another TEAM TPPA goal that has received criticism is the "TPP access window."[155] The white paper proposes that "pharmaceutical-

146. Yu, *supra* note 145, at 998-99.

147. Sell, supra note 145, at 464.

148. Cox, *supra* note 128; *Trans-Pacific Partnership*, *supra* note 129.

149. Generally, the term "white paper" is used to describe a government report.

150. *Trans-Pacific Partnership*, *supra* note 129; *Trans-Pacific Partnership Trade Goals to Enhance Access to Medicines*, OFF. OF THE U.S. TRADE REPRESENTATIVE, http://www.ustr.gov/webfm _send/3059 (last visited Nov. 11, 2012).

151. *Trans-Pacific Partnership Trade Goals to Enhance Access to Medicines*, *supra* note 150.

152. *Id.*

153. *See* Ruse-Khan, *supra* note 4, at 353-58 (discussing inclusion of "Doha" language in sub-sequent agreements as a way to preserve flexibilities established in TRIPS).

154. James Love, *USTR Releases New White Paper on Access to Medicine: Includes Almost No Specifics in Terms of Negotiating Positions*, KNOWLEDGE ECOLOGY INT'L (Sept. 12, 2011), http:// keionline.org/node/1262.

155. *See* Deborah Gleeson, *Trade Talks Set to Undermine Access to Medicines for the World's Poor*, THE CONVERSATION (Sep. 16, 2011), http://theconversation.edu.au/trade-talks-set-to-undermine-access-to-medicines-for-the-worlds-poor-3392; *see also* Brook K. Baker, *US Trade-Enhancing Access to Medicines (Access Window) in its Proposed TPP IP Text is a Sham,* INFOJUSTICE.ORG (Oct. 25, 2011), http://infojustice.org/resource-library/trans-pacific-partnership/us-trade-enhancing-access-to-medicines-access-window-in-its-proposed-tpp-ip-text-is-a-sham.

specific intellectual property protections" be available, provided that the pharmaceutical introduces medicines within an expedited time frame.[156] This language is also general, however, when a new draft was leaked of the USTR's proposal for the TPPA, the pharmaceutical-specific intellectual property protections manifested through provisions allowing longer patent terms to compensate for granting delays,[157] data exclusivity,[158] and patent-registration linkage.[159]

The access window applies where a TPPA party allows a patent applicant "to obtain approval for marketing a new . . . product in its territory by relying, in whole or in part, on the prior approval of the . . . product by the regulatory authority in another [country]."[160] By contrast, where a country does not rely on patents elsewhere to grant approval domestically, these provisions will be "automatic and absolute."[161] Where the access window is applicable, satisfying its early-access requirements is relatively easy: a pharmaceutical may begin the approval process by relying on any available information, including prior approval by another country.[162] To complete the patent registration, a party may impose additional requirements,[163] but, in the context of applying the access window provisions, satisfying these requirements will "necessarily [occur] after the commencement of the marketing approval process."[164]

While the access window may help to "drive access,"[165] longer patent terms, data exclusivity, and patent-registration linkage may be too high of a price to pay. For developing and least developed countries, expedited physical access to patented medications does not solve the problem of pricing which inherently inhibits meaningful access to lifesaving drugs.[166] In the context of HIV medications, there is a severe price differential between branded and generic drugs.[167] The problem is exacerbated by the fact that HIV becomes resistant of first-line drugs, which generally do have affordable generics available.[168] This necessitates switching to second and third-line drugs.[169] However, pricing of

156. *Trans-Pacific Partnership Trade Goals to Enhance Access to Medicines*, *supra* note 150.

157. *Trans-Pacific Partnership Intellectual Property Rights Chapter Draft*, *supra* note 144, at art. 8.6(c)-(e).

158. *See id.* at art. 9.2.

159. *Id.* at art. 9.5.

160. *Id.* at art. 9.4, 9.6, 8.6(e).

161. Baker, *supra* note 155.

162. *Trans-Pacific Partnership Intellectual Property Rights Chapter Draft*, *supra* note 144, at art. 9.

163. *Id.*

164. *Id.*

165. *Trans-Pacific Partnership Trade Goals to Enhance Access to Medicines*, *supra* note 150.

166. Gleeson, *supra* note 155.

167. *Background: Access to Antiretrovirals*, MEDECINS SANS FRONTIERS, http://utw.msfaccess.org/background (last visited Oct. 3, 2012).

168. *Id.*

169. *Id.*

second-line drugs is "over six times more than the most affordable first-line regimen" and a potential third-line drug could cost "[twenty] times more than the most affordable . . . first line regimen."[170] Therefore, while the drugs may be available, they will be priced out of reach for years before the requisite testing and registration of a generic patent can make the drug available at an affordable price point. Even when an affordable generic does become available, the virus may have again become immune, making the generic obsolete.[171] Professor Brook K. Baker[172] provides insightful criticism of the access window text, namely on how the interplay between provisions will generally lead to longer patent terms, which cancel out any benefit of expedited access.[173] He argues, "[t]he desirability of earlier product introduction should have nothing to do with a trade off involving greater [intellectual property] protections that extend and strengthen drug company patent and data-related monopolies."[174]

The ninth round of negotiations, which took place in Lima, Peru, concluded on October 28, 2011.[175] Though the previously leaked USTR proposal was not discussed, international disapproval over the contents of the leaked text was more than just background noise.[176] On October 25, 2011, Peruvian groups staged a demonstration and appeared on the evening news.[177] Additionally, during this round, various groups and individuals circulated five letters containing over eighty signatures imploring their respective countries to increase transparency of the negotiations by releasing negotiating text and guidelines.[178]

In the March 2012 round of negotiations, for the first time since the U.S. text was leaked, patent protection discussions focused on the "access window."[179] An observer noted that the concept seemed to get little support, and stakeholder organizations from at least four Trans-Pacific Partnership countries heavily criticized it.[180]

170. *Id.*

171. *Id.*

172. Baker is a law professor at Northeastern University School of Law, a board chair, and policy analyst for Health GAP (Global Access Project).

173. Baker, *supra* note 155.

174. *Id.*

175. Cox, *supra* note 132.

176. *Id.*

177. *Id.*

178. *Id.*

179. *Id.*

180. *Id.*

C. What Next?[181]

Since March 2012, the United States has been markedly more inclusive in its official coverage of TPP negotiations. The USTR website now features a blog and links to its Twitter and Facebook pages.[182] Prior to the twelfth round of negotiations, which were held on May 8–18, 2012, in Dallas, Texas, the office had only been issuing "updates" at the close of each round.[183] The Dallas round also marked a step in the direction of more transparency.[184] According to the USTR, "more than 300 stakeholders from non-governmental organizations, academia, business, and the public" were invited to present their views directly to negotiators.[185] In response to concerns from Congress and the public regarding Internet freedom issues, the USTR took steps to be more transparent by releasing an outline of proposals that would touch on those issues.[186] This may be a signal that communication and transparency between negotiators and the public in general are on an upward trend.[187] Specifically for public health advocates, it may mean that transparency in the pharmaceutical-related proposals will follow closely behind.[188]

V. CONCLUSION

While pharmaceutical interests have historically been well-represented, the public-health lobby has grown exponentially in size and resources. It is no longer appropriate to view the battle between increased intellectual property rights and protection of public-health objectives as one that is fought between mismatched opponents. Public health professionals, non-governmental organizations, legal scholars, and whole governments have all responded to free trade agreements such as CAFTA, and most recently to the potential Trans-Pacific Partnership Agreement. The demand of the public-health lobby is clear: stop building trade

181. For up-to-date- information regarding TPP negotiation rounds, see *TPP Blog,* OFF. OF THE U.S. TRADE REPRESENTATIVE, http://www.ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-outreach-and-updates (last visited July 12, 2012).

182. *Id.*; OFF. OF THE U.S. TRADE REPRESENTATIVE, http://www.ustr.gov/ (last visited Nov. 11, 2012).

183. *See TPP Blog, supra* note 181.

184. *See U.S. Welcomes Stakeholders to 12th Round of Trans-Pacific Partnership Talks,* OFF. OF THE U.S. TRADE REPRESENTATIVE (May 10, 2012, 3:39 PM), http://www.ustr.gov/about-us/press-office/blog/2012/may/US-Welcomes-Stakeholders-to-TPP-Talks.

185. *Id.*

186. *See* Zach Carter, *Obama Trade Policy Seeks To Include Exceptions In Trans-Pacific Partnership*, HUFFINGTON POST (July 3, 2012, 4:46 PM), http://www.huffingtonpost.com/2012/07/03/obama-trade-policy-trans-pacific-partnership-ron-kirk-ustr_n_1646921.html.

187. *Id.*

188. Negotiations continued in San Diego, California in July. During that round, USTR Ambassador Ron Kirk sent letters to Congress notifying them of Canada and Mexico's inclusion in TPP negotiations. *Important Progress Made at TPP Talks in San Diego*, OFF. OF THE U.S. TRADE REPRESENTATIVE (July 2012), http://www.ustr.gov/about-us/press-office/press-releases/2012/july/ important-progress-tpp-talks-san-diego.

agreements with restrictions that operate to render TRIPS flexibilities useless and push out generic competition.

"Prices fall as generic competition increases."[189] When countries are obligated to incorporate intellectual property rights that stifle generic competition, prohibitive pricing continues to block access to essential medicines like anti-retrovirals for HIV/AIDS patients. At the end of the day, each of the protections discussed in this Comment (data exclusivity, prohibition of parallel importation, and patent/registration linkage) make meaningful generic competition nearly impossible. Furthermore, when waiting for market-entry of a generic is impracticable in the face of a health crisis, TRIPS flexibilities like compulsory licensing are rendered useless because TRIPS-plus obligations effectively block the use of them.[190] The DOHA Declaration was supposed to make public health a priority. However, a patent scheme that allows for public-health measures in theory, but in its application, prohibits such measures cannot be said to comply with TRIPS and the DOHA Declaration.

As it stands, the United States' proposal for the Trans-Pacific Partnership Agreement includes data exclusivity, patent/registration linkage, and longer patent terms in general,[191] all of which are masked in the TEAM approach as a tradeoff for expedited access.[192]

One size certainly does not fit all. Broadly speaking, in a "living" agreement like the Trans-Pacific Partnership Agreement, it is essential that policy space be kept open so that lesser-developed countries may take advantage of the other benefits of the agreement without giving away their ability to respond to the health needs of their citizens.[193] While it is impractical to suggest that the agreement contain no TRIPS-plus intellectual property rights, it is irresponsible to include all of them without regard to how countries can continue to use TRIPS flexibilities to provide access to essential drugs.

In June 2011, at the conclusion of a United Nations High Level Meeting on AIDS, governments pledged to extend the reach of HIV treatment to nine million more patients.[194] To reach this goal, pricing of treatment must come down. This can

189. *Background: Access to Antiretrovirals*, *supra* note 167.

190. *See* Harris, *supra* note 28, at 390-94.

191. *Trans-Pacific Partnership Intellectual Property Rights Chapter Draft*, *supra* note 144, at art. 9.2, 9.5. While the proposed chapter on pharmaceuticals did not address parallel imports, a ban has been proposed in the context of copyrighted goods. Based on the USTR's advocacy of harmonizing the agreement's provisions with that of U.S. law, it is likely that a ban on parallel importation could be incorporated. *See* E.D. Kain, *IP Protection Standards in TPP Represent the Downside of The Trans-Pacific Partnership*, FORBES (Jan. 25, 2012, 12:08 PM), http://www.forbes.com/sites/erikkain/ 2012/01/25/ip-protection-standards-in-tpp-represent-the-dark-side-of-the-trans-pacific-partnership/.

192. *Compare Trans-Pacific Partnership Trade Goals to Enhance Access to Medicines*, *supra* note 150, *with* Baker, *supra* note 155.

193. *See* Lewis, *supra* note 134 (discussing the TPPA as a new type of agreement requiring negotiation tactics that depart from merely pushing the U.S. intellectual property model in its entirety).

194. MÉDECINS SANS FRONTIÈRES, *supra* note 8, at 8

only happen if countries can utilize compulsory licensing and enjoy the benefits of generic competition.[195] Developing countries must have the flexibility to account for this continuing public crisis.[196] This will not come to fruition unless future trade agreements, including the Trans-Pacific Partnership Agreement, resist the temptation to burden all parties with intellectual property obligations that mirror U.S. domestic law.

195. *Id.* at 7-8.

196. *Id.* at 8.