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Neglected Diseases: How Intellectual Property Can Incentivize New Treatment

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NEGLECTED DISEASES: HOW INTELLECTUAL PROPERTY CAN INCENTIVIZE NEW TREATMENT

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I. INTRODUCTION

In 2003, seven organizations[1] from around the world collaborated to create the Drugs for Neglected Diseases initiative (DNDi)—an organization to address the current imbalance in the development of drugs

1. Drugs for Neglected Diseases initiative (DNDi) was created by "the Oswaldo Cruz Foundation from Brazil, the Indian Council for Medical Research, the Kenya Medical Research Institute, the Ministry of Health of Malaysia and France's Pasteur Institute; one humanitarian organization, Médecins sans Frontières (MSF); and one international research organization, the UNDP/World Bank/WHO's Special Programme for Research and Training in Tropical Diseases." *The Drugs for Neglected Diseases Initiative – DNDi*, WORLD HEALTH ORG., http://www.who.int/trypanosomiasis_african/partners/dndi/en/ (last visited May 3, 2016).

for diseases affecting poor populations.[2] While approximately $240.00 of public funding is spent per person on pharmaceutical research in developed countries, only $20.00 is spent per person in developing countries, and only $6.00 per head in sub-Saharan Africa.[3] This public funding significantly incentivizes manufacturers in developed countries to research and develop new treatments, while the lack thereof impedes drug development in less developed countries.[4]

Once a new drug is on the market, the cost of developing the drug is more likely to be recovered in developed nations, where patients have higher incomes and can afford treatment. In contrast, potential customers in poorer countries are unlikely to be able to pay a price for the drug that will allow the manufacturer to recoup the cost of developing it.[5] This lack of support for research and development has contributed to over seventeen diseases in developing countries being neglected by research efforts.[6] In fact, drugs that treat diseases that are more prevalent in the developed world, such as cancers and conditions of the central nervous system, are thirteen times more likely to be developed than a drug for a neglected disease, such as a parasitic disease.[7] For example, 1393 new chemical compounds were authorized worldwide between 1975 and 1999, but only sixteen of these were for tropical diseases.[8]

In May 2013, the World Health Organization's 66th World Health Assembly adopted resolution WHA66.12, in which Member States resolved to enhance efforts to reduce the worldwide impact of neglected tropical diseases (NTD), with a specific focus on completely eradicating two NTDs by 2020.[9] The criteria listed for a disease to qualify as a NTD includes: (1) the disease is disproportionately prevalent among people

2. DRUGS FOR NEGLECTED DISEASES INITIATIVE, *Vision & Mission*, http://www.dndi.org/about-dndi/vision-mission/ (last visited May 5, 2016).

3. Patrice Trouiller et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 THE LANCET 2188, 2191 (2002).

4. *Id.*

5. Philip Stevens, *Diseases of Poverty and the 10/90 Gap*, WORLD HEALTH ORG. (Nov. 2004), http://who.int/intellectualproperty/submissions/InternationalPolicyNetwork.pdf.

6. There is some disagreement over the number of neglected diseases. *See infra* Part II. Section A.

7. Patrice Trouiller et al., *Drug development for neglected diseases: a deficient market and a public-health policy failure, PublicHealth* 359 THE LANCET 2188 (2002). http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.620.5966&rep=rep1&type=pdf.

8. Trouiller et al., *supra* note 3, at 2188.

9. WORLD HEALTH ORG. [WHO], *Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases: A Roadmap for Implementation*, WHO/HTM/NTD/2012.1 (2012), http://apps.who.int/iris/bitstream/10665/70809/1/WHO_HTM_NTD_2012.1_eng.pdf.

living in poverty, causing unique morbidity and mortality considerations such as stigma, discrimination, and perpetuated poverty; (2) the disease predominantly affects tropical areas; (3) the disease may be immediately controlled or eradicated through application of the five public health strategies adopted by the Department for Control of NTDs,[10] or (4) the disease has generally been ignored by research initiatives and resource allocations. In order to qualify, a disease must either meet a combination of criteria (1), (2), and (3) or criteria (1), (2), and (4).[11]

Overall, neglected diseases affect 1 billion people—about one-sixth of the world's population—but neglected diseases are not proportionally addressed.[12] These neglected diseases include: "Buruli ulcer disease, Chagas disease, dengue and chikungunya, dracunculiasis, echinococcosis, endemic treponematoses (yaws), foodborne trematodiases, human African trypanosomiasis, leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis, rabies, schistosomiasis, soil-transmitted helminthiases, taeniasis/cysticercosis and trachoma."[13] Treatment regimens for these diseases fall under two categories: tool-ready, and "tool-deficient", depending on how much research has been done, and how much more is needed to control the diseases.[14]

This paper addresses the imbalance in the development of treatments for neglected diseases. It analyzes the causes behind the imbalances, and the current legal and societal initiatives that are in place to address the diseases. In particular, the paper suggests that the current patent system fails to effectively incentivize the development of treatment for neglected diseases. It further argues that the current international patent landscape creates some Band-Aid solutions to pharmaceutical access in developing countries in times of need, but does not adequately foster research and

10. These strategies include: "(i) preventive chemotherapy; (ii) innovative and intensified disease-management; (iii) vector control and pesticide management; (iv) veterinary public health; and (v) provision of safe drinking water, sanitation, and hygiene education." *e-Recruitment- Scientist, Vector and Ecology Management (HQ.16/NTD/FT256)*, WORLD HEALTH ORG. (Oct. 22, 2016), https://erecruit.who.int/public/hrd-cl-vac-view.asp?o_c=1000&jobinfo_uid_c=33428&vaclng=en.

11. *Recommendation for the Adoption of Additional Diseases as Neglected Tropical Diseases*, WORLD HEATH ORG. (2013), http://www.who.int/neglected_diseases/diseases/Adoption_additional_NTDs.pdf?ua=1 [hereinafter WHO Recommendation].

12. CTRS. FOR DISEASE CONTROL AND PREVENTION, *Neglected Tropical Diseases*, http://www.cdc.gov/globalhealth/ntd/ (last updated June 7, 2016).

13. *See* WHO Recommendation, *supra* note 10; *but see* Trouiller et al., *supra* note 3, at 2188.

14. *For neglected tropical diseases, pocket change goes a long way*, CTR. FOR HIGH IMPACT PHILANTHROPY (Sept. 14, 2010), http://endtheneglect.org/2010/09/for-neglected-tropical-diseases-0-40-goes-a-long-way/.

development in these areas. As a result of these shortcomings, developing countries are unable to enhance their own research and manufacturing capacities to meet their unique drug needs, and pharmaceutical companies in developed countries lack incentives to develop treatment for diseases impacting the world's poorest populations. Finally, this paper offers some recommendations about how the current status of treatment can be improved.

II. BACKGROUND ON NEGLECTED TROPICAL DISEASES

A. Neglected Diseases: What are they?

There is some debate regarding the number of neglected diseases, and estimates range from twelve[15] to over thirty.[16] The World Health Organization has identified seventeen tropical neglected diseases as most important and the ones that it plans to focus on. The diseases are divided into four main groups of pathogens: (1) Protozoa (i.e. Chagas disease, human African trypanosomiasis, leishmaniases); (2) Bacteria (Buruli ulcer, leprosy, trachoma, yaws); (3) Helminths or Metazoan worms (i.e. cysticercosis/taeniasis, dracunculiasis, echinococcosis, foodborne trematodiases, lymphatic filariasis, onchocerciasis, schistosomiasis, soil-transmitted helminthiasis); and (4) Viruses (dengue and chikungunya, rabies).[17] As all of these are parasitic infections, NTDs occur most commonly in areas of poverty and poor sanitation, including areas with polluted water sources, livestock, and infection vectors.[18] Many of these illnesses disproportionately impact women and children because these groups tend to be most in contact with disease agents.[19]

Some of the diseases can be treated or prevented with existing technologies but have not yet been eliminated due to poor health policies and lack of organized action against the diseases. These tool-ready

15. Alan Fenwick, *The Global Burden of Neglected Tropical Diseases*, 3 PUBLIC HEALTH 233, 234 (Mar. 2012).

16. Kamal K. Midha, *Presidential Address at the FIP Congress Opening Ceremony*, 25 INT'L PHARM. J. 4 (Dec. 2009), *available at* https://www.fip.org/files/fip/IPJ/IPJ_2009V25web.pdf.

17. *Neglected Tropical Diseases,* WORLD HEALTH ORG. (Nov. 24, 2015), http://www.who.int/neglected_diseases/diseases/en/. *See also* Lecture Notes: TROPICAL MEDICINE (Geoff Gill & Nick Beeching eds., 6th ed. 2011) (discussing the categorization of tropical diseases).

18. *Neglected Tropical Diseases,* WORLD HEALTH ORG. (Nov. 24, 2015), http://www.who.int/neglected_diseases/diseases/en/.

19. THE HENRY J. KAISER FAMILY FOUND., *The U.S. Government and Global Neglected Tropical Disease Efforts* (July 19, 2016), http://kff.org/global-health-policy/fact-sheet/the-u-s-government-and-global-neglected-tropical-diseases/ [hereinafter KAISER].

diseases, such as foodborne trematode infections, lymphatic filariasis, onchocerciasis, schistosomiasis, soil-transmitted helminthiases and trachoma could be prevented by coordinating large-scale, single-dose administration of therapies,[20] such as vaccines, immune-booster pills, and other long-lasting treatment.[21] For example, a four-drug concoction works to prevent up to seven diseases, but needs to be administered across a large population to control against re-contamination.[22] Some regions already have control programs set up to provide mass drug administrations (or MDAs) to populations prone to the disease.[23] Other NTDs such as Buruli ulcer, endemic treponematoses (yaws), leprosy (Hansen disease), Chagas disease, human African trypanosomiasis (sleeping sickness), leishmaniasis, cysticercosis and echinococcosis will require new technologies, tools and strategies to eliminate.[24] Some of the diseases cannot be treated with existing MDA programs, or will require individual diagnostic and treatment mechanisms that involve more resources. Overall, the total cost of eliminating or eradicating neglected diseases from the world is estimated to be only $1.5 to 2 billion, if it is employed in conjunction with human resources and policy measures.[25] This method of treatment would cost less than fifty cents per person per year but would require considerable governmental and private sector cooperation to organize and administer.[26]

Section B. of this paper further discusses the governmental and social initiatives that could be implemented to accelerate the elimination of these diseases.

20. LORENZO SAVIOLOI ET AL., WORLD HEALTH ORG., A ROADMAP FOR IMPLEMENTATION 1 (David W.T. Crompton ed. 2012), http://apps.who.int/iris/bitstream/10665/70809/1/WHO_HTM_NTD_2012.1_eng.pdf [hereinafter WHO ROADMAP].

21. Jeffrey M. Bethony et al., *Vaccines to Combat the Neglected Tropical Diseases*, 239 IMMUNOL REV. 237, 242–46 (2011).

22. SABIN VACCINE INST., *The Solution,* GLOBAL NETWORK| NEGLECTED TROPICAL DISEASES, http://www.globalnetwork.org/solution (last visited May 10, 2016).

23. SABIN VACCINE INST., *The Most Common NTDs*, GLOBAL NETWORK| NEGLECTED TROPICAL DISEASES, http://www.globalnetwork.org/neglected-tropical-diseases/fact-sheets (last visited Sept. 23, 2016).

24. WHO ROADMAP, *supra* note 19, at 1; CTRS. FOR DISEASE CONTROL AND PREVENTION, *Neglected Tropical Diseases, Other NTDs*, http://www.cdc.gov/globalhealth/ntd/diseases/otherntds.html (last visited May 10, 2016).

25. Fenwick, *supra* note 14, at 235.

26. CTRS. FOR DISEASE CONTROL AND PREVENTION, *Neglected Tropical Diseases—Fast Facts*, http://www.cdc.gov/globalhealth/ntd/fastfacts.html (last visited May 4, 2016).

B. Current Legal and Social Initiatives in Place to Address Neglected Diseases

Section 740 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriation Act of 2010 (Appropriation Act) states that the Commissioner of Food and Drugs of the U.S. Food and Drug Administration (FDA) shall establish a "review group which shall recommend . . . appropriate preclinical, trial design, and regulatory paradigms and optimal solutions for the prevention, diagnosis, and treatment of neglected diseases of the developing world."[27] In July 2014, the FDA released its Guidance for Industry regarding Section 740 of the Appropriation Act. The FDA Guidance states that NTD applications will be reviewed as Investigative New Drug (IND) applications, regardless of where clinical trials take place. The same regulatory and review standard will be applied to NTD therapies as is applied to diseases endemic to the United States.[28] Specifically, the Guidance gives the FDA "considerable latitude to exercise its scientific judgment to determine the kind and quality of data and information an applicant is required to provide . . . to meet the statutory standards" for NTD approval.[29] The FDA commits to weigh the severity of the NTD against the quality of alternative therapies (or lack thereof) in determining whether the benefits of therapy outweigh risks.[30] Finally, the FDA acknowledges that certain circumstances may justify requiring only one, well-controlled clinical trial for approval of an NTD drug.[31]

Section 524(b)(1) of the Food, Drug and Cosmetic (FD&C) Act formally acknowledges seventeen "tropical diseases" that have been neglected by traditional medical efforts.[32] In addition, Section 524 of the FD&C Act introduces priority review vouchers for pharmaceutical manufacturers or sponsors that develop treatment for NTDs. A priority review voucher "entitles the holder of such voucher to priority review of a

27. Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriation Act, Pub. L. No. 111-80, § 740(b) (2010).

28. U.S. DEP'T OF HEALTH AND HUMAN SERV., FOOD AND DRUG ADMIN., GUIDANCE FOR INDUSTRY NEGLECTED TROPICAL DISEASES OF THE DEVELOPING WORLD: DEVELOPING DRUGS FOR TREATMENT OR PREVENTION, 2 (2014), *available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm269221.pdf [hereinafter FDA GUIDANCE].

29. *Id.* at 5; *see also* 21 C.F.R. § 314.105(c) (2008).

30. 21 C.F.R. § 312.84(a) (2008).

31. FDA GUIDANCE, *supra* note 27.

32. 21 U.S.C. § 360n(a)(3) (2016).

single human drug application submitted under section 355(b)(1) of this title or section 262 of title 42 after the . . . approval of the tropical disease product application." Hence, the sponsor of the tropical disease application can use the voucher to expedite review of one of its more profitable drugs.[33] These public policies have been geared toward diseases that do not have current treatment options, or need new vaccine generations. However, existing international patent laws impact drugs that are already available but expensive or unavailable in developing countries due to patent rights.[34]

Between 1986 and 1994, World Trade Organization (WTO) drafted the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to establish international standards for intellectual property rights and grant equal rights in all member countries.[35] The TRIPS Agreement provides specific provisions relating to patents. First, it requires that patents be available in every field, including, pharmaceuticals and medical devices, which were previously not patentable in many countries.[36] Second, the national treatment provision requires countries to grant inventors from other countries the same rights as it grants to its own citizens. The most-favored-nation provision states that if a member nation grants one of its trading partners a special IP protection, it must grant that protection to all other member nations.[37]

Some exceptions may be made for countries that need to provide their population with emergency "diagnostic, therapeutic and surgical methods."[38] Article 27 of TRIPS permits a suspension of patent rights to protect "*ordre public* or morality." However, it has not been properly defined what constitutes "*ordre public* or morality" and the term continues to be debated.[39] Article 30 permits "limited exceptions" to patent rights, granted they do not unreasonably interfere with the patent holder's rights.[40]

33. 21 U.S.C. § 360n(a)(2) (2016).

34. Kyle Wamstad, *Priority Review Vouchers: A Piece of the Incentive Puzzle*, 14 VA. J.L. & TECH. 126, 135 (2009).

35. *Intellectual property: protection and enforcement,* WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited May 5, 2016).

36. Agreement on Trade Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, 33 I.L.M. 81 [hereinafter TRIPS Agreement].

37. *Principles of the Trading System,* WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact2_e.htm#national (last visited Oct. 22, 2016).

38. UNIVERSITY OF KERALA DEPARTMENT OF LAW, *Exclusion of Diagnostic, Therapeutic, and Surgical Methods from Patentability.* 18 J. INTELL. PROP. RTS. 242, 242-50 (2013).

39. TRIPS Agreement, *supra* note 35, art. 27, at 93-94.

40. TRIPS Agreement, *supra* note 35, art. 30, at 95.

Article 31 allows exceptions for "national emergency or other circumstances of extreme urgency" where a government may circumvent patent rights without authorization of the right holder "for other use . . . of the subject matter of [the] patent,"[41] implying "use other than that allowed under Article 30."[42] This article allows governments to occasionally grant compulsory licenses without negotiating with the patent owner, as long as the license is for a national emergency and noncommercial public use.[43] A compulsory license authorizes the government or a third party country to manufacture a generic drug, with the condition that (1) it will predominantly supply the domestic market;[44] and (2) the patent holder will be compensated based on the value of the license.[45]

However, there is considerable debate regarding what constitutes a national emergency, and when this exception is permissible. The United States has insisted that developing countries are responsible for TRIPS provisions following 2005, which was the end of the adjustment grace period afforded to developing countries. However, developing countries argue that their economies are not prepared for a full-blown, U.S. style patent system, as they must prioritize other basic human needs such as affordable access to health care.[46]

In response to this debate, member nations reconvened to resolve some of these controversies and questions, and created the 2001 Doha Declaration on TRIPS and Public Health (Doha Declaration).[47] The Doha Declaration affirmed the importance of the "right to protect public health and, in particular, to promote access to medicines for all", and affirmed "the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."[48] In addition, the Doha Declaration clarified that each country has the right to define a

41. TRIPS Agreement, *supra* note 35, art. 31, at 95.

42. TRIPS Agreement, *supra* note 35, n.7, at 111.

43. TRIPS Agreement, *supra* note 35, art. 31(b), at 95.

44. TRIPS Agreement, *supra* note 35, art. 31(f), at 95.

45. TRIPS Agreement, *supra* note 35, art. 31(h), at 95.

46. *See* Kimberly A. Czub, *Argentina's Emerging Standard of Intellectual Property Protection: A Case Study of the Underlying Conflicts Between Developing Counties, TRIPS Standards, and the United States*, 33 CASE W. RES. J. INT'L L. 191, 199–202 (2001); Robert C. Bird, *Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side-Effects*, 37 J.L. MED. & ETHICS 209, 210 (2009).

47. James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health and the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291, 292 (2009).

48. World Trade Organization, Ministerial Declaration of 14 November 2001, ¶ 4, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM (2001), *available at* https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.pdf [hereinafter Doha Declaration].

national emergency for itself, and that epidemics of any disease can always qualify as national emergencies. The Doha Declaration further clarified that compulsory licenses are permissible at any time during these national emergencies, even after a developing nation has fully adopted the TRIPS Agreement.[49] Finally, recognizing that compulsory licenses may not be feasible for least developed nations that lack resources to manufacture the drugs, the Doha Declaration provided the option of parallel importation, which allows nations to import certain amounts of pre-made pharmaceuticals in return for reasonable compensation.[50] Usually, the pharmaceutical companies will be able to sell the drugs cheaper in poorer countries, and recover costs with higher prices in developed countries.[51] Alternatively, third-party countries could apply for compulsory licenses, produce the biologic drugs, and provide them to least developed countries through parallel importation.[52]

III. ARGUMENT/ANALYSIS

A. Why Should We Care?: Impact of the Neglected Diseases on Communities—Overseas and In the United States

The United States has fought long and hard to preserve the current status of international IP rights, which theoretically aims to gradually transfer all countries' IP programs to look like the U.S.'s.[53] While this might be a strong system in the long run, the U.S. and the rest of the world would benefit from a flexible and more country-specific IP system in the beginning, which later transitions into a uniform system. The concept of providing private companies incentives for developing novel, useful technologies has benefited several countries in promoting innovation.[54] This system could be used in a similar, but tailored way, to incentivize

49. *Parallel Imports*, WORLD HEALTH ORG. (May 12, 2016), http://www.who.int/trade/glossary/story070/en/.

50. *Id.*

51. *Id.*

52. C. James Attridge & Alexander S. Preker, IMPROVING ACCESS TO MEDICINES IN DEVELOPING COUNTRIES APPLICATION OF NEW INSTITUTIONAL ECONOMICS TO THE ANALYSIS OF MANUFACTURING AND DISTRIBUTION ISSUES, 28 (Mar. 2005), *available at* http://apps.who.int/medicinedocs/documents/s16743e/s16743e.pdf.

53. Robert C. Bird, *Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side-Effects*, 37 J.L. MED. & ETHICS 209, 210 (2009).

54. Gene Quinn, *The Story of How Patents Promote Innovation*, IPWATCHDOG (May 12, 2014), http://www.ipwatchdog.com/2014/05/12/the-story-of-how-patents-promote-innovation/id=49520/.

innovation in developing countries. Implementing a flexible and tailored system according to each country's developmental status and needs will benefit the entire world because developing countries will eventually be able to contribute more to technological advancements and emerge with stronger economies.[55]

Furthermore, all countries in the world have an inherent self-interest in helping eliminate or control neglected diseases, which currently cause many young people to experience life-long disability, discrimination, stigma, and sometimes death.[56] These living conditions lead communities into a state of distress, and prevent them from exiting poverty, leaving the community economically dependent on humanitarian efforts and government resources to pay for health care, food, and sanitation.[57] In addition, the community is less productive and unable to contribute to the development of its country.[58] Neglected diseases are also confounded with other diseases such as malaria, HIV, and tuberculosis, which causes heightened morbidity and mortality among people suffering from neglected diseases.[59] Therefore, in order to see an expedited elimination of these three big diseases, it is important to address collateral disease factors, including neglected diseases.[60]

The improvement in the health system of developing countries will lead to economic progress, which will in turn lead to a more robust IP system over time. The shift to a more U.S.-like patent system will benefit U.S. pharmaceutical companies, which will then be able to pursue more meaningful IP protection in foreign countries in the future. The local populations in developing countries will also be more financially capable of affording U.S.-developed pharmaceuticals.[61]

Some scholars have argued that countries suffering from NTDs are of interest to the United States for foreign policy reasons; therefore, advancing

55. Ileana Dominguez-Urban, *Harmonization in the Regulation of Pharmaceutical Research and Human Rights: The Need to Think Globally*, 30 CORNELL INT'L L.J. 245, 253 (1997).

56. *See generally, Id.*

57. PETER J. HOTEZ, *The Neglected Tropical Diseases and the Neglected Infections of Poverty: Overview of Their Common Features, Global Disease Burden and Distribution, New Control Tools, and Prospects for Elimination, in* THE CAUSES AND IMPACTS OF NEGLECTED TROPICAL AND ZOONOTIC DISEASES: OPPORTUNITIES FOR INTEGRATED INTERVENTION STRATEGIES 221, 231-32 (2011), *available at* http://www.ncbi.nlm.nih.gov/books/NBK62521/.

58. WHO Recommendation, supra note 10, at 1.

59. Mike Shanahan, *'Beat neglected diseases' to fight HIV, TB and malaria*, SCIDEV.NET (Jan. 31, 2006), http://www.scidev.net/global/disease/news/beat-neglected-diseases-to-fight-hiv-tb-and-mal.html.

60. Hoetz, *supra* note 57.

61. *See generally* Dominguez-Urban, *supra* note 53, at 253.

the elimination of NTDs would serve as a "low-cost yet high-profile" humanitarian effort for the U.S., with a high chance of success. Finally, Hotez and Thompson believe that poverty and isolation caused by NTDs promote conflicts in the world's Islamic nations, which may possess nuclear weapons and could pose threats to the United States and their own regions.[62] This threat of increased conflict adds urgency to the world's purpose to ultimately eliminate NTDs. Collaborative research and development projects between the United States and Islamic countries to eliminate NTDs from unstable or conflict-ridden states and to develop a new generation of NTD vaccines, could build relationships between the regions, similar to the cooperation between the United States and former Soviet Union on polio and smallpox treatment development in the 20th century.[63]

B. Reasons for the Lag in Treatment Development for Neglected Tropical Diseases

Neglected diseases are a product of several factors, including a lack of governmental health initiatives, poor health policies, and misapplied patent laws. NTDs disproportionately impact low income countries, in Africa, Asia and South America, and tropical areas of the Caribbean.[64] Because each neglected disease does not have a high death toll or rapid-onset death, they often do not receive wide-spread publicity or media attention. However, they often occur in combination with each other and lead to long-term, debilitating conditions that prevent individuals from engaging in daily activities such as going to work or school.[65] This traps the individuals in these communities in a cycle of poverty, whereby they continue to lack access to sanitary food, water and housing, which exposes them to more diseases.[66] This paper briefly touches on the broad governmental and social factors that impact the status of neglected diseases; and then focuses particularly on IP factors that are preventing development of new treatment and prevention technologies for neglected diseases.

62. Hoetz, *supra* note 57.

63. Peter J. Hotez & Tommy G. Thompson, *Waging Peace Through Neglected Tropical Disease Control: A US Foreign Policy for the Bottom Billion*, PLOS NEGLECTED TROPICAL DISEASES, Jan. 2009, at 1, 3; Hotez, *supra* note 56, at 233-34.

64. NAT'L INST. OF HEALTH, *Neglected Diseases, Genetic and Rare Diseases*, https://rarediseases.info.nih.gov/files/neglected_diseases_faqs.pdf (last visited May 11, 2016).

65. KAISER, *supra* note 18.

66. Thomas Kariuki et al., *Research and Capacity Building for Control of Neglected Tropical Diseases: The Need for a Different Approach*, PLOS NEGLECTED TROPICAL DISEASES, May 2011, at 1.

i. Social, Scientific and Governmental Actions That Hinder the Development of Neglected Disease Treatment

Neglected diseases affect the world's poorest and most vulnerable populations, and have been ignored due to a lack of political will, scientific advancement, and funds. For instance, NTDs represent a class of diseases that have especially complex genomes (particularly the eukaryotic[67] pathogens), making it a challenge to develop *in vitro* systems to maintain the NTD pathogens in the laboratory. It is also difficult to discover suitable animal models of the diseases, and adequate correlates of protection, such as antibodies.[68] Without these experimental materials and methods, it is hard to develop antigens, adjuvants, and other platform technologies, making it challenging to manufacture an administrable treatment.[69] In addition, many of these platform technologies are patented, therefore only available to richer populations.[70] Some of the patent solutions discussed in the second part of this section will also address these scientific shortcomings.

Due to the scientific complexity of NTDs, the cost of developing new technologies to address outbreaks is high. Because the diseases mostly impact people living in poverty, the target patients are not able to afford the price of the drugs. Even for tool-ready diseases, for which some form of treatment is available, governments do not have enough incentives to update treatment, coordinate mass-administration programs, or implement a system of diagnosis and treatment.[71]

In contrast, diseases such as HIV/AIDS, malaria, and tuberculosis have received far more publicity and funding, through their prominent inclusion in the Millennium Development Goals, where neglected diseases were only referred to as "other diseases."[72] International efforts such as the U.S. President's Emergency Plan for AIDS Relief , the U.S. President's Malaria Initiative, and the Global Fund to Fight AIDS, Tuberculosis, and

67. Organisms whose cells have membrane-bound organelles, such as a nucleus. *Eukaryotic Cell v. Prokaryotic* Cell, DIFFEN, http://www.diffen.com/difference/Eukaryotic_Cell_vs_Prokaryotic_Cell (last visited May 3, 2016).

68. Bethony et al., *supra* note 20, at 242.

69. *Global Funding of Innovation for Neglected Diseases: G-FINDER*, POLICY CURES http://www.policycures.org/downloads/G-FINDER_Year_3_summary.pdf (last visited May 11, 2016).

70. Jason Macleod, TB DIAGNOSTIC DEVELOPMENT IN THE DEVELOPING WORLD – IP SOLUTIONS THROUGH PUBLIC PRIVATE PARTNERSHIPS, https://www.jasondmacleod.com/law-articles/tb-diagnostic-development-developing-world-ip-solutions-public-private-partnerships/ (last visited May 1, 2016).

71. WHO RECOMMENDATION, *supra* note 10.

72. Bethony et al., *supra* note 20, at 237-38.

Malaria, provided millions of people antiretrovirals, antimalarial drugs and insecticide-treated nets.[73] Public private partnerships formed to develop and test new vaccines, through support from the Bill & Melinda Gates Foundation, the US National Institutes of Health, and the Wellcome Trust.[74] As a result of the international effort to address these illnesses, the malaria mortality rate declined by 58% between 2000 and 2015. And, by 2014, 13.6 million people globally were receiving antiretroviral therapy (ART) for HIV infection, while new infection rates dropped by 40%. Plus, nearly 37 million lives have been saved between 2000 and 2013 as a result of tuberculosis initiatives.[75]

Other recent diseases, such as Zika and Ebola, have spread to the developed nations across the West, sparking international pressure and global efforts to develop a treatment." Most NTDs do not spread quickly to developed nations, eliminating the immediate need for rich countries to invest in treatment development.[76] For example, although parasitic infections account for one-third of the world's total disease burden and are more prevalent in the developing world, they only account for 5% of diseases in the developed world.[77] As international travel and trade increase, the world will be more at risk of diseases spreading rapidly on an international scale, pushing all countries to engage in a collaborative effort to reduce the impacts.[78]

Hence, a successful solution to the neglected disease problem will have to be multi-faceted, and will likely include new regulation, social and humanitarian initiatives, and intellectual property (IP) reform. These strategies for reform are discussed below.

73. Peter J. Hotez, FORGOTTEN PEOPLE, FORGOTTEN DISEASES: THE NEGLECTED TROPICAL DISEASES AND THEIR IMPACT ON GLOBAL HEALTH AND DEVELOPMENT 3 (Am. Soc'y for Microbiology Press ed., 2nd ed. 2008).

74. Bethony et al., *supra* note 20, at 238.

75. U.N. Secretary-General, MILLENNIUM DEVELOPMENT GOALS REPORT, *Goal 6: Combat HIV/AIDS, Malaria, and Other Diseases* (2015) http://www.un.org/millenniumgoals/2015_MDG_Report/pdf/MDG%202015%20rev%20(July%201).pdf.

76. WHO RECOMMENDATION, *supra* note 10.

77. Trouiller et al., *supra* note 3, at 2188.

78. Dr. Mary Moran et al., *NEGLECTED DISEASE RESEARCH AND DEVELOPMENT: THE EBOLA EFFECT*, POLICY CURES, http://policycures.org/downloads/Y8%20GFINDER%20full%20report%20web.pdf (last visited Oct. 25, 2016).

ii. Current Patent Law and its Impact on Disease Treatment Development

The TRIPs Agreement benefits countries and companies that introduce innovative products into the developing markets and wish to seek IP protection. For example, U.S. pharmaceutical companies can theoretically obtain patents for new pharmaceuticals in Asia and Africa, under similar patent terms as the U.S.[79] However, many of these countries do not have the resources or infrastructure to invest in setting up a comprehensive patent system. For example, developing countries sometimes do not have IP offices and examiners to review patents, or courts and judges to enforce them. They may also have different cultural preferences, and not be interested in patent rights for medical instruments for moral reasons.[80] Hence, many scholars have argued that the TRIPs Agreement favors a U.S.-style patent system and benefits developed countries, but is not best suited to meet the needs of developing countries. In addition, some scholars have argued that the current international IP scheme has hindered access to essential medicines in developing countries, because cheap generic versions of pharmaceuticals are slower to enter the market, and because developing countries are unable to conduct research to manufacture their own versions of medicines, due to over broad patenting by U.S. pharmaceutical companies and potential infringement issues.[81]

However, the biggest issue in IP is the fact that the implementation has inhibited developing countries from taking full advantage of the principles of an IP system. While some previous scholarship has suggested that developing countries should disregard Western patenting ideals, it is advisable to implement a less stringent version of patent rights to jumpstart kick-start development of new technologies in emerging economies, and eventually in less developed countries. This method will be more effective than incentives such as the Doha Declaration, which allows countries to grant compulsory licenses and parallel importation. While current international initiatives such as the Doha Declaration provide some emergency access to already developed treatment, they are a Band-Aid

79. *Protecting Intellectual Property Rights (IPR) Overseas*, U.S. PAT. AND TRADEMARK OFF., http://www.uspto.gov/patents-getting-started/international-protection/protecting-intellectual-property-rights-ipr (last visited May 13, 2016).

80. Ganiyou Gassikia, Implementing and Enforcing Intellectual Property Right in West Africa JOHN MARSHALL REV. INT. PROP., 782, 785 (2014). *See also* E. Richard Gold et al., *Are Patents Impeding Medical Care and Innovation?* PLOS MED., Jan. 2009, at 1, 3.

81. Kristina Lybecker, *Patent Law 2.0: Not the Answer the Developing World Needs*, IPWATCHDOG (Aug. 18, 2013), http://www.ipwatchdog.com/2013/08/18/patent-law-2-0-not-the-answer-the-developing-world-needs/id=44699/.

solution, and do not encourage local development of treatment. Therefore, this proposal also involves incentivizing U.S. pharmaceutical companies to invest more in solutions for neglected diseases.[82]

IV. RECOMMENDATIONS

One way in which U.S. patent law could indirectly benefit developing countries is through joint or collaborated research, and shared patent rights. Drugs for diseases effecting the developed world could be the basis for drugs that treat NTDs, and vice versa, as some diseases may be similar.[83] For example, Zika virus is in the same family at dengue and West Nile, and the current search for a vaccine for Zika is drawing on previous findings from the development of the dengue vaccine.[84] Once a Zika vaccine is developed, the manufacturers will be best positioned to update the vaccine for use in dengue, and other water-associated mosquito diseases.[85] Additionally, diagnostic measures that are used for comparable diseases in the United States and other developed countries could be used for neglected diseases. However, many of these diagnostic procedures are patented, which inhibits affordable diagnostics in developing countries.[86]

Second, another potential IP solution could involve treating different developing countries differently. The preamble to the WTO Agreement, which is the umbrella agreement for all WTO initiatives, including the TRIPs Agreement, "*Recogniz[es]* that . . . relations in the field of trade and economic endeavor should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable

82. *See generally* Angela J. Anderson, *Global Pharmaceutical Patent Law in Developing Countries- Amending TRIPS to Promote Access for All*, BEPRESS LEGAL REPOSITORY (Mar. 2006), http://law.bepress.com/expresso/eps/1109/.

83. *See generally* Hanna Waters, *Patent-sharing Scheme for Neglected Diseases May Have Catch*, 17 NATURE MEDICINE 1529 (2011).

84. Maggie Fox, *New Dengue Vaccine May Form Basis for Zika Vaccine*, NBC NEWS (Mar. 17, 2016, 12:08 PM), http://www.nbcnews.com/storyline/zika-virus-outbreak/new-dengue-vaccine-may-form-basis-zika-vaccine-n540851.

85. Veronica Sikka, et al., *The Emergence of Zika Virus as a Global Health Security Threat: A Review and a Consensus Statement of the INDUSEM Joint Working Group (JWG)*, 8 J. OF GLOBAL INFECTIOUS DISEASES 3 (2016).

86. *See, e.g.*, Catherine Jewell, *Catalyzing research into neglected tropical diseases*, WIPO MAG. (Feb. 2013), http://www.wipo.int/wipo_magazine/en/2013/01/article_0004.html (discussing initiatives to license diagnostic tools).

development".[87] This differential treatment of countries based on their economic and development status would be justified by the WTO Agreement's Preamble, which recognizes the "need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development," indicating that each developing country should be treated differently.[88] The reason the U.S. patent system offers such a strong push for innovation is because the system was carefully tailored to meet the needs of this country. Hence, implementing a patent system that is unique to each developing country will enable both U.S., and developing countries, to acquire increased access to treatments but in a different manner. Instead of relying solely on imports and compulsory licenses, developing countries will be able to use their comparative advantages to set up manufacturing and innovation. Developing countries possess cheap raw materials, fewer regulations for clinical trials, and easier access to trial subjects, which will enable them to eventually set up comprehensive and locally beneficial research centers.[89]

While developed countries could continue to operate under the current international patent framework, more flexible systems could be implemented in developing countries. For instance, one reason why many developing countries do not implement robust patent systems is because they are expensive to run. Conducting patent searches, tracking the filing process, and conducting examinations all require considerable resources. In addition, not all countries aspire to grant patents for all fields or products. Some countries exclude patents on food, agricultural products, and chemical compounds.[90] In achieving a more user-friendly patent system, countries could lower the requirements for showing non-obviousness, could limit the kinds of products that patents are available for, and could reduce the number of years a patent term lasts. This would reduce the time to review and grant a patent, and would release the invention into the public domain in a shorter time frame. Implementing a system whereby local

87. Appellate Body Report, *European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries*, WTO Doc. WT/DS246/AB/R (Apr. 7, 2004).

88. Rohan K. George, Conference Paper, *Does One Size Fit All? A Comparative Study to Determine an Alternative to International Patent Harmonization*, Cornell L. Libr. (2009).

89. Roy Zwahlen, *Neglected Diseases: What if IP was the Cure?*, BIOTECH NOW (Oct. 29, 2013), http://www.biotech-now.org/public-policy/patently-biotech/2013/10/neglected-diseases-what-if-ip-was-the-cure.

90. George, *supra* note 83, at 9.

researchers and manufacturers are enabled to conduct clinical trials will be a better long-term solution.[91]

One way manufacturers are currently incentivized to develop drugs for neglected diseases is through Priority Review Vouchers (PRV). A drug manufacturer could get a PRV when it develops a treatment for a neglected disease or a disease primarily affecting the developing world. The manufacturer could apply the PRV to get priority review for one of its more profitable drugs, or a blockbuster drug. This could potentially increase a manufacturer's profits by $300 million if it gains an extra six months on the market. This solution increases incentives for branded and reference product companies without extending patent terms or limiting generic entrance.[92] However, it may be used with regards to patents too. For example, if a manufacturer develops a treatment for a neglected disease, upon approval of that diseases, the manufacturer could be entitled to a "priority examination voucher," which could be used to hasten a patent application examination for a blockbuster drug or a more profitable invention.

In addition, if a government wants to further incentivize implementation of the diseases treatment, it could condition the receipt of a priority examination voucher on the company ensuring that the neglected diseases treatment is property delivered and administered in an area of need. Furthermore, the government could also provide vouchers for slightly longer patent terms for another invention, if the manufacturing company offers to sponsor other activities such as sanitization or deworming in developing countries.

V. CONCLUSION

As the world becomes smaller and more interconnected, neglected diseases are a growing international concern that must be addressed through joint efforts between the developed and developing worlds. In particular, discrete patent systems for developing countries, joint patents and technology sharing agreements, and enhanced incentives for pharmaceutical companies will contribute to controlling and eliminating these diseases. Of course, these patent-related driving forces must he

91. Kameron W. Kramer, *The High Value (and Cost) of Patents*, ALBUQUERQUE BUS. L. (Oct. 12, 2011), http://www.albuquerquebusinesslaw.com/intellectual-property/the-high-value-and-cost-patents/.

92. Lesley Hamming, *The Promise of Priority Review Vouchers as a Legislative Tool to Encouraging Drugs for Neglected Diseases,* 11 DUKE L. & TECH. REV. 390, 394 (2013).

accompanied by governmental and societal initiatives in order to arrive at a timely and comprehensive solution.