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Forward:

As a student in the Joint Degree Program at the University of Minnesota, pursuing both a Law Degree and Masters in Public Health Administration and Policy, I am very passionate about working to address barriers that prevent individuals from accessing medical treatment. This is a cause I plan to fight for long after I graduate. I am eager to have the opportunity to submit my Note, entitled "A Public Health Imperative: The Need For Meaningful Change in the Trans–Pacific Partnership's Intellectual Property Chapter" to be considered for the MSBA's Student Writing Competition. I prepared this Note as part of my participation as a student editor for the Minnesota Journal of Law, Science and Technology (MJSLT). The research for the piece stems from work I did as the recipient of a grant from the Consortium on Law and Values in Health, Environment and the Life Sciences. My Note explores the adverse impact that aggressive intellectual property rights have on accessing essential medicines in developing nations. The Note was accepted for publication in Volume 16.1 of the Minnesota Journal of Law Science and Technology.

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

INTRODUCTION

Roma Patel

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 has been 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, only 51.8 percent of public and 68.5 percent of private health facilities in developing countries are able to provide patients with essential medicines.[3] Drugs of available essential medicines tend to be the multiple of international reference prices.[4] As a result, obtaining essential medicines, especially for treatment of chronic diseases, remains prohibitive for low–income families in developing nations.[5]

Improving access to essential medicines has the potential to save almost 10 million lives a year, with 4 million of those lives being in Africa and South-East Asia alone.[6] Better health is critical to happiness and well being, it also contributes to economic growth and progress.[7] A number of factors contribute to this massive inequity: weak infrastructure, broken health

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[1] Constitution of the World Health Organization, July 22, 1946, *available at* http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf.

[2] Lisa Forman, Gaby Gable & Benjamin Mason Meier, *Employing Human Rights to Develop and Implement the Framework Convention on Global Health*, 15 HEALTH & HUMAN RIGHTS: AN INT.J. 17, 17 (2013).

[3] Millennium Gap Development Task Force Report, *The Global Partnership for Development Making Rhetoric a Reality,* (2012) at 61

[4] *Id.*

[5] *Id.*

[6] Department for International Development U), Increasing Access to Essential Medicines in the Developing World: U.K. Government Policy and Plans (2004), at 8.

[7] *Health and Development*, WORLD HEALTH ORGANIZATION (2014), http://www.who.int/hdp/en/.

systems, health worker shortages, weak regulatory regimes, expensive and time consuming research and development, and markups throughout the distribution chain all lead to higher drug prices.[8] 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)[9]—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 of Intellectual Property Rights (widely known as TRIPS).[10] The TRIPS Agreement employs various provisions to ensure public health needs are addressed through international trade; these provisions are referred to as "flexibilities."[11] The past two decades have seen an increasing number of developing nations successfully utilize the flexibilities provided by TRIPS which aims to lower costs and increase access to medicine by facilitating importation of generic formulas.[12] 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.[13] An increasing number of bilateral and multilateral free trade agreements include intellectual property protections that greatly exceed the minimum standards of TRIPS, thus hindering the use of such

[8] Brook Baker, *Patents Pricing and Access to Medicines in Developing Countries*, 11 AM. MED. ASS'N J. OF ETHICS 527, 527 (2009).
[9] UNDP, The Potential Impact of Free Trade Agreements on Public Health, Issue Brief JC2349E (May 2012).
[10] *See* TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr.15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S.299, 33 I.L.M.1197 (1994).
[11] *Id.*
[12] *Id.* at 4.
[13] Pedro Roffe, *Impact of FTAs on Public Health and TRIPS Flexibilities*, 1 INT. J. INTELLECTUAL PROPERTY MANAGEMENT 75, 80 (2006).

flexibilities.[14]

The advent of the Trans-Pacific Partnership (TPP), a proposed trade agreement between twelve countries including the United States (U.S.), poses the most aggressive pharmaceutical intellectual property provisions to date.[15] 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 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[16] free trade agreement currently under negotiations between the United States and a number of nations in the Asia–Pacific.[17] It stems from earlier established trade negotiations between four nations: Brunei Darussalam, Chile, New Zealand and Singapore.[18] These four nations initially set out to establish a viable path to liberalize regional trade in the Asia–Pacific.[19] At various points the U.S., Australia, Peru, Canada, Mexico, Japan,

[14] Baker *supra* note 8, at 55.
[15] Medicines Sans Frontires, *How Does Evergreening Restrict Access to Medicines*, July 2012, *available at* http://aids2012.msf.org/2012/the-trans-pacific-partnership-agreement-evergreening/.
[16] A plurilateral agreement is a multi-national trade agreement among a limited number of countries. Michitaka Nakatomi, *Plurilateral Agreements: A Viable Alternative to the World Trade Organization?*, ADBI Working Paper 439. Tokyo: Asian Development Bank Institute, *available at* http://www.adbi.org/workingpaper/2013/10/24/5914.plurilateral.agreements.alternative.wto/.
[17] UNITED STATES TRADE REPRESENTATIVE, FAQ http://www.ustr.gov/sites/default/files/TPPFAQ.pdf.
[18] Meredith Kolsky Lewis, *The Trans Pacific Partnership: New Paradigm or Wolf in Sheep's Clothing?*, 34 B.C. INT'L &COMP.L.REV.27, 27 (2011).
[19] Ian Fergusson, et.al., CONG. RESEARCH SERV., R42694 ,THE TRANS PACIFIC PARTNERSHIP NEGOTIATIONS AND ISSUES FOR CONG.3 (2013).

Vietnam and Malaysia have joined the negotiations.[20] Some nations are committed parties to the TPP, while others, such as Taiwan, The Philippines and South Korea, have expressed interest in joining the negotiations.[21]

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.[22] For the U.S., the TPP offers a strong foothold in an increasingly important area of global commerce.[23] Additionally, the U.S. hopes more countries will join the TPP, increasing financial opportunities and access to an even larger market.[24] The TPP is established to be a living agreement, meaning membership can expand and covenants will adapt as issues emerge.[25]

Overall, the TPP aims to liberalize the economies of the Asia-Pacific through a comprehensive tariff reduction.[26] Its scope goes further by addressing issues related to market access, rules of origin, investment, financial services, intellectual property, agriculture, internet usage, competition, and the environment.[27] Member nations also discuss issues pertaining to market access packages for goods, services, temporary workers, customs and government procurement.[28]

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[20] T Rajamoorthy, The Origins and Evolution of the Trans-Pacific Partnership, CENTRE FOR GLOBALIZATION, (Nov. 10, 2013) http://www.globalresearch.ca/the-origins-and-evolution-of-the-trans-pacific-partnership-tpp/5357495.

[21] Joint Position Statement on TPP Negotiations (2013), *available at* http://www.gphaonline.org/media/cms/Joint_Position_Statement_on_the_Trans_Pacific_Partnership.pdf.

[22] N.Z. MINISTRY OF FOREIGN AFFAIRS & TRADE, The Trans-Pacific Strategic Economic Partnership Agreement 1, *available at* http:// www.mfat.govt.nz/downloads/trade-agreement/transpacific/transPac-Factsheet-2Mar09.pdf.

[23] *See* OFFICE OF U.S. TRADE REP., 2009 Trade Policy Agenda; EXEC. OFFICE OF THE PRESIDENT 2008 Annual Report of the President of the United States on the Trade Agreements Program, 123–24.

[24] *See* Rajamoorthy, *supra* note 20.

[25] AUS. DEPT. OF FOREIGN AFFAIRS AND TRADE, TRANS-PACIFIC PARTNERSHIP NEGOTIATIONS (2013) *available at* http://www.dfat.gov.au/fta/tpp/.

[26] *See* Fergusson, *supra* note 19 at Summary.

[27] FOREIGN AFFAIRS, TRADE AND DEVELOPMENT CANADA, Trans-Pacific Partnership Free Trade Agreement Negotiations (2013), available at http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/tpp-ptp/info.aspx?lang=eng

[28] *Id.*

The TPP concluded its most recent round of negotiations in February of 2014.[29] 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.[30] The TPP's proposed intellectual property provisions are significantly responsible for delays in reaching a consensus among parties.[31]

The TPP's intellectual property chapter, which was proposed by the U.S., is a major source of controversy, particularly its effects on pharmaceutical patents and digital innovation.[32] 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.[33] However, in May of 2012 Congressman Darrell Issa of California leaked the February and September 2011 drafts of the U.S.'s proposal for intellectual property protections.[34] Additionally, on November 11, 2013 Wikileaks founder Jullian Assange leaked the a draft of the TPP—right before chief negotiators met in Salt Lake City, Utah.[35]

TPP member nations agree to abide by the minimum standards established by TRIPS and also expand on those standards, greatly increasing patent protections.[36] The negotiations have covered trademark, geographical indication, copyright and related rights, patents, trade secrets,

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[29] UNITED STATES TRADE REPRESENTATIVE, Statement of the Ministers and Heads of Delegation for the Trans-Pacific Partnership Countries (Feb. 25, 2014), *available at* http://www.ustr.gov/about-us/press-office/press-releases/2014/February/Statement-of-Ministers-and-Heads-of-Delegation-for-TPP-countries.
[30] Shawn Donnan, *TPP leaders say 'significant progress'* made, FINANCIAL TIMES, Oct.8, 2013, http://www.ft.com/cms/s/0/fdfe4b36-2fe5-11e3-9eec-00144feab7de.html#axzz2ixpGnIL3.
[31] Henry Farrell, *The TPP is not an Agreement Among Like-Minded Countries*, WASHINGTON 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/.
[32] Carolina Rossini & Maira Sutton, *What is Wrong with the Trans–Pacific Partnership*, ELECTRONIC FRONTIER FOUNDATION, Aug. 21, 2012, https://www.eff.org/deeplinks/2012/08/whats-wrong-tpp.
[33] *Id.*
[34] Press Release, Public Citizen, Public Interest Analysis of Leaked Trans-Pacific Partnership (TPP) Investment Text (June 13, 2012) (on file with author) *available at* http://www.citizen.org/documents/Leaked-TPP-Investment-Analysis.pdf.
[35] Press Release, Wikileaks, Secret TPP treaty: Advanced Intellectual Property chapter for all 12 nations with negotiating positions (2013), *available at* http://www.wikileaks.org/tpp/#start.
[36] UNITED STATES TRADE REPRESENTATIVE, Outlines of the Trans-Pacific Partnership Agreement (2011) *available at* http://www.ustr.gov/about-us/press-office/fact-sheets/2011/november/outlines-trans-pacific-partnership-agreement.

genetic resources, and traditional knowledge.[37] Statements from U.S. officials seem to indicate that the TPP is intended to set a precedent for future trade agreements and practices.[38]

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.[39] The TRIPS Agreement introduced intellectual property law standards into the global trading system in 1996.[40] TRIPS requires member nations to abide by minimum standards for the protection and enforcement of nearly all forms of intellectual property rights, patents, copyrights, trade secrets, including those applicable to pharmaceuticals.[41] 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. 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.

TRIPS's scope covers general principles, standards for the use of patents, intellectual property enforcement, dispute settlement and other subjects.[42] Under its key provision, WTO member nations must protect patents for a minimum of 20 years from the filing date of the patent application for any product, invention or process that fulfills the criteria of novelty, inventive

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[37] *Id.*
[38] *Trans Pacific Partnership Agreement: Challenges and Potential: hearing Before the Subcomm. on Terrorism, Nonproliferation and Trade and Subcomm. on Asia Pacific on the Comm. of Foreign Affairs of the U.S.H.R.,* (2012) (testimony of Susan Schwab, former U.S. Trade Rep.), *available at* http://archives.republicans.foreignaffairs.house.gov/112/HHRG-112-FA18-WState-SchwabS-20120517.pdf.
[39] *The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation*, SOUTH CENTRE, Policy Brief 7, Nov. 1, 2011.
[40] *Id.*
[41] *See generally* TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr.15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S.299, 33 I.L.M.1197 (1994) [hereinafter TRIPS Agreement].
[42] *Id.*

step and usefulness.[43] Before TRIPS, the duration for such protection was significantly shorter– around 16 years.[44] Certain developing countries granted patents for even shorter terms, 5 to 7 years.[45] TRIPS also standardizes the absolute protection of a product rather than protecting only a process.[46] Process patents would protect respective technology and the process or manufacturing method.[47] Such patent protection does not prevent skilled manufacturers from reverse engineering medicine and marketing it.[48]

Prior to patent rule pluralism, countries routinely discriminated between fields of invention, for example excluding medicine patents—giving national policymakers more control over drug prices rather than market forces.[49] TRIPS expressly outlaws such discrimination.[50] Additionally, it is no longer permissible to discriminate against importation in favor of local products.[51] This allows pharmaceutical companies to control the place of production.[52] Pharmaceutical producers have consolidated their monopoly power internationally. TRIPS gives them exclusive rights to exclude others from "making, using, offering for sale, selling, or importing" patented pharmaceutical products or "products made with a patented process."[53] Patent exclusions often raise monopoly prices. Typically, the profit-maximizing strategy for drug companies is to sell medicines at high prices, and thus only to the rich, even if the price-points exclude the vast majority of a developing country's population.[54]

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[43] *Id.* at Art.33 and 27.1.
[44] WORLD HEALTH ORGANIZATION, *WTO and the TRIPS Agreement,* 2013, at *http*://www.who.int/medicines/areas/policy/wto_trips/en/.
[45] *Id.*
[46] TRIPS Agreement, supra note 41 at Art.27.1.
[47] TRIPS Agreement, supra note 41 at Art.27.1.
[48] TRIPS Agreement, *supra* note 41 at Art.27.1
[49] Baker, *supra* note 8 at 529.
[50] TRIPS Agreement, supra note 41 at Art.27.
[51] TRIPS Agreement, *supra* note 41 at Art.27
[52] Brook Baker, *Patents Pricing and Access to Medicines in Developing Countries*, 11 AM. MED. ASS'N J. OF ETHICS 527, 527 (2009).
[53] *Id.*
[54] *Id.*

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.[55] TRIPS instituted an undisclosed data protection standard.[56] 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.[57] TRIPS provides an exception to its test data protection when the use of such data would protect the public.[58]

In order to balance the rights of pharmaceutical patent holders with international public health needs TRIPS offers flexibilities to countries, helping safeguard access to medicines. Nations are permitted to apply their own rigorous patentability standards such as degree of novelty or inventive step.[59] TRIPS compliant nations are also allowed to issue compulsory licenses[60]which permits a government to allow the sale and manufacture of patented medicine, without the patent holder's consent.[61] Compulsory licensing and government use are subject to a number of conditions aimed at protecting patent holder interests.[62] 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. If this attempt is not successful, then the country can seek a compulsory license.[63] If a compulsory

[55] WORLD TRADE ORGANIZATION, *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health Intellectual Property and Trade*, (2013), WTO, 65.
[56] TRIPS Agreement, *supra* note 41 at Art. 39.3 (stating that WTO members must protect undisclosed test data on pharmaceutical products against unfair competition).

[57] Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, THE SOUTH CENTRE, *available at* http://www.who.int/medicines/areas/policy/protection_of_data.pdf
[58] WORLD TRADE ORGANIZATION, *supra* note 55 at 64.
[59] TRIPS Agreement, supra note 41 at Art.27.
[60] TRIPS Agreement, *supra* note 41 at Art.31.
[61] *Id.*
[62] *Id.*
[63] *Id.*at Art.31 b.

license is granted, appropriate remuneration must be paid to the patent holder.[64] 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.[65] In situations of national emergency or other circumstances of extreme urgency, the right holder must still be notified as soon as reasonably practicable.[66]

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.[67] This is a key provision as it allows nations in need to take advantage of pharmaceutical pricing differentials. Parallel importation operates under the legal principle that the original patent rights are exhausted once a batch of drugs is initially sold.[68] 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. The parallel importation flexibility allows nations to comparison shop for a brand-name medicine if it was sold elsewhere at a lower price.

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 Heath in 2001—a statement that aims to clarify the scope of TRIPS.[69] The Doha Declaration provides articles

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[64] *Id.*
[65] TRIPS Agreement, supra note 41 at Art.31 (b).
[66] *Id.*at Art.31 h.
[67] World Trade Organization, Ministerial Declaration of 14 November 2001, WT.MIN(01)/DEC/1.41.I.L.M.746 (2002) [hereinafter Doha Declaration] at Art. 6 and para.5d.
[68] *Id.*
[69] *Id.*

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.[70] The Doha Declaration clarifies that this means member nations can choose how to deal with drug patent terms in a way that best fits their domestic policy objectives.[71]

The Doha Declaration provides that TRIPS does not and should not prevent members from taking measures to protect public health.[72] It underscores a country's ability to utilize the flexibilities that are built into TRIPS, including compulsory licensing and parallel importation. 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. 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.[73]

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 are required by the TRIPS Agreement–these are known as 'TRIPS plus' provisions.[74] Countries are by no means obligated by international law to do this, but many, such as Brazil,

[70] *Id.*at para.17
[71] World Trade Organization, Ministerial Declaration of 14 November 2001, WT.MIN(01)/DEC/1.41.I.L.M.746 (2002) [hereinafter Doha Declaration] at para.5d.
[72] *Id.*
[73] *Id.*at para. 5c.
[74] UNDP, *supra* note 9 at 7.

China and several Central American states have had no choice but to adopt these, as part of trade agreements with the U.S. and the European Union. Trade agreements heavily filled with TRIPS-Plus provisions have a fairly adverse impact on access to medicines.[75]

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."[76] 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.

The U.S. 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 for attempting to utilize the flexibilities guaranteed by the Agreement to access more affordable medicines.[77] This retaliation, taking the form of withdrawing special zero-tariff trade access or pulling U.S. foreign investment, continues even after the U.S. signed the Doha Declaration on the TRIPS Agreement and Public Heath.[78]

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 use

[75] *See generally* Medcines Sans Frontires *available at* http://www.msfaccess.org/content/trips-trips-plus-and-doha.
[76] El Said, Mohammed K., *Public health related TRIPS-plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiators and Implementers in the Eastern Mediterranean Region,* WORLD HEALTH ORGANIZATION: REGIONAL OFFICE FOR THE EASTERN MEDITERRANEAN at 92.
[77] 't Hoen E.TRIPS, *Pharmaceutical Patents, and Access to Essential Medicines: a Long way from Seattle to Doha,* 3(1) CHIC J.INT.LAW.27-46 (2002).
[78] *Id.*

existing inventions and creations.[79] TRIPS's flexibilities allow governments to fine-tune the protection granted in order to meet social goals. For patents, it allows governments to make exceptions to patent holders' rights in the case of national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled.[80]

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.[81] A United Nations' Development Program study conducted in 2007 found that only six countries have a provision on the international exhaustion of rights in their legislation[82] Findings from a recent study conducted by the World Intellectual Property Organization (WIPO), within the framework of the implementation of the WIPO Development Agenda, showed a diverse picture regarding to the incorporation of TRIPS flexibilities in national patent laws.[83]

Past TRIPS-Plus provisions that may adversely impact public health or hamper the use of TRIPS flexibilities include: limiting the grounds and conditions under which compulsory licenses may be issued; providing for the possibility extending patent terms beyond the 20 years in order to compensate for delays in the patent granting procedure or in marketing approval processes; requiring drug regulatory authorities, most of which have limited expertise in patents, to consider the patent status of medicines before granting marketing authorizations to generic manufacturers; requiring strict test data protection that restricts drug regulatory authorities from

[79] Doha Declaration, *supra* note 71 at para.1.
[80] *Supra* discussion of parallel importation and condition of compliance.
[81] TRIPS Agreement, supra note 41 at Art.8(1).
[82] UNDP, *supra* note 9.
[83] WORLD INTELLECTUAL PROPERTY ORGANIZATION, *Patent Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels*. (2010) CDIP/5/4. Geneva, WIPO http://www.wipo.int/meetings/en/details.jsp?meeting_id=19686.

using clinical test data on pharmaceutical products in order to approve generic medicines for a certain period of time.[84] This prevents generic companies from relying on such data for proving the efficacy and safety of their products and thus delays the entry of cheaper alternatives on to the market; limiting the grounds of patent revocation; requiring countries to loosen the criteria for patentability and to expand the scope of protection by allowing patenting of new uses or methods of using a known product; allowing patent-holders to restrict parallel imports, which may prevent developing countries from buying medicines from the cheapest global supplier.[85] The aggregate effect of these barriers essentially eviscerates a TRIPS-compliant nation's opportunity to offer its consumers accessible and affordable drugs. This is particularly harmful for cases involving patented second-line HIV/AIDS drugs for which generics are not available.[86]

Patents should be of the highest quality and should reward only genuine innovations in order to prevent the so-called "evergreening" of patents. 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."[87] Providing for public health sensitive patent examination guidelines[88] as well as pre- or post-grant opposition procedures can help to prevent the patenting of products and processes that lack innovation.

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[84]UNAIDS, *Using TRIPS Flexibilities to Improve Access to HIV Treatment: Policy Brief, available at* http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf.

[85] In December 2009 the UNITAID board approved the establishment of a voluntary patent pool for antiretroviral drugs. A dedicated Medicines Patent Pool Foundation under Swiss law has recently been established. *See* http://www.medicinespatentpool.org.

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

[87] WORLD HEALTH ORGANIZATION, Rep. of the Comm. on Intellectual Property Rights, Innovation and Public Health (2006) 131.Geneva, WHO. http://www.who.int/intellectualproperty/report/en/index.html.

[88] Correa, *supra* 57.

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.[89] This failure is exemplified by the lack of guidance for developing nations to operationalize the flexibilities clarified by the Doha Declaration.

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.[90] The document reflects deep divisions between the U.S.'s aggressive stance and most other negotiating parties positions on intellectual property rights and pharmaceuticals.[91] The commentary also iterates that the U.S. Chief Negotiators continue to put great pressure on opposing nations.[92] 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 regards to pharmaceutical patents, has caused a great deal of controversy among public interest groups around the world.[93] The TPP's intellectual property controversy is significant due to the historical complexities surrounding access to affordable medicines in developing nations.[94] Senator Ron Wyden, Chair of the Congressional Committee with jurisdiction over TPP who was also denied access to the negotiation texts said, "the majority of Congress is being kept in the

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[89] Erik Alsegård, *Global Pharmaceutical Patents After the Doha Declaration–What Lies in the Future*, 1 SCRIPT-ED 12,19 (2004).
[90] Press Release, Wikileaks, Second release of secret Trans-Pacific Partnership Agreement documents (2013) *available at http://wikileaks.org/Second-release-of-secret-Trans.html*.
[91] Wikileaks Status Report, Tans–Pacific Partnership Salt Lake City Extracts (Dec. 09, 2013), http://wikileaks.org/IMG/pdf/tpp-salt-lake-extracts-.pdf.
[92] *Id.* at 1.
[93] Press Release, Public Citizen, Controversial Trade Pact Text Leaked, Shows U.S. Trade Officials Have Agreed to Terms That Undermine Obama Domestic Agenda (June 13, 2012), *available at* http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=3630.
[94] *See supra* discussion of TRIPS-Plus provisions.

dark as to the substance of the TPP negotiations, while representatives of U.S. corporations — like Halliburton, Chevron, PhRMA,[95] Comcast and the Motion Picture Association of America — are being consulted and made privy to details of the agreement."[96]

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. In a leaked letter, the Intellectual Property Task Force of the U.S. Business Coalition for TPP, representing a cross-sectoral group of US companies and business groups including PhRMA, the US Chamber of Commerce, and the Motion Picture Association of America (MPAA), 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."[97] The language used in the letter, which was sent to the Office of the United States Trade Representative, alludes to mechanisms such as research that is cost-effective and reference pricing systems.[98]

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 on them.

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[95] Pharmaceutical Research and Manufacturers of America is a trade organization representing the lobbying interests of the American pharmaceutical industry. *See* PhRMA, http://www.phrma.org/about (last visited Jan. 19, 2013).

[96] Nile Bowie, *The Trans-Pacific Partnership (TPP), An Oppressive US-Led Free Trade Agreement, A Corporate Power-Tool of the 1%,* CENTER FOR GLOBAL RESEARCH (Apr.2, 2013), *available at* http://www.globalresearch.ca/the-trans-pacific-partnership-tpp-an-oppressive-us-led-free-trade-agreement-a-corporate-power-tool-of-the-1/5329497

[97] IP Task Force of the U.S. Business Coalition for the Trans-Pacific Partnership Agreement, TPP Intellectual Property Negotiations (2010) (leaked paper), *available at* http://keionline.org/node/1034. Reference pricing systems refers to a system that establishes a common reimbursement level or reference price for a group of interchangeable medicines. *See* Pieter Dylst, *Reference Pricing Systems in Wurope: Charecteristics and Consequences*, 1(3-4) GENERICS AND BIOSIMILARS INITIATIVE J. 127 (2012).

[98] Thomas Faunce & Ruth Townsend, The Trans-Pacific Partnership Agreement: Challenges for Australian Health and Medicine Policies, 194 MED. J. AUSTL. 83, 83 (2011).

II. ANALYSIS: 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. However, concerned citizens, such as Congressmen Issa[99] and organizations, such as Wikileaks,[100] 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 to the Chief Negotiators of the 12 party nations, who account for approximately 40% of the world's GDP in August.[101] The fact that corporate advisors are being considered "experts and key negotiators", the breadth of these expanded rights, and the immense lack of transparency is likely to lead the U.S. to push negotiations toward a speedy conclusion as possible while maintaining its hard line stance on key provisions.[102]

The draft, which was written by the U.S.[103] begins with "General Provisions" which describe relevant definitions, objectives and principles.[104] What follows is a list of articles relating to trademarks, copyrights, geographic indication and enforcement and other areas covered by the TPP. [105] Most relevant here, are the articles under the "General Provisions" and "Section E: Patents/Undisclosed Test Data/Traditional Knowledge." 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.

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

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[99] Public Citizen, *supra* note 34.
[100] Wikileaks, *supra* note 35.
[101] Intellectual Property Rights Chapter, TPP Negotiations IP Group (Aug. 30, 2013), *available at* http://wikileaks.org/tpp/.
[102] Kevin Drum, *Leaked Treaty Puts U.S. Hard Line on Patents and Copyrights on Public Display*, MOTHER JONES, (Nov. 15, 2013), *available at* http://www.motherjones.com/kevin-drum/2013/11/leaked-treaty-puts-us-hard-line-patents-and-copyrights-public-display.
[103] Rossini & Sutton, *supra* note 32.
[104] *Id.* at 3–6.
[105] *Id.* at 29–35.

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.[106] Acknowledging the commitment made to the WTO's TRIPS Agreement nearly 15 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 against TRIPS flexibility utilization in the TPP's subsequent proposal. Thus, this article is essentially an empty gesture that ties together a series of aggressive patent provisions that will impede many nations from accessing medicine at a competitive price point. Including a generic phrase about commitments to public health and TRIPS is meaningless. The U.S. and other negotiation 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. Including Article QQ.A.5 in the TPP is the U.S.'s way of trying to pulls 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."[107] One 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 expeditious mechanism to export and import medicines into countries with insufficient drug manufacturing capabilities this is accomplished through the compulsory licensing.[108] The TRIPS/Health Solution is a procedurally complex waiver for a developing nation facing a public health crisis to

[106] *Id.* at QQ.A.5.
[107] TPP Leak, *supra* note 101 at QQ.A.5 (b).
[108] World Trade Organization, Ministerial Declaration of 14 November 2001, WT.MIN(01)/DEC/1.41.I.L.M.746 (2002) [hereinafter Doha Declaration] at para. 6.

obtain a compulsory license.[109] This waiver requires certain safeguards to be met before a country is allowed such a flexibility. The TRIPS/Health Solution is burdensome and dizzying; in order to use a compulsory license a WTO member nation must establish: specification of the expected quantities of drugs needed, evidence from every importing country to establish a lack or insufficiency of manufacturing capabilities, various notifications from an exporting country and an assurance that the medicine will be used for public health purposes. The TRIPS/Health Solution does not provide instructions or standards as to what kind of evidence would satisfy such requirements.[110] 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 "do[es] not and should not prevent" the access to medicines 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. 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 as being TRIPS compliant, even under the Doha Declaration's clarifying language. The provision, however, restricts the express language in the Declaration that the TRIPS flexibilities can and should be fully used.[111] The TPP's silence speaks volumes about the agreement's unwillingness to balance conflicting interests.

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[109] Rojina Thapa, *Waiver Solution in Public Health and Pharmaceutical Doman under TRIPS Agreement*, 16 J. OF INTELL. PROP. RIGHTS 470, 473 (2011).
[110] *Id.*
[111] Doha Declaration, *surpa* note 71 para.9.

C. CHAGAS DISEASE AND CHRONIC ILLNESS

Instead of mirroring the balance the TRIPS Agreement strives for,[112] the TPP implicitly limits its language suggesting that the TRIPS and Doha flexibilities are available only for the diseases and conditions enumerated in the provision. 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."[113]

The prevalence of non-communicable disease is on the rise around the world.[114] The global burden of disease is shifting from infectious diseases to non-communicable diseases, with chronic conditions such as heart disease and stroke now being the chief causes of death globally.[115] 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.[116] The U.S's has a history of trying to exclude non-infectious 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 UN High Level Meeting on Non-Communicable Diseases.[117]

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[112] TRIPS Agreement, *supra* note 41.
[113] Intellectual Property Rights Chapter, TPP Negotiations IP Group QQ.A.5(a) (Aug. 30, 2013), *available at* http://wikileaks.org/tpp/.
[114] WORLD HEALTH ORGANIZATION, *Rep. on Chronic Diseases in Low and Middle Income Countries*, (2005), *available at* http://www.who.int/chp/chronic_disease_report/media/Factsheet3.pdf.
[115] Press Release, *Non communicable Diseases are Now the Biggest Killers* (May 19, 2008), *available at http*://www.who.int/mediacentre/news/releases/2008/pr14/en/.
[116] Dele O Abegunde, *The burden and costs of chronic diseases in low-income and middle-income countries*, 370 THE LANCET 1929-38, 1936 (2007), *available at* http://www.who.int/choice/publications/p_2007_Chronic_disease_burden_Lancet.pdf at 1936.
[117] William New, *Questions Arise over UN Policy on Non-Communicable Diseases and IP Rights,* IP-WATCH (Sept.16, 2011), *available at* http://www.ip-watch.org/weblog/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. *See*, *Political Declaration of the High-*

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 need. For example, the U.S. opposes adding Chagas disease to the list of illnesses the TPP deems to qualify for the use of TRIPS flexibilities.[118] Chagas disease is a deadly infection caused by the protozoan parasite *Trypanosoma cruzi*. Afflicting approximately 8 million people in Latin America, it is now becoming a serious global health problem proliferating beyond the traditional geographical borders, mainly due to human-vector migration.[119] The chronic form remains incurable, there are no vaccines, and the only two existing drugs for the acute form are toxic and have low efficacy—and those drugs also come at a cost upward of $11,000, making them out of reach for most.[120]

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. VNI specifically inhibits a *T.cruzi* enzyme (CYP51) involved in the synthesis of sterols, lipid molecules essential for cell membrane function and integrity. In mice with Chagas disease, VNI achieved cures with 100 percent survival and without toxic side effects.[121] 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 U.S. has explicitly opposed adding Chagas to the TPP's list of diseases that will grant nations the ability to circumvent certain patent protections

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level Meeting of the General Assembly on the Prevention and Control of Non-communicicable Diseases, A/66/L1 (Sept.19-20, 2011), *available at* http://www.un.org/en/ga/ncdmeeting2011/.

[118] TPP Leak, *supra* note 101 at QQ.A.5 (a).
[119]Fernando Villalta et.al., *VNI Cures the Acute and Chronic Experimental Chagas Disease*, J. OF INFEC. DIS. (2013) *available at* http://jid.oxfordjournals.org/content/early/2013/01/31/infdis.jit042.short
[120] Katie Moisse, *Chagas the New AIDS? Experts Disagree*, ABC NEWS, June 12, 2012 *available at* http://abcnews.go.com/blogs/health/2012/06/01/chagas-the-new-aids-experts-disagree/.
[121] Bill Snyder, *Cure in Site for Kissing Bug's Bite,* RESEARCH NEWS AT VANDERBILT, Feb.2013 *available at* http://news.vanderbilt.edu/2013/02/chagas-cure-kissing-bug/.

for the sake of public health.[122] The U.S.'s opposition to adding Chagas to the explicitly enumerated list of conditions when a partner nation attempts to obtain a compulsory license. A country trying to use a compulsory license for Chagas treatment will have to rely on "other epidemic" which will be much more difficult because the procedurally tedious nature of the TRIPS/Health Solution.[123] Considering approximately 600 U.S. corporate advisors have negotiating power and the ability to amend proposals that suit their interest,[124] it is possible industry lobbying groups such as PhRMA see this as an opportunity to lock Chagas out of such patent law circumvention. This would 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. Article QQ.E.17 lays out measures that relate to certain regulated products, particularly the U.S.'s proposals for data exclusivity and patent registration linkage.[125] 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.[126] Linkage is not mentioned in TRIPS and is also not required in most of the TPP negotiating countries,[127] however, the U.S. has incorporated it into many of its free trade

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[122] TPP Leak, *supra* note 101 at QQ.A.5 (a).
[123] *Supra* discussion Part II B.
[124] Public Citizen, *supra* note **Error! Bookmark not defined.**. *See also* Connor Sheets, *New TPP Talks Decried as Most Secretive Discussions of Trans-Pacific Partnership to Date,* INT. BUS. TIMES, Nov.22, 2013, *available at* http://www.ibtimes.com/new-tpp-talks-decried-most-secretive-discussions-trans-pacific-partnership-date-1482970.
[125] TPP Leak, *supra* note 101 at QQ.E.17.
[126] Baker, *supra* note 8 at 33.
[127] *See* Kiliç B. & Maybarduk P., *Comparative Analysis of the United States' TPFTA Intellectual Property Proposal and Vietnamese Law*, PUBLIC CITIZEN, June 2011 (Updated December 2011) *available at*: www.citizen.org/access (explaining that "Vietnamese law contains no provision that links the patent system to the drug marketing approval process" and that many U.S.FTAs require patent linkage which "shifts burdens of early patent enforcement to drug

agreements.[128] Under such 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. The only way around this presumptive denial is if the pioneer inventor consents to such approval.[129] 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.[130] 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. 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, to demonstrate the efficacy and safety of a generic drug as long as the generic in question was chemically identical or bioequivalent.[131] The prior lack of data exclusivity allowed rapid introduction of generics into market without the need for separate, and costly, test data.[132] Data exclusivity standards have posed an obstacle for

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regulatory authorities."); *see also* Kılıç B. & Maybarduk P., *Comparative Analysis of the United States' TPFTA Intellectual Property Proposal and Malaysian Law*, PUBLIC CITIZEN, September 2011 (Updated December 2011) *available at*: www.citizen.org/access (noting that "Malaysian law contains no provision that links the patent system to marketing approval process."); *cf.* : Kılıç B. & Maybarduk P., *Comparative Analysis of the United States' TPPA Intellectual Property Proposal and Australian Law*, PUBLIC CITIZEN, August, 2011, *available at* www.citizen.org/access (explaining that although "AUSFTA introduced patent linkage in Australia, Australia sought to limit its effect through statutory measures imposing penalties for linkage evergreening" and subsequently, the USTR attacked these safeguards and therefore, the TPP proposal "raises a serious concern that the US may seek to limit or eliminate Australian safeguards.)

[128] *See* Korea-US Free Trade Agreement Art.18.9.5.

[129] Sell, *supra* note 86 at 454.

[130] Baker, *supra* note 8 at 33.

[131] WORLD HEALTH ORGANIZATION, *supra* note 44.

[132] *Id.*

flexibilities such as compulsory licenses because of the extra time generic approvals now require.[133] TRIPS, itself, only precludes reliance on undisclosed test data in the regulatory approval process.[134]

Facially, the TPP offers a generic provision with respect to the utilization of data for regulatory approval.[135] Even including a boilerplate exception to "protect the public".[136] However, the TPP provides absolutely no means for the actual use of data to protect the public. TRIPS also failed to identify such means of action, rendering the data exclusivity exception ultimately useless. Data exclusivity provisions are intended to force generic producers to develop their own clinical test data.[137] This is not only a waste of time and resources, this practice 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. 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 of five to ten years."[138]

Like other sections of the TPP,[139] the data exclusivity provision restates that "a Party may take measures to protect public health" in accordance to the Doha Declaration and current waivers, including the TRIPS/Health solution.[140] This standard text fails to identify concrete ways governments can override such mandates in order to allow generic medicines to market more swiftly. The TPP should include language either ensuring rights to gain market approval

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[133] *Id.*
[134] WORLD TRADE ORGANIZATION, *supra* note 55.
[135] TPP Leak, *surpa* note 101 at QQ.E.XX.4.
[136] TPP Leak, *supra* note 101 at QQ.E.XX.4.
[137] Sell, *supra* note 86 at 453.
[138] Jerome Reichman, *Undisclosed Clinical Trial Data Under the TRIPS Agreement and Its Progeny: A Broader Perspective*, 2 (2004), available at http://www.iprsonline.org/un ctadictsd/bellagio/docs/Reichman_Bellagio4.pdf.

[139] TPP Leak, *supra* note 101 at QQ.A.5; QQ.E.16, and QQ.E.XX.4.
[140] TPP Leak, *supra* note 101 at QQ.E.XX.4.

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.[141]

Such exceptions are not out of the ordinary. In fact, the New Trade Policy of 2007, led to revisions of the U.S.'s free trade agreements with Panama, Peru and Columbia.[142] These revisions gave explicit guidance on how to operationalize a public health exception to data exclusivity and patent linkage rules.[143] 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 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."[144]

Patent linkage and data exclusivity provisions will result in needless replication of data. These provisions also allow the pharmaceutical industry from using 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.[145] This will ultimately result in a reduction of competition and continued limited access.

E. DEFINING PATENTABILITY CRITERIA

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[141] Baker, *supra* note 8.
[142] Jean-Frederic Morin, *Multilateralizing TRIPS-Plus Agreements: Is the US Strategy a Failure?,* 12 J. WORLD INTELL. PROP. 191 (2009).
[143] Médecins Sans Frontières, *Doctors Without Borders/Médecins Sans Frontières (MSF) Campaign for Access to Essential Medicines TPP Issue Brief* (Sept.2011), *available at* http://www.doctorswithoutborders.org/press/2011/MSF-TPP-Issue-Brief.pdf.
[144] *Id.*
[145] Carlos Correa, *Implications of Bilateral Free Trade Agreements on Access to Medicines*, 84 BULL. WORLD HEALTH ORG. 401 (2006).

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.[146] 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."[147] This particular provision of the TPP is proposed only by the U.S. and Japan, with every other member nation opposed.[148] Lowering patentability standards too much tends to restrict innovation.[149] Advocates for access to medicine argue that it allows pharmaceutical companies to delay generic entry through what is known as "evergreening."[150] 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.[151] It allows pharmaceutical companies to extend their monopoly protection for old drugs by making small changes to existing formulas. This abuse of the patent system directly slows the ability of generic manufacturers from getting their products to market.[152] TRIPS does not require patent protection of new uses, or new forms of known

[146] TRIPS Agreement, *supra* note 41 at Art.1.
[147] Intellectual Property Rights Chapter, TPP Negotiations IP Group, 28 (Aug. 30, 2013), *available at* http://wikileaks.org/tpp/.
[148] *Id.* at 28.
[149] Parker Higgins & Maira Sutton, *TPP Leak Confirms the Worst: US Negotiators Still Trying to Trade Away Internet Freedoms*, ELECTRONIC FRONTIER FOUNDATION, (Nov. 13, 2013), *available at* https://www.eff.org/deeplinks/2013/11/tpp-leak-confirms-worst-us-negotiators-still-trying-trade-away-internet-freedoms.
[150] WORLD TRADE ORGANIZATION, *supra* note 55 at 131.
[151] World Health Organization, *Public Health, Innovation and Intellectual Property Rights: Report of the Commision on Intellectual Property Rights, Innovation and Public Health* (2006), Geneva.
[152] Médecins Sans Frontières, *supra* note 143.

substances.[153] 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.[154] The patentability standards in the TPP are directly contradictory to TRIPS, which allows countries to set their own standards. The U.S.'s proposal that efficacy need not be shown for the grant of a patent directly contradicts a county's right to determine what passes patentable muster. 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 U.S. 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.[155] Article 27 of TRIPS explicitly states, "[m]embers 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."[156] A number of multi-lateral and bi-lateral free trade agreements, including the North American Free Trade Agreement, reinforce article 27 of TRIPS.[157] In fact the only countries where patenting a medical

[153]Gaëlle P.Krikorian and D.Szymkowiak, *Intellectual Property Rights in the Making: the Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicines,* 10(5) J. OF WORLD INTELL. PROP., 2007, 388-418, at 394.
[154] WORLD INTELLECTUAL PROPERTY ORGANIZATION, *Regional Seminar for Certain Latin American and Caribbean Countries of the Implementation and Use of Several Patent Related Flexibilities* (Feb 6, 2012), *available at* http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_bog_12/wipo_ip_bog_12_ref_t6_kampf.pdf.
[155] TPP Leak, *supra* note 101 at QQ.E.1 (3)(a) and (c).
[156] TRIPS Agreement, *supra* note 41 at Art 27.3 (a) and (b).
[157] NAFTA Article 1709(3)(a), US-Australia FTA Art.17.9(2)(b), US-Bahrain FTA Art.14.8(1), US-Colombia FTA Art.16.9(2), US-Jordan FTA Art.18(a), US-Korea FTA Art.18.8(2)(a), US-Oman FTA Art.15.8(2)(a), US-Panama FTA Art.15.9(2), US-Peru TPA Art.16.9(2), US-Singapore FTA Art.16.7(1).

procedure is legal is the U.S. and Australia.[158] Over 80 nations have banned the practice of patenting medical procedures, diagnostic and surgical methods.[159]

Since the TPP's Intellectual Property chapter dictates that nations that are party to the TPP should make patents available for such subject matter there is an inherent conflict between rights guaranteed by TRIPS. 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. . . patenting of medical procedures is unethical and contrary to the values of the medical profession."[160] Similarly, the American Academy of Orthopedic Surgeons have also opposed the practice, "[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 health care."[161] Allowing patents for diagnostic and surgical methods will increase the cost of medical practice, apart from the price of medicine. This provision would also take away a country's right to dictate what is best for its own national policy. The U.S. is the only negotiating country in support of this provision; every other party is opposed.[162] The TPP's plan to lower patentability criteria to such a degree will be very damaging to the practice of medicine and the available of generic medical alternatives.

III. BEFORE IT'S 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

[158] WORLD MEDICAL ASSOCIATION, *Statement on Patenting Medical Procedures*, *available at* http://www.wma.net/en/30publications/10policies/m30/.
[159] *Id.*

[160] *Id.*
[161] AMERICAN ACADEMY OF ORTHOPEDIC SURGEONS, Opinions on Ethics and Professionalism, *available at* http://www.aaos.org/about/papers/ethics/1209eth.asp.
[162] TPP Leak, *supra* note 101 at QQ.E.1.3.

aggressive provisions that do a severe disservice to millions of people whose voices are not represented in the negotiations. 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.

Thirteen years ago the international community, including the U.S. 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.