Note

A Public Health Imperative: The Need for Meaningful Change in the Trans-Pacific Partnership's Intellectual Property Chapter

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The World Health Organization (WHO) declares that every human being has the fundamental right to enjoy "the highest attainable standard of health."[1] This essential human right is codified in national constitutions and international treaties, not simply as a goal but an expectation for the welfare of populations subjected to adverse economic and medical conditions.[2] While access to healthcare and medicine is an integral part of the right to health, "[o]nly 51.8 per cent of public and 68.5 per cent of private health facilities" in developing countries can provide essential medicines to their patients.[3] "Prices of available essential medicines tend to be the multiple of international reference prices."[4] A recent example of excessive drug pricing comes from Gilead Pharmaceuticals,

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1. Constitution of the World Health Organization, pmbl., July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185.

2. Lance Gable & Benjamin Mason Meier, *Global Health Rights: Employing Human Rights to Develop and Implement the Framework Convention on Global Health*, 15 HEALTH & HUM. RTS., no. 1, June 2013, at 17, 17–21.

3. MDG GAP TASK FORCE, MILLENNIUM DEVELOPMENT GOAL 8: THE GLOBAL PARTNERSHIP FOR DEVELOPMENT: MAKING RHETORIC A REALITY, at xvi, U.N. Sales No. E.12.I.5 (2012).

4. *Id*.

charging $1000 per pill of Sovaldi, a hepatitis C treatment.[5] This extreme pricing differential makes purchasing medicine, particularly for chronic illness, essentially prohibitive for low-income families in developing countries.[6]

Increasing affordable access to essential medicines has the potential to save nearly ten million lives a year, with four million of those lives being in Africa and Southeast Asia.[7] While better health is critical to happiness and wellbeing, it also contributes to economic growth and progress.[8] A number of factors are responsible for the enormous inequity in the pricing of medicine: weak infrastructure, broken health systems, health worker shortages, "weak regulatory regimes," expensive and time-consuming research and development, and markups "throughout the distribution chain" that lead to higher drug prices.[9] A significant cause of the exorbitant cost of medicine is the current complex and aggressive intellectual property landscape, which is exemplified in numerous free trade agreements, such as the Trans-Pacific Partnership (TPP)[10]—allowing proprietary protections over pharmaceutical patents to surpass public health needs.

In order to address the immense public health inequity in trade and patent law practices, the World Trade Organization (WTO) administered the Agreement on Trade-Related Aspects

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5. Margot Sangor-Katz, *Boon for Hepatitis C Patients, Disaster for Prison Budgets*, N.Y. TIMES, Aug. 7, 2014, at A3; *see Innovating and Expanding Access to Hepatitis C Treatments*, GILEAD SCI. (Oct. 2014), http://www.gilead.com/~/media/Files/pdfs/Policy-Perspectives/ExpandingAccesstoHCVTreatments10214.pdf (discussing Gilead's drug Sovaldi).

6. *See* MDG GAP TASK FORCE, *supra* note 3, at 63–64.

7. DEP'T FOR INT'L DEV., INCREASING ACCESS TO ESSENTIAL MEDICINES IN THE DEVELOPING WORLD: U.K. GOVERNMENT POLICY AND PLANS 8 (2004), *available at* https://hospicecare.com/uploads/2011/8/dfid_access_medicines.pdf.

8. *Health and Development*, WORLD HEALTH ORG., http://www.who.int/hdp/en/ (last visited Sept. 11, 2014).

9. Brook K. Baker, *Patents, Pricing, and Access to Medicines in Developing Countries*, 11 VIRTUAL MENTOR 527, 527 (2009).

10. *See generally* U.N. DEV. PROGRAMME, U.N. AIDS, THE POTENTIAL IMPACT OF FREE TRADE AGREEMENTS ON PUBLIC HEALTH 3–5 (2012), *available at* http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/JC2349_Issue_Brief_Free-Trade-Agreements_en.pdf (discussing TRIPS-plus obligations contained in free trade agreements and the potential negative impacts on price and access).

of Intellectual Property Rights (widely known as TRIPS).[11] The TRIPS Agreement employs various provisions to ensure public health needs are addressed through international trade; these provisions are referred to as "flexibilities."[12] The past two decades have seen an increasing number of developing nations successfully utilize the flexibilities provided by TRIPS, which aim to lower costs and increase access to medicine by facilitating the importation of generic formulas.[13] While TRIPS has made progress by bringing public health needs on par with global patent rights, many countries have not yet amended their laws to incorporate full TRIPS flexibilities.[14] An increasing number of bilateral and multilateral free trade agreements include intellectual property protections that greatly exceed the minimum intellectual property standards of TRIPS, thus hindering the use of such flexibilities.[15]

The advent of the TPP, a proposed trade agreement between twelve countries including the United States, potentially poses the most aggressive pharmaceutical intellectual property provisions to date.[16] Part I of this Note will review the development of the TPP and its intellectual property provisions as well as the history of trade and medicine, particularly focusing on the restrictions of the TRIPS flexibilities. Part II will specifically discuss how the TPP's intellectual property provisions will adversely impact global

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11. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 108 Stat. 4809, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

12. *See* MDG GAP TASK FORCE, *supra* note 3, at xvi (introducing TRIPS flexibilities).

13. *Id.*

14. U.N. DEV. PROGRAMME, U.N. AIDS, USING TRIPS FLEXIBILITIES TO IMPROVE ACCESS TO HIV TREATMENT: POLICY BRIEF 2–3, 8 (2011), *available at* http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf.

15. Pedro Roffe & Christoph Spennemann, *The Impact of FTAs on Public Health and TRIPS Flexibilities*, 1 INT'L J. INTELL. PROP. MGMT. 75, 76–80, 86 (2006).

16. *How Does Evergreening Restrict Access to Medicines?*, MEDECINS SANS FRONTIERES, http://aids2012.msf.org/2012/the-trans-pacific-partnership-agreement-evergreening/ (last visited Sept. 11, 2014) (stating that the United States is "demanding aggressive intellectual property" provisions); *see infra* Part I.

access to affordable medicines and a partner nation's ability to utilize existing TRIPS flexibilities. Part II will also include recommendations to keep the TPP consistent with TRIPS in order to balance patent rights for the pharmaceutical industry with broader public health and bioethical goals.

I. BACKGROUND

A. THE TRANS-PACIFIC PARTNERSHIP DEFINED

The TPP is a proposed plurilateral[17] free trade agreement currently under negotiations between the United States and a number of nations in the Asia-Pacific.[18] It stems from earlier established trade negotiations between four nations: Brunei Darussalam, Chile, New Zealand, and Singapore.[19] In 2003, Chile, New Zealand, and Singapore set out to establish a viable path to liberalize regional trade in the Asia-Pacific, and Brunei Darussalam joined in 2005.[20] At various points the United States, Australia, Peru, Canada, Mexico, Japan, Vietnam, and Malaysia have joined the negotiations.[21] Some nations are committed parties to the TPP, while others, such as Taiwan, the Philippines, and South Korea "have expressed interest in joining the TPP negotiations."[22]

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17. A plurilateral agreement is a multi-national trade agreement between three or more countries. *See* Michitaka Nakatomi, *Plurilateral Agreements: A Viable Alternative to the World Trade Organization?* 2 (Asian Dev. Bank Inst., Working Paper No. 439, 2013), *available at* http://www.adbi.org/files/2013.10.24.wp439.plurilateral.agreements.alternative.wto.pdf.

18. *Trans-Pacific Partnership: Frequently Asked Questions*, OFF. U.S. TRADE REPRESENTATIVE, http://www.ustr.gov/sites/default/files/TPPFAQ.pdf (last visited Sept. 15, 2014).

19. 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).

20. IAN F. FERGUSSON ET AL., CONG. RESEARCH SERV., THE TRANS-PACIFIC PARTNERSHIP NEGOTIATIONS AND ISSUES FOR CONGRESS 3 (2013), *available at* http://fas.org/sgp/crs/row/R42694.pdf.

21. T. Rajamoorthy, *And Then There Were Twelve: The Origins and Evolution of the TPPA*, THIRD WORLD RESURGENCE, no. 275, July 2013, at 4–6, *available at* http://www.twnside.org.sg/title2/resurgence/2013/pdf/275.pdf.

22. GENERIC PHARM. ASS'N ET AL., JOINT POSITION STATEMENT ON THE TRANS PACIFIC PARTNERSHIP (TPP) NEGOTIATIONS 1 (2013), *available at* http://www.gphaonline.org/media/cms/Joint_Position_Statement_on_the_Trans_Pacific_Partnership.pdf.

The stated goals of the nations negotiating the TPP vary. For some, it serves as a model free trade agreement that will set high standards for trade and investment in the region.[23] For the United States, the TPP offers a strong foothold in an increasingly important area of global commerce.[24] Additionally, the United States hopes more countries will join the TPP, increasing financial opportunities and access to an even larger market.[25] The TPP is established to be a living agreement, meaning membership can expand and covenants will adapt as issues emerge.[26]

Overall, the TPP aims to liberalize the economies of the Asia-Pacific through a comprehensive tariff reduction.[27] Its scope goes further by addressing issues related to market access, rules of origin, investment, financial services, intellectual property, agriculture, competition, and the environment.[28] Member nations also discuss issues pertaining

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23. N.Z. MINISTRY OF FOREIGN AFFAIRS & TRADE, THE TRANS-PACIFIC STRATEGIC ECONOMIC PARTNERSHIP AGREEMENT 1 (2009), *available at* http://www.mfat.govt.nz/downloads/trade-agreement/transpacific/transPac-Fa ctsheet-2Mar09.pdf.

24. *See* OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2009 TRADE POLICY AGENDA AND 2008 ANNUAL REPORT OF THE PRESIDENT OF THE UNITED STATES ON THE TRADE AGREEMENTS PROGRAM 127 (2009), *available at* http://www.ustr.gov/webfm_send/2558 ("The TPP will serve to strengthen U.S. trade and investment ties to the Trans-Pacific region, which is a priority given the economic significance of the region to the United States now and in the future.").

25. *See* Rajamoorthy, *supra* note 21, at 4–5.

26. *Outlines of the Trans-Pacific Partnership Agreement*, OFF. U.S. TRADE REPRESENTATIVE, http://www.ustr.gov/about-us/press-office/fact-sheets/2011 /november/outlines-trans-pacific-partnership-agreement (last visited Oct. 22, 2014); *see also Trans-Pacific Partnership Agreement Negotiations*, AUSTL. GOV. DEPARTMENT FOREIGN AFF. & TRADE, http://www.dfat.gov.au/fta/tpp/ (last visited Nov. 17, 2014) (noting Australia's position in support of expanding membership to strengthen trade relationships in the region).

27. *See* FERGUSSON ET AL., *supra* note 20, at summary.

28. *Outlines of the Trans-Pacific Partnership Agreement*, *supra* note 26; *see also Trans-Pacific Partnership Free Trade Agreement Negotiations*, FOREIGN AFF. TRADE & DEV. CAN. (Dec. 12, 2013), http://www.international .gc.ca/trade-agreements-accords-commerciaux/agr-acc/tpp-ptp/info.aspx ("The TPP addresses new trade issues and 21st century challenges, exploring both tariff and non-tariff barriers to trade and investment, with the goal of facilitating the movement of people, goods, services, capital, and data across borders.").

to market access, packages for goods, services, temporary workers, customs, and government procurement.[29]

The TPP concluded its most recent round of negotiations in May of 2014.[30] The negotiations were expected to come to a close by the end of 2013; however, some issues have taken longer to iron out, thus extending the timeline.[31] The TPP's proposed intellectual property provisions are one of the main provisions responsible for delays in reaching a consensus among parties.[32]

The TPP's intellectual property chapter, which was proposed by the United States, is a major source of controversy, particularly its effects on pharmaceutical patents and digital innovation.[33] The negotiations for the TPP are closed to the public as well as members of Congress and details of the agreement have been shrouded in secrecy.[34] However, in May 2012 Congressman Darrell Issa of California leaked the February and September 2011 drafts of the U.S. proposal for intellectual property protections.[35] Additionally, on November 13, 2013, WikiLeaks founder Jullian Assange leaked a draft of

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29. *Outlines of the Trans-Pacific Partnership Agreement*, *supra* note 26.

30. Press Release, Office of the U.S. Trade Representative, Joint Statement at the TPP Ministers Meeting in Singapore (May 2014), *available at* http://www.ustr.gov/about-us/press-office/press-releases/2014/May/Joint-Statement-at-the-TPP-Ministers-Meeting-in-Singapore.

31. Shawn Donnan & Ben Bland, *TPP Leaders Say 'Significant Progress' Made*, FIN. TIMES (Oct. 8, 2013), http://www.ft.com/cms/s/0/fdfe4b36-2fe5-11e3-9eec-00144feab7de.html#axzz2ixpGnIL3.

32. Henry Farrell, *The TPP Is Not an Agreement Among Like-Minded Countries*, WASH. POST (Dec. 12, 2013), http://www.washingtonpost.com/blogs/monkey-cage/wp/2013/12/12/the-tpp-is-not-an-agreement-among-like-minded-countries/ (highlighting the United States' hardline stance on intellectual property chapter negotiations).

33. *Trans-Pacific Partnership Agreement*, ELECTRONIC FRONTIER FOUND., https://www.eff.org/issues/tpp (last visited Sept. 16, 2014).

34. Carolina Rossini & Maira Sutton, *What Is Wrong with the Trans-Pacific Partnership*, ELECTRONIC FRONTIER FOUND. (Aug. 21, 2012), https://www.eff.org/deeplinks/2012/08/whats-wrong-tpp.

35. Press Release, Congressman Darrell Issa, Issa Releases the Trans Pacific Partnership Intellectual Property Rights Chapter on KeepTheWebOPEN.com (May 15, 2012), *available at* http://issa.house.gov/press-releases/2012/05/issa-releases-the-trans-pacific-partnership-intellectual-property-rights-chapter-on-keepthewebopencom/.

the TPP—right before chief negotiators met in Salt Lake City, Utah.[36]

TPP member nations agree to abide by the minimum standards established by TRIPS and also expand on those standards, greatly increasing patent protections. [37] The negotiations have covered "trademarks, geographical indications, copyright and related rights, patents, trade secrets," genetic resources, and traditional knowledge. [38] Statements from U.S. officials seem to indicate that the TPP is intended to set a precedent for future trade agreements and practices.[39]

B. HISTORICAL LANDSCAPE OF TRADE AND MEDICINES

Historically, the limited availability and high price of essential medicines were attributed to the lack of consistent patent law and trade practices in the global market. [40] The TRIPS Agreement introduced intellectual property law standards into the global trading system in 1995. [41] TRIPS requires member nations to abide by minimum standards for the protection and enforcement of "nearly all forms of intellectual property rights (IP), patents, copyrights, and trade

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36. Press Release, WikiLeaks, Secret Trans-Pacific Partnership Agreement (TPP)—IP Chapter (Nov. 13, 2013), *available at* https://wikileaks.org/tpp/pressrelease.html.

37. *Outlines of the Trans-Pacific Partnership Agreement*, *supra* note 26.

38. *Id.*

39. *The Trans Pacific Partnership Agreement: Challenges and Potential: Hearing Before the Subcomm. on Terrorism, Nonproliferation & Trade & the Subcomm. on Asia Pac. of the Comm. of Foreign Affairs of the U.S.H.R.*, 112th Cong. 2–3 (2012) (statement of Susan C. Schwab, former U.S. Trade Rep.), *available at* http://archives.republicans.foreignaffairs.house.gov/112/HHRG-112-FA18-WState-SchwabS-20120517.pdf.

40. Ellen 't Hoen, *TRIPS*, *Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 27–31 (2002). *See generally* S. CTR., THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH TEN YEARS LATER: THE STATE OF IMPLEMENTATION 1–4 (2011), *available at* http://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf (discussing the "significant changes" brought on by TRIPS to create more consistent "standards of IP protection").

41. *See WTO and the TRIPS Agreement*, WORLD HEALTH ORG., http://www.who.int/medicines/areas/policy/wto_trips/en/ (last visited Sept. 11, 2014).

secrets, including those applicable to pharmaceuticals." [42] Developing countries that did not previously acknowledge product patents in areas such as pharmaceuticals had to modify their laws to become TRIPS compliant and grant patents on medicines.[43] Such compliance makes it even more difficult for cheaper drugs to enter the market since TRIPS-obliging countries would have to abide by long pharmaceutical patent terms.[44]

TRIPS's scope covers general principles, standards for the use of patents, intellectual property enforcement, dispute settlement, and other subjects.[45] Under its key provision, WTO member nations must offer patent protection for at least twenty years from the filing date of the patent application for any product or process that fulfills the criteria of novel, non-obvious, and usefulness.[46] Before TRIPS, the duration for such protection was significantly shorter—around sixteen years.[47] Certain developing countries granted patents for even shorter terms, such as five to seven years.[48] TRIPS also standardizes the absolute protection of a product rather than protecting only a process. [49] Process patents would protect respective technology and the process or manufacturing method.[50] Such patent protection does not prevent skilled manufacturers from reverse engineering medicine and marketing it.[51]

Prior to patent rule pluralism, countries routinely discriminated between fields of invention, for example excluding medicine patents, giving national policymakers

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42. Baker, *supra* note 9, at 528.

43. S. CTR., *supra* note 40, at 1.

44. *See* Baker, *supra* note 9 (expressing concern that TRIPS may in fact lead to even higher prices for medicine). *But see* S. CTR., *supra* note 40, at 1, 4–5 ("[TRIPS flexibilities] may be used to stimulate competition . . . in order to encourage access to medicines at prices affordable to governments and patients."); *WTO and the TRIPS Agreement*, *supra* note 41 (discussing how TRIPS flexibilities help offset higher prices in the face of long pharmaceutical patent terms).

45. *See generally* TRIPS Agreement, *supra* note 11.

46. *Id.* at art. 27.1, 33.

47. *WTO and the TRIPS Agreement*, *supra* note 41.

48. *Id.*

49. TRIPS Agreement, *supra* note 11, at art. 27.

50. *Id.*

51. *Id.*

rather than market forces control over drug prices.[52] TRIPS explicitly prohibits this type of market bias.[53] Pharmaceutical manufacturers are better able to dictate where drugs are made because countries cannot "discriminate against importing goods in favor of local products."[54] This allows pharmaceutical producers to consolidate monopoly power globally by controlling the place of production.[55] TRIPS prohibits non-inventors from utilizing, marketing, importing, and manufacturing patented processes and products.[56] Such intellectual property protection can proliferate monopolies and raise prices.[57] Drug companies further alienate needy populations by pricing them out, selling primarily to insured or the wealthy even if much of a nation's population cannot benefit from the innovation.[58]

Many countries that undertake evaluating the quality, safety, and efficacy of medicines require new pharmaceutical products to submit test data for review by a regulatory agency.[59] TRIPS instituted an undisclosed data protection standard.[60] This provision grants the original inventor exclusive rights over their undisclosed test data, preventing national regulatory authorities, such as the U.S. Food and Drug Administration, from relying on such data when evaluating generic alternatives.[61] TRIPS provides an exception

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52. Baker, *supra* note 9, at 528.

53. TRIPS Agreement, *supra* note 11, at art. 27.1.

54. Baker, *supra* note 9, at 528; *see also* TRIPS Agreement, *supra* note 11, at art. 27.1 ("[P]atent rights shall be available and patent rights enjoyable without discrimination as to the place of invention . . . and whether products are imported or locally produced.").

55. Baker, *supra* note 9, at 528.

56. *Id*.; *see* TRIPS Agreement, *supra* note 11, at art. 28 (providing the rights a patent confers on its owner under TRIPS).

57. Baker, *supra* note 9, at 528.

58. *See id*. ("[I]ts profit-maximizing strategy in developing countries is typically to sell medicines at high prices to the rich even if that price excludes purchase by or for the vast majority of a country's population.").

59. WORLD HEALTH ORG. ET AL., PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE 65–66 (2012), *available at* http://wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.

60. TRIPS Agreement, *supra* note 11, at art. 39.3 (stating that WTO members must protect undisclosed test data on pharmaceutical products against unfair competition).

61. CARLOS MARÍA CORREA, S. CTR., PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE

to its test data protection when the use of such data would protect the public.[62]

In order to balance the rights of pharmaceutical patent holders with international public health needs, TRIPS offers flexibilities to countries to safeguard access to medicines.[63] Nations are permitted to apply their own rigorous patentability standards such as degree of novelty or inventive step.[64] TRIPS-compliant nations are also allowed to issue compulsory licenses, which permit a government to allow the sale and manufacture of patented medicine without the patent holder's consent.[65] Compulsory licensing and government use are subject to a number of conditions aimed at protecting patent holder interests.[66] For example, a company applying for such a license to market or manufacture patented medicine must first attempt to obtain a voluntary license from the patent holder "on reasonable commercial grounds."[67] If this attempt is not successful, then the country can seek a compulsory license.[68] If a compulsory license is granted, appropriate remuneration must be paid to the patent holder.[69] To further balance intellectual property protection with public health goals, TRIPS allows this requirement to be waived by a member nation in the event of a "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."[70] "In situations of national emergency or other circumstances of extreme urgency," the right holder must still "be notified as soon as reasonably practicable."[71]

STANDARDS OF THE TRIPS AGREEMENT 8 (2002), *available at* http://www.who.int/medicines/areas/policy/protection_of_data.pdf.

62. WORLD HEALTH ORG. ET AL., *supra* note 59, at 64.

63. *Globalization, TRIPS and Access to Pharmaceuticals*, WHO POL'Y PERSP. ON MEDS. (World Health Org., Geneva, Switz.), Mar. 2001, at 5, *available at* http://apps.who.int/medicinedocs/pdf/s2240e/s2240e.pdf.

64. Baker, *supra* note 9, at 528.

65. *See* TRIPS Agreement, *supra* note 11, at art. 31 (establishing the availability and parameters of compulsory licenses); *Globalization, TRIPS and Access to Pharmaceuticals*, *supra* note 63, at 3 (labeling TRIPS article 31 as compulsory licensing).

66. TRIPS Agreement, *supra* note 11, at art. 31.

67. *Id*. at art. 31(b).

68. *Id.*

69. *Id.* at art. 31(h).

70. *Id.* at art. 31(b).

71. *Id.*

Another key flexibility TRIPS provides is permissible parallel importation, which is the practice of taking drugs "marketed by the patent holder . . . or with the patent owner's permission in one country" and importing them "into another country without approval" from the patent holder.[72] This is a key provision as it allows nations in need to take advantage of pharmaceutical pricing differentials.[73] Parallel importation operates under the legal principle that the original patent rights are exhausted once a batch of drugs is initially sold.[74] For example, if a pharmaceutical company markets a patented drug more cheaply in country A than in country B, country B could import the drug from country A and save money. This is perfectly permissible under TRIPS.[75] The parallel importation flexibility allows nations "to comparison shop for a brand-name medicine if it was sold elsewhere at a lower price."[76]

TRIPS remains the most comprehensive international covenant on intellectual property. However, many developing nations called for a narrow interpretation of TRIPS, leading the WTO to adopt the Doha Declaration on the TRIPS Agreement and Public Health in 2001—a statement that aims to clarify the scope of TRIPS.[77] The Doha Declaration provides articles requiring the interpretation of TRIPS to reflect a manner supportive of public health, by promoting both access to existing medicines as well as research and development into new medicines.[78] The Doha Declaration clarifies that this means member nations can choose how to deal with drug

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72. World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755, at para. 5(d) (2002) [hereinafter Doha Declaration]; World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Ministerial Declaration]; *see also* TRIPS Agreement, *supra* note 11, at art. 6; *Fact Sheet: TRIPS and Pharmaceutical Patents Obligations and Exceptions*, WORLD TRADE ORG. (Sept. 2006), http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.

73. Baker, *supra* note 9, at 528.

74. *Fact Sheet: TRIPS and Pharmaceutical Patents Obligations and Exceptions*, *supra* note 72.

75. *Id.*

76. Baker, *supra* note 9, at 528.

77. *See generally* Doha Declaration, *supra* note 72 (attempting to delineate the scope and purpose of TRIPS).

78. *Id.* at paras. 4, 7.

patent terms in a way that best fits their domestic policy objectives.[79]

The Doha Declaration provides that TRIPS "does not and should not prevent Members from taking measures to protect public health."[80] It underscores a country's ability to utilize the flexibilities that are built into TRIPS, including compulsory licensing and parallel importation.[81] Unfortunately, the Doha Declaration does not give guidance on what conditions must be met to utilize the compulsory licensing flexibility for a national public health emergency.[82] The extent of the direction provided gives member states the right to determine what constitutes a national emergency or other circumstance of extreme urgency with regard to public health, such as matters related to "HIV/AIDS, tuberculosis, malaria and other epidemics . . . or other circumstances of extreme urgency."[83]

C. EXPANDING BEYOND TRIPS PATENT PROTECTION

While TRIPS has made progress bringing public health needs on par with global patent rights, barriers preventing access to affordable medicines still remain complex and prevalent. Despite the clarity provided by the Doha Declaration, in recent years, many developing nations were pressured to enact or implement even more strict and restrictive conditions in their patent laws than required by the TRIPS Agreement—these are known as TRIPS-plus provisions.[84] International law does not require countries to do this; however, as part of trade agreements with the European Union and United States, many nations such as Brazil, China, and several Central American states have had no choice but to

79. *Id.* at para. 5(d).

80. *Id.* at para. 4.

81. *See id.* ("[W]e reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.").

82. *See, e.g.*, *id.* at para. 5 (providing no guidance on specific requirements or conditions, and instead granting each member "the right to determine what constitutes a national emergency or other circumstances of extreme urgency").

83. *Id.* at para. 5(c).

84. U.N. DEV. PROGRAMME, *supra* note 10, at 3.

adopt TRIPS-plus provisions.[85] Trade agreements heavily filled with TRIPS-plus provisions have a fairly adverse impact on access to medicines.[86]

Mohammad El Said, an international trade law professor at Lancashire Law School says,

> The post-TRIPS era may be best described as a dynamic one. Contrary to the developing countries' belief that TRIPS would put an end to the regulation of intellectual property globally, the post-TRIPS era has witnessed the intensification of efforts to strengthen the protection levels of intellectual property beyond those established under TRIPS, creating the TRIPS-plus phenomenon.[87]

While the TRIPS flexibilities and the Doha Declaration's clarifying text help ensure more equitable access to affordable medicines in theory, the reality is quite different.[88]

The United States has taken a heavy-handed approach to trade policy, threatening countries such as Thailand, South Africa, and Brazil with trade sanctions because they refused to grant patent protections stronger than those required in TRIPS and attempted to utilize the flexibilities guaranteed by TRIPS to access more affordable medicines.[89] This retaliation, taking the form of withdrawing special zero-tariff trade access or pulling U.S. foreign investment, continues even after the United States signed the Doha Declaration.[90]

TRIPS is intended to strike a balance between long term social objectives of providing incentives for future inventions and creation, and short term objectives of allowing people to

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85. *TRIPS, TRIPS Plus and Doha,* MEDECINS SANS FRONTIERES, http://www.msfaccess.org/content/trips-trips-plus-and-doha (last updated July 2011).

86. *Id.*

87. MOHAMMED K. EL SAID, WORLD HEALTH ORG., PUBLIC HEALTH RELATED TRIPS-PLUS PROVISIONS IN BILATERAL TRADE AGREEMENTS: A POLICY GUIDE FOR NEGOTIATORS AND IMPLEMENTERS IN THE WHO EASTERN MEDITERRANEAN REGION 92 (2010), *available at* http://applications.emro.who.int/dsaf/dsa1081.pdf.

88. Jerome H. Reichman, Comment, *Compulsory Licensing of Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 247, 248 (2009).

89. *See* 't Hoen, *supra* note 40, at 29–33 (discussing U.S. pressure and threats against South Africa and Brazil); Reichman, *supra* note 88, at 247, 258–59 (highlighting pressure and threats against Thailand).

90. Reichman, *supra* note 88, at 258.

use existing inventions and creations.[91] TRIPS's flexibilities allow governments to modify broad intellectual property protections granted in order to meet social goals—to some degree.[92] Governments are able to permit exceptions to patent holder rights in the face of national emergencies, anti-competitive practices, and lack of access.[93]

Unfortunately, the flexibilities provided by TRIPS were not able to significantly improve access to medicine as barriers continue to suppress utilization. "Many countries have yet to amend their laws to incorporate" optimal use of the flexibilities, "which is a precondition for their use."[94] A United Nations' Development Program study "conducted in 2007 found that only six countries had a provision on the international exhaustion of rights in their legislation."[95] The World Intellectual Property Organization (WIPO) suggests a fairly diverse picture of the uniform incorporation of TRIPS flexibilities in national patent laws.[96]

Past TRIPS-plus provisions that may adversely impact public health or hamper the use of TRIPS flexibilities include: limiting the conditions for granting compulsory licenses; allowing for the possibility of expanding patent terms beyond twenty years in order to make up for delays in the patent granting or regulatory approval processes; "requiring drug regulatory authorities, most of which have" little experience with patentable criteria, to evaluate the patent status of a drug as a condition for "granting marketing authorizations to generic manufacturers"; and requiring stringent test data protection limiting drug regulatory authorities from relying on

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91. *E.g.*, Doha Declaration, *supra* note 72, at para. 7 ("We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members . . . ."); Ministerial Declaration, *supra* note 72, at para. 17.

92. *See* Doha Declaration, *supra* note 72.

93. *See supra* notes 72–76 and accompanying text; *see also* Doha Declaration, *supra* note 72, at paras. 4–5.

94. U.N. DEV. PROGRAMME, *supra* note 14, at 8.

95. *Id*.

96. WORLD INTELLECTUAL PROP. ORG., PATENT RELATED FLEXIBILITIES IN THE MULTILATERAL LEGAL FRAMEWORK AND THEIR LEGISLATIVE IMPLEMENTATION AT THE NATIONAL AND REGIONAL LEVELS (2010), *available at* http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=131629.

clinical test data from bio-similar pharmaceutical products in order to approve generic alternatives for a certain length of time.[97] This practice: prohibits generic manufacturers from relying on such data to demonstrate the safety and efficacy of their bio-similars, thus delaying the entry of low cost alternatives to the market; restricts the grounds of patent revocation; requires countries to broaden patentability criteria without taking domestic policy into account; expands the breadth of intellectual property protection by permitting the patenting of new uses or methods of using a known product; and allows patent-holders to squander parallel importation, which will effectively "prevent developing nations from buying medicines from the cheapest global supplier."[98] The aggregate effect of these barriers essentially eviscerates a TRIPS-compliant nation's opportunity to offer its consumers accessible and affordable drugs.[99] This is particularly harmful for cases involving treatments where generic alternatives are not available, such as patented second-line HIV/AIDS drugs.[100]

Patents should be of the highest quality and should reward only genuine innovations in order to prevent so-called "evergreening."[101] According to the WHO Commission on Intellectual Property Rights, Innovation and Public Health, "'evergreening' occurs when, in the absence of any apparent additional therapeutic benefits, patent-holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term."[102] Providing for public health sensitive patent examination guidelines as well as a process to challenge patent claims before and after they are granted may reduce the

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97. *E.g.*, U.N. DEV. PROGRAMME, *supra* note 14, at 8–9.

98. *Id.*

99. Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP*, 18 J. INTELL. PROP. L. 447, 454 (2011).

100. *See* U.N. DEV. PROGRAMME, *supra* note 14, at 1–2 (discussing the pricing and affordability of HIV/AIDS drugs); Sell, *supra* note 99, at 454.

101. *See infra* note 102 and accompanying text.

102. WORLD HEALTH ORG., PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH 131 (2006) [hereinafter COMMISSION REPORT ON IP RIGHTS], *available at* http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf.

prevalence of patenting products and process with no true innovation.[103]

D. THE NEED TO SCRUTINIZE THE TRANS-PACIFIC PARTNERSHIP

TRIPS set the standard for public health and trade on an international scale. However, it has yet to meet its own goals.[104] This failure is exemplified by the lack of guidance for developing nations to operationalize the flexibilities clarified by the Doha Declaration.[105]

On December 9, 2013, WikiLeaks released excerpts of internal government commentary on the state of current TPP negotiations, including the issue positions of countries negotiating after a recent round of talks in Salt Lake City.[106] The document reflects deep divisions between the United States' aggressive stance and most other negotiating parties' positions on intellectual property rights and pharmaceuticals.[107] The commentary also iterates that the U.S. Chief Negotiators continue to put great pressure on opposing nations. [108] This suggests that the TPP talks might only conclude if the Asia-Pacific nations acquiesce on key national interest issues, otherwise the treaty could fail to come to fruition altogether.

The TPP's potential impact on intellectual property laws, particularly with regard to pharmaceutical patents, has caused a great deal of controversy among public interest groups around the world. [109] The TPP's intellectual property

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103. *Id.* at 131–34.

104. *See generally* Erik Alsegård, *Global Pharmaceutical Patents After the Doha Declaration—What Lies in the Future*, 1 SCRIPTED 12, 19–23 (2004), *available at* http://www2.law.ed.ac.uk/ahrc/script-ed/docs/doha.asp (examining the complaints against and problems caused by TRIPS).

105. *See, e.g.*, *id*. at 29–36 (highlighting the lack of guidance, particularly in the context of compulsory licensing, under TRIPS).

106. Press Release, WikiLeaks, Second Release of Secret Trans-Pacific Partnership Agreement Documents (Dec. 9, 2013), *available at* https://wikileaks.org/tpp/pressrelease.html.

107. *TPP State of Play After Salt Lake City 19–24 November 2013 Round of Negotiations*, WIKILEAKS, http://wikileaks.org/IMG/pdf/tpp-salt-lake-extracts-.pdf (last visited Nov. 18, 2014).

108. *Id.*

109. *See, e.g.*, Press Release, Pub. Citizen, Controversial Trade Pact Text Leaked, Shows U.S. Trade Officials Have Agreed to Terms That Undermine

controversy is significant due to the historical complexities surrounding access to affordable medicines in developing nations.[110] Senator Ron Wyden, Congressional Chair of the Committee with jurisdiction over the TPP and who was also denied access to the negotiation texts said, "'[t]he majority of Congress is being kept in the dark as to the substance of the TPP negotiations, while representatives of U.S. corporations—like Halliburton, Chevron, PhaRMA [sic], Comcast and the Motion Picture Association of America—are being consulted and made privy to details of the agreement.'"[111]

There is also evidence of the pharmaceutical industry's efforts to persuade TPP negotiators to protect intellectual property rights over any efforts to mitigate the adverse impact of such aggressive intellectual property right protections.[112] In a leaked letter, "the Intellectual Property (IP) Task Force of the U.S. Business Coalition for TPP, [which] represents a cross-sectoral group of US companies and business groups including the Pharmaceutical Research and Manufacturers of America (PhRMA), the US Chamber of Commerce, and the Motion Picture Association of America (MPAA),"[113] stated that the TPP should "provide that IP rights should not be undermined by other government pricing and regulatory mechanisms that significantly devalue IP protection."[114] The language used in the letter, which was sent to the Office of the United States

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Obama Domestic Agenda (June 13, 2012), *available at* http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=3630 (expressing significant concern over the secrecy of the TPP negotiations and the contents of the leaked text).

110. *See supra* notes 94–100 and accompanying text.

111. Nile Bowie, *The Trans-Pacific Partnership (TPP), An Oppressive US-Led Free Trade Agreement, A Corporate Power-Tool of the 1%,* GLOBAL RES. (Apr. 2, 2013), http://www.globalresearch.ca/the-trans-pacific-partnership-tpp-an-oppressive-us-led-free-trade-agreement-a-corporate-power-tool-of-the-1/5329497. Pharmaceutical Research and Manufacturers of America (PhRMA) is a trade organization representing the lobbying interests of the American pharmaceutical industry. *See About PhRMA*, PhRMA, http://www.phrma.org/about (last visited Jan. 11, 2015).

112. Judit Rius, *US Industry IP Memo for the TPP Negotiations Leaked*, KNOWLEDGE ECON. INT'L (Dec. 13, 2010), http://keionline.org/node/1034.

113. *Id.*

114. INTELLECTUAL PROP. TASK FORCE, U.S. BUS. COAL. FOR TPP, TPP INTELLECTUAL PROPERTY NEGOTIATIONS: KEY GOALS AND OBJECTIVES 2 (n.d.); Rius, *supra* note 112.

Trade Representative,[115] alludes to mechanisms such as cost-effective research and reference pricing systems.[116]

As the TPP inches closer toward becoming a binding agreement, greater scrutiny of its intellectual property provisions is needed. Trade agreements where major drug producing nations act as signatories have a stronger impact than ever. They can help fulfill TRIPS' goals or continue to impede them.

II. THE TRANS-PACIFIC PARTNERSHIP IN A POST-TRIPS WORLD

A. THE TRANS-PACIFIC PARTNERSHIP: STRUCTURE

The entirety of the TPP's negotiations is intended to be confidential. [117] However, concerned citizens such as Congressman Issa,[118] and organizations such as WikiLeaks,[119] have released drafts of the intellectual property chapter allowing the public access to the deleterious intergovernmental dealings. The most current publicly available draft was distributed in August 2013 to the Chief Negotiators of the twelve party nations, which account for approximately forty percent of the world's GDP.[120] The fact that corporate advisors are being considered "experts and key negotiators," the breadth of these expanded patent rights, and the immense lack of transparency is likely to lead the United States to push

115. Rius, *supra* note 112.

116. INTELLECTUAL PROP. TASK FORCE, *supra* note 114; Thomas A. Faunce & Ruth Townsend, *The Trans-Pacific Partnership Agreement: Challenges for Australian Health and Medicine Policies*, 194 MED. J. AUSTL. 83, 83 (2011). Reference pricing systems refers to a system that establishes a common "reimbursement level or reference price for a group of interchangeable medicines." Pieter Dylst et al., *Reference Pricing Systems in Europe: Characteristics and Consequences*, 1 GENERICS & BIOSIMILARS INITIATIVE J. 127, 127 (2012).

117. *Public Interest Analysis of Leaked Trans-Pacific Partnership (TPP) Investment Text*, PUB. CITIZEN (June 13, 2012), http://www.citizen.org/documents/Leaked-TPP-Investment-Analysis.pdf [hereinafter *TPP Investment Text*].

118. Press Release, Congressman Darrell Issa, *supra* note 35.

119. Press Release, WikiLeaks, *supra* note 36.

120. *Id.*

negotiations toward as speedy a conclusion as possible while maintaining its hard line stance on key provisions.[121]

The draft, written by the United States,[122] begins with "General Provisions" that describe relevant definitions, objectives, and principles.[123] What follows is a list of articles relating to trademarks, copyrights, geographic indication and enforcement, and other areas covered by the TPP.[124] Most relevant here are the articles under the "General Provisions" and "Section E: Patents/Undisclosed Test Data/Traditional Knowledge."[125] These articles reveal a trade deal that greatly favors the pharmaceutical industry over basic public health access needs, which will impose a significant burden on developing nations.[126]

B. THE TRANS-PACIFIC PARTNERSHIP'S COMMITMENT TO PUBLIC HEALTH

Article QQ.A.5 of the TPP's intellectual property chapter begins with what is now a standard affirmation of the parties' standing commitment to the Doha Declaration.[127] Acknowledging the commitment made to the WTO's TRIPS Agreement nearly fifteen years ago is boilerplate. However, the article does not include specific language that clarifies the TPP's commitment to operationalize the Doha Declaration or any language that indicates the goal to mitigate the barriers

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121. Kevin Drum, *Leaked Treaty Puts US Hard Line on Patents and Copyrights on Public Display*, MOTHER JONES (Nov. 15, 2013, 12:00 PM), http://www.motherjones.com/kevin-drum/2013/11/leaked-treaty-puts-us-hard-line-patents-and-copyrights-public-display ("It's no surprise that the United States is pushing the hardest line on IP protections . . . ."); *TPP Investment Text*, *supra* note 117.

122. Julian Assange, *US, Australia Isolated in TPP Negotiations*, WIKILEAKS (Nov. 15, 2013), https://wikileaks.org/US-Australia-isolated-in-TPP.html ("The US appears to be responsible for the base text.").

123. WIKILEAKS, SECRET TPP TREATY: ADVANCED INTELLECTUAL PROPERTY CHAPTER FOR ALL 12 NATIONS WITH NEGOTIATING POSITIONS 2–12 (2013) [hereinafter LEAKED IP CHAPTER], *available at* https://wikileaks.org/tpp/.

124. *Id.* at art. QQ.C.1–D.14.

125. *Id.* at art. QQ.A.3, QQ.E.

126. *See id.* (granting nations the ability to "provide more extensive protection for, and enforcement of, intellectual property rights under its law than is required by this Chapter").

127. *Id.* at art. QQ.A.5.

against TRIPS flexibility utilization in the TPP's subsequent proposal.[128] Thus, this article is essentially an empty gesture that ties together a series of aggressive patent provisions that will likely impede many nations from accessing medicine at a competitive price point.[129] Including a generic phrase about commitments to public health and TRIPS is meaningless. The United States and other negotiating countries should be well aware that the provision following this article directly contradicts the goal of TRIPS and Doha. The further away trade agreements, like the TPP, get from the flexibilities promised within TRIPS, the more difficult it will be for developing nations to utilize the public health protections they are entitled to.[130] Including Article QQ.A.5 in the TPP is the United States' way of trying to pull the wool over the public's eyes.

Article QQ.A.5(b) of the TPP narrows the interpretation of the compulsory license provisions of TRIPS into a procedurally tedious entity called the "TRIPS/Health Solution."[131] One of the main flexibilities TRIPS provides, and one of the major factors that allows for a semblance of balance between patent rights and public health rights, is a quick and efficient method to export and import medicines into countries with insufficient drug manufacturing capabilities, which is accomplished through the compulsory licensing.[132] The TRIPS/Health Solution is a procedurally complex waiver of TRIPS obligations for a developing nation facing a public health crisis.[133] This waiver requires certain safeguards to be met before a country is allowed such flexibility.[134] The TRIPS/Health Solution is burdensome and dizzying; in order to use a compulsory license a WTO member nation must provide: specification of the quantities of drugs needed, evidence to establish an inability to

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128. *See id.* (stating only that the intellectual property chapter "does not and should not prevent the effective utilization of the TRIPS/health solution").

129. *See generally id.* (tying together the Doha Declaration and TRIPS).

130. *See supra* notes 94–100 and accompanying text.

131. LEAKED IP CHAPTER, *supra* note 123, at art. QQ.A.5(b).

132. Doha Declaration, *supra* note 72, at paras. 5–6.

133. Rojina Thapa, *Waiver Solution in Public Health and Pharmaceutical Domain Under TRIPS Agreement*, 16 J. INTELL. PROP. RIGHTS 470, 472–73 (2011).

134. *Id.*

manufacture the drug, a number of notices from an exporting country, and a guarantee that the drug will be used for public health services.[135] The TRIPS/Health Solution does not provide instructions or standards as to what kind of evidence would satisfy such requirements.[136] For a nation facing a public health epidemic, the TRIPS/Health Solution is no solution at all.

The TPP's "benevolent proclamation" to prioritize partner nations' efforts to effectively deal with serious public health issues comes up empty. The affirmation, that the TPP "does not and should not prevent" access to medicines,[137] may set an unhealthy precedent. Larger drug-producing nations may use the TPP's inadequate efforts to uphold public health priorities as an acceptable standard in future free trade agreements while piling increasingly aggressive intellectual property protections after them. Since so much of the TPP's intellectual property chapter is an aggregate of TRIPS-plus standards, the outcome will likely be that drugs will become less available and priced higher. The TPP seems to define this standard—of only superficially honoring a country's ability to utilize TRIPS flexibilities—as being TRIPS compliant, even under the Doha Declaration's clarifying language. The provision, however, restricts the express language in the Doha Declaration that the TRIPS flexibilities can and should be fully used.[138] The TPP's silence speaks volumes about the agreement's unwillingness to balance conflicting interests.

C. CHAGAS DISEASE AND CHRONIC ILLNESS

Instead of mirroring the balance the TRIPS Agreement strives for,[139] the TPP implicitly limits its language suggesting that the TRIPS and Doha Declaration flexibilities are available only for the diseases and conditions enumerated in the

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135. *Id.*

136. *E.g.*, *id.*

137. LEAKED IP CHAPTER, *supra* note 123, at art. QQ.A.5(b).

138. Doha Declaration, *supra* note 72, at para. 4–5; *see also* LEAKED IP CHAPTER, *supra* note 123, at art. QQ.A.3 (granting nations the ability to provide more extensive IP protections than required under TPP, which may inherently undermine TRIPS flexibilities).

139. TRIPS Agreement, *supra* note 11.

provision. [140] Article QQ.A.5(a) goes on to state, "[t]he obligations of this 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."[141]

The prevalence of noncommunicable disease is on the rise around the world.[142] "The global burden of disease is shifting from infectious diseases to noncommunicable diseases, with chronic conditions such as heart disease and stroke now being the chief causes of death globally." [143] This is particularly troublesome in low- and middle-income nations where the cost of medication to treat chronic disease, such as cancers, mental illness, and heart disease are far too expensive for individual patients, insurers, and governments. [144] The United States' history of trying to exclude noninfectious chronic illness from multinational trade agreements is exemplified in its efforts to ensure that they were not described as an epidemic or emergency at the U.N. High Level Meeting on Non-Communicable Diseases.[145]

Developing countries also face the persistent consequences of neglected tropical diseases where newer, and thus more expensive, treatments will be unaffordable to those most in

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140. *See* LEAKED IP CHAPTER, *supra* note 123, at art. QQ.A.5(a).

141. *Id.*

142. *See* WORLD HEALTH ORG., CHRONIC DISEASES IN LOW AND MIDDLE INCOME COUNTRIES (2005), *available at* http://www.who.int/chp/chronic_disease_report/media/Factsheet3.pdf.

143. Press Release, World Health Org., Noncommunicable Diseases Now Biggest Killers (May 19, 2008), *available at* http://www.who.int/mediacentre/news/releases/2008/pr14/en/.

144. *See* Dele O. Abegunde et al., *The Burden and Costs of Chronic Diseases in Low-Income and Middle-Income Countries*, 370 LANCET 1929, 1936 (2007), *available at* http://www.who.int/choice/publications/p_2007_Chronic_disease_burden_Lancet.pdf.

145. William New, *Questions Arise Over UN Policy on NonCommunicable Diseases and IP Rights*, INTELL. PROP. WATCH (Sept. 16, 2011), http://www.ip-watch.org/2011/09/16/questions-arise-over-un-policy-on-non-communicable-diseases-and-ip-rights/. These efforts were ultimately successful, though there were two references to countries' need to use intellectual property flexibilities to access medicines. G.A. Res. 66/117, U.N. Doc. A/RES/66/L.1 (Sept. 16, 2011), *available at* http://www.un.org/ga/search/view_doc.asp?symbol=A/66/L.1.

need.[146] For example, the United States opposes adding Chagas disease to the list of illnesses the TPP deems to qualify for the use of TRIPS flexibilities.[147]

> Chagas disease is a deadly infection caused by the protozoan parasite *Trypanosoma cruzi*. Afflicting approximately 8 million people in Latin America, Chagas disease is now becoming a serious global health problem proliferating beyond the traditional geographical borders, mainly because of human and vector migration. The chronic form remains incurable, there are no vaccines, and 2 existing drugs for the acute form are toxic and have low efficacy.[148]

Those drugs also cost upward of $11,000, making them unaffordable for most.[149]

Recently, Vanderbilt University and Meharry Medical College reported "curing both the acute and chronic forms of the [Chagas] infection in mice with a small molecule, [called] VNI."[150] In mice with Chagas disease, "VNI achieved cures with 100 percent survival and without toxic side effects."[151] The success of this study has opened a major door for significant research and development that will likely lead to lucrative patentability in the near future. The United States has explicitly opposed adding Chagas to the TPP's list of diseases that will grant nations the ability to circumvent certain patent protections for the sake of public health.[152] A country trying to use a compulsory license for Chagas treatment will have to rely on the "other epidemic" language from QQ.A.5(a), which will be much more difficult because of the procedurally tedious nature of the TRIPS/Health Solution.[153] Considering approximately 600 U.S. corporate advisors have negotiating power and the

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146. *See infra* notes 147–54 and accompanying text.

147. LEAKED IP CHAPTER, *supra* note 123, at art. QQ.A.5(a).

148. Fernando Villalta et al., *VNI Cures the Acute and Chronic Experimental Chagas Disease*, 208 J. INFECTIOUS DISEASES 504, 504 (2013).

149. Katie Moisse, *Chagas the New AIDS? Experts Disagree*, ABC NEWS (June 1, 2012, 3:41 PM), http://abcnews.go.com/blogs/health/2012/06/01/chagas-the-new-aids-experts-disagree/.

150. Bill Snyder, *Cure in Sight for Kissing Bug's Bite*, RES. NEWS @ VAND. (Feb. 15, 2013, 8:00 AM), http://news.vanderbilt.edu/2013/02/chagas-cure-kissing-bug/.

151. *Id.*

152. *See* LEAKED IP CHAPTER, *supra* note 123, at art. QQ.A.5(a) (noting explicit U.S. opposition to adding Chagas disease to QQ.A.5).

153. *Id.*; *see also* discussion *supra* Part II.B.

ability to amend proposals that suit their interest,[154] it is possible that industry lobbying groups such as PhRMA see this as an opportunity to lock Chagas out of such patent law circumvention. This could mean future medical developments, such as VNI, will be priced out of reach for most of the global population.

D. EXPANDING ON PATENT LINKAGE AND DATA EXCLUSIVITY

The TPP strives to expand on international patent protections in two major ways: through patent linkage and test data exclusivity provisions.[155] Article QQ.E.17 lays out measures that relate to certain regulated products, particularly the United States' proposals for data exclusivity and patent registration linkage.[156] Patent linkage is the concept of linking marketing approval to patent status, thus giving patent holders a powerful method to block the entry of low-cost generic medicine.[157] Linkage is not mentioned in TRIPS and is also not required in most of the TPP negotiating countries,[158] however,

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154. *TPP Investment Text*, *supra* note 117; *see* Connor Adams Sheets, *New TPP Talks Decried As Most Secretive Discussions of Trans-Pacific Partnership to Date*, INT'L BUS. TIMES (Nov. 22, 2013, 3:22 PM), http://www.ibtimes.com/new-tpp-talks-decried-most-secretive-discussions-trans-pacific-partnership-date-1482970 ("The only thing about the TPP that's not a secret is who it stands to benefit: big corporations.").

155. *See infra* notes 156–67 and accompanying text.

156. LEAKED IP CHAPTER, *supra* note 123, at art. QQ.E.17.

157. Ravikant Bhardwaj et al., *The Impact of Patent Linkage on Marketing of Generic Drugs*, 18 J. INTELL. PROP. RTS. 316, 316 (2013).

158. *See* BURCU KILIÇ & PETER MAYBARDUK, PUB. CITIZEN, DANGERS FOR ACCESS TO MEDICINES IN THE TRANS-PACIFIC PARTNERSHIP AGREEMENT: COMPARATIVE ANALYSIS OF THE UNITED STATES' TPFTA INTELLECTUAL PROPERTY PROPOSAL AND VIETNAMESE LAW (2011), *available at* http://www.citizen.org/documents/Comparative-Analysis-of-the-US-TPFTA-IP-Proposal-and-Vietnamese-Law.pdf (explaining that "Vietnamese law contains no provision that links the patent system to the [drug] marketing approval process" and that many U.S. free trade agreements require patent linkage, which shifts burdens of early patent enforcement to drug regulatory authorities); *see also* BURCU KILIÇ & PETER MAYBARDUK, PUB. CITIZEN, DANGERS FOR ACCESS TO MEDICINES IN THE TRANS-PACIFIC PARTNERSHIP AGREEMENT: COMPARATIVE ANALYSIS OF THE U.S. INTELLECTUAL PROPERTY PROPOSAL AND AUSTRALIAN LAW (2011), *available at* http://www.citizen.org/documents/Australia-TPPA-chart.pdf (explaining that although "AUSFTA introduced patent linkage in Australia," Australia sought to limit its effect through statutory measures imposing penalties for linkage evergreening and thus, the U.S. Trade Representative attacked these

the United States has incorporated it into many of its free trade agreements.[159] Under patent linkage rules a partner nation's regulatory authority is required to deny marketing approval to a generic drug if there is an active patent term for the original formula.[160] The only way around this presumptive denial is if the pioneer inventor consents to such approval.[161] The TPP will allow a company that is in the process of filing a patent claim to prohibit the regulatory approval of a competitor without seeking a private enforcement action and without having to address the validity of its proposed patent claim.[162] The likely result of such a provision will be an incentive for pharmaceutical companies to file frivolous patent claims as a means to delay marketing approval for the competition. Generic manufacturers will have to wait out a pharmaceutical company's tactics used to delay regulatory review, which could take years.[163] Adding the cost of litigation and delays that result from an unconscionable use of the patent system by original patent holders is likely to deter many generic manufacturers attempting to enter markets with smaller populations.

Before TRIPS, most countries allowed what is known as originator test data, meaning clinical testing data submitted by pioneer inventors could also be used to demonstrate the efficacy and safety of a generic drug as long as the generic in question was chemically identical or bioequivalent.[164] The prior lack of data exclusivity allowed rapid introduction of generics into the

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safeguards and therefore, the TPP proposal raises a serious concern that the United States may seek to limit or eliminate Australian safeguards); BURCU KILIÇ & PETER MAYBARDUK, PUB. CITIZEN, DANGERS FOR ACCESS TO MEDICINES IN THE TRANS-PACIFIC PARTNERSHIP AGREEMENT: COMPARATIVE ANALYSIS OF THE U.S. INTELLECTUAL PROPERTY PROPOSAL AND MALAYSIAN LAW (2011), *available at* http://www.citizen.org/documents/malaysia-chart.pdf ("The Malaysian law contains no provision that links the patent system to marketing approval process.").

159. *E.g.*, United States-Korea Free Trade Agreement, U.S.-S. Kor., June 30, 2007, 125 Stat. 428, at art. 18:9(5), *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text.

160. Bhardwaj et al., *supra* note 157, at 316–18.

161. Sell, *supra* note 99, at 454.

162. *Id*. at 453–54.

163. *Id.*

164. *WTO and the TRIPS Agreement*, *supra* note 41.

market without the need for separate, and costly, test data.[165] Data exclusivity standards have posed an obstacle for flexibilities such as compulsory licenses because of the extra time generic approvals now require.[166] TRIPS itself only precludes reliance on undisclosed test data in the regulatory approval process.[167]

Facially, the TPP offers a generic provision with respect to the utilization of data for regulatory approval,[168] and even includes a boilerplate exception to "protect the public."[169] However, the TPP provides absolutely no means for the actual use of data to protect the public.[170] TRIPS also failed to identify such means of action,[171] rendering the data exclusivity exception ultimately useless. Data exclusivity provisions are intended to force generic producers to develop their own clinical test data.[172] This practice is not only a waste of time and resources, but it will also increase the price of generic medicines because of the time and money generic producers will need to spend on duplicative clinical trials and bench testing.[173] Additionally, as intellectual property law Professor Jerome Reichman explains, restricting the submission of clinical trial data "could effectively empower rights holders to negate a state's ability to authorize marketing approval of equivalent drugs, for a period from five to ten years."[174]

Like other sections of the TPP,[175] the data exclusivity provision restates that "each Party may take measures to

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165. *Id.*

166. *Id.*

167. WORLD HEALTH ORG. ET AL., *supra* note 59, at 65.

168. LEAKED IP CHAPTER, *supra* note 123, at art. QQ.E.XX.4.

169. *Id.* at art. QQ.E.XX.4(1).

170. *See id.* at art. QQ.E.XX.4(3) (stating only that nations may take "measures to protect public health in accordance" with the Doha Declaration, TRIPS waivers, and amendments to TRIPS itself).

171. *Id.*

172. Sell, *supra* note 99, at 453.

173. JEROME H. REICHMAN, UNDISCLOSED CLINICAL TRIAL DATA UNDER THE TRIPS AGREEMENT AND ITS PROGENY: A BROADER PERSPECTIVE 2–3 (2004), *available at* http://www.iprsonline.org/unctadictsd/bellagio/docs/Reichman_Bellagio4.pdf.

174. *Id.* at 2.

175. LEAKED IP CHAPTER, *supra* note 123, at art. QQ.A.5, QQ.E.16, QQ.E.XX.4.

protect public health in accordance" with the Doha Declaration and current waivers, including the TRIPS/Health solution.[176] This standard text fails to identify concrete ways governments can override such mandates in order to allow generic medicines to market more swiftly.[177] The TPP should include language either ensuring rights to gain market approval when a compulsory or government use license is issued or the provision should include an explicit exception to the data exclusivity and patent linkage standard, thus giving generic manufacturers a way to enter the market as soon as the original patent holder's rights expire.[178]

Such exceptions are not out of the ordinary. In fact, the New Trade Policy of 2007 led to revisions of the United States' free trade agreements with Panama, Peru, and Columbia.[179] These revisions gave explicit guidance on how to operationalize a public health exception to data exclusivity and patent linkage rules.[180] According to a Doctors Without Borders Issue Brief:

> The agreement specifies that the USTR [United States Trade Representative] should modify its intellectual property demands in trade agreement negotiations so that important public health safeguards are included. Yet in several meetings with U.S. civil

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176. *Id*. at art. QQ.E.XX.4(3).

177. *See supra* notes 170–71 and accompanying text.

178. *See generally* Brook K. Baker, *Leaked TPP Investment Chapter Presents a Grave Threat to Access to Medicines*, HEALTH GAP GLOBAL ACCESS PROJECT (Aug. 14, 2012), http://infojustice.org/wp-content/uploads/2012/09/Baker-Investment-in-the-TPP.pdf (discussing "four main dangers" present in the current version of the TPP's IP chapter); Mike Palmedo, *AARP to Obama Administration: Trans Pacific Partnership Should Not Require 12 Years of Data Exclusivity for Biologic Drugs*, INFOJUSTICE (Oct. 24, 2013), http://infojustice.org/archives/31052 (summarizing the AARP's opposition to the TPP's data exclusivity provisions).

179. *See* Christoph Spennemann, Legal Expert, Intellectual Prop. Unit Div. on Inv. & Enter., Address at the 2008 United Nations Conference on Trade and Development: Protection of Pharmaceutical Test Data Under TRIPS and FTAs (Apr. 2008), *available at* http://www.ictsd.org/downloads/2010/01/test-data-under-trips-and-ftas-rev.pdf (providing that linkage is optional). *See generally* MÉDECINS SANS FRONTIERES, HOW THE TRANS-PACIFIC PARTNERSHIP AGREEMENT THREATENS ACCESS TO MEDICINES (2011), *available at* http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Briefing_TPP_ENG_2011.pdf (discussing the 2007 New Trade Policy as a bipartisan U.S. Congressional agreement, signed by the Bush Administration to "scale-back the harshest IP protections in order to strike a better balance between protection of IP and public health needs").

180. *See* MÉDECINS SANS FRONTIERES, *supra* note 179.

> society, the USTR has stated on the record that they are considering options in the TPP that would shift U.S. policy away from the 2007 New Trade Policy.[181]

Patent linkage and data exclusivity provisions will likely result in needless replication of data. These provisions also allow the pharmaceutical industry to use unconscionable tactics to keep generic competitors out of the market, even after the preliminary patent term expires, all while governments with populations in need of a cheaper alternative to pioneer drugs have to wait for new test data to be developed.[182] This could ultimately result in a reduction of competition and continued limited access.

E. DEFINING PATENTABILITY CRITERIA

The TPP also attempts to take away a member nation's ability to determine its own standards for patentability, which is an express right afforded to TRIPS member nations.[183] Perhaps the most disconcerting component of the TPP's intellectual property chapter is article QQ.E.1(1)(b) which states, "a Party may not deny a patent solely on the basis that the product did not result in enhanced efficacy of the known product when the applicant has set forth distinguishing features establishing that the invention is new, involves an inventive step, and is capable of industrial application."[184] This particular provision of the TPP is proposed only by the United States and Japan, with every other member nation opposed.[185] Lowering patentability standards too much tends to restrict innovation.[186] Advocates for access to medicine argue that it allows pharmaceutical companies to delay generic entry

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181. *Id.*

182. Carlos María Correa, *Implications of Bilateral Free Trade Agreements on Access to Medicines*, 84 BULL. WORLD HEALTH ORG. 399, 401 (2006).

183. TRIPS Agreement, *supra* note 11, at art. 1 ("Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.").

184. LEAKED IP CHAPTER, *supra* note 123, at art. QQ.E.1(1)(b).

185. *Id.*

186. *See* Parker Higgins & Maira Sutton, *TPP Leak Confirms the Worst: US Negotiators Still Trying to Trade Away Internet Freedoms*, ELECTRONIC FRONTIER FOUND. (Nov. 13, 2013), https://www.eff.org/deeplinks/2013/11/tpp-leak-confirms-worst-us-negotiators-still-trying-trade-away-internet-freedoms.

through what is known as "evergreening."[187] This deceptive industry technique is the practice of making minor, often arbitrary, modifications to a drug and seeking patent protection for the article, regardless of whether they offer any therapeutic efficacy for patients.[188] It allows pharmaceutical companies to extend their monopoly protection for old drugs by making small changes to existing formulas.[189] This abuse of the patent system directly slows the ability of generic manufacturers to get their products to market.[190] TRIPS does not require patent protection of new uses, or new forms of known substances.[191] Additionally, under TRIPS, countries have sufficient leeway to define patentability criteria; for example, to only grant patents for truly innovative products and to exclude certain products from patentability altogether.[192] The patentability standards in the TPP are directly contradictory to TRIPS, which allows countries to set their own standards.[193] The U.S. proposal, that efficacy need not be shown for the grant of a patent, directly contradicts a country's right to determine what passes patentable muster.[194] This provision of the TPP essentially gives pharmaceutical companies the advantage of capitalizing on old formulas while locking generic formulas out of the market entirely.

The United States further proposes that patents should be made available for inventions of biological products made from plants and animals as well as diagnostic and surgical methods.[195] Article 27 of TRIPS explicitly states, "[m]embers

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187. WORLD HEALTH ORG. ET AL., *supra* note 59, at 131.

188. COMMISSION REPORT ON IP RIGHTS, *supra* note 102, at 131–32.

189. WORLD HEALTH ORG. ET AL., *supra* note 59, at 131.

190. MÉDECINS SANS FRONTIERES, *supra* note 179.

191. WORLD HEALTH ORG. ET AL., *supra* note 59, at 131–32. *See generally* TRIPS Agreement, *supra* note 11 (providing no such provisions throughout the agreement).

192. *See* Roger Kampf, Counsellor, World Trade Org. Secretariat, Address at the World Intellectual Property Organization Regional Seminar for Certain Latin American and Caribbean Countries on the Implementation and Use of Several Patent Related-Flexibilities: Patent-Related Flexibilities in the TRIPS Agreement (Feb. 2012), *available at* http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_bog_12/wipo_ip_bog_12_ref_t6_kampf.pdf.

193. *See supra* notes 183–92 and accompanying text.

194. LEAKED IP CHAPTER, *supra* note 123, at art. QQ.E.1(1)(b).

195. *Id*. at art. QQ.E.1(3)(a)–(c).

may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."[196] A number of multilateral and bilateral free trade agreements, including the North American Free Trade Agreement, reinforce article 27 of TRIPS.[197] In fact, the only countries where patenting a medical procedure is legal is the United States and Australia.[198] Over eighty nations have banned the practice of patenting medical procedures, diagnostic methods, and surgical methods.[199]

Since the TPP's intellectual property chapter dictates that nations party to the TPP should make patents available for such medical procedures, diagnostic methods, and surgical methods there is an inherent conflict between rights guaranteed by TRIPS.[200] The World Medical Association came out against the proposition of forcing countries to allow patenting diagnostic and surgical methods, stating, "patenting of medical procedures poses serious risks to the effective practice of medicine by potentially limiting the availability of new procedures to patients . . . . [P]atenting of medical procedures is unethical and contrary to the values of the medical profession."[201] Similarly, the American Academy of Orthopedic Surgeons has also opposed the practice, stating that "[t]he granting of Medical Procedure Patents may pose a serious threat to medical advancement, medical education, and patient care, as well as contribute to the spiraling costs of

196. TRIPS Agreement, *supra* note 11, at art. 27.3(a)–(b).

197. *E.g.*, North American Free Trade Agreement art. 1709(3)(a), Dec. 17, 1992, 32 I.L.M. 605, at 673; United States-Colombia Free Trade Agreement, U.S.-Colom., art.16.9(2), Nov. 22, 2006, *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/colombia-fta/final-text.

198. Priyanka Rastogi, *World Wide Legal Status of Medical Method Patents: An Overview*, MONDAQ, http://www.mondaq.com/india/x/311404/Patent/World+Wide+Legal+Status+Of+Medical+Method+Patents+An+Overview (last updated May 6, 2014).

199. *Id.*; *see* WORLD MED. ASS'N, STATEMENT ON PATENTING MEDICAL PROCEDURES 1 (2009), *available at* http://www.wma.net/en/30publications/10policies/m30/ ("Over 80 countries prohibit medical procedure patents.").

200. *See supra* notes 195–99 and accompanying text.

201. WORLD MED. ASS'N, *supra* note 199, at 4.

health care."[202] Allowing patents for diagnostic and surgical methods will increase the cost of medical practice, apart from the price of medicine.[203] This provision would also rob a country of its right to dictate what is best for its own national policy. The United States is the only negotiating country in support of this provision; every other party is opposed.[204] The TPP's plan to lower patentability criteria to such a degree will be very damaging to the practice of medicine and the availability of generic medical alternatives.

III. BEFORE IT IS TOO LATE . . .

There is little doubt that the TPP, once effective, will have a resounding impact on the global economy. As discussed, the TPP's intellectual property chapter contains numerous aggressive provisions that do a severe disservice to millions of people whose voices are not represented in the negotiations.[205] The TPP's proposed data exclusivity rule, promotion of patent-linkage, lower patentability standards, lack of focus on chronic illness, as well as its decision not to balance public health interests with its aggressive intellectual property agenda make the proposed trade deal a divisive one.

Trade negotiations involving public health must include at least some degree of transparency. The TPP should allow for meaningful congressional and public scrutiny and allow access to negotiation texts. Negotiators should strongly pursue an agreement that does not call for such an array of extreme TRIPS-plus provisions. Above all else, it is imperative for negotiating countries to use the TPP as an opportunity to renew a global commitment toward improving access to affordable medication. Ensuring the final text is aligned with the global public health priorities made in the 2001 WTO Doha Declaration on TRIPS and Public Health is a critical step toward equity in the TPP.

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202. AM. ACAD. OF ORTHOPAEDIC SURGEONS, OPINIONS ON ETHICS AND PROFESSIONALISM: MEDICAL AND SURGICAL PROCEDURE PATENTS (2009), *available at* http://www.aaos.org/about/papers/ethics/1209eth.asp.

203. *See generally id*. (highlighting the potential for such patents to impede the ability of medical providers in the orthopaedic context to assure "the highest quality and most cost-effective musculoskeletal health care").

204. LEAKED IP CHAPTER, *supra* note 123, at art. QQ.E.1(3).

205. *See supra* Part II.

Thirteen years ago the international community, including the United States, vowed to address the growing injustice many face around the world. This promise is embodied in numerous human rights declarations as well as TRIPS and the Doha Declaration. The TRIPS legacy is littered with complexities and tedious restrictions making access to affordable medicine a continuing global problem. The TPP is not just another empty gesture; it is a blatant and shameful attempt to place intellectual property rights above human rights. If the TPP goes ahead as is, it will set a precedent we, as global citizens, cannot afford to support.