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MAGIC AND HOPE: RELAXING TRIPS-PLUS PROVISIONS TO PROMOTE ACCESS TO AFFORDABLE PHARMACEUTICALS

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Abstract: Competing interests and values collide at the intersection of public health, international trade, and intellectual property. Although highly successful in securing rigid patent protection provisions in the Agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS), the United States was dissatisfied with features of the agreement. In response, the United States began to negotiate bilateral free trade agreements which, while compliant with the TRIPS Agreement, include unflinchingly rigid intellectual property provisions. This Note argues that invidious "TRIPS-Plus" provisions in U.S. Free Trade Agreements, which require greater patent protections than the TRIPS Agreement, obstruct access to affordable pharmaceuticals desperately needed by impoverished populations around the globe. To encourage access to affordable drugs in low-income countries, the United States should amend its free trade agreements by incorporating a balancing test to determine when it is necessary to relax rigid trade provisions.

Introduction

On November 7, 1991, Earvin "Magic" Johnson, an all-star basketball player for the Los Angeles Lakers, announced his retirement from the National Basketball Association (NBA).[1] Johnson had recently been diagnosed with the Human Immunodeficiency Virus (HIV), which causes Acquired Immune Deficiency Syndrome (AIDS).[2] Winner of five NBA championships, a twelve-time All-Star, league most valuable player (MVP), and three-time NBA Finals MVP, Johnson was at the pinnacle of his profession.[3] Disclosing his diagnosis shocked the world and many

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[1] Tracey E. George, *Secondary Break: Dealing with AIDS in Professional Sports After the Initial Response to Magic Johnson*, 9 U. Miami Ent. & Sports L. Rev. 215, 216 (1992).

[2] *Id.*

[3] Avi Sinensky, Comment, *Not That There Is Anything Wrong with That: The Practical and Legal Implications of a Homosexual Professional Athlete*, 10 U. Pa. J. Bus. & Emp. L. 1009, 1017 (2008).

thought the end of Johnson's storied NBA career also meant the end of his life.[4] After all, in the early 1990s, treatment for HIV/AIDS was rare and diagnosis was considered a death sentence.[5] In fact, before 1996, an estimated fifty percent of those diagnosed with HIV would develop AIDS within ten years.[6]

Twenty years later, Johnson is a thriving fifty-two-year-old.[7] On November 7, 2011, Johnson celebrated with athletes, politicians, researchers, and celebrities as his foundation pledged a one million dollar gift to promote continued HIV/AIDS awareness and testing.[8] Upon his initial diagnosis, Johnson took nearly twenty pills a day to manage the disease, but thanks to breakthroughs in the pharmaceutical industry, Johnson is now on highly effective antiretroviral therapy (HAART), which requires only a few daily medications.[9] Antiretroviral therapy prolongs life and improves the health of those infected with HIV/AIDS.[10] On that somber November day in 1991, Johnson defiantly proclaimed that he would "'beat the disease.'"[11] Twenty years later, access to HAART has enabled Johnson's proclamation to ring true.[12]

A world away in Bwindi, Uganda, Hope Tukahirwa has not been as fortunate.[13] Tukahirwa's husband and son both contracted AIDS and died before HAART was even nominally available in sub-Saharan Africa.[14] Like Johnson, Tukahirwa contracted HIV and currently receives

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[4] Jack McCallum, *20 Years Later: Magic Putting on Performance of His Life Off the Court*, Sports Illustrated (Nov. 7, 2011, 11:23 AM), http://sportsillustrated.cnn.com/2011/writers/jack_mccallum/11/06/magic.johnson.hiv.announcement/index.html.

[5] Ronda B. Goldfein & Sarah R. Schalman-Bergen, *From the Streets of Philadelphia: The AIDS Law Project of Pennsylvania's How-to Primer on Mitigating Health Disparities*, 82 Temp. L. Rev. 1205, 1208 (2010).

[6] *Living with HIV/AIDS*, Ctrs. for Disease Prevention & Control, http://www.cdc.gov/hiv/resources/brochures/livingwithhiv.htm (last modified June 21, 2007).

[7] Greg Beacham, *Magic Johnson Still Beating HIV 20 Years Later*, Huffington Post (Nov. 7, 2011, 9:09 PM), www.huffingtonpost.com/2011/11/08/magic-johnson-hiv-20-years-later_n_1081752.html.

[8] *Id.*

[9] *Id.*

[10] 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, 786 (2008).

[11] *See* George, *supra* note 1, at 215 (quoting Magic Johnson with Roy S. Johnson, *I'll Deal with It*, Sports Illustrated, Nov. 18, 1991, at 16, 19).

[12] *See* Beacham, *supra* note 7.

[13] Daniel Howden, *Licensing Deal Threatens Cheap Pharmaceuticals*, Independent (Dec. 1, 2010), http://www.independent.co.uk/life-style/health-and-families/health-news/licensing-deal-threatens-cheap-pharmaceuticals-2148089.html.

[14] *See id.* The earliest statistics on HAART coverage in sub-Saharan Africa demonstrate that, in 2005, a mere seventeen percent of persons living with HIV/AIDS had access to antiretroviral drugs (ARVs). *See* World Health Org. & UNAIDS, Progress on Global

antiretroviral therapy.[15] Unlike Johnson, however, Tukahirwa's access to HAART hangs in a tenuous balance as trade laws dictate her ability to procure treatment.[16] Tukahirwa understands that HAART has prolonged her life and she expresses concern about the effect of trade laws on her access to this life-saving therapy.[17] "'In the old days, people were dying like rats. The drugs were too expensive and if it happened again we would be back in the old days.'"[18]

Infectious diseases plague the developing world.[19] By the end of 2009, an estimated 33.3 million people were living with HIV/AIDS.[20] Of that total, 22.5 million live in sub-Saharan Africa, 4.1 million live in Southeast Asia, and 1.4 million live in Central and South America, demonstrating a disproportionate impact on low and middle-income countries (LMICs).[21] In 2009, approximately 1.8 million people died from AIDS-related causes, contributing to an estimated 16.6 million children orphaned from HIV/AIDS.[22] The disease continues to spread as approximately 2.6 million new cases developed in 2009.[23] Globally, only an estimated thirty-six percent of those needing antiretroviral

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Access to HIV Antiretroviral Therapy: A Report on the "3 by 5" and Beyond 19 (2006), *available at* www.who.int/hiv/fullreport_en_highres.pdf.

[15] *See* Howden, *supra* note 13.

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *See* UNAIDS, Global Report: UNAIDS Report on the Global AIDS Epidemic 16, 19 (2010), *available at* http://www.unaids.org/documents/20101123_globalreport_em.pdf; World Health Org., Global Tuberculosis Control 2011, at 1 (2011) [hereinafter WHO TB Report 2011], *available at* http://www.who.int/tb/publications/global_report/2011/gtbr11_full.pdf; World Health Org., World Malaria Report 2011 viii–xii (2011) [hereinafter WHO Malaria Report 2011], *available at* http://www.who.int/malaria/world_malaria_report_2011/9789241564403_eng.pdf. While this Note primarily considers HIV/AIDS, other infectious diseases like malaria and tuberculosis have contributed to dire public health outcomes in LMICs. WHO TB Report 2011, *supra*, at 1; WHO Malaria Report 2011, *supra*, at viii–xii. For example, the World Health Organization (WHO) estimates that 216 million people were infected with malaria during 2010 resulting in 655,000 deaths, ninety-one percent of which occurred in sub-Saharan Africa. WHO Malaria Report 2011, *supra*, at 73. Moreover, 8.8 million people contracted tuberculosis in 2010 and nearly 1.5 million people died from the disease. WHO TB Report 2011, *supra*, at 9. Low and middle-income countries (LMICs) are overwhelmingly impacted by tuberculosis, with fifty-nine percent of all cases occurring in Asia and twenty-six percent in Africa. *Id.* at 10.

[20] UNAIDS, *supra* note 19, at 180.

[21] *See id.* at 180, 187, 201; *see also* United Nations Dev. Programme, Human Development Report 2011, Sustainability and Equity: A Better Future for All 163–64 (2011) [hereinafter UNDP 2011], *available at* http://hdr.undp.org/en/ (noting that LMICs are typically in sub-Saharan Africa, Southeast Asia, and Latin America).

[22] *See* UNAIDS, *supra* note 19, at 185–86.

[23] *See id.* at 16.

therapy actually receive it.[24] In sub-Saharan Africa and Southeast Asia, less than forty percent of those in need of HAART currently receive treatment.[25] Finally, less than thirty percent of children under the age of fifteen in need of antiretroviral therapy are currently on HAART.[26]

An international trade tug of war threatens access to lifesaving pharmaceuticals for Hope Tukahirwa and millions like her.[27] High-income countries (HICs) seek patent protection to promote innovation produced by pharmaceutical companies.[28] LMICs seek flexible patent laws that permit the advancement of public health by promoting access to affordable treatment.[29]

Competing interests and values collide at the intersection of public health, international trade, and intellectual property.[30] In an attempt to mediate these countervailing issues, the international community sought to establish trade standards through the World Trade Organization (WTO), which promulgated the Agreement on Trade-Related Aspects of Intellectual Property Rights ("the TRIPS Agreement").[31] The TRIPS Agreement established minimum standards for "[t]he protection and enforcement of intellectual property rights" among WTO

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[24] World Health Org., UNAIDS, & UNICEF, Towards Universal Access: Scaling Up Priority HIV/AIDS Interventions in the Health Sector 53 (2010), *available at* http://whqlibdoc.who.int/publications/2010/9789241500395_eng.pdf. Access to pharmaceutical treatment for diseases other than HIV/AIDS is quite low. *See* WHO Malaria Report 2011, *supra* note 19, at 20, 44. For example, access to anti-malarial medication serves as a barrier to treatment in the developing world, hampered by marked pricing increases in 2011. *See id.* Additionally, opportunistic infections combined with HIV/AIDS further complicate treatment, due, in large part, to the cost of drugs. *See* Ellen 't Hoen et al., *Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All*, 14 J. Int'l AIDS Soc'y, Mar. 27, 2011, at 1, 7. For example, tuberculosis is a common opportunistic infection of HIV/AIDS, and pharmaceuticals for patients struggling with co-infection are expensive. *See id.*

[25] *See* World Health Org., UNAIDS, & UNICEF, *supra* note 24, at 53.

[26] *Id.* at 5.

[27] *See* Rudolf V. Van Puymbroeck, *Basic Survival Needs and Access to Medicines—Coming to Grips with TRIPS: Conversion + Calculation*, 38 J.L. Med. & Ethics 520, 520–21 (2010); Howden, *supra* note 13.

[28] *See* Richard A. Epstein & F. Scott Kieff, *Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents*, 78 U. Chi. L. Rev. 71, 71–72 (2011); Cynthia M. Ho, *Global Access to Medicine: The Influence of Competing Patent Perspectives*, 35 Fordham Int'l L.J. 1, 4 (2011).

[29] *See* Epstein & Kieff, *supra* note 28, at 71–72; Ho, *supra* note 28, at 4.

[30] *See* Epstein & Kieff, *supra* note 28, at 71–72; Ho, *supra* note 28, at 3–4.

[31] *See* Charles R. McManis, *Intellectual Property and International Mergers and Acquisitions*, 66 U. Cin. L. Rev. 1283, 1286 (1998); Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 Hous. L. Rev. 979, 980 (2009).

members.[32] Critics accused the stringent patent protections under the TRIPS Agreement of favoring HICs, asserting that the agreement "ignore[s] . . . public health conditions" of LMICs.[33] In response to growing concerns about the effects of rigid patent laws on public health, WTO signatories adopted the Doha Declaration on the TRIPS Agreement and Public Health ("the Doha Declaration") in November 2001.[34] The Doha Declaration emphasizes that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[35]

In subsequent years, however, the United States has diminished the import of the Doha Declaration by instituting more rigid intellectual property protection provisions in bilateral and multilateral free trade agreements (FTAs).[36] These stringent provisions are called "TRIPS-Plus" provisions because they require higher levels of patent protection than mandated by the TRIPS Agreement.[37] TRIPS-Plus provisions have been criticized for limiting access to pharmaceuticals.[38]

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[32] Agreement on Trade-Related Aspects of Intellectual Property Rights, arts. 7, 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round Vol. 1c. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement]; *see* McManis, *supra* note 31, at 1286; Yu, *supra* note 31, at 980. WTO membership offers numerous advantages and countries at all levels of development ratified the TRIPS Agreement to exploit these benefits. Aileen M. McGill, Note, *Compulsory Licensing of Patented Pharmaceuticals: Why a WTO Administrative Body Should Determine What Constitutes a Public Health Crisis Under the Doha Declaration*, 10 Wake Forest Intell. Prop. L. J. 69, 72 (2009).

[33] Peter K. Yu, *The International Enclosure Movement*, 82 Ind. L.J. 827, 828 (2007). At the same time, the AIDS pandemic began gaining notoriety, advancing serious concerns regarding public health and infectious diseases. *See* Hoen et al., *supra* note 24, at 3 (discussing a lawsuit between the post-apartheid government of South Africa and pharmaceutical companies regarding amendments that South Africa had made to legislation in order to readily provide low-cost antiretrovirals); Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP*, 18 J. Intell. Prop. L. 447, 448 (2011).

[34] *See* Peter K. Yu, *TRIPS and Its Achilles' Heel*, 18 J. Intell. Prop. L. 479, 504–05 (2011); Beatrice Lindstrom, Note, *Scaling Back TRIPS-Plus: An Analysis of Intellectual Property Provisions in Trade Agreements and Implications for Asia and the Pacific*, 42 N.Y.U. J. Int'l L. & Pol. 917, 949 (2010).

[35] *See* World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1,41.I.L.M. 746, ¶ 4 (2002) [hereinafter Doha Declaration]. The Doha Declaration promoted LMICs' interests in the predominance of public health over commercial priorities. *See* Puymbroeck, *supra* note 27, at 526.

[36] *See* Puymbroeck, *supra* note 27, at 531–33.

[37] *See id.* at 532.

[38] *See* Oxfam Int'l, Undermining Access to Medicines: Comparison of Five US FTA's 1 (June 2004), *available at* http://www.twnside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/UnderminingAccessToMedicines.pdf; Puymbroeck, *supra* note 27, at 532–33.

In particular, the United States has taken an unyielding approach to data exclusivity and compulsory licensing, which Congress failed to address in the "Bipartisan Agreement on Trade Policy."[39] To ensure that Hope Tukahirwa and millions like her are afforded access to inexpensive pharmaceuticals, all U.S. FTAs should be amended to include a balancing test that weighs the benefits and detriments to determine when it is necessary to relax data exclusivity and compulsory licensing provisions.[40] This balancing test, which has been used by the WTO in the past when resolving disputes, looks at: "(1) the importance of interests or values that the challenged measure is intended to protect; (2) the extent to which the challenged measure contributes to the realization of the end pursued by that measure; and (3) the trade impact of the challenged measure."[41]

Part I of this Note identifies the problem of rigid TRIPS-Plus provisions in U.S. FTAs by tracing their development through intellectual property laws in the United States, the TRIPS Agreement, and the Doha Declaration. Part II demonstrates how TRIPS-Plus provisions limit access to affordable pharmaceuticals by examining current and proposed U.S. FTAs. Part III asserts that the Bipartisan Agreement for Trade Policy failed to address problematic TRIPS-Plus provisions and asserts that the United States must amend its FTAs so that impoverished populations have access to affordable pharmaceuticals.

I. The Development of TRIPS-Plus Provisions in U.S. Free Trade Agreements

TRIPS-Plus provisions in U.S. FTAs impede access to pharmaceuticals for indigent populations.[42] The similarities between U.S. patent law

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[39] Henning Grosse Ruse-Khan, *The International Law Relation Between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities?*, 18 J. Intell. Prop. L. 325, 331 (2011) (describing how the United States reasserted its commitment to protecting public health and promoting access to medicines in U.S. FTAs); *see* Puymbroeck, *supra* note 27, at 532–33; Charles B. Rangel, *Moving Forward: A New, Bipartisan Trade Policy That Reflects American Values*, 45 Harv. J. on Legis. 377, 387–88 (2008).

[40] *See infra* notes 205–254 and accompanying text.

[41] *See* Appellate Body Report, *United States—Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, ¶¶ 305–308, WT/DS285/AB/R (Apr. 7, 2005) [hereinafter WTO Gambling]; Appellate Body Report, *Korea—Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, ¶ 164, WT/DS169/AB/R (Dec. 11, 2000) [hereinafter WTO Beef]; Sharon E. Foster, *Prelude to Compatibility Between Human Rights and Intellectual Property*, 9 Chi. J. Int'l L. 171, 206 (2008).

[42] *See* Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. Int'l Econ. L. 921, 962–63 (2007); Cynthia M. Ho, *A New World Order for*

and the TRIPS Agreement demonstrate the United States's influence in establishing global intellectual property standards.[43] Despite the success of the United States in shaping global intellectual property standards, the TRIPS Agreement maintains several flexibilities, namely data exclusivity and compulsory licensing, which were affirmed by the Doha Declaration.[44] The United States's dissatisfaction with the level of intellectual property protection afforded by the TRIPS Agreement prompted the proliferation of TRIPS-Plus provisions in U.S. FTAs.[45]

A. *Values and Ideals in U.S. Patent Law*

The preeminence of patents in the United States is evidenced by the fact that patents are constitutionally protected to promote innovation and discovery.[46] A patent is a grant of property issued by a government that provides limited rights to the patent owner.[47] A patent owner in the United States is granted monopolistic control over his or her invention for twenty years, during which time no one may make, sell, or use the patented product, absent permission from the patent holder.[48] This exclusive right promotes innovation by enabling the patent owner to avoid pricing competition when selling the patented product.[49] In return for monopolistic power to exclude, a patent owner must disclose the technological processes and data behind the product.[50] Other producers use this information, saving on the cost of re-

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Addressing Patent Rights and Public Health, 82 CHI.-KENT L. REV. 1469, 1497–502 (2007); Puymbroeck, *supra* note 27, at 532; Sell, *supra* note 33, at 453–55.

[43] McGill, *supra* note 32, at 78.

[44] *See* Doha Declaration, *supra* note 35, ¶ 5.

[45] *See* Puymbroeck, *supra* note 27, at 532; Sell, *supra* note 33, at 448, 553–55.

[46] U.S. CONST. art. 1, § 8, cl.8 (authorizing Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries").

[47] BLACK'S LAW DICTIONARY 970 (9th ed. 2009) (defining patents as "the governmental grant of a right, privilege or authority"). It is also important to note that patent rights are geographically finite, requiring protection from each country in which innovators seek to distribute their patents. Ho, *supra* note 28, at 9.

[48] *See, e.g.*, 35 U.S.C. § 154(a)(2) (2006) (providing that a patent term in the United States begins on the date the patent is granted and extends twenty years from the application date); *id.* § 271(a) (establishing that patent infringement occurs when one "makes, uses, offers to sell, or sells any patented invention").

[49] *See* Caroline Manne, Note, *Pharmaceutical Patent Protection and TRIPS: The Countries That Cried Wolf and Why Defining "National Emergency" Will Save Them from Themselves*, 42 GEO. WASH. INT'L L. REV. 349, 349–50 (2010).

[50] *See* Jon Matthews, Note, *Renewing Healthy Competition: Compulsory Licenses and Why Abuses of the TRIPS Article 31 Standards Are Most Damaging to the United States Healthcare Industry*, 4 J. BUS. ENTREPRENEURSHIP & L. 119, 121 (2010).

search and development while also expediting the regulatory process, in order to offer competitive pricing when the patent terminates.[51]

Patents are particularly valuable to the drug industry given the plethora of research and development required to produce pharmaceuticals.[52] When a drug is no longer under patent, pharmaceutical companies must compete with generic producers who provide medicines at much lower prices.[53] Pharmaceutical companies assert that research and development challenges require a rigid patent system to recover investment, turn profit, and promote continued innovation.[54]

In the context of international trade, pharmaceutical companies have much at stake as LMICs produce generic versions of patented drugs and sell these medications around the world, undercutting brand-name profitability.[55] Although the pharmaceutical industry ranks as one of the most profitable industries in the United States, these patent concerns have led to the development of powerful special interest groups that the United States relies on when considering trade agreements, including the TRIPS Agreement.[56]

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[51] *See* Rangel, *supra* note 39, at 403–04; Matthews, *supra* note 50, at 121.

[52] *See* Manne, *supra* note 49, at 353 (noting that "[a]mong high technology industries, the pharmaceutical industry as a whole reinvests the greatest percentage of sales revenue into research and development," requiring a rigid patent system to recover investment and turn profit). *But see* Zita Lazzarini, *Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil*, 6 Yale Hum. Rts. & Dev. L.J. 103, 111 (2003) (noting that drug companies invest more profits on administration and marketing than on research and development). To develop a drug, pharmaceutical companies invest an average of twelve years and eight hundred million dollars. *See* Cong. Budget Office, A CBO Study: Research and Development in the Pharmaceutical Industry 2 (2006) [hereinafter Pharma R&D]. Additionally, many of the products and chemicals developed are never sold and of those sold, only approximately three of ten are profitable. *See* Manne, *supra* note 49, at 353.

[53] *See* Lindstrom, *supra* note 34, at 974; Matthews, *supra* note 50, at 133; McGill, *supra* note 32, at 86; Frank Jordans, *Novartis Drug Company to Cut Almost 2,000 Jobs*, Huffington Post (Jan. 13, 2012, 12:08 PM), http://huffingtonpost.com/2012/01/13/novartis-job-cuts_n_1204137.html (examining the dramatic impact of losing a patent on brand-name producers by detailing drug maker Novartis's decision to cut nearly two thousand jobs once its best-selling hypertension drug, Diovan, comes off patent).

[54] *See* Manne, *supra* note 49, at 353–54. The most profitable multinational pharmaceutical companies, however, spend more on advertising and administration (approximately thirty percent) than they do on research and development (approximately nineteen percent). Jennifer Bjornberg, Note, *Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation?*, 27 Nw. J. Int'l L. & Bus. 199, 219 (2006).

[55] *See, e.g.*, Adam Chilton, *India's Evolving Patent Laws and WTO Obligations: The Rejection of Abbott Laboratories' Application for a New Kaletra Patent*, 39 J.L. Med. & Ethics 296, 297 (2011) (referring to India as "the pharmacy of the world").

[56] *See* Pharma R&D, *supra* note 52, at 2, 4; Sell, *supra* note 33, at 464; McGill, *supra* note 32, at 78. Many commentators note the apparent revolving door between the pharmaceutical industry and the U.S. government. *See* Sell, *supra* note 33, at 455; Zach Carter,

B. *Global Expansion of U.S. Patent Ideals Through the TRIPS Agreement*

The combination of special interests and traditional value placed on patent protection has encouraged the United States to enforce its patent ideals globally by linking patent protection and international trade through the TRIPS Agreement.[57] Touted as "unquestionably the most important development in international intellectual property law [in a century]," the TRIPS Agreement "attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations."[58] To accomplish this, the agreement requires all WTO signatories to implement minimum standards of intellectual property law.[59]

The United States's influence is acutely evident throughout the TRIPS Agreement's patent provisions, which practically mirror U.S. patent law.[60] For example, like U.S. patent law, the TRIPS Agreement grants patent owners exclusive rights to prevent others from making,

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Bill Daley's Big Pharma History: Drugs, Profits and Trade Deals, Huffington Post (Nov. 28, 2011, 5:12 AM), http://www.huffingtonpost.com/2011/09/28/bill-daley-big-pharma-trans-pacific-partnership_n_981973.html. For example, William Daley served as the Commerce Secretary under the Clinton administration and worked with U.S. pharmaceutical giants to curtail the use of more affordable generic drugs abroad. *See* Carter, *supra*. Daley later served as a board member for Abbott Laboratories, while the company clashed with Thailand over compulsory licenses for antiretroviral medications. *Id.* Daley most recently served as the White House Chief of Staff under President Obama. *Id.* Moreover, Mickey Kantor, formerly the U.S. Trade Representative, is currently a pharmaceutical industry lobbyist, vigorously advocating for TRIPS-Plus provisions. *See* Sell, *supra* note 33, at 455. Pharmaceutical lobbying efforts are not limited to the United States and the pharmaceutical industry in the European Union (EU) works hard to influence the EU's trade commission with regard to patent protections in trade agreements. *See* Abbott & Reichman, *supra* note 42, at 962.

[57] *See* McGill, *supra* note 32, at 76, 78.

[58] McManis, *supra* note 31, at 1286; *see* Yu, *supra* note 31, at 1007; *Fact Sheet: TRIPS and Pharmaceutical Patents*, World Trade Org. (Sept. 2006),http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm01_e.htm.

[59] *See* Manne, *supra* note 49, at 358. Although the TRIPS Agreement regulates all aspects of intellectual property, including copyright, trademark, and patents, the standards for patents are particularly poignant with regard to access to pharmaceuticals. *See* TRIPS Agreement, *supra* note 32, Part II, §§ 1–8; Manne, *supra* note 49, at 350–51.

[60] McGill, *supra* note 32, at 78. Many WTO signatories had little or no experience with intellectual property prior to the TRIPS Agreement. *See* Matthew Turk, Note, *Bargaining and Intellectual Property Treaties: The Case for a Pro-Development Interpretation of TRIPS but Not TRIPS Plus*, 42 N.Y.U. J. Int'l L. & Pol. 981, 991, 994 (2010). The United States was able to exploit the lack of intellectual property expertise in LMICs to its advantage during the TRIPS Agreement negotiations. *See id.* at 994.

using, selling, or importing the patented product for twenty years.[61] Moreover, neither the TRIPS Agreement nor U.S. patent law permits exceptions for patenting pharmaceuticals or pharmaceutical processes.[62] Both the United States and the TRIPS Agreement prohibit the use of compulsory licensing for products not developed locally.[63] Lastly, both the United States and the TRIPS Agreement stipulate that in exchange for a period of monopolistic control, the patent owner must disclose the invention "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art . . . ."[64]

Although the United States was largely successful in expanding its patent ideals through the TRIPS Agreement, LMICs maintained considerable flexibility to promote access to drugs.[65] This success is highlighted by the TRIPS Agreement's treatment of data exclusivity and compulsory licensing.[66]

1. Data Exclusivity

The TRIPS Agreement requires patent holders to disclose relevant information regarding the development of the patented product, including clinical data.[67] Pharmaceutical companies invest a significant amount of time and money to develop the clinical data required to patent new drugs.[68] Generic drug companies rely on the clinical data collected by brand-name drug companies in order to demonstrate that the generic drug is pharmacologically equivalent to the brand-name pharmaceutical.[69] In doing so, generic producers avoid the inordinate time and expense required to generate this data, enabling expeditious regulatory approval and delivery of affordable medicines upon the ex-

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[61] TRIPS Agreement, *supra* note 32, arts. 28.1, 33; *see, e.g.*, 35 U.S.C. §§ 154(a)(2), 271(a) (2006).

[62] McGill, *supra* note 32, at 78–79.

[63] *Id.*

[64] 35 U.S.C. § 112(a)(4); TRIPS Agreement, *supra* note 32, art. 29.

[65] *See* Sell, *supra* note 33, at 448; Yu, *supra* note 34, at 493–95 (noting that because of negotiation tactics used by LMICs, the TRIPS agreement maintains ambiguities and flexibilities which promote the interests of LMICs); McGill, *supra* note 32, at 78–79.

[66] Donald Harris, *TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J. Intell. Prop. L. 367, 383 (2011); Pedro Roffe & Christoph Spennemann, *The Impact of FTAs on Public Health Policies and TRIPS Flexibilities*, 1 Int'l J. Intell. Prop. Mgmt. 75, 78–79 (2006).

[67] TRIPS Agreement, *supra* note 32, art. 29.

[68] *See* Pharma R&D, *supra* note 52, at 2.

[69] *See* Rangel, *supra* note 39, at 403–04.

piration of brand-name patents.[70] The TRIPS Agreement requires protection of such data but affords signatories broad discretion to utilize clinical data to protect the public and promote public health, as long as steps are taken to prevent unfair commercial use.[71] Moreover, scholars contend that in light of the TRIPS Agreement's purpose and objectives, the agreement does not require a period of data exclusivity, contrary to U.S. patent law.[72]

2. Compulsory Licensing

A compulsory license is a government authorized license to a third party for the purpose of manufacturing and producing a patented innovation without consent from the patent owner.[73] Article 31 governs compulsory licenses under the TRIPS Agreement, granting a government broad discretion in issuing these licenses.[74] The following requirements must be met in order to obtain a compulsory license: (1) the country must ensure that the third party seeking the license attempts to obtain authorization from the patent holder on reasonable commercial grounds; (2) the scope and duration of the compulsory license must be limited to the purpose for which the license was authorized; (3) the compulsory license must be predominately used "for the supply of the domestic market of the Member authorizing such use;"

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[70] *See* Laura Chung, *Use of Paragraph 6 System for Access to Medicine*, 36 N.C. J. Int'l L. & Com. Reg. 137, 180–81 (2010); Roffe & Spennemann, *supra* note 66, at 82.

[71] *See* TRIPS Agreement, *supra* note 32, arts. 31, 39(3); Georgetown Univ. Law Ctr., Human Rights Inst., Prescription for Failure: Health & Intellectual Property in the Dominican Republic 28 (2010) [hereinafter Georgetown], *available at* http://scholarship.law.georgetown.edu/hri_papers/5; Roffe & Spennemann, *supra* note 66, at 82.

[72] *See* Carlos María Correa, *Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 Chi. J. Int'l L. 69, 84 (2002); Rangel, *supra* note 39, at 403–04. The objectives of the TRIPS Agreement note 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 Agreement, *supra* note 32, art. 7 (emphasis added). The principles of the TRIPS Agreement note that "[m]embers 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." *Id.* art. 8.1 (emphasis added). Correa asserts that in light of the objectives and principles, data exclusivity is only required in limited instances and that governments should have access to clinical data for the purposes of protecting public health. *See* Correa, *supra*, at 84.

[73] Donald P. Harris, *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet Back Against the United States*, 25 Nw. J. Int'l L. & Bus. 99, 107 (2004).

[74] *See* Harris, *supra* note 66, at 383; Harris, *supra* note 73, at 107–08.

and finally (4) the country must provide the patent holder with "adequate remuneration . . . taking into account the economic value of the authorization."[75] Article 31 may be waived in cases of extreme urgency, national emergency, or public non-commercial use.[76]

Although HICs and LMICs reached a compromise on compulsory licensing, the issue became increasingly contentious upon implementation.[77] HICs were dismayed with the lack of clarity surrounding terms like "adequate remuneration" and "national emergency."[78] LMICs were frustrated with Article 31(f) which stipulates that compulsory licenses must be predominately used for distribution within the domestic market.[79] Because many low-income countries lack manufacturing capacity, compulsory licensing under Article 31 does not provide a viable method of obtaining pharmaceuticals at a competitive price.[80] At the same time, alarm over HIV/AIDS, malaria, and tuberculosis grew as developing countries struggled to contain and treat infectious disease epidemics.[81] These concerns led to the signing of the Doha Declaration at the WTO Ministerial Conference in 2001.[82]

C. *A Blow to U.S. Interests: The Doha Declaration and Article 31bis*

As WTO signatories began implementing the TRIPS Agreement, the scourge of HIV/AIDS proliferated and infections increased by ten percent from 2000 to 2001.[83] At that time, the World Health Organiza-

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[75] *See* TRIPS Agreement, *supra* note 32, art. 31(b)–(h).

[76] *Id.* art. 31(b).

[77] *See* Chung, *supra* note 70, at 140–41; Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS*, 34 N.C. J. Int'l L. & Com. Reg. 371, 409–10 (2009).

[78] Ho, *supra* note 77, at 409–10 (providing that "[w]ith no clear limits, the interpretation of what constitutes adequate remuneration seems left to the discretion of national authorities"); Antony Taubman, *Rethinking TRIPS: 'Adequate Remuneration' for Non-Voluntary Patent Licensing*, 11 J. Int'l Econ. L. 927, 962 (2008) (noting that royalty rates for remuneration have ranged from 0.02% to 8%).

[79] *See* Chung, *supra* note 70, at 140–41.

[80] *Id.*

[81] *See* Harris, *supra* note 66, at 385–86. The South African government attempted to reduce the cost of antiretrovirals by enacting the South African Medicines and Related Substances Control Amendment Act of 1997. *Id.* at 384. This act enabled local manufactures to produce antiretrovirals through compulsory licensing and also enabled manufactures to import these pharmaceuticals from countries that produced generic versions of the antiretrovirals at lower costs than the patented versions. *Id.*

[82] *Id.* at 385–86.

[83] *Compare* UNAIDS & World Health Org., AIDS Epidemic Update 1 (2001), *available at* http://www.unaids.org/en/media/unaids/contentassets/dataimport/publications/irc-pub06/epiupdate01_en.pdf (noting that forty million people were living with HIV/ AIDS

tion estimated that less than four percent of those in need of HAART had access.[84] It is in this context that the Doha Declaration "recognize[d] the gravity of the public health problems afflicting many [LMICs], especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."[85] WTO delegates agreed that signatories should interpret and implement the TRIPS Agreement in a way that promotes public health and access to medicines for all.[86]

Intellectual property flexibilities promoted by the TRIPS Agreement were reaffirmed in the Doha Declaration.[87] Specifically, the Doha Declaration implicitly affirmed the TRIPS Agreement's deferential data exclusivity provisions and explicitly confirmed the use of compulsory licenses.[88] The Doha Declaration granted broad discretion with regard to compulsory licensing, asserting that WTO signatories have "the right to grant compulsory licences [sic] and the freedom to determine the grounds upon which such licences [sic] can be granted."[89] Perhaps

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in 2001), *with* UNAIDS & World Health Org., AIDS Epidemic Update 3 (2000), *available at* http://www.unaids.org/en/media/unaids/contentassets/dataimport/publications/irc-pub05/aidsepidemicreport2000_en.pdf (demonstrating that thirty-six million people were living with HIV/AIDS in 2000).

[84] World Health Org. & UNAIDS, Accelerating Access Initiative: Widening Access to Care and Support for People Living with HIV/AIDS 1 (2002), *available at* http://www.who.int/hiv/pub/prev_care/isbn9241210125.pdf (noting that only an estimated 230,000 people were receiving antiretrovirals in 2001 although approximately six million people were in need of treatment).

[85] Doha Declaration, *supra* note 35, ¶ 1.

[86] *Id.* ¶ 4.

[87] *See id.*; Roffe & Spennemann, *supra* note 66, at 78.

[88] *See* Doha Declaration, *supra* note 35, ¶ 5.

[89] *Id.* ¶ 5(b). Another flexibility affirmed by the Doha Declaration is the TRIPS Agreement's silence on parallel importation as granting approval for individual signatories to establish their own regime for parallel importation and exhaustion. *See id.* ¶ 5(d) (confirming that "[t]he effect of the provisions in the TRIPS agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge"). Parallel importation occurs when products produced and marketed by a patent holder in one country are imported to another country without approval from the original patent owner. World Health Org. & Directorate Gen. of Drug & Food Control, The TRIPS Agreement and Pharmaceuticals 33–34 (2000), *available at* http://apps.who.int/medicinedocs/pdf/h1459e/h1459e.pdf. The legal principle, exhaustion, provides that when a company begins selling its product in the market of a particular country, the patent holder's rights in the product are exhausted. *See* Ho, *supra* note 42, at 1501 n.147. Thus, the purchaser of the product may resell the patented good in another country at varying prices, without regard to the patent holder. *See id.*; Sell, *supra* note 33, at 453–54 (illustrating parallel importation by asserting that if a drug company sells a patented drug more affordably in country X than in country Y, then country Y is permitted to import the drug from country X). Parallel importation favors LMICs because it enables them to exploit differential pharmaceutical pricing policies thereby obtaining more affordable drugs. *See* Ho, *supra* note 42, at 1501; Lindstrom, *supra* note 34, at 951. Pharmaceutical

most importantly, the Doha Declaration recognized the ineffectiveness of compulsory licensing for countries with limited or no manufacturing capacity.[90] To address this weakness, WTO signatories amended the TRIPS Agreement with Article 31bis, which enables countries with limited or no manufacturing capacity to import generic drugs from other countries, thereby promoting access to more affordable medicines.[91]

Despite the Doha Declaration's affirmance of deferential data exclusivity and compulsory licensing as valuable mechanisms to promote access to medicine, the United States dominated the TRIPS Agreement negotiations.[92] A World Bank study concluded that low-income coun-

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companies are opposed to parallel importation given that the profitability of their products relies, in part, on differential pricing. Ho, *supra* note 42, at 1501. The TRIPS agreement explicitly declines to reach the issue of parallel importation, thereby promoting flexibility with regard to this mechanism and deferring to the discretion of WTO signatories. TRIPS Agreement, *supra* note 32, art. 6 (noting that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights").

[90] *See* Doha Declaration, *supra* note 35, ¶ 6; Chung, *supra* note 70, at 140–41; Harris, *supra* note 66, at 386.

[91] World Trade Org., *Annex to the Protocol Amending the TRIPS Agreement: Article 31bis*, WTO (Dec. 6, 2005), http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm [hereinafter Article 31bis]; *see* Chung, *supra* note 70, at 141, 152; Harris, *supra* note 66, at 386. To import pharmaceuticals under Article 31bis, a country must be a "least developed country" or demonstrate that it lacks manufacturing capacity to produce the desired product; the country must inform the WTO about the type and quantity of drug it seeks to import; and the country must take reasonable measures to prevent dispersion of the drug to other countries. *See* Abbott & Reichman, *supra* note 42, at 939–42; Chung, *supra* note 70, at 143. The exporting country must issue a compulsory license to a manufacturer within the country and notify the WTO. Abbott & Reichman, *supra* note 42, at 942–43. The compulsory license may only be issued for noncommercial use, a national emergency, or circumstances in extreme urgency. *Id.* Article 31bis exempts the importing country from providing "adequate remuneration" to the patent holder but requires the exporting country to provide an unspecified amount for remuneration. *See id.* at 944; Chung, *supra* note 70, at 141. Very few countries have amended their trade laws to promote the use of Article 31bis, thereby negating its usefulness. *See* Chung, *supra* note 70, at 139, 166 (noting that only Switzerland, the European Communities, and Pakistan amended their national trade laws to enable the issuance of compulsory licenses for the purpose of exportation). In 2007, Canada and Rwanda became the first and only countries to use Article 31bis. *See id.* at 152, 170. The complicated Canada-Rwanda deal took over three years to complete, thereby diminishing the system's ability to respond to national emergencies. *See id.* at 169–74 (highlighting the difficulties associated with use of Article 31bis in the Canada-Rwanda deal). The generic pharmaceutical company partnering with Rwanda has indicated that it is not likely to participate in another deal given that it was required to absorb tremendous expenses, including the cost of negotiations with the patent holding pharmaceutical company, the cost of providing unique packaging or labeling for the generic drugs, and the cost of export. *See* Daniel R. Cahoy, *Breaking Patents*, 32 Mich. J. Int'l. L. 461, 469 (2011); Chung, *supra* note 70, at 169–74.

[92] Peter K. Yu, *TRIPS and Its Discontents*, 10 Marq. Intell. Prop. L. Rev. 369, 380, 401 (2006); McGill, *supra* note 32, at 79.

tries stand to lose twenty billion dollars from transfers of technology, including pharmaceuticals, if the TRIPS Agreement is fully implemented.[93] Still, the United States had to accept compromises during the negotiations and has remained discontent with the level of protection afforded to pharmaceutical patents by the TRIPS Agreement.[94] This dissatisfaction spurred the proliferation of TRIPS-Plus provisions in bilateral U.S. FTAs.[95]

D. *The Proliferation of TRIPS-Plus Provisions in U.S. FTAs*

The TRIPS Agreement creates a regulatory "floor," consisting of minimum levels of protection that must be afforded to intellectual property by all WTO signatories.[96] Countries are therefore permitted to seek higher levels of protection in FTAs, and the United States has done so in negotiating bilateral FTAs with numerous countries.[97] These trade agreements are commonly called TRIPS-Plus U.S. FTAs because they incorporate more stringent intellectual property protection provisions than the TRIPS Agreement, while also limiting the freedoms and flexibilities provided by the TRIPS Agreement.[98]

Beginning with the Bush administration and continuing through the Obama administration, the U.S. has 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

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[93] Int'l Bank for Reconstr. & Dev., Global Economic Prospects and the Developing Countries 2002 xvii (2001), *available at* http://siteresources.worldbank.org/INTGEP/Resources/335315-1257200370513/gep2002complete.pdf.

[94] Roffe & Spennemann, *supra* note 66, at 79; Sell, *supra* note 33, at 448.

[95] *See* James Thuo Gathii, *The Neoliberal Turn in Regional Trade Agreements*, 86 Wash. L. Rev. 421, 466 (2011); Roffe & Spennemann, *supra* note 66, at 79.

[96] *See* Gathii, *supra* note 95, at 466; Ruse-Khan, *supra* note 39, at 329; Taubman, *supra* note 78, at 944.

[97] TRIPS Agreement, *supra* note 32, art. 1(1); Gathii, *supra* note 95, at 466. Since 2001, the United States has negotiated FTAs with Vietnam, Jordan, Singapore, Chile, Morocco, Australia, El Salvador, Guatemala, Honduras, Nicaragua, Costa Rica, the Dominican Republic, Columbia, Ecuador, Peru, Thailand, Panama, Oman, Republic of Korea, and the United Arab Emirates. *See* Puymbroeck, *supra* note 27, at 532. Moreover, the United States attempted an FTA with the Southern African Customs Union which includes Botswana, Lesotho, Namibia, South Africa, and Swaziland. *See* Gathii, *supra* note 95, at 469. Additionally, the United States is in the midst of negotiating an enormous FTA with Australia, Brunei, Chile, New Zealand, Singapore, Peru, and Vietnam. Meredith Kolsky Lewis, *The Trans-Pacific Partnership: New Paradigm or Wolf in Sheep's Clothing?*, 34 B.C. Int'l & Comp. L. Rev. 27, 29 (2011).

[98] *See* Abbott & Reichman, *supra* note 42, at 962–63; Puymbroeck, *supra* note 27, at 532; Sell, *supra* note 33, at 453.

law."[99] Pressure from the pharmaceutical industry led to the implementation of several TRIPS-Plus provisions, including rigid data exclusivity policies and limitations on compulsory licensing, thereby impeding access to affordable medicines for indigent populations in desperate need.[100]

1. TRIPS-Plus Impact on Data Exclusivity Provisions

TRIPS-Plus data exclusivity provisions in U.S. FTAs constrict the flexibilities afforded by the TRIPS Agreement.[101] Whereas the TRIPS Agreement applies a deferential approach towards data exclusivity, U.S. FTAs apply the same level of protection afforded under U.S. patent

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[99] Bipartisan Trade Promotion Authority Act of 2002, Pub. L. No. 107–210, § 2101(b)(4)(A)(i)(II), 116 Stat. 993, 996 (2002) (codified at 19 U.S.C. § 3802(b)(4)(A)(i)(II) (2006)); *see also* Sell, *supra* note 33, at 466 (criticizing the Obama administration's approach to international trade as it relates to pharmaceutical patents).

[100] *See* Abbott & Reichman, *supra* note 42, at 962; Ho, *supra* note 42, at 1497–502; Puymbroeck, *supra* note 27, at 532; Sell, *supra* note 33, at 453. Several other TRIPS-Plus provisions are commonly found in U.S. FTAs, including: limitations on parallel importation; linkages between marketing and drug approval; and extensions for patent terms. Ho, *supra* note 42, at 1495–502; Sell, *supra* note 33, at 453–55. Several U.S. FTAs provide patent holders with an exclusive right to bar parallel importation. *See* Ho, *supra* note 42, 1501–02 (noting that U.S. FTAs with Morocco and Singapore require each country to grant patent holders the right to block parallel imports). Moreover, the U.S.-Australia FTA prohibits parallel importation where the patent holder has indicated that a product is solely meant for sale within a specified country. *See* United States-Australia Free Trade Agreement, U.S.-Austl., art. 17.9(4), May 18, 2004, 43 I.L.M. 1248 [hereinafter U.S.-Aus. FTA], *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/australian-fta. As one author noted, these provisions "eliminate[] a TRIPS-compliant opportunity to access more affordable patented drugs; this is especially crucial in the case of second-line HIV/AIDS drugs that are patented and for which no generics are available." Sell, *supra* note 33, at 454. Another method of deterring generic pharmaceutical competition found in U.S. FTAs but not in the TRIPS Agreement, involves the link between marketing and drug registration, known as linkage. *See* Carlos María Correa, *Implications of Bilateral Free Trade Agreements on Access to Medicines*, 84(5) Bull. World Health Org., 399, 401–02 (2006). Linkage provisions require national health authorities to deny marketing approval to generic pharmaceuticals prior to patent expiration unless the patent holder consents. *See id.* at 401. Moreover, national health authorities must notify a patent holder about applications for generic pharmaceutical approval. *See id.* Linkage systems may delay generic pharmaceutical companies from introducing more affordable medications and may even deter generic competition. *See id.* at 402; Sell, *supra* note 33, at 454. Finally, although the TRIPS Agreement requires that patents last for twenty years, many TRIPS-Plus FTAs incorporate patent term extensions. *See* Correa, *supra*, at 400; Sell, *supra* note 33, at 454. The United States permits patent term extensions for the pharmaceutical industry because drug companies must seek regulatory approval before distributing new drugs and the industry asserts that extended patent periods account for regulatory delays. *See* Correa, *supra*, at 400. U.S. FTAs include patent term extensions without allocating a maximum time period for the extension. *See id.* at 400–01.

[101] Georgetown, *supra* note 71, at 28.

law.[102] In U.S. FTAs, competing manufacturers are prohibited from relying on clinical data for five to fifteen years after the date of a pharmaceutical's initial regulatory approval.[103] Brand-name pharmaceutical companies favor data exclusivity provisions because they enable drug companies to exploit profits by suspending competition.[104]

Clinical data is costly and time consuming, and data exclusivity provisions may prohibit generic producers from introducing more affordable medication immediately following a patent's expiration by prohibiting access to data previously gathered by the patent holder.[105] To compete, generic producers may be forced to conduct their own costly research and development, negating their ability to provide affordable drugs.[106] Alternatively, generic companies would have to delay regulatory approval and production of generic drugs.[107] Thus, TRIPS-Plus data exclusivity provisions in U.S. FTAs effectively empower patent holders to extend monopolistic control of pharmaceuticals by obstructing generic competition, consequently diminishing access to medicines for indigent populations.[108]

2. TRIPS-Plus Impact on Compulsory Licensing

Although to the TRIPS Agreement enables WTO signatories to establish their own national compulsory licensing scheme, TRIPS-Plus

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[102] *See* 35 U.S.C. §§ 154(a)(2), 271(a) (2006); United States-Panama Trade Promotion Agreement, U.S.-Pan., art. 15.10, June 28, 2007 [hereinafter U.S.-Panama FTA], *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/panama-tpa/final-text; United States-Peru Trade Promotion Agreement, U.S.-Peru, art. 16.10, Apr. 12, 2006 [hereinafter U.S.-Peru FTA], *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/peru-tpa/final-text; United States-Morocco Free Trade Agreement, U.S.-Morocco, art. 15.10, June 15, 2004, 44 I.L.M. 544 [hereinafter U.S.-Morocco FTA], *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/morocco-fta; United States-Chile Free Trade Agreement, U.S.-Chile, art 17.10, June 6, 2003, 42 I.L.M. 1026 [hereinafter U.S.-Chile FTA], *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/chile-fta; Georgetown, *supra* note 71, at 28; Chung, *supra* note 70, at 180–81; Rangel, *supra* note 39, at 404.

[103] Chung, *supra* note 70, at 180–81; Ellen R. Shaffer & Joseph E. Brenner, *A Trade Agreement's Impact on Access to Generic Drugs*, 28 Health Affairs w957, w961–64 (2009).

[104] Sell, *supra* note 33, at 453.

[105] *See* Chung, *supra* note 70, at 180–81; Sell, *supra* note 33, at 453.

[106] *See* Sell, *supra* note 33, at 453.

[107] *See* Chung, *supra* note 70, at 180–81; Sell, *supra* note 33, at 453.

[108] *See* Jerome H. Reichman, Undisclosed Clinical Trial Data Under the TRIPS Agreement and Its Progeny: A Broader Perspective 2 (2004), *available at* http://www.iprsonline.org/unctadictsd/bellagio/docs/Reichman_Bellagio4.pdf; Chung, *supra* note 70, at 180–82 (discussing FTAs with Chile, Jordan, and Morocco); Harris, *supra* note 66, at 394 (discussing FTAs with Singapore, Australia, South Korea, and Oman); Roffe & Spennemann, *supra* note 66, at 82; Sell, *supra* note 33, at 453–55.

provisions in U.S. FTAs significantly limit compulsory licensing.[109] Under U.S. FTAs, parties may typically only grant compulsory licenses in emergency situations, as an anti-trust remedy, or for public non-commercial use.[110] Notably, U.S. FTAs do not define "emergency situations" or "public non-commercial use."[111] Some TRIPS-Plus provisions require "reasonable and entire" remuneration for patent owners as opposed to "adequate remuneration" required by the TRIPS Agreement.[112] Finally, U.S. FTAs permit challenges to compulsory licenses on the grounds that a license was not warranted under the specific circumstances.[113] By confining a government's ability to issue compulsory licenses and providing an opportunity for the patent holder to challenge the issuance of compulsory licenses, TRIPS-Plus compulsory licensing provisions diminish a generic producer's ability to compete and enable the patent holder to manipulate drug pricing.[114] The net result is diminished access to medicines for Hope Tukahirwa and millions like her.[115]

II. Why TRIPS-Plus Provisions are Problematic: Rigid Data Exclusivity Provisions and Compulsory Licensing Provisions Obstruct Access to Medicine

TRIPS-Plus provisions promote unyielding data exclusivity and limit compulsory licensing to the detriment of indigent populations

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[109] *See* TRIPS Agreement, *supra* note 32, art. 31(b)–(h); Doha Declaration, *supra* note 35, ¶ 5(a)–(d); *see also* Ho, *supra* note 42, at 1499–1500 (noting that U.S. FTAs limit compulsory licensing beyond TRIPS requirements).

[110] U.S.-Aus. FTA, *supra* note 100, art. 17.9(7); United States-Singapore Free Trade Agreement, U.S.-Sing., art. 16.7(6), May 6, 2003, 42 I.L.M. 1026 [hereinafter U.S.-Singapore FTA], *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/singapore-fta/final-text; Agreement Between the United States of America and the Socialist Republic of Vietnam on Trade Relations, U.S.-Viet., art. 7.8, July 13, 2000 [hereinafter U.S.-Vietnam Agreement], *available at* http://www.arts.uwaterloo.ca/~vecon/download/uvta/text.pdf; Roffe & Spennemann, *supra* note 66, at 80.

[111] Roffe & Spennemann, *supra* note 66, at 80.

[112] U.S.-Singapore FTA, *supra* note 110, art. 16.7(6)(b)(ii); TRIPS Agreement, *supra* note 32, art. 31(h).

[113] *See* Lindstrom, *supra* note 34, at 949 (noting that these rules are often more restrictive than U.S. domestic compulsory licensing laws given that compulsory licenses are broadly protected beyond situations of national emergency).

[114] *See* Roffe & Spennemann, *supra* note 66, at 80; Sell, *supra* note 33, at 454–55; Lindstrom, *supra* note 34, at 949.

[115] *See* Roffe & Spennemann, *supra* note 66, at 80; Sell, *supra* note 33, at 454; Howden, *supra* note 13.

lacking access to affordable pharmaceuticals.[116] Data exclusivity provisions in U.S. FTAs with Guatemala and Vietnam, two countries struggling with staggering poverty, have led to increased pharmaceutical prices by delaying generic competition.[117] Moreover, the exclusion of compulsory licensing from FTAs or proposed FTAs with the Dominican Republic, Thailand, and the Southern African Customs Union (SACU) could lead to overwhelming public health challenges as generic competition is strangled from the market while patent holders maintain monopolistic control over pharmaceutical prices.[118]

A. *Examples of How Rigid TRIPS-Plus Data Exclusivity Provisions Have Had a Deleterious Effect on Public Health*

U.S. FTAs include rigid data exclusivity provisions that ultimately obstruct generic drug competition, resulting in disastrous public health consequences for destitute populations.[119] Trade agreements with Gua-

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[116] *See* Georgetown, *supra* note 71, at 15, 29, 32; Ana Revenga et al., The World Bank, The Economics of Effective AIDS Treatment, at xxxix–xl (2006); 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, 708 (2004); Shaffer & Brenner, *supra* note 103, at w961–64; Collins-Chase, *supra* note 10, at 792; Carter, *supra* note 56.

[117] UNDP 2011, *supra* note 21, at 144; Anh Tuan Nguyen et al., *Medicine Prices, Availability, and Affordability in Vietnam*, S. Med Rev., Sept. 2009, at 2, 2; Shaffer & Brenner, *supra* note 103, at w960–64.

[118] *See* Georgetown, *supra* note 71, at 33; Revenga et al., *supra* note 116, at xxxix–xl; Gathii, *supra* note 95, at 470; Jakkrit Kuanpoth, *Patents and Access to Antiretroviral Medicines in Vietnam After World Trade Organization Accession*, 10 J. of World Intell. Prop. 201, 219 (2007). Given the concessions required to sign U.S. FTAs, it is interesting to consider a country's decision to assent to these agreements. *See* Sell, *supra* note 33, at 451. One commentator notes that "[t]he U.S. [is] able to wield the carrot of increased market access and potential future investment along with the stick of economic coercion in order to get developing countries to sign on to much higher standards of intellectual property protection." *Id.* Indeed, the United States utilizes its tremendous market power to secure significant yields from LMICs. Gathii, *supra* note 95, at 438. Moreover, forum shifting enables a country to seek its trade objectives in an alternative forum. *See id.* at 443–44. WTO multilateral negotiations pit competing interests of HICs and LMICs against one another. *See id.* at 438, 443. Amendments to the TRIPS Agreement are time consuming and may result in stalemate given the number of signatories and the ability of large LMICs to form opposition blocks against the interests of HICs. *See id.* at 446–47 (noting that Thailand, Brazil, and India established a formidable opposition block against HICs during the WTO Ministerial Meeting of 2003). "Forum shifting allows countries to choose a new forum where they will encounter less concerted resistance to their agenda, which in turn gives them more wiggle room or policy space to achieve their objectives more readily." *Id.* at 443–44. Because countries are able to simplify and accelerate trade agreements bilaterally as opposed to multilaterally, these agreements are sometimes favored. *See id.* at 443–44, 446.

[119] *See* Nguyen et al., *supra* note 117, at 2; Shaffer & Brenner, *supra* note 103, at w961–64; Carter, *supra* note 56.

temala and Vietnam illustrate the injurious effect that data exclusivity provisions have on access to affordable drugs.[120]

1. Guatemala

The number of people living with HIV/AIDS in Guatemala has doubled since 2001; an estimated 62,000 people are living with the disease and less than 11,000 are receiving antiretroviral therapy.[121] Furthermore, approximately twenty percent of Guatemala's largely rural population lacks regular access to health facilities and services.[122] TRIPS-Plus data exclusivity provisions exacerbate these public health concerns by restricting access to affordable pharmaceuticals in Guatemala where over fifty percent of the population lives below the national poverty line.[123]

The U.S.-Dominican Republic-Central American Free Trade Agreement (DR-CAFTA) came into effect in Guatemala in 2006.[124] The

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[120] *See* Nguyen et al., *supra* note 117, at 2; Shaffer & Brenner, *supra* note 103, at w961–64; Carter, *supra* note 56. Jordan, which ratified a trade agreement with the United States in 2001, has also experienced the negative effects of data exclusivity provisions in U.S. FTAs. Rohit Malpani, Oxfam Int'l, All Costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines 2 (2007); *see* Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, U.S.-Jordan, art. 15, Oct. 24, 2000, 41 I.L.M. 63 [hereinafter U.S.-Jordan FTA], *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/jordan-fta. A recent study on the effects of data exclusivity provisions in the U.S.-Jordan FTA demonstrated that of 103 drugs launched since 2001, which are no longer under patent, nearly eighty percent have no generic counterpart. Malpani, *supra*, at 9. Generic producers attribute this lack of competition to rigid data exclusivity provisions. *Id.* at 9–10. Rigid data exclusivity provisions have also contributed to elevated pharmaceutical costs as the same drugs in Jordan cost eight hundred percent more than in similarly situated countries with less stringent data exclusivity provisions. *Id.* (demonstrating that the same pharmaceuticals in Egypt are significantly more affordable). Furthermore, drug prices in Jordan have risen by approximately twenty percent since 2001. *Id.* at 2. Given that nearly one-third of the country lives in poverty, higher drug costs as a result of rigid data exclusivity provisions strain access to necessary drugs for low-income populations. *Id.* at 5, 19.

[121] UNAIDS, *supra* note 19, at 201; World Health Org., UNAIDS, & UNICEF, Global HIV/AIDS Response: Epidemic Update and Health Sector Progress Towards Universal Access 191 (2011) [hereinafter Global HIV/AIDS Response 2011], *available at* http://www.who.int/hiv/pub/progress_report2011/en/index.html.

[122] *Country Cooperation Strategy at a Glance: Guatemala*, WHO, http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_gtm_en.pdf (last updated May 2007). Moreover, sixty percent of all reported cases of malaria in Central America occur in Guatemala. *Id.*

[123] UNDP 2011, *supra* note 21, at 144; Shaffer & Brenner, *supra* note 103, at w961.

[124] Shaffer & Brenner, *supra* note 103, at w966 n.1; *Free Trade Agreements*, Office of the U.S. Trade Rep., http://www.ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta (last visited Jan. 7, 2013) [hereinafter *Free Trade*].

DR-CAFTA is an agreement between the United States and six Central American countries, namely Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and the Dominican Republic.[125] Rigid data exclusivity provisions in the DR-CAFTA have prohibited a number of generic drugs from entering the Guatemalan pharmaceutical market, despite the fact that many of these drugs may successfully treat major causes of morbidity and mortality.[126] For example, Pfizer's Vfend, which is used to treat invasive fungal infections generally found in patients with compromised immune systems (like those suffering from HIV/AIDS), costs 810% more than the generic version.[127] Vfend, however, is subject to fifteen years of data exclusivity, thus barring generic producers' access to clinical information, quashing competition, and granting Pfizer monopolistic pricing control.[128]

Similarly, data exclusivity provisions have restricted access to affordable antiretrovirals.[129] For example, the Guatemalan government provides a list of drugs that public organizations may procure at subsidized costs.[130] A generic antiretroviral was registered in 2004, yet when Abbott Laboratories' patented version of the same drug, Kaletra, which costs 166% more than the generic pharmacological equivalent, was registered a year later, it was granted retroactive data exclusivity through 2000—the patent expires in 2015.[131] Accordingly, only Kaletra, and not the generic version, has been listed by the Guatemalan government as available through subsidized costs.[132] Public organizations seeking the more affordable generic drug are required to procure the drug elsewhere.[133] Thus, rigid TRIPS-Plus data exclusivity provisions in the DR-CAFTA have reduced or eliminated generic pharmaceutical competi-

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[125] J.F. Hornbeck, Cong. Research Serv., RL31870, The Dominican Republic-Central America-United States Free Trade Agreement (DR-CAFTA) 1 (2005).

[126] Shaffer & Brenner, *supra* note 103, at w961–64.

[127] *See id.* at w962; PubMed Health, *Voriconazole*, U.S. Nat'l Library of Med. (Jan. 1, 2010), http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0001926/.

[128] *See* Chung, *supra* note 70, at 180–82; Shaffer & Brenner, *supra* note 103, at w962–63.

[129] *See* Shaffer & Brenner, *supra* note 103, at w962, w964.

[130] *Id.* at w960.

[131] *Id.* at w962–64.

[132] *Id.* at w964.

[133] *Id.* at w960. Another example is the Bristol-Myers Squib pharmaceutical, Plavix, which is used to treat heart disease. *Id.* at w961. Plavix is patented in Guatemala and subject to fifteen years of data exclusivity. *Id.* When Bristol-Myers Squib received a patent for Plavix, Guatemala revoked patents for four generic producers of the pharmacological equivalent of Plavix, thereby eliminating competition. *Id.*

tion, resulting in an inordinate pricing structure making critical drugs unavailable to much of Guatemala's indigent population.[134]

2. Vietnam

The United States signed a trade agreement with Vietnam in 2000.[135] When Vietnam adopted data exclusivity provisions as part of the agreement, the United States praised the country for its alignment with U.S. data exclusivity standards.[136] From 2000 through 2005, the Vietnamese government saw a threefold increase in health spending, much of which was attributed to rising pharmaceutical costs.[137] This is particularly evident in the pricing of antiretrovirals produced in Vietnam, which cost five to seven times more than the lowest international prices for the same pharmaceuticals.[138]

The precipitous increase in the cost of antiretrovirals occurred as HIV/AIDS became increasingly problematic in Vietnam.[139] In 2009, an estimated 280,000 people were living with HIV/AIDS, a figure that has doubled since 2001, shortly after the U.S.-Vietnam Trade Agreement was reached.[140] Nearly seven percent of all people living with HIV/AIDS in Southeast Asia live in Vietnam.[141] In 2009, over fourteen thousand Vietnamese died from AIDS related causes.[142] Additionally, only half of those in need of HAART currently receive antiretroviral therapy.[143] Under these conditions, stringent data exclusivity provisions limit access to medicines in Vietnam, exacerbating an already dire public health situa-

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[134] *See id.* at w960–64.

[135] *Fact Sheet: U.S. Relations with Vietnam*, U.S. Dep't. of State (Aug. 1, 2012), http://www.state.gov/r/pa/ei/bgn/4130.htm.

[136] Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 Am. J.L. & Med. 303, 326 (2008); *see* Peter Maybarduk, Burcu Kilic & Brook Baker, *Vietnam and the Trans-Pacific Partnership Agreement*, Pub. Citizen (June 16, 2011), http://www.citizen.org/tppa-vietnam-summary.

[137] Nguyen et al., *supra*, note 117, at 2. Moreover, there is evidence to suggest that pharmaceutical companies price medicines higher in Vietnam than in other countries. *Id.*

[138] *Id.* at 2–3.

[139] *See* UNAIDS, *supra* note 19, at 187 (providing a comparison of HIV/AIDS in 2009 and 2001); Carter, *supra* note 56.

[140] UNAIDS, *supra* note 19, at 187; Maybarduk, Kilic & Baker, *supra* note 136.

[141] UNAIDS, *supra* note 19, at 187 (noting that of the 4.1 million people living with HIV/AIDS in Southeast Asia, 280,000 live in Vietnam).

[142] *Id.* at 192.

[143] Global HIV/AIDS Response 2011, *supra* note 121, at 193 (noting that 49,492 citizens are on HAART though over 96,000 citizens are in need of antiretrovirals).

tion in a country where fifteen percent of the population lives below the national poverty line.[144]

For example, like many LMICs, Vietnam requires greater access to second-line antiretroviral treatment.[145] As HIV/AIDS evolves, it may grow resistant to first-line treatment, requiring second-line drugs, many of which are patented by multinational pharmaceutical companies.[146] One of these second-line pharmaceuticals is Kaletra from Abbott Laboratories.[147] It was recently reported that Abbott Laboratories has a patent pending for Kaletra in Vietnam, and it intends to use that patent to prevent the procurement of generic alternatives.[148] Unyielding TRIPS-Plus data exclusivity provisions prohibit the use of clinical data for at least five years (and upwards of fifteen years, as seen in Guatemala), thereby eliminating generic competition for a pharmacological equivalent to Kaletra.[149] Thus, Abbott Laboratories will be able to charge inordinate prices, rendering access to affordable pharmaceuticals unattainable for low-income populations gravely in need of second-line antiretroviral therapy.[150]

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[144] *See* Carter, *supra* note 56; *see also* Global HIV/AIDS Response 2011, *supra* note 121, at 193; UNAIDS, *supra* note 19, at 187; UNDP 2011, *supra* note 21, at 144; Maybarduk, Kilic & Baker, *supra* note 136 (detailing the impact of trade on health in Vietnam). Significantly, Vietnam is also a member of the proposed Trans-Pacific Partnership (TPP), which includes Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, and the United States. *See* Lewis, *supra* note 97, at 29; Sell, *supra* note 33, at 464. President Obama proclaimed that he would be "America's first Pacific president," and the Obama Administration has made the TPP a top priority. *See* Lewis, *supra* note 97, at 30, 35–37 (quoting President Barack Obama, Remarks at Suntory Hall (Nov. 14, 2009, 10:12 AM), *available at* http://www.whitehouse.gov/the-press-office/remarks-president-barack-obama-suntory-hall). The TPP may serve as a launching point to a much larger agreement between the Asia-Pacific region that would include economic powerhouses like China, Russia, Canada, Japan, and Mexico. *See id.* at 28 n.2. Thus, the United States views the TPP as a critical agreement which may open new markets and lead to tremendous business opportunities for U.S. industries. *See id.* at 39–40. Still, the United States is likely to press for TRIPS-Plus provisions in the TPP, which may provide even more stringent data exclusivity standards, thereby further crippling public health and access to medicines in Vietnam. *See* Carter, *supra* note 56; Maybarduk, Kilic & Baker, *supra* note 136.

[145] *See* Carter, *supra* note 56.

[146] Abbott & Reichman, *supra* note 42, at 951.

[147] *See* Puymbroeck, *supra* note 27, at 534; Carter, *supra* note 56.

[148] *See* Carter, *supra* note 56.

[149] Kuanpoth, *supra* note 118, at 218; Puymbroeck, *supra* note 27, at 534; Shaffer & Brenner, *supra* note 103, at w961, w964.

[150] *See* Global HIV/AIDS Response 2011, *supra* note 121, at 193; Kuanpoth, *supra* note 118, at 219; Carter, *supra* note 56. It is interesting to note that Vietnam is a recipient of HIV/AIDS funding through the President's Emergency Plan for AIDS Relief (PEPFAR), which enables countries to procure antiretrovirals in order to stem the tide of HIV/AIDS. *See* U.S. Dep't of State, The U.S. President's Emergency Plan for AIDS Relief: Five-Year Strategy 11 (2009) [hereinafter PEPFAR Report], *available at* http://pepfar.gov/

B. *U.S. Policy Towards Compulsory Licensing Severely Harms Public Health in Middle and Low-Income Countries*

TRIPS-Plus provisions in U.S. FTAs discourage the use of compulsory licensing thereby restricting generic competition and furthering a patent holder's monopolistic control of pricing, which results in restricted access to affordable drugs.[151] These potentially negative effects of U.S. policy towards compulsory licensing are illustrated in two proposed, but stalled, FTAs with Thailand and the Southern African Customs Union.[152]

1. Dominican Republic

The island of Hispaniola, comprised of the Dominican Republic and Haiti, contains approximately eighty-five percent of all HIV/AIDS cases in the Caribbean, the region with the second highest per capita prevalence of HIV/AIDS after sub-Saharan Africa.[153] In 2009, an estimated 57,000 people living with HIV/AIDS were domiciled in the Do-

strategy; Maybarduk, Kilic & Baker, *supra* note 136. PEPFAR is active in nearly forty countries and by 2009 had provided HAART to over 2.4 million people worldwide. PEPFAR Report, *supra*, at 11; U.S. Dept. of State, *Countries*, PEPFAR, http://www.pepfar.gov/countries/index.htm (last visited Jan. 7, 2013). Using PEPFAR funding, the United States often procures generic pharmaceuticals, including in Vietnam, where ninety-eight percent of antiretrovirals purchased by the United States are generic. *See* Carter, *supra* note 56. The remaining two percent are patented second-line treatments like Kaletra. *See id.* Thus, the United States employs competing policies in Vietnam. *See* Carter, *supra* note 56; Maybarduk, Kilic & Baker, *supra* note 136. First, data exclusivity provisions prolong the patent for Kaletra, thus obstructing generic competition and increasing the cost of treatment. *See* Carter, *supra* note 56; Maybarduk, Kilic & Baker, *supra* note 136. At the same time, however, the PEPFAR program seeks affordable pharmaceuticals to purchase in order to treat persons living with HIV/AIDS in Vietnam. *See* Carter, *supra* note 56; Maybarduk, Kilic & Baker, *supra* note 136. The patent on Kaletra prohibits the PEPFAR program's procurement of more affordable second-line treatment, projecting the increased costs on to U.S. taxpayers who fund PEPFAR. *See* Carter, *supra* note 56; Maybarduk, Kilic & Baker, *supra* note 136.

[151] Roffe & Spennemann, *supra* note 66, at 80; Sell, *supra* note 33, at 454. The United States's stance on compulsory licensing is perplexing given its prior and threatened use of these licenses. Abbott & Reichman, *supra* note 42, at 939. For example, in 2001, the United States threatened to grant a compulsory license for Bayer's Cipro in response to an Anthrax scare. Pier DeRoo, Note, *"Public Non-Commercial Use" Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs*, 32 Mich. J. Int'l L. 347, 359 (2011); *see also* Abbott & Reichman, *supra* note 42, at 939 n.76 (explaining that "the United States makes greater routine use of compulsory licensing of patent inventions for a variety of government purposes than most other countries combined").

[152] Revenga et al., *supra* note 116, at xxxix; Baker, *supra* note 116, at 708; Gathii, *supra* note 95, at 470; Sell, *supra* note 33, at 476; Collins-Chase, *supra* note 10, at 798–801.

[153] Rahul Rajkumar, Note, *The Central American Free Trade Agreement: An End Run Around the Doha Declaration on TRIPS and Public Health*, 15 Alb. L.J. Sci. & Tech 433, 459 (2005).

minican Republic, with 3,200 new infections that year.[154] Also in 2009, an estimated 2,300 people died from AIDS-related causes.[155] TRIPS-Plus compulsory licensing provisions further exacerbate the Dominican Republic's public health landscape by contributing to rising pharmaceutical costs and discouraging generic competition, thereby limiting access to affordable drugs in a country where fifty percent of the population lives below the national poverty line.[156]

Although it has never issued a compulsory license, the Dominican Republic maintains liberal compulsory licensing provisions in its national intellectual property law.[157] Moreover, the Dominican Republic's commitment to compulsory licensing as a vital mechanism for securing access to medicines is evidenced by the fact that the Dominican Republic was a sponsor of both the Doha Declaration and the Article 31bis Amendment, which sought to ease the process for issuing compulsory licenses.[158] The Dominican Republic also maintains a strong generic pharmaceutical industry with generic firms controlling approximately fifty percent of the domestic pharmaceutical market.[159] In fact, the introduction of generic antiretrovirals in the Dominican Republic led to a ninety-nine percent decrease in their cost.[160]

The Dominican Republic ratified the DR-CAFTA on March 1, 2007.[161] TRIPS-Plus provisions in the DR-CAFTA have been characterized as the most "onerous" protections among all U.S. FTAs with LMICs.[162] Researchers assert that by 2027, the Dominican Republic will

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[154] UNAIDS, *supra* note 19, at 201, 206.

[155] *Id.* at 206. It is also important to note that the Dominican Republic has seen a dramatic increase in the incidence of malaria with nearly five hundred thousand reported cases of malaria in 2010. WHO Malaria Report 2011, *supra* note 19, at 110.

[156] *See* Georgetown, *supra* note 71, at 15, 19, 29, 32; UNDP 2011, *supra* note 21, at 143.

[157] *See* Georgetown, *supra* note 71, at 14; Rajkumar, *supra* note 153, at 456–58.

[158] *See* Rajkumar, *supra* note 153, at 458.

[159] *See id.* at 459.

[160] Georgetown, *supra* note 71, at 2. For example, approximately seventy percent of HIV/AIDS patients in the Dominican Republic use Abbott's Kaletra. *Id.* at 15. Before a generic version of Kaletra had been produced, the average international price of Kaletra was $183 per patient per month, which is equivalent to the average Dominican's monthly income. *See id.* In 2007, however, Abbott faced generic competition after Thailand issued a compulsory license for Kaletra and the average international cost of Kaletra decreased to $83 per patient per month. *Id.* If Kaletra had been patented in the Dominican Republic, Dominicans would likely have faced prohibitively high pricing, however, because Kaletra was not patented in the Dominican Republic, Dominicans benefitted from Thailand's issuance of the compulsory license. *See id.*

[161] *See Free Trade*, *supra* note 124.

[162] Georgetown, *supra* note 71, at 25.

experience a nine to fifteen percent increase in pharmaceutical prices as a result of the DR-CAFTA.[163] Evidence of TRIPS-Plus compulsory licensing provisions on price increases and diminished access to pharmaceuticals, however, is already prevalent as illustrated by the second-line antiretroviral Efavirenz, which costs three times more than its generic pharmacological equivalent.[164]

TRIPS-Plus patent provisions in the DR-CAFTA effectively bar compulsory licensing by linking marketing approval of generic pharmaceuticals to the consent of patent holders.[165] Thus, if a generic drug company developed the pharmacological equivalent to Efavirenz under a compulsory license issued by the Dominican Republic, the generic producer would still be required to obtain consent from the patent holder to sell the generic version of the drug, which is highly unlikely.[166] Because debilitating poverty prohibits procurement of brand name Efavirenz and compulsory licensing provisions constrict generic competition, Dominicans are forced to use a similar but slightly more harmful drug, Nevirapine.[167] Nevirapine may weaken a patient's immune system if provided too early in the progression of HIV/AIDS, thereby further compromising the patient's health.[168] By delaying treatment, however, individuals diagnosed with HIV/AIDS face the same risk of a weakened immune system.[169]

Given rampant poverty and rising pharmaceutical costs, one healthcare provider suggested that Dominicans have the bleak choice of, "[buying] medication [or] buying lunch."[170] TRIPS-Plus compulsory licensing standards included in the DR-CAFTA have paralyzed the Do-

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[163] *Id.* at 34.

[164] *Id.* at 19.

[165] Dominican Republic-Central America-United States Free Trade Agreement, DR-CAFTA, art. 15.9, Aug. 5, 2004 [hereinafter DR-CAFTA], *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta; Roffe & Spennemann, *supra* note 66, at 85; Rajkumar, *supra* note 153, at 468.

[166] *See* DR-CAFTA, *supra* note 165, art. 15.9; GEORGETOWN, *supra* note 71, at 19; Rajkumar, *supra* note 153, at 468.

[167] GEORGETOWN, *supra* note 71, at 19; Roffe & Spennemann, *supra* note 66, at 85; Rajkumar, *supra* note 153, at 468.

[168] GEORGETOWN, *supra* note 71, at 19.

[169] *Id.*

[170] *Id.* This desperate situation is illustrated by Dominican women infected with Hepatitis B. *Id.* at 5–6. Given that a Dominican woman typically earns less than $200 per month and likely has no health insurance, being diagnosed with Hepatitis B is extremely detrimental because the standard Hepatitis B treatment costs approximately $1,320 per month. *Id.* Lack of treatment for Hepatitis B leads to liver failure—notably another side effect of Nevirapine—and most certainly death. *Id.* at 5–6, 19.

minican Republic from utilizing this TRIPS-compliant method of providing affordable access to antiretrovirals and other drugs.[171]

2. Thailand

In 2002, an estimated 670,000 people were living with HIV/AIDS in Thailand.[172] The Thai government recognized the threat posed by the pandemic and initiated a national HIV/AIDS program aiming to provide its citizens with universal access to HAART.[173] The program has been widely successful; the number of people receiving treatment rose from 3,000 in 2002 to 52,000 by 2005.[174] The annual number of HIV/AIDS related deaths prior to the universal access program was approximately 52,000, but in 2009, after several years of universal access, that number decreased by nearly fifty percent.[175] By 2010, nearly seventy percent of those in need of antiretroviral therapy received treatment.[176] Thailand's commitment to universal access to antiretroviral therapy has been praised by the World Health Organization and nongovernmental organizations from around the world.[177] The most critical aspect to the success of the universal access program has been the Thai government's ability to promote the availability of inexpensive generic antiretrovirals.[178]

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[171] *Id.* at 15, 19, 29, 32. Similarly, the data exclusivity provisions of TRIPS-Plus agreements have also contributed to the increase in pharmaceutical prices since the Dominican Republic ratified the DR-CAFTA agreement. *Id.* at 27–29; Shaffer & Brenner, *supra* note 103, at w960–64.

[172] UNAIDS, Report on the Global HIV/AIDS Epidemic 194 (2002), *available at* http://data.unaids.org/pub/report/2002/brglobal_aids_report_en_pdf_red_en.pdf.

[173] Abbott & Reichman, *supra* note 42, at 952; Puymbroeck, *supra* note 27, at 533–34.

[174] Puymbroeck, *supra* note 27, at 533–34.

[175] UNAIDS, *supra* note 19, at 192 (noting that Thailand had fifty-two thousand HIV/AIDS related deaths in 2001 and twenty-eight thousand HIV/AIDS related deaths in 2009).

[176] *See* Global HIV/AIDS Response 2011, *supra* note 121, at 192. Moreover, nearly seventy percent of Thai children in need of antiretroviral therapy currently receive treatment. *Id.* at 163.

[177] Ministry of Pub. Health of Thai. & World Health Org., External Review of the Health Sector Response to HIV/AIDS in Thailand 35–36 (2005), *available at* http://203.90.70.117/PDS.DOCS/B0181.pdf; Press Release, Doctors Without Borders, MSF Welcomes Move to Overcome Patent on AIDS Drug in Thai (Nov. 29, 2006), *available at* http://www.doctorswithoutborders.org/press/release.cfm?id=1905.

[178] *See* Gawain Kripke & Stephanie Weinberg, Oxfam Int'l, Public Health at Risk: A US Free Trade Agreement Could Threaten Access to Medicines in Thailand 4 (2006), *available at* http://policy-practice.oxfam.org.uk/publications/public-health-at-risk-a-us-free-trade-agreement-could-threaten-access-to-medici-114576.

To ensure the success of the HIV/AIDS program, however, Thailand required access to patented second-line pharmaceuticals.[179] These patented medications are significantly more expensive than the generic alternatives.[180] For example, Abbott's Kaletra cost well over two thousand dollars per patient per year, limiting the Thai government's provision of the medication to six hundred patients out of eight thousand in need.[181] The World Bank reported that by issuing compulsory licenses, Thailand could reduce the cost of second-line antiretroviral treatments by ninety percent.[182] Thailand attempted to negotiate reduced prices for several pharmaceuticals, including Kaletra, but failed to reach an agreement.[183] Thus, in late 2006 and early 2007, the Thai government issued compulsory licenses for two antiretrovirals, including Kaletra, and a third compulsory license for Plavix, a pharmaceutical used to treat cardiovascular disease.[184]

The United States and Thailand began negotiating a trade agreement in 2004, but suspended negotiations in 2006 following a military coup in Thailand.[185] The World Bank concluded that TRIPS-Plus provisions in the proposed U.S.-Thailand FTA would have crippled Thailand's ability to issue compulsory licenses, resulting in costs exceeding 3.2 billion dollars over twenty years.[186]

U.S. FTAs permit challenges to compulsory licenses on the grounds that the license was not warranted under the specific circumstances.[187] Given that Abbott Laboratories and Thailand were unable to reach an

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[179] Puymbroeck, *supra* note 27, at 534.

[180] *Id.*

[181] *Id.*

[182] Revenga et al., *supra* note 116, at xxxix–xl.

[183] Ho, *supra* note 77, at 412; Puymbroeck, *supra* note 27, at 534.

[184] Abbott & Reichman, *supra* note 42, at 952; Ho, *supra* note 77, at 413–14. The Thai government received sharp criticism for issuing these compulsory licenses, though many scholars have asserted that Thailand's actions were within the confines of the TRIPS Agreement. Abbott & Reichman, *supra* note 42, at 956 ("There is little doubt that Thailand would win a dispute settlement action based on the TRIPS-compliance of its government use licensing."); Ho, *supra* note 77, at 424–43; Jerome H. Reichman, Comment, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. Med. & Ethics 247, 256 (2009) (stipulating that Thailand's "approach was a perfectly 'legitimate' exercise of the State's powers under the TRIPS Agreement").

[185] *Thailand*, Office of the U.S. Trade Rep., http://www.ustr.gov/countries-regions/southeast-asia-pacific/thailand (last visited Jan. 7, 2013).

[186] Kripke & Weinberg, *supra* note 178, at 19; Revenga et al., *supra* note 116, at xxxix–xl. Although Thailand would have received economic benefits from a U.S.-Thailand FTA, estimates suggest that those gains may have been negated by projected drops in economic production typically experienced by countries with a high prevalence of HIV/AIDS. Collins-Chase, *supra* note 10, at 790.

[187] Lindstrom, *supra* note 34, at 949.

agreement about the price of Kaletra, it is likely that Abbott Laboratories challenged the Thai government's decision to issue a compulsory license.[188] In fact, Abbott was so furious with Thailand's issuance of a compulsory license for Kaletra, that it withdrew several pending pharmaceutical patents from Thailand—an unprecedented move in which a U.S. drug company retaliated against a foreign government by cutting off the supply of certain pharmaceuticals.[189] If Abbott Laboratories were to prevail in such a challenge, Thailand may have been subject to U.S. sanctions and may have been required to discontinue the license.[190] Thus, rigid TRIPS-Plus compulsory licensing provisions in the proposed U.S.-Thailand FTA may have curbed Thailand's use of this critical mechanism for improving access to affordable antiretrovirals necessary for Thailand's remarkably successful HIV/AIDS program.[191]

3. The Southern African Customs Union

Perhaps nowhere on Earth has the scourge of HIV/AIDS afflicted more people than the members of the Southern African Customs Union (SACU), which is comprised of Botswana, Lesotho, Namibia, South Africa, and Swaziland.[192] The SACU is burdened by over twenty percent

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[188] *See* Ho, *supra* note 77, at 412; Puymbroeck, *supra* note 27, at 534; *cf.* Matthews, *supra* note 50, at 136 (arguing that Thailand's issuance of compulsory licenses "lowered the bar" with regard to patent protection for pharmaceuticals); Carter, *supra* note 56 (describing Abbott Laboratories' angry response to the Thai government's decision to issue a compulsory license for Kaletra).

[189] *See* Carter, *supra* note 56. Thailand's issuance of a compulsory license for Plavix is another example of how rigid TRIPS-Plus compulsory licensing provisions in the proposed U.S.-Thailand FTA could limit access to drugs. Collins-Chase, *supra* note 10, at 789; Matthews, *supra* note 50, at 136. The global community was concerned about Thailand's compulsory license for Plavix given that it was the first license issued for a chronic, as opposed to infectious, disease. Matthews, *supra* note 50, at 136. The proposed U.S.-Thailand FTA limited the issuance of compulsory licenses for public non-commercial use, national emergencies, or to limit anticompetitive practices. Collins-Chase, *supra* note 10, at 789. Given that U.S. FTAs do not define these terms, it is foreseeable that pharmaceutical companies could have challenged the issuance of a compulsory license for Plavix on the grounds that heart disease should not be considered a national emergency. *See* Ho, *supra* note 42, at 1486; Roffe & Spennemann, *supra* note 66, at 80.

[190] *Cf.* David A. Gantz, *Settlement of Disputes Under the Central America-Dominican Republic-United States Free Trade Agreement*, 30 B.C. Int'l & Comp. L. Rev. 331, 392, 400–02, 408 (2007) (describing dispute resolution under U.S. FTAs).

[191] Kripke & Weinberg, *supra* note 178, at 19–20; Puymbroeck, *supra* note 27, at 533–34; Collins-Chase, *supra* note 10, at 789; Press Release, Doctors Without Borders, *supra* note 177.

[192] *See* Danielle Langton, Cong. Research Serv., RS21387, United States-Southern African Customs Union (SACU) Free Trade Agreement Negotiations: Background

of the global HIV/AIDS epidemic, as approximately seven million people living with HIV/AIDS inhabit SACU member countries.[193] The SACU member countries are rife with poverty as nearly one-quarter of the population in each country live below the national poverty line.[194] This rampant poverty has quashed access to antiretrovirals, with less than sixty percent of those in need of treatment currently receiving therapy.[195] Despite extreme poverty, the SACU forms a formidable trading block and has agreed to treaties with several European countries, South American countries, and is in the midst of negotiating a trade agreement with India.[196]

In fact, in 2003, the United States and the SACU entered negotiations to establish a U.S.-SACU FTA.[197] The United States insisted on several TRIPS-Plus provisions, many of which are similar to those included in current U.S. FTAs.[198] The SACU nations expressed particular concern over the proposed compulsory licensing provisions.[199] The United

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AND POTENTIAL ISSUES 1 (2008), *available at* http://fpc.state.gov/documents/organization/109530.pdf; UNAIDS, *supra* note 19, at 180.

[193] UNAIDS, *supra* note 19, at 180 (noting that in 2009, approximately seven million people living with HIV/AIDS lived in Botswana, Lesotho, Namibia, South Africa, and Swaziland, representing twenty-one percent of the entire global HIV/AIDS population); *see also* WHO TB REPORT 2011, *supra* note 19, at 123–25 (providing that the SACU member states had nearly half a million citizens infected with tuberculosis in 2010); WHO MALARIA REPORT 2011, *supra* note 19, at 220 (finding over sixty thousand suspected cases of malaria in SACU countries).

[194] UNDP 2011, *supra* note 21, at 144. In Lesotho, fifty-seven percent of the population lives below the national poverty line; in Swaziland, approximately seventy percent of the population lives below the national poverty line; in Botswana, thirty-one percent of the population lives below the national poverty line; in Namibia, nearly forty percent of the population lives below the national poverty line; in South Africa, nearly twenty-five percent of citizens live below the national poverty line. *See id.*

[195] GLOBAL HIV/AIDS RESPONSE 2011, *supra* note 121, at 190–92. Botswana and Namibia have been extremely successful in providing affordable antiretrovirals to persons living with AIDS. *See id.* In Botswana and Namibia, ninety-three percent and ninety percent, respectively, of those in need of antiretroviral therapy currently receive treatment. *See id.* Lesotho, South Africa, and Swaziland have struggled to achieve similar success as coverage rates for antiretroviral therapy in each country is fifty-seven percent, fifty-five percent, and seventy-two percent, respectively. *Id.*

[196] Southern African Customs Union, *Bi-lateral Trade Negotiations*, SACU, http://www.sacu.int/traden.php?id=414 (last visited Jan. 7, 2013).

[197] *See* LANGTON, *supra* note 192, at 1.

[198] *See* Gathii, *supra* note 95, at 470.

[199] *Id.* The SACU member nations also expressed serious reservations about the data exclusivity provisions within the proposed agreement as the United States sought to include a five-year minimum period of data exclusion on pharmaceuticals. *See id.*; Collins-Chase, *supra* note 10, at 792. These rigid data exclusivity provisions would have limited the impoverished SACU countries' ability to provide access to affordable medicines. *See* Gathii, *supra* note 95, at 470; Collins-Chase, *supra* note 10, at 792.

States sought to impose a ban on exportation of pharmaceuticals developed by compulsory licenses, which would have prohibited South Africa's generic pharmaceutical industry from supplying SACU nations with affordable drugs, including antiretrovirals.[200] Thus, rigid TRIPS-Plus compulsory licensing provisions in the proposed U.S.-SACU FTA would have compromised access to generic drugs that SACU nations rely on to handle the scourge of HIV/AIDS in sub-Saharan Africa.[201]

The SACU refused the TRIPS-Plus provisions that the United States obstinately sought, recognizing that such compulsory license provisions would limit the delivery of affordable medicines, and as a result, negotiations stalled in 2006.[202] Nevertheless, in 2008, the United States and the SACU signed a Trade, Investment, and Development Cooperative Agreement that "establishes a forum for consultative discussions, cooperative work, and possible agreements on a wide range of trade issues" which would "[i]deally . . . put in place the 'building blocks' for a future FTA. . . ."[203] Given the tremendous burden of HIV/AIDS on SACU nations, standard U.S. TRIPS-Plus compulsory licensing provisions could provoke devastating consequences.[204]

III. Promoting Access to Medicine Through Amendment of U.S. FTAs

TRIPS-Plus provisions in U.S. FTAs have come under fire and have even been criticized by Congress.[205] The congressional response to TRIPS-Plus provisions in the Bipartisan Agreement on Trade Policy has fallen short of addressing the burdensome data exclusivity and compulsory licensing provisions in U.S. FTAs.[206] To remedy these shortcomings, the United States should amend all U.S. FTAs to incorporate a balancing test that would provide review panels an opportunity to

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[200] Baker, *supra* note 116, at 708; Collins-Chase, *supra* note 10, at 801.

[201] Collins-Chase, *supra* note 10, at 801.

[202] Gathii, *supra* note 95, at 469–70.

[203] *Southern African Customs Union*, Office of the U.S. Trade Rep., http://www.ustr.gov/countries-regions/africa/regional-economic-communities-rec/southern-african-customs-union-sacu (last visited Jan. 7, 2013).

[204] *See* Baker, *supra* note 116, at 708; Gathii, *supra* note 95, at 470; Collins-Chase, *supra* note 10, at 792, 801.

[205] Minority Staff of H.R. Comm. on Gov't Reform, Special Investigations Div., 109th Cong., Trade Agreements and Access to Medications Under the Bush Administration, at i–ii (2005) [hereinafter Waxman], *available at* http://www.twnside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/TradeAgreementsandAccesstoMedicationsUnderTheBushAdmini.pdf.

[206] *See id.*

weigh the benefits and detriments associated with relaxing data exclusivity and compulsory licensing provisions for various drugs.[207]

A. *The Bipartisan Agreement on Trade Policy*

In response to criticism that U.S. FTAs undermine the Doha Declaration and restrict LMIC's access to affordable drugs, Congress and the Bush administration reached the Bipartisan Agreement on Trade Policy in May 2007.[208] The agreement sought to promote public health and access to medicines by adding or changing language for future U.S. FTAs.[209] For example, new FTAs still require five year data exclusivity provisions, but when a foreign country relies on marketing approval granted by the U.S., the five year period begins immediately after the drug is approved in the U.S.[210] This encourages pharmaceutical companies to seek patents from the U.S. and its trading partners simultaneously, because the "clock is ticking" on the five years of protection once U.S. regulatory approval is granted.[211] Thus, this new provision

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[207] *Cf.* Foster, *supra* note 41, at 205–10 (utilizing a balancing test to differentiate between necessary and unnecessary copyright infringement regarding the international trade of educational materials); Gantz, *supra* note 190, at 391–92 (detailing the role of the Joint Committees).

[208] *See* Abbott & Reichman, *supra* note 42, at 964; Ho, *supra* note 42, at 1503; Puymbroeck, *supra* note 27, at 532; Ruse-Khan, *supra* note 39, at 331. U.S. Representative Henry A. Waxman has asserted that:

> [b]y delaying generic drug approvals, extending patent terms, limiting compulsory licensing, prohibiting parallel importation, and otherwise restricting countries' efforts to improve access to affordable drugs, [U.S. FTAs] undermine the safeguards outlined in the Doha Declaration. These agreements may offer advantages to multinational pharmaceutical companies, but they do so at a serious cost to public health in the developing nations.

See Waxman, *supra* note 205, at 13 (quoting Rep. Henry A. Waxman).

[209] *See* Ho, *supra* note 42, at 1503; Rangel, *supra* note 39, at 400–05. Congressman Charles B. Rangel, Chairman of the House Ways and Means Committee at the time, posited five fundamental principles for the policy: (1) ensuring that U.S. FTAs improve standards of living while also creating new markets for U.S. products; (2) promoting American industries; (3) expanding and opening trade markets to provide new opportunities; (4) supporting those economically harmed by the effects of increased trade and technology; and (5) expanding national security and diplomacy by using trade and aid to foster development in LMICs. Rangel, *supra* note 39, at 387–88. The Bipartisan Agreement on Trade Policy addresses numerous trade issues within U.S. FTAs, but is chiefly concerned with labor standards, intellectual property, and the environment. *Id.*; Ruse-Khan, *supra* note 39, at 331.

[210] *See* Rangel, *supra* note 39, at 404.

[211] *See id.*

truncates the waiting period faced by generic drug manufacturers and the populations that rely on more affordable medicines.[212]

Perhaps the most significant change to FTAs in the Bipartisan Agreement on Trade Policy is the inclusion of a statement regarding the importance of public health, which had previously only been submitted as a side letter.[213] Though this language requires U.S. FTAs to affirm the Doha Declaration, provisions in the Bipartisan Agreement on Trade Policy are limited.[214] For example, the language intended to reduce data exclusivity presumes that a country will be able to efficiently and expeditiously administer its regulatory process or that the U.S. regulatory process moves at the same pace as regulatory schemes in other countries.[215] Additionally, the Bipartisan Agreement on Trade Policy does not apply retroactively, and thus countries that signed U.S.

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[212] *See id.* Moreover, rather than requiring countries to "'compensate for unreasonable delays,'" in regulatory approval by extending patent terms, FTAs now requires countries to "'make [their] best efforts to process patent applications . . . . expeditiously with a view to avoiding unreasonable delays.'" *See id.* at 402 (quoting U.S.-Peru FTA, art. 16.9.6(a)). Representative Rangel asserts that this provision promotes efficient regulatory practices, thereby avoiding delays which would result in patent extensions. *See id.* The agreement also addresses linkage systems by no longer requiring national health authorities to deny approval of generic pharmaceuticals without first certifying that no other patent rights are violated. Ho, *supra* note 42, at 1503; Rangel, *supra* note 39, at 403.

[213] *See e.g.*, U.S.-Peru FTA, *supra* note 102, art. 16.13; Ho, *supra* note 42, at 1504; Ruse-Khan, *supra* note 39, at 31. The enforceability of side letters has been questioned given that they do not appear within the actual text of the FTA. *See* Carlos M. Correa, Protecting Test Data for Pharmaceutical and Agrochemical Products Under Free Trade Agreements 10 (2004), *available at* www.iprsonline.org/unctadictsd/bellagio/docs/Correa_Bellagio4.pdf; Roffe & Spennemann, *supra* note 66, at 86. Moreover, the USTR had asserted that the side letters do not exempt parties from the intellectual property provisions within the FTAs. Roffe & Spennemann, *supra* note 66, at 86. The new FTAs include the following language:

> The obligations of [the Intellectual Property] Chapter do not and should not prevent a Party from taking measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all.

See Rangel, *supra* note 39, at 404–05.

[214] *See* Abbott & Reichman, *supra* note 42, at 964; Ho, *supra* note 42, at 1503–04; Puymbroeck, *supra* note 27, at 532–33. For example, the allegedly relaxed linkage provisions now require expeditious adjudication that some countries may be ill-equipped or unable to provide; this may encourage criticism and negate gains promoted by this particular revision. *See* Ho, *supra* note 42, at 1503.

[215] *See* Ho, *supra* note 42, at 1503; Rangel, *supra* note 39, at 403–04.

FTAs prior to 2007 have not benefited from these limited changes in U.S. trade policy.[216]

Finally, the Bipartisan Agreement on Trade Policy does little to address a country's ability to enhance data exclusivity provisions or to issue compulsory licenses under U.S. FTAs.[217] Given that data exclusivity and compulsory licensing are critical flexibilities provided by the TRIPS Agreement and affirmed by the Doha Declaration, the Bipartisan Agreement on Trade Policy may not enhance access to medicines.[218] Thus, to address the issues posed by Representative Henry Waxman, Congress should amend U.S. FTAs with a balancing test that would consider the public health benefits of relaxing data exclusion and compulsory licensing with regard to pharmaceuticals.[219]

B. *Finding the Right Balance: Amending U.S. FTAs to Institute a Balancing Test*

Restrictive data exclusivity and compulsory licensing provisions in U.S. FTAs impede access to affordable medicines in LMICs.[220] Although Congress attempted to remedy some TRIPS-Plus restrictions through the Bipartisan Agreement on Trade Policy, data exclusivity and compulsory licensing provisions were scantly addressed or altogether ignored.[221] Therefore, Congress should amend the agreements themselves through the Joint Committees, established in each FTA, to enhance access to medicines by instituting a balancing test for data exclusivity and compulsory licensing.[222]

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[216] Puymbroeck, *supra* note 27, at 532; Shaffer & Brenner, *supra* note 103, at w965. Thus, many signatories to U.S. FTAs do not receive these mild benefits, including signatories to the DR-CAFTA, signatories to NAFTA, Israel, Jordan, Australia, Bahrain, Chile, Morocco, and Singapore. *See Free Trade*, *supra* note 124.

[217] *See* Abbott & Reichman, *supra* note 42, at 964–65; Ho, *supra* note 42, at 1503; Puymbroeck, *supra* note 27, at 532.

[218] *See* TRIPS Agreement, *supra* note 32, art. 31(b)–(h); Doha Declaration, *supra* note 35, ¶¶ 4–5; Abbott & Reichman, *supra* note 42, at 964–65; Ho, *supra* note 42, at 1503; Puymbroeck, *supra* note 27, at 532.

[219] *See* Waxman, *supra* note 205, at 13; Abbott & Reichman, *supra* note 42, at 964–65; Ho, *supra* note 42, at 1503; Puymbroeck, *supra* note 27, at 532.

[220] *See* Georgetown, *supra* note 71, at 15, 29, 32; Revenga et al., *supra* note 116, at xxxix–xl; Baker, *supra* note 116, at 708; Shaffer & Brenner, *supra* note 103, at w961–64; Collins-Chase, *supra* note 10, at 792; Carter, *supra* note 56.

[221] *See* Abbott & Reichman, *supra* note 42, at 964–65; Ho, *supra* note 42, at 1503–04; Puymbroeck, *supra* note 27, at 532–33.

[222] *Cf.* Foster, *supra* note 41, at 205–10 (utilizing a balancing test to differentiate between necessary and unnecessary copyright infringement regarding the international trade of educational materials); Gantz, *supra* note 190, at 391–92 (detailing the role of the Joint Committees).

U.S. FTAs include provisions designating responsibilities to Joint Committees.[223] These committees are comprised of delegates from the United States Trade Representative and ministers, cabinet level representatives, or their delegates from the U.S. counterpart in the FTA.[224] Joint Committees are responsible for dispute settlement as well as general administration of the FTAs.[225] For example, the committees may: (1) review the general functioning of the FTA; (2) oversee "further elaboration" of the FTA; (3) develop guidelines for proper implementation of the FTA; (4) consider adopting amendments to the FTA; and (5) facilitate the avoidance of disputes.[226] Given these responsibilities, Joint Committees are ideal for establishing smaller working groups that could implement a balancing test to measure the benefits of relaxing data exclusivity and compulsory licensing provisions in U.S. FTAs.[227]

A balancing test would enable FTA signatories to weigh innovation and access, thereby eliminating seriously objectionable patent practices while at the same time promoting practices that would improve public health.[228] An illustrative example of the need for such a test is the case of Egypt, where, in 2002, the Egyptian government granted regulatory approval for Pfizer to produce Viagra, an erectile dysfunction drug.[229] Just two months after Viagra entered the Egyptian market, the Egyptian Health Ministry, under pressure from local drug manufacturers, issued a compulsory license allowing a local manufacturer to produce a ge-

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[223] *See, e.g.*, U.S.-Peru FTA, *supra* note 102, art. 20; DR-CAFTA, *supra* note 165, art. 19; U.S.-Morocco FTA, *supra* note 102, art. 19; U.S.-Chile FTA, *supra* note 102, art. 21; U.S.-Jordan FTA, *supra* note 120, art. 15; Gantz, *supra* note 190, at 391–92.

[224] *See, e.g.*, U.S.-Peru FTA, *supra* note 102, art. 20; DR-CAFTA, *supra* note 165, art. 19; U.S.-Morocco FTA, *supra* note 102, art. 19; U.S.-Chile FTA, *supra* note 102, art. 21; U.S.-Jordan FTA, *supra* note 120, art. 15; Gantz, *supra* note 190, at 391–92.

[225] *See, e.g.*, U.S.-Peru FTA, *supra* note 102, art. 20; DR-CAFTA, *supra* note 165, art. 19; U.S.-Morocco FTA, *supra* note 102, art. 19; U.S.-Chile FTA, *supra* note 102, art. 21; U.S.-Jordan FTA, *supra* note 120, art. 15; Gantz, *supra* note 190, at 391–92.

[226] *See, e.g.*, U.S.-Peru FTA, *supra* note 102, art. 20; DR-CAFTA, *supra* note 165, art. 19; U.S.-Morocco FTA, *supra* note 102, art. 19; U.S.-Chile FTA, *supra* note 102, art. 21; U.S.-Jordan FTA, *supra* note 120, art. 15; Gantz, *supra* note 190, at 391–92.

[227] *See* Gantz, *supra* note 190, at 391–92 (noting that Joint Committees are able to establish working groups to assist the administration of FTAs); *cf.* Foster, *supra* note 41, at 205–10 (describing application of a balancing approach to conflicting rights).

[228] *Cf.* Foster, *supra* note 41, at 205–10 (detailing the use of a balancing test in response to copyright of educational materials between different countries in order to differentiate between necessary and unnecessary copyright infringement). The approach applied to copyright of educational materials could also address patent concerns in the pharmaceutical industry. *See id.*

[229] Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 Am. Bus. L.J. 283, 306 (2008); *see* Foster, *supra* note 41, at 207–08.

neric version of Viagra.[230] The generic version of Viagra was to hit the market at one-twentieth of Pfizer's price.[231] The Egyptian government cited the public health interests of the poor in defending its decision to enable generic versions of Viagra to flourish, though it seems unlikely that limiting a compulsory license in this instance would have resulted in dire public health consequences.[232]

Furthermore, the WTO has used balancing tests in the past when resolving disputes between trade partners.[233] This three-part test balances: "(1) the importance of interests or values that the challenged measure is intended to protect; (2) the extent to which the challenged measure contributes to the realization of the end pursued by that measure; and (3) the trade impact of the challenged measure."[234] In the context of U.S. FTAs, the Joint Committees would conduct the balancing test when a signatory to the FTA requested the use of relaxed data exclusivity or compulsory licensing provisions in order to provide more affordable access to pharmaceuticals.[235]

1. Importance of the Interests or Values That the Challenged Measure Is Intended to Protect

Under the first prong of the balancing test, the more important the interests and values (promoting public health and access to medicine), the more likely that a Joint Committee will find the challenged measure (relaxing data exclusivity and/or compulsory licensing provisions) necessary.[236] It is unlikely that signatories to U.S. FTAs, including the U.S., would underscore the value of health.[237] Therefore, the Joint

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[230] Bird & Cahoy, *supra* note 229, at 306–07.

[231] *See* Abeer Allam, *Seeking Investment, Egypt Tries Patent Laws*, N.Y. Times, Oct. 4, 2002, at W1.

[232] *See* Bird & Cahoy, *supra* note 229, at 306–07. As a result of the Egyptian Health Ministry's actions, Pfizer cancelled plans to build a state-of-the-art manufacturing facility, asserting that the government's decision would "send a chill down foreign investor's spines." *See id.* at 306 (citing Richard A. Castellano, Note, *Patent Law for New Medical Uses of Known Compounds and Pfizer's Viagra Patent*, 46 IDEA 283, 289 (2006)). Some assert that extensive compulsory licensing in Egypt led to a decrease of foreign direct investment from $948 million in 1987 to $509.4 million in 2001–02. *See* McGill, *supra* note 32, at 90.

[233] *See* WTO Gambling, *supra* note 41, ¶¶ 305–308; WTO Beef, *supra* note 41, ¶ 164.

[234] *See* Foster, *supra* note 41, at 206.

[235] *See* Bird & Cahoy, *supra* note 229, at 306–07; Foster, *supra* note 41, at 205–10.

[236] *See* WTO Beef, *supra* note 41, ¶ 162 (noting that for the first element of the balancing test, if the value or interest pursued is considered significant, it is more likely that the challenged measure will be deemed necessary); Foster, *supra* note 41, at 208.

[237] *See* Rangel, *supra* note 39, at 404–05 (explaining that Congress recognized the importance of public health by explicitly acknowledging public health in the Bipartisan Agreement on Trade Policy and in subsequent FTAs).

Committees will need to develop more specific and tailored inquiries.[238] For example, the Joint Committees should consider the prevalence and incidence of a disease, which will provide evidence of the burden that the disease poses for the population at issue.[239] The greater the burden of a particular disease, the stronger a country's interest in promoting access to drugs by relaxing data exclusivity or compulsory licensing provisions.[240] Another important consideration is determining the potential impact of maintaining stringent data exclusivity or compulsory licensing provisions.[241] If continued use of obstinate TRIPS-Plus provisions would significantly harm a country's public health, then the balancing test should tip in favor of relaxing data exclusivity and compulsory licensing standards.[242]

2. The Extent to Which the Challenged Measure Contributes to the Realization of the End Pursued by That Measure

The more that a challenged measure contributes to the end pursued, the more likely that the Joint Committee will recognize the measure as necessary.[243] To evaluate this prong, the Joint Committee should

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[238] *Cf.* Foster, *supra* note 41, at 208 (positing potential inquiries to consider under the first prong of the balancing test within the context of copyright and educational materials).

[239] R. Bonita et al., World Health Org., Basic Epidemiology 18, 118 (2d ed. 2006), *available at* http://whqlibdoc.who.int/publications/2006/9241547073_eng.pdf. Determining the burden of a disease requires understanding both prevalence and incidence. *See id.* at 18. Prevalence is the total number of existing cases of disease at a specified time while incidence is the number of new cases of disease that have developed in a specified time. *See id.* Understanding the epidemiologic features of a disease, like prevalence and incidence, enhances a population's ability to control and treat a disease. *See id.* at 118.

[240] *C.f.* WTO Beef, *supra* note 41, ¶ 162 (asserting that the necessity of a measure depends on the importance of the values or interests that the measure seeks to protect or promote); Ho, *supra* note 42, at 413–14 (tracing the Thai government's use of compulsory licensing provisions in response to the burden of HIV/AIDS in Thailand). For example, Thailand recognized that HIV/AIDS placed an enormous burden on its population. Collins-Chase, *supra* note 10, at 786. Although the Thai government may not have utilized a balancing test, it is likely the high burden of HIV/AIDS led to the issuance of several compulsory licenses. *See* Ho, *supra* note 42, at 413–14; Collins-Chase, *supra* note 10, at 787.

[241] *See* Georgetown, *supra* note 71, at 34 (describing the life-threatening impact of failing to relax TRIPS-Plus provisions in the Dominican Republic, for example).

[242] *See* Georgetown, *supra* note 71, at 15, 29, 32; Foster, *supra* note 41, at 208 (noting that when the challenged measure promotes the value sought, for example public health or access to drugs, then the scale tips in favor of the challenged measure); Rangel, *supra* note 39, at 404–05; Shaffer & Brenner, *supra* note 103, at w961–64.

[243] *See* WTO Beef, *supra* note 41, ¶ 163 (concluding that, with respect of the second prong, the more that the challenged measure contributes to the end pursued, the more likely that the challenged measure is necessary).

consider current access to the particular pharmaceutical within the country seeking to relax data exclusivity or compulsory licensing provisions.[244] Extremely limited access to an affordable pharmaceutical would indicate that relaxed data exclusivity or compulsory licensing provisions could improve access.[245] Moreover, the Joint Committee should assess how many people expect to gain access if these provisions are relaxed.[246] The more individuals that would gain access to affordable pharmaceuticals under the challenged measure, the more likely that the challenged measure should be deemed necessary.[247] Finally, the Joint Committee should evaluate how improved access to treatment will alleviate a particular disease.[248]

3. The Trade Impact of the Challenged Measure

The Joint Committee should also consider the impact that loosened data exclusivity or compulsory licensing provisions will have on trade.[249] A slight impact on trade will tip the scales in favor of the challenged measure, while a considerable impact on trade may have the

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[244] *See id.*; Foster, *supra* note 41, at 208–09. *See generally* Global HIV/AIDS Response 2011, *supra* note 121, at 1–9 (establishing access to antiretrovirals as a critical indicator to improving the HIV/AIDS burden).

[245] *See* Shaffer & Brenner, *supra* note 103, at w961–64; *see, e.g.*, WTO Beef, *supra* note 41, ¶ 163. For example, in Guatemala, the introduction of TRIPS-Plus provisions led to increased drug costs. *See* Shaffer & Brenner, *supra* note 103, at w961–64. In that case, because only fifty percent of those in need of antiretrovirals had access to treatment, applying the second prong of the balancing test, the Guatemalan government might conclude that relaxed data exclusivity or compulsory licensing provisions would improve access to antiretrovirals. *See* Global HIV/AIDS Response 2011, *supra* note 121, at 191; *supra* notes 121–134 and accompanying text.

[246] *C.f.* Foster, *supra* note 41, at 208 (noting that a government should provide data about the number of people that expect to benefit from a challenged measure to tip the second prong in favor of the challenged measure).

[247] *See* Georgetown, *supra* note 71, at 15, 29, 32; Foster, *supra* note 41, at 208; Shaffer & Brenner, *supra* note 103, at w961–64.

[248] *See* Kripke & Weinberg, *supra* note 178, at 4–5 (noting that the Thai government relied on access to affordable drugs to achieve success in addressing its HIV/AIDS problem and access to these drugs could be threatened by TRIPS-Plus provisions thereby negating the government's success); Foster, *supra* note 41, at 208–09. For example, a country may consider Thailand's success in improving access to HAART along with reducing the burden of HIV/AIDS to conclude that relaxed TRIPS-Plus provisions are necessary to alleviate the effects of a disease. *See* Puymbroeck, *supra* note 27, at 533–34. *See generally* Erin M. Anderson, *Unnecessary Deaths and Unnecessary Costs: Getting Patented Drugs to Patients Most in Need*, 29 B.C. Third World L.J. 85, 112 (2009) (encouraging the use of compulsory licensing).

[249] *See* WTO Beef, *supra* note 41, ¶ 163.

opposite effect.[250] For example, the Joint Committee should examine the amount of revenue that a patent owner derives from the drug at issue.[251] If a drug company derives a significant amount of its income through a particular drug, the committee may disfavor relaxing data exclusivity and compulsory licensing provisions.[252] The Joint Committee should also evaluate how the challenged measure will be used.[253] For example, a country seeking to issue a compulsory license for a drug in order to establish a strong export industry, thereby interrupting pricing structures or trade within other markets, may not result in a favorable result for the challenged measure.[254]

Conclusion

While Earvin "Magic" Johnson celebrated his remarkable health twenty years after contracting HIV, Hope Tukahirwa's access to lifesaving pharmaceuticals remains in a tenuous balance of competing interests. TRIPS-Plus data exclusivity and compulsory licensing provisions have stifled access to medicines and may continue to do so without intervention. In 2006, then Senator Barack Obama said "[l]ike no other illness, AIDS tests our ability to put ourselves in someone else's shoes—to empathize with the plight of our fellow man."[255] By amending U.S. FTAs to promote a balancing of innovation and access, the United States will truly affirm its commitment to public health and ensure that millions of people like Hope Tukahirwa have access to the affordable pharmaceuticals they so desperately need.

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[250] *See id.* (providing that when the challenged measure has a relatively slight impact on trade, it is more likely that the challenged measure is necessary).

[251] *See id.*; *see, e.g.*, GlaxoSmithKline, *Global Public Policy Issues: Regulatory Data Protection*, GSK (Aug. 2011), www.gsk.com/content/dam/gsk/globals/documents/pdf/GSK-on-regulatory-data-protection.pdf (justifying data exclusivity provisions because they represent a fair return on the development of clinical data).

[252] *See* WTO Beef, *supra* note 41, ¶ 163; Foster, *supra* note 41, at 209–10; GlaxoSmithKline, *supra* note 251.

[253] *Cf.* Foster, *supra* note 41, at 209–10 (considering the way in which the challenged measure will actually be used is a critical aspect of determining the impact of the challenged measure).

[254] *See, e.g.*, Baker, *supra* note 116, at 708; Bird & Cahoy, *supra* note 229, at 306–07; Foster, *supra* note 41, at 209–10 (noting that the third prong favors a challenged measure when it does not affect trade markets of other countries); Collins-Chase, *supra* note 10, at 801.

[255] William Crawley, *The Purpose-Driven Presidency*, BBC (Dec. 3, 2006, 3:48 PM), http://www.bbc.co.uk/blogs/ni/2006/12/the_purposedriven_presidency.html (quoting Barack Obama).