

**ACCESS TO ESSENTIAL MEDICINES IN
DEVELOPING COUNTRIES:
THE ROLE OF INTERNATIONAL
INTELLECTUAL PROPERTY LAW & POLICY
IN THE ACCESS CRISIS**

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ABSTRACT

Effective changes to intellectual property law and policy are necessary in order to adapt to the fast-paced nature and high-speed travel of the twenty-first century and ensure global access to essential medicines, thereby promoting and safeguarding global public health. Specifically, developed countries must be encouraged to use the Trade-Related Aspects of Intellectual Property Rights (TRIPS) compulsory licensing scheme and adopt national legislation to incentivize innovation and production of affordable essential medicines for developing countries. Poor health in developing countries results in suffering and fatalities within the borders of those countries. Additionally, poor health in developing countries causes broad-reaching effects in the global community, to which developed countries are not immune. Bacteria and infectious disease are not restricted by state or national borders and thus, the health crisis of one country can quickly become the health crisis of another country. This Article discusses the impact of infectious disease on the health, economy, and national security of developed countries, primarily focusing on the effects of the tuberculosis and HIV/AIDS pandemics on the United States as a model. Access to immunizations and essential

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medicines is a critical factor in maintaining global public health and protecting the economy and national security of developing and developed countries. Thus, this Article proposes critical changes to international intellectual property law and policy in order to ensure access to essential medicines that would promote and safeguard global public health.

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I. INTRODUCTION

Global public health must be a foremost priority in all developed countries. Bacteria and infectious disease are not deterred by state or national borders and thus, the health crisis of one country can quickly become the health crisis of another country.¹ For instance, an outbreak of an infectious disease in sub-Saharan Africa will not remain restricted to that region by national borders or oceans.² In today's society of mass international travel, an outbreak in sub-Saharan Africa is one plane ride to JFK International Airport away from being an outbreak in New York City, where it could then easily spread throughout the entire United States.³

One example of an infectious disease that has crossed international borders and devastated communities worldwide is HIV/AIDS.⁴ The 2010 U.S. federal fiscal year budget request included over \$13 billion to account for the healthcare expenses of people living in the United States with HIV/AIDS.⁵ Yet, the percentage of people in the United States living with HIV/AIDS is drastically lower than the number of people living with the disease in many developing countries, which account for the vast majority of the HIV/AIDS burden.⁶ However, unlike the United States, which allocates substantial funding to cover the cost of HIV/AIDS treatment, developing countries cannot provide proper access to healthcare and thus people with HIV/AIDS have minimal access to the essential medicines necessary for their treatment.⁷ In Zimbabwe, for example—a country with one of the

¹ See Andreas Schloenhardt, *From Black Death to Bird Flu: Infectious Diseases and Immigration Restrictions in Asia*, 12 NEW ENG. J. INT'L & COMP. L. 263, 264 (2006) (discussing the globalized spread of disease).

² See *id.* (explaining how readily infectious diseases such as HIV/AIDS, SARS, and avian H5N1 influenza A (bird flu) have traveled readily across continents).

³ See *id.* (“Global commerce and travel enable infectious diseases to move around the world within days.”)

⁴ *Id.*

⁵ KAISER FAMILY FOUND., U.S. FEDERAL FUNDING FOR HIV/AIDS: THE PRESIDENT'S FY 2010 BUDGET REQUEST 1 (2009) [hereinafter KFF FACT SHEET], available at <http://www.kff.org/hiv/aids/upload/7029-05.pdf>.

⁶ See generally World Health Organization [WHO], *World Health Statistics 2009*, at 22 (2009) [hereinafter WHO Statistics 2009], available at http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf (reporting the prevalence of HIV among adults age 15 years and older). Compare the United States with 452 infected persons per 100,000 to Zimbabwe, a developing country, with 14,609 infected persons per 100,000. *Id.*

⁷ See *id.* at 25 (reporting the percentage of antiretroviral therapy coverage

highest rates of HIV/AIDS infections globally—only 17 percent of those infected with advanced HIV/AIDS have access to antiretroviral therapy coverage.⁸

The pandemic of HIV/AIDS is just one example of an infectious disease devastating the developing world while simultaneously having a drastic impact on the developed world.⁹ In order to safeguard global public health from threats such as the HIV/AIDS pandemic, the United Nations established the World Health Organization (WHO).¹⁰ The WHO Constitution grants the agency the authority to adopt conventions and seek member state adoption of such conventions (Article 19); promulgate regulations, such as the International Health Regulations (IHR) to be enforced by member states (Articles 21 and 22); and make recommendations to member states (Article 23) on public health matters.¹¹ As a member state of the WHO, the United States is required to follow the IHR and other regulations promulgated by the WHO.¹²

In addition to adopting and following WHO regulations, the United States has acted on many additional fronts to preserve global public health and prevent the spread of disease. For example, the U.S. federal government contributes substantial financial support to developing countries to fight disease.¹³ The United States, like many other countries, has also codified immigration restrictions aimed at preventing the spread of communicable diseases.¹⁴ Additionally, Congress has passed

among people with advanced HIV infection). Compare the rates of Zimbabwe at 17 percent and Madagascar at 4 percent to the regional average for the Americas (not including the United States) at 62 percent. *Id.* See also KFF FACT SHEET, *supra* note 5; Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 850–51 (2007).

⁸ See WHO Statistics 2009, *supra* note 6, at 22, 25.

⁹ See Schloenhardt, *supra* note 1, at 264 (citing the bird flu and SARS as other diseases that have negatively affected both developed and undeveloped countries).

¹⁰ Lawrence O. Gostin, *World Health Law: Toward a New Conception of Global Health Governance for the 21st Century*, 5 YALE J. HEALTH POL'Y L. & ETHICS 413, 414–15 (2005) [hereinafter Gostin, *World Health Law*].

¹¹ Constitution of the World Health Organization, *opened for signature* July 22, 1946, 62 Stat. 2679, 2685, available at <http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf>.

¹² See *id.*

¹³ See KFF FACT SHEET, *supra* note 5 (reporting that the U.S. 2010 federal fiscal year budget request allocated \$6.5 billion to fund global HIV/AIDS activity alone).

¹⁴ See 8 U.S.C.A. § 1182(a)(1)(A)(i) (West, Westlaw through P.L. 112-29 approved 9/16/11) (including under the category of ineligible aliens, any alien

legislation such as the Tom Lantos and Henry J. Hyde Global Leadership on HIV/AIDS, Tuberculosis and Malaria Reauthorization Act of 2008, which evidences the United States' commitment to the fight against the global HIV/AIDS pandemic.¹⁵

U.S. philanthropists are a driving force revolutionizing the quality of global public health. One such philanthropic organization, the Bill and Melinda Gates Foundation, has an endowment of over \$33 billion dedicated to improving global public health, poverty, and overall quality of life.¹⁶ The Gates Foundation has a wide range of commitments related to improving global public health.¹⁷ For example, the Gates Foundation's Path Malaria Vaccine Initiative and their Global Health Program focused on fighting and preventing infectious diseases, including HIV/AIDS.¹⁸

But, while the United States has proven to be a major player in improving global public health through both actions of the government and private citizens, the United States has failed to act substantially in one critical area, intellectual property rights regarding essential medicines.¹⁹ A key component to fighting and preventing infectious disease is access to the appropriate drugs and immunizations.²⁰ In its 2009 report, the WHO revealed that

“who is determined (in accordance with regulations prescribed by the Secretary of Health and Human Services) to have a communicable disease of public health significance”).

¹⁵ See Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, Pub. L. No. 110-293, 122 Stat. 2918, (“An act to authorize appropriations for fiscal years 2009 through 2013 to provide assistance to foreign countries to combat HIV/AIDS, tuberculosis, and malaria . . .”).

¹⁶ BILL & MELINDA GATES FOUND., FACT SHEET 1 (2009), available at <http://www.gatesfoundation.org/about/Documents/BMGFFactSheet.pdf>.

¹⁷ See *id.*

¹⁸ See *id.* at 2; BILL & MELINDA GATES FOUND., GLOBAL HEALTH PROGRAM FACT SHEET 1 (2009) [hereinafter GATES FOUND. GLOBAL HEALTH FACT SHEET], available at <http://www.gatesfoundation.org/global-health/Documents/global-health-fact-sheet-english-version.pdf> (discussing the Gates's global health mission and the programs they have created to fight diseases such as malaria and HIV/AIDS).

¹⁹ See Jessica L. Greenbaum, Comment, *TRIPS and Public Health: Solutions for Ensuring Global Access to Essential AIDS Medication in the Wake of the Paragraph 6 Waiver*, 25 J. CONTEMP. HEALTH L. & POL'Y 142, 143, 152, 155 (2008) (articulating the tension created by the conflicting interests of large countries like the United States, which often protect pharmaceutical patent holders and developing countries that try to gain increased access to medications through compulsory licensing).

²⁰ Lawrence O. Gostin, *Meeting Basic Survival Needs of the World's Least*

in 2008 approximately 33 million people were infected with HIV worldwide, while less than 50 percent of those people had access to antiretroviral treatment.²¹ As a member of the World Trade Organization (WTO), the United States is bound by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).²² However, the U.S. federal government has failed to effectively implement the Paragraph 6 Waiver of the 2001 Doha Declaration, which amended the TRIPS Agreement to include a compulsory licensing scheme.²³ In failing to amend federal law to effectively implement the Paragraph 6 Waiver, the United States has failed to give developing countries any confirmation that they will be permitted to take advantage of the compulsory licensing schemes available to them.²⁴

This article will focus on the need for developed countries, using the United States as a model, to assist developing countries in coping with public health crises in order to safeguard global public health. Part II of this Article will discuss the impact of infectious disease on the health, economy, and national security of developed countries, using the United States as a model and will specifically focus on the effects of the tuberculosis and HIV/AIDS pandemics. Part III will discuss the background of relevant international intellectual property law and policy regarding global public health, specifically the TRIPS Agreement, the Doha Declaration, and the Paragraph 6 Waiver. Part IV will discuss proposed changes to the national intellectual property laws and policies of developed countries, suggested in

Healthy People: Toward a Framework Convention on Global Health, 96 GEO. L.J. 331, 367–368 (2008) [hereinafter Gostin, *Basic Survival Needs*].

²¹ Joint United Nations Programme on HIV/AIDS [UNAIDS] & WHO, *09 AIDS Epidemic Update*, at 6, 9, UNAIDS/09.36E/JC1700E (Nov. 2009) [hereinafter UNAIDS 2009 Update], available at http://data.unaids.org/pub/Report/2009/JC1700_Epi_Update_2009_en.pdf.

²² Agreement on Trade Related Aspects of Intellectual Property Agreements, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1125, 1197 [hereinafter TRIPS], available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf *Members and Observers*, WORLD TRADE ORG. (2011), http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.

²³ See Greenbaum, *supra* note 19, at 150 (explaining that, as of 2006, only Norway, Canada, India, and the European Union have informed the WTO that national legislation has been enacted to allow for export under a compulsory license).

²⁴ See *id.* at 160–61 (discussing the importance of a commitment from countries to implement a compulsory licensing scheme to ensure the success of the Paragraph 6 Waiver).

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an effort to increase access to essential medicines in the developing world, again focusing on the United States as a model.

II. INFECTIOUS DISEASE HAS A GLOBAL IMPACT

In order to emphasize the nexus between health crises relating to infectious disease in developing countries and their effect and impact on developed countries, this part will focus on the potential health, economic, and national security hazards posed to developed countries as a result of poor health in developing countries. More specifically, this part will highlight these concerns in light of two current pandemics disproportionately affecting developing countries, HIV/AIDS and tuberculosis (TB), and their impact on the health, economy and national security of the United States.

During the fourteenth century, the Black Death (bubonic plague), thought to have originated in Central Asia, was one of the deadliest pandemics of mankind, killing at least 30 percent of the European population.²⁵ A later outbreak of plague, which began in Hong Kong in the late 1800s, became widespread among five continents within ten years, spread by means of rats traveling on steamships.²⁶ Thus, the concept of infectious disease crossing international borders is far from a new concept. However, unlike the fourteenth century, the twenty-first century boasts international flights and mass global travel, which naturally yields the possibility of the rapid transmission of infectious diseases worldwide.²⁷ A prime example of the speed at which a pandemic can arise in today's society is the 2009 H1N1 pandemic.²⁸ The first case of H1N1 in the United States was detected in April 2009.²⁹ By June 2009, the WHO had announced

²⁵ See Didier Raoult et al., *Molecular Identification by "Suicide PCR" of Yersinia Pestis as the Agent of Medieval Black Death*, 97 PROC. NAT'L ACAD. SCI. U.S. AM. 12800 (2000), available at <http://www.pnas.org/content/97/23/12800.full.pdf>.

²⁶ WHO, *WHO Report on Global Surveillance of Epidemic-prone Infectious Diseases*, at 26, WHO/CDS/CSR/ISR/2000.1 (2000), available at <http://www.who.int/csr/resources/publications/surveillance/plague.pdf>.

²⁷ Holly Rogers, Note, *Protecting Americans from Disease in a Global Society*, 22 SUFFOLK TRANSNAT'L L. REV. 205, 208–09 (1998).

²⁸ See *2009 H1N1 Flu ("Swine flu") and You*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Feb. 10, 2010, 5:00 PM), <http://www.cdc.gov/h1n1flu/qa.htm> [hereinafter *CDC H1N1*].

²⁹ *Id.*

that a pandemic was underway, and by January 2010 there were almost 14,000 deaths attributed to H1N1.³⁰

A. *United States Health Interests in the Health of Developing Countries*

“Globalization . . . is a powerful force, propelling people, pathogens, goods, and even cultures to far-off places. Moreover, the mechanisms that spread disease across the globe are principally manmade and exist in almost every society. Thus, the only effective response is through global cooperation, which has proved highly elusive.”³¹ In the past three decades, new diseases such as HIV/AIDS, SARS, hantavirus, and H1N1 have emerged and migrated between developing and developed countries causing massive global public health crises.³² Additionally, diseases such as West Nile virus, which were once solely a health concern of developing countries, have traveled to developed countries such as the United States.³³ Perhaps one of the most troubling recent developments, however, is the emergence of “super-bugs,” or mutated strains of already existing pathogens that are resistant to treatment, such as methicillin-resistant staphylococcus aureus (MRSA), TB, malaria, and HIV.³⁴

One-third of the world’s population is currently infected with TB, which is a highly contagious airborne disease that is a leading killer in developing countries, evidenced by the approximate 1.7 million TB deaths worldwide in 2009.³⁵ Multidrug-resistant tuberculosis (MDR-TB), however, is a more dangerous mutated strain of TB resistant to multiple antibiotics, which has emerged everywhere from South Africa to the United States.³⁶ “MDR-TB is a man-made phenomenon caused by the

³⁰ *Id.*; Eur. Centre for Disease Prevention and Control [ECDC], *2009 Influenza A (H1N1) Pandemic*, at 1, 5 (Jan. 4, 2009), available at http://www.ecdc.europa.eu/en/healthtopics/Documents/100104_Influenza_AH1N1_Situation_Report_1400hrs.pdf (analyzing official information provided by national public health sources regarding the number of confirmed 2009 pandemic influenza cases by country).

³¹ Gostin, *Basic Survival Needs*, *supra* note 20, at 352.

³² *See id.* at 353; *CDC H1N1*, *supra* note 28.

³³ Gostin, *Basic Survival Needs*, *supra* note 20, at 353.

³⁴ *Id.* at 354.

³⁵ *See Tuberculosis*, WHO (Nov. 2010), <http://www.who.int/mediacentre/factsheets/fs104/en/>.

³⁶ Jeremy R. Tarwater, Note, *The Tuberculosis & HIV Debate in Immigration Law: Critical Flaws in United States Academic Anti-Exclusion Arguments*, 15 GEO. IMMIGR. L.J. 357, 366–67 (2001).

inconsistent or unsuccessful treatment of the common TB disease. An incomplete course of medication may leave behind a new TB bacteria which is made resistant to the drugs previously utilized.”³⁷

While TB has not been common in the United States since prior to 1992, its prevalence has increased in some states, and New York City recently reported cases of a “w” strain of the MDR-TB, which is resistant to every major drug used to treat TB.³⁸ The MDR-TB strain resulted from the “inconsistent or unsuccessful treatment of the common TB disease,” and thus, TB proves to be an obvious example of the health consequences within the United States which result from poor health and treatment in developing countries.³⁹ The “MDR-TB is a man-made phenomenon” which has clearly resulted from the lack of TB treatment in developing countries, where access to drugs remains limited due to cost.⁴⁰ In sum, the resulting TB impact on the health of United States citizens is demonstrated by the almost 282,000 new cases of TB throughout the WHO Region of the Americas in 2008, with a growing percentage of those cases consisting of MDR-TB.⁴¹

In addition to developing countries’ battles with TB, the WHO estimates that at the end of 2005 there were 3.1 million AIDS deaths, most of those deaths attributed to developing countries, which alone account for 95 percent of new HIV/AIDS infections.⁴² Access to antiretroviral medicine has improved in developing countries, and by the close of 2008, the number of AIDS related deaths decreased to two million, while there were 33.4 million people living with HIV/AIDS in 2008.⁴³ However, the percentage of access to antiretrovirals still remains far lower in developing countries: for example, only 17 percent of HIV/AIDS patients in

³⁷ *Id.* at 366.

³⁸ *Id.* at 365–67.

³⁹ *See id.* at 366–67.

⁴⁰ *See id.*

⁴¹ *See* WHO, *Global Tuberculosis Control: A Short Update to the 2009 Report*, at 1, 5, WHO/HTM/TB/2009.426 (2009), available at http://whqlibdoc.who.int/publications/2009/9789241598866_eng.pdf.

⁴² UNAIDS & WHO, *AIDS Epidemic Update: Special Report on HIV Prevention*, at 1, UNAIDS/05.19E (Dec. 2005), available at http://www.unaids.org/epi/2005/doc/EPIupdate2005_pdf_en/epi-update2005_en.pdf; Christopher-Paul Milne, *Racing the Globalization of Infectious Diseases: Lessons from the Tortoise and the Hare*, 11 NEW ENG. J. INT’L & COMP. L. 1, 4–5 (2004).

⁴³ UNAIDS 2009 Update, *supra* note 21, at 6–7.

Zimbabwe have access to antiretrovirals, which not only impedes treatment in such countries, but also leads to elevated mortality rates and shorter life spans.⁴⁴ In addition to the increased suffering that results from poor access to treatment, the lack of access to complete treatment can also cause microbial adaption, resulting in mutated strains with changes in virulence and further development of drug resistance.⁴⁵

While most countries have experienced a decrease in the number of newly infected persons with HIV, this is not the case in Eastern Europe and Central Asia, where HIV prevalence (notably in the Ukraine and Russia) continues to rise.⁴⁶ As discussed above, the combination of MDR-TB, the substantial number of HIV cases occurring globally, and the lack of access to proper treatment, could result in an increased likelihood of mutations.⁴⁷ The increased number of mutations could thus increase the chances that a more virulent strain of HIV will emerge which could easily travel to the United States.⁴⁸ The HIV incidence in the United States has been relatively stable since the 1990s.⁴⁹ However, there are still approximately 56,000 new cases annually in the United States, evidencing the continuing health risk posed by HIV/AIDS to the population of the United States.⁵⁰

B. United States Economic Interests in the Health of Developing Countries

The impact of infectious disease on the United States is not limited to the health interests of its citizens. The U.S. 2010 federal fiscal year budget request included over \$13 billion to provide healthcare for people living with HIV/AIDS in the United States, and the total request for federal funding for domestic and global HIV/AIDS related expenses was an estimated \$25.8

⁴⁴ See WHO Statistics 2009, *supra* note 6, at 25; Greenbaum, *supra* note 19, at 142–43.

⁴⁵ Gostin, *Basic Survival Needs*, *supra* note 20, at 350.

⁴⁶ UNAIDS 2009 Update, *supra* note 21, at 48.

⁴⁷ See Tarwater, *supra* note 36, at 363, 366–69.

⁴⁸ See *id.* at 366–67 (emphasizing the pervasive quality of MDR-TB, a mutant strain of tuberculosis, that is “highly dangerous” because of its nature as an airborne illness, and that very resistant strains have already been discovered in the United States).

⁴⁹ UNAIDS 2009 Update, *supra* note 21, at 64.

⁵⁰ *Id.*

billion.⁵¹ Furthermore, seasonal flu activity in the United States each year causes an estimated \$10 billion in losses due to hospitalization expenses.⁵² Additionally, the World Bank estimates that a severe flu pandemic could potentially cost the United States upwards of \$623 billion.⁵³ While these examples illustrate the direct financial impact that illness can have on the United States' economy, the financial impact does not stop at hospitalization costs.

In the event of an outbreak of any highly communicable disease, a country is harmed not only by additional medical expenses, but also by possible international travel restrictions, decreased tourism, and decreased trade and commerce.⁵⁴ Moreover, even if a country itself is not affected directly by an outbreak within its own borders, it may nevertheless suffer substantial indirect economic loss as a result of the devastation to the economies of other countries due to health crises.⁵⁵ One extreme example of economic loss suffered as a result of a public health crisis is the effect of HIV/AIDS on the economy of sub-Saharan Africa, a region which accounted for 72 percent of the global HIV/AIDS deaths in 2008.⁵⁶

In some countries in sub-Saharan Africa, the average life expectancy is as low as 37 years, which could continue to decrease as sub-Saharan Africa accounted for 91 percent of the new HIV infections globally, in children for 2008.⁵⁷ Additionally, more than 14.1 million children in sub-Saharan Africa lost one or both parents to HIV/AIDS in 2008.⁵⁸ Many sub-Saharan African communities have been robbed of working-age citizens, typically responsible for raising families, contributing to the workforce, and participating in politics and other public service.⁵⁹ As a result, in some cases, the economic losses felt by countries in sub-

⁵¹ KFF FACT SHEET, *supra* note 5.

⁵² Jason Gale, *Flu Pandemic May Cost \$623 Billion, World Bank Says (Update1)*, BLOOMBERG.COM (Nov. 23, 2006), <http://www.bloomberg.com/apps/news?pid=20601087&sid=aU0JloNIbVAc>.

⁵³ *Id.*

⁵⁴ See Gostin, *Basic Survival Needs*, *supra* note 20, at 355–57.

⁵⁵ *Id.*

⁵⁶ See *id.* (discussing the economic ripple effect caused by such high rates of HIV/AIDS illness and deaths beginning with the family and continuing its devastating effects on the private market and public sphere); UNAIDS 2009 Update, *supra* note 21, at 21.

⁵⁷ UNAIDS 2009 Update, *supra* note 21, at 21.

⁵⁸ *Id.*

⁵⁹ Gostin, *Basic Survival Needs*, *supra* note 20, at 356–57.

Saharan Africa have been estimated to be as high as 20 percent of GDP.⁶⁰

Economic losses, such as those in sub-Saharan African countries, hold substantial potential to affect those countries' ability to trade and participate in commerce.⁶¹ For example, countries in health crises that have lost significant numbers of working-age citizens will likely have difficulty cultivating crops and developing their resources to create products for exportation.⁶² Furthermore, countries devastated by poor health will likely have decreased markets for imports from their trading partners, thus affecting their trading partners from both an import and export perspective.⁶³ The United States may not currently feel substantial effects from the indirect economic losses resulting from the decreased trading abilities of countries in sub-Saharan Africa discussed above.⁶⁴ However, the continued rise of the prevalence of HIV/AIDS in Eastern European and Central Asian countries could pose a significantly greater threat to the United States economy as well as to national security.⁶⁵

C. United States National Security Interest in the Health of Developing Countries

Infectious disease epidemics/pandemics, such as the HIV/AIDS pandemic threaten United States national security on many levels.⁶⁶ For example, outbreaks threaten the health and safety of U.S. troops while deployed in regions experiencing crises

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.* (explaining the ways in which countries with poor health become problematic trade partners as they become less able to spend money on imports and loan payments and more dependent upon international aid and humanitarian interventions).

⁶⁴ *See id.* (suggesting that disease in developing countries could pose a significant threat to trade and commerce in developed countries).

⁶⁵ Harley Feldbaum et al., *The National Security Implications of HIV/AIDS*, 3PLOS MED. 0774, 0774–76 (2006), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1475649/pdf/pmed.0030171.pdf>. (articulating the national security concerns that could arise if what has been called a “second wave” of HIV were to arise in countries such as Russia, China, and India, which are critical to U.S. political, military, and economic interests); *see id.* at 361 (listing the problems developed countries can face as a result of poor health in foreign countries); UNAIDS 2009 Update, *supra* note 21, at 48 (providing statistics that AIDS is spreading in Central Asia and Eastern Europe).

⁶⁶ *See* Feldbaum, *supra* note 65, at 0774–75.

involving infectious disease.⁶⁷ Additionally, poor health in a country leads to social and political instability which can affect a country's ability to prevent and deal with war, civil unrest, and humanitarian crises.⁶⁸ Lastly, as discussed above, outbreaks of infectious disease in developing countries endanger both the health of U.S. citizens, including U.S. troops, on U.S. soil and the health of U.S. citizens traveling or living abroad, resulting in increased healthcare expenses and potential loss of productivity.⁶⁹

In 1998, UNAIDS reported a substantially higher risk for transmission of sexually transmitted diseases (STDs including HIV/AIDS) among military personnel.⁷⁰ "In peacetime, STD infection rates among armed forces are generally two to five times higher than in comparable civilian populations."⁷¹ Deployed troops regularly have sexual contact with sex workers in the local community, increasing troop exposure to infectious disease, and possibly increasing the likelihood of exposure to families of troops upon their return from deployment.⁷² Additionally, as a result of troop exposure to infectious disease, the success of military missions can be threatened, and troop casualties during wartime can be significantly increased.⁷³ Furthermore, the effect of increased exposure of troops to infectious disease will also have broader effects on the militaries of developed countries.⁷⁴ For example, the cost of military funding will rise due to increased medical costs for disease treatment and the cost of replacing trained soldiers who fall ill as a result of infectious disease.⁷⁵

Perhaps more concerning to national security, however, is the research-based association between poor public health and social

⁶⁷ *Id.* at 0775; see also Gostin, *Basic Survival Needs*, *supra* note 20, at 358 (explaining that instances of endemic infectious disease have a negative effect on the success of military missions and lead to a high rate of troop casualties).

⁶⁸ Gostin, *Basic Survival Needs*, *supra* note 20, at 357–58.

⁶⁹ See Feldbaum, *supra* note 65, at 0775; KFF FACT SHEET, *supra* note 5 (reporting that 51 percent of the domestic portion of the U.S. federal budget for HIV/AIDS goes to care and treatment programs).

⁷⁰ UNAIDS, *AIDS and the Military*, at 2 (May 1998), available at http://data.unaids.org/Publications/IRC-pub05/militarypv_en.pdf (UNAIDS Best Practice Collection).

⁷¹ *Id.*

⁷² *Id.*

⁷³ Gostin, *Basic Survival Needs*, *supra* note 20, at 358.

⁷⁴ Feldbaum, *supra* note 65, at 0775.

⁷⁵ *Id.*

and political instability.⁷⁶ Health crises and overall unhealthy populations can lead to dysfunctional governments and increase the likelihood of further crises, including “gross human rights abuses such as torture, trafficking of young girls for sex, enlisting child soldiers, and even genocide.”⁷⁷ Additionally, political instability can lead to increased engagement in international political conflicts, and increased harboring and recruitment of terrorists, which could thus translate into national security issues for both allies and enemies.⁷⁸ The potential increase in political instability in allied countries as well as enemy territories could affect the need for United States military presence in those regions for humanitarian and peacekeeping measures.⁷⁹ Moreover, such increased political instability could increase the likelihood of enemy territories engaging in war or terrorist activities directed towards the United States or its allies.⁸⁰

Currently, the HIV/AIDS burden falls disproportionately on sub-Saharan Africa.⁸¹ While sub-Saharan Africa has been plagued with instability, there has been little evidence that this instability has directly resulted in trade-related economic losses or threats, through political or military powers, to the United States.⁸² Such instability in sub-Saharan Africa, however, may not be likely to cause the predicted effects in developed countries, as this region does not represent a key political, military, or economic world leader.⁸³ Alternatively, it is important to note that while the United States has not seen substantial direct economic losses due to decreased trading with sub-Saharan African countries, the United States has seen indirect economic

⁷⁶ See Gostin, *Basic Survival Needs*, *supra* note 20, at 358 (“The Central Intelligence Agency, for example, finds that high infant mortality is one of the leading predictors of State failure.”).

⁷⁷ *Id.*

⁷⁸ *Id.* at 357–59.

⁷⁹ See *id.* at 357–58.

⁸⁰ See *id.* (suggesting that unhealthy and fragmented states act as a vacuum for terrorist recruitment and/or harboring).

⁸¹ See UNAIDS 2009 Update, *supra* note 21, at 21 (showing that sub-Saharan Africa represents over two-thirds of the world’s HIV infections as of 2008).

⁸² See Gostin, *Basic Survival Needs*, *supra* note 20, at 357–59 (explaining that the rest of the world has largely avoided the harmful effects of sub-Saharan Africa’s HIV crisis); Feldbaum, *supra* note 65, at 0776–77 (stressing that more evidence on the links between HIV and national security is necessary, as the correlation is currently perceived but not yet definitively established).

⁸³ Gostin, *Basic Survival Needs*, *supra* note 20, at 359.

losses through the billions of dollars in U.S. federal and private aid that is directed to the fight against infectious disease in sub-Saharan Africa.⁸⁴

Fortunately, the sub-Saharan Africa region has been a main target for humanitarian efforts to reduce the prevalence of HIV/AIDS and has been experiencing a continued decrease in the rate of new HIV/AIDS infections.⁸⁵ However, Eastern Europe and Central Asia, unlike sub-Saharan Africa, have been experiencing a significant increase in the prevalence of HIV/AIDS, shown by the 66 percent increase in the number of people living with HIV/AIDS from 2001 to 2008.⁸⁶ While the rate of HIV/AIDS mortality has been on the decline in Asia, the mortality rate has continued to increase in East Asia (including China), and accounts for the second highest number of HIV/AIDS cases worldwide, behind sub-Saharan Africa.⁸⁷ Asia holds more than 60 percent of the global population, and unlike sub-Saharan Africa, many countries in Asia and Eastern Europe are key players in the global economy and have substantial military and political influence worldwide.⁸⁸

The increase in HIV/AIDS prevalence in Eastern Europe, Central Asia, and East Asia has been described as a “second wave” of HIV/AIDS, and it is predicted that the global burden of HIV/AIDS will shift from Africa to this region.⁸⁹ Furthermore, the percentage of access to antiretrovirals in these regions remain significantly lower than the global average, with an average of 22 percent of those in need receiving coverage.⁹⁰ Eastern Europe, Central Asia, and East Asia are regions of strategic importance, and China, in particular, is the second largest trading partner to the United States and a key global

⁸⁴ *See id.* (stating that most of the world has remained insulated from the poor health implications of sub-Saharan Africa’s HIV pandemic); KFF FACT SHEET, *supra* note 5 (showing that the U.S. government’s proposed budget for Fiscal Year 2010 included an estimated \$6.5 billion for funding for global HIV/AIDS causes); GATES FOUND. GLOBAL HEALTH FACT SHEET, *supra* note 18 (listing several multi-million dollar grants targeted towards infectious disease prevention and treatment).

⁸⁵ UNAIDS 2009 Update, *supra* note 21, at 8, 21–22.

⁸⁶ *Id.* at 21, 48.

⁸⁷ *Id.* at 37.

⁸⁸ *Id.*; Gostin, *Basic Survival Needs*, *supra* note 20, at 360–61.

⁸⁹ Gostin, *Basic Survival Needs*, *supra* note 20, at 359–60; *see* Feldbaum, *supra* note 65, at 0776.

⁹⁰ UNAIDS 2009 Update, *supra* note 21, at 48.

military power.⁹¹ Thus, it is clear that infectious disease outbreaks resulting in a decrease in political stability and/or economic productivity in the more powerful and high trading countries of Eastern Europe, Central Asia, and East Asia could pose a much greater threat to the U.S. economy and national security as compared to similar instability in sub-Saharan Africa.⁹²

The availability of essential medicines, such as immunizations and drugs used for treatment, is a critical factor in improving public health and preventing infectious disease epidemics, which could result in the instability discussed above.⁹³ However, there are many factors which affect access to essential medicines, most notably the cost of drugs.⁹⁴ Given the importance of access to essential medicines in obtaining and maintaining public health in developing and developed countries, the next section discusses the global intellectual property laws and policies relevant to access to essential medicines and thus global public health.

III. BACKGROUND ON INTERNATIONAL INTELLECTUAL PROPERTY LAW RELEVANT TO IMPROVING GLOBAL PUBLIC HEALTH THROUGH ACCESS TO ESSENTIAL MEDICINES

Intellectual property on an international level is regulated through the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which was created by the WTO in 1995.⁹⁵ TRIPS creates a minimum standard of intellectual property protection and allows member states to determine how to implement TRIPS requirements into their own law by providing that “[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”⁹⁶ Articles 27–35 of TRIPS detail patent rights and allow for patent protection for at least twenty years from the date the patent

⁹¹ Gostin, *Basic Survival Needs*, *supra* note 20, at 359–61; *Foreign Trade Statistics: Top Trading Partners—Total Trade, Exports, Imports*, U.S. CENSUS BUREAU, <http://www.census.gov/foreign-trade/statistics/highlights/top/top1012yr.html> (last modified July 12, 2011).

⁹² See Gostin, *Basic Survival Needs*, *supra* note 20, at 360–61; Feldbaum, *supra* note 65, at 0776–77.

⁹³ See Gostin, *Basic Survival Needs*, *supra* note 20, at 367–69.

⁹⁴ David W. Opperbeck, *Patents, Essential Medicines, and the Innovation Game*, 58 VAND. L. REV. 501, 508–09 (2005).

⁹⁵ TRIPS, *supra* note 22, 33 I.L.M. at 1197.

⁹⁶ *Id.* at 1198.

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application was filed.⁹⁷ However, the Agreement provides for exceptions where member states are not required to grant patents in certain limited circumstances.⁹⁸

Article 30 of TRIPS provides for an exception to patent rights, referred to as compulsory licensing, where “[m]embers may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”⁹⁹ Article 31 further delineates a list of requirements, which need to be met in order for a compulsory license to be issued, including requirements that the person seeking the license must first attempt to obtain a voluntary license from the patent holder, and the patent holder must receive sufficient remuneration costs.¹⁰⁰

In response to concerns of developing countries regarding compliance with the compulsory license requirements set forth by TRIPS, the WTO adopted the Doha Declaration on the TRIPS Agreement and Public Health in 2001.¹⁰¹ In the midst of concern regarding the effect of TRIPS on public health, the Doha Declaration stated that TRIPS “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”¹⁰² In paragraph six of the Declaration, the WTO stated “WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem”¹⁰³

In 2003, in response to paragraph six of the Doha Declaration, the WTO released a General Council Decision, which became

⁹⁷ *Id.* at 1208–11.

⁹⁸ *Id.* at 1209; Greenbaum, *supra* note 19, at 146–47.

⁹⁹ TRIPS, *supra* note 22, 33 I.L.M. at 1209; Greenbaum, *supra* note 19, at 146–47.

¹⁰⁰ *See* TRIPS, *supra* note 22, 33 I.L.M. at 1209–10.

¹⁰¹ WTO, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration], *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf; Greenbaum, *supra* note 19, at 148.

¹⁰² Doha Declaration, *supra* note 101, 33 I.L.M. at 755.

¹⁰³ *Id.* at 33 I.L.M. at 756.

known as the Paragraph 6 Waiver.¹⁰⁴ The Paragraph 6 Waiver addressed and modified the language of Article 31(f) of TRIPS, which originally required that in order to use compulsory licensing the use “shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.”¹⁰⁵ In order to alleviate this requirement, paragraph six waived the domestic market requirement of Article 31(f), stating that

[T]he obligation of that [exporting] Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question.¹⁰⁶

In 2005, the WTO approved the changes to the TRIPS Agreement proposed by the Paragraph 6 Waiver, and the United States accepted those changes.¹⁰⁷ The deadline for these changes to be formally accepted by two-thirds of the WTO and built into the TRIPS Agreement was extended from December 2011 to December 2013.¹⁰⁸ However, since the acceptance of the Paragraph 6 Waiver, the implementation of compulsory licensing by developing countries has been almost non-existent.¹⁰⁹ Furthermore, post-TRIPS and the Paragraph 6 Waiver, cost and access to affordable essential medicines remains a crucial problem in developing countries, as indicated by the continued inability of developing countries to provide proper access to antiretroviral therapy for HIV/AIDS patients.¹¹⁰

“Policies that result in lower prices for pharmaceuticals in developing countries thus represent a crucial step towards

¹⁰⁴ See Greenbaum, *supra* note 19, at 149.

¹⁰⁵ See General Council Decision, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 3, 2003) [hereinafter Paragraph 6 Waiver], available at <http://www.worldtradelaw.net/misc/dohapara6.pdf>; TRIPS, *supra* note 22, 33 I.L.M. at 1210; *id.*

¹⁰⁶ Paragraph 6 Waiver, *supra* note 105.

¹⁰⁷ *Members accepting amendment of the TRIPS Agreement*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last updated Jan. 5, 2012) [hereinafter WTO Members Accepting Paragraph 6].

¹⁰⁸ *Id.*

¹⁰⁹ See Greenbaum, *supra* note 19, at 157–61 (noting that as of 2007, Rwanda was the only developing country to give the WTO notice of its intent to employ the waiver).

¹¹⁰ See WHO Statistics, *supra* note 6, at 11–12, 25.

increasing access to essential medicines.”¹¹¹ Given the above discussion on the continued problem of access to affordable essential medicines in developing countries and the potential threats of poor global public health on developed countries, policy proposals relating to international intellectual property law and improved access to essential medicines are crucial.

IV. PROPOSED INTELLECTUAL PROPERTY LAW & POLICY CHANGES

The broad efforts by the United States to improve public health and prevent the spread of disease have included, but not been limited to: substantial disbursements of federal funding to developing countries; generous private philanthropic donations of financial and humanitarian support to developing countries; legislation to guarantee financial support to the HIV/AIDS crisis; and legislation to prevent immigration into the United States by any alien “who is determined (in accordance with regulations prescribed by the Secretary of Health and Human Services) to have a communicable disease of public health significance.”¹¹²

However, when it comes to changing intellectual property law and policy in order to assist in the improvement of global public health, the United States has made an insufficient effort. The United States has accepted the changes to the TRIPS agreement proposed by the Paragraph 6 Waiver.¹¹³ Though the United States, where many of the world’s major pharmaceutical companies are based, has yet to enact legislation or guidelines regarding the exportation of licensed drugs to developing countries and compliance with the amended version of the TRIPS Agreement.¹¹⁴ Furthermore, in addition to the absence of federal legislation regarding the use of compulsory licensing schemes by developing countries, the United States has failed to make any

¹¹¹ Opperbeck, *supra* note 94, at 509.

¹¹² 8 U.S.C.A. § 1182(a)(1)(A)(i) (West, Westlaw through P.L. 112-28 approved 8/12/11); Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, Pub. L. No. 110-293, §§ 202, 204, 122 Stat. 2918, 2936–38, 2942–43 (2008) (codified as amended at 22 U.S.C. §§ 7622–7623 (Supp. 2009)); see GATES FOUND. GLOBAL HEALTH FACT SHEET *supra* note 18; KFF FACT SHEET, *supra* note 5 (indicating the increasing amount of federal funds that has been allocated to combating the HIV/AIDS epidemic).

¹¹³ WTO Members Accepting Paragraph 6, *supra* note 107.

¹¹⁴ See Greenbaum, *supra* note 19, at 149–50, 152, 155–58, 161–62 (explaining that as of 2006 only Norway, Canada, India, and the European Union have informed the WTO that national legislation has been enacted to allow for export under a compulsory license).

strong public commitment to show developing countries that they will indeed be able to successfully implement the TRIPS compulsory licensing scheme.¹¹⁵ To the contrary, the United States has arguably given the impression to developing countries that they may be in danger of having sanctions imposed upon them for requesting to import under compulsory licenses.¹¹⁶

In 2001, for example, the United States sought to have sanctions through the WTO imposed against Brazil, regarding a national law that subjected patent holders who did not manufacture their products in Brazil to compulsory licensing after three years.¹¹⁷ The request for sanctions was later withdrawn from the WTO panel.¹¹⁸ However, this action, on behalf of a powerful country, such as the United States, arguably discouraged developing countries from utilizing the TRIPS compulsory licensing scheme.¹¹⁹ As a result of the United States' actions, "[e]ven if countries do not fear direct sanctions, the United States sent a strong message for its distaste of compulsory licensing."¹²⁰ Thus, while the United States has formally accepted the Paragraph 6 Waiver, it is possible that developing countries fear that notifying developed countries of a compulsory license request may result in possible trade retaliation or loss of foreign investment from developed countries seemingly hostile towards granting compulsory licenses abroad.¹²¹

As this article has highlighted, access to treatment remains a key challenge in fighting health crises in developing countries, and also continues to drive the emergence of new, more virulent, and more resistant strains of pathogens.¹²² Thus, it is clear that one of the most crucial contributions the United States could make to help safeguard global public health would be to increase

¹¹⁵ *See id.*

¹¹⁶ *See id.* at 155–56.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 156.

¹¹⁹ *See id.* at 156–57.

¹²⁰ *See id.* at 153–57 (referring to the United States' decision to seek sanctions against Brazil for their "local working requirement" in 2001, while Brazil was attempting to decrease the cost of individual antiretrovirals for HIV/AIDS).

¹²¹ Graham Dutfield, *Delivering Drugs to the Poor: Will the TRIPS Amendment Help?*, 34 AM. J.L. & MED. 107, 123 (2008); Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 283, 330 (2008).

¹²² *See supra* text accompanying notes 33–49.

access to vaccinations and essential medical treatment in developing countries.¹²³ Therefore, in addition to continued efforts to promote public health through funding and incentives unrelated to intellectual property, the United States should promote and encourage developing countries to take advantage of the TRIPS compulsory licensing scheme rather than discourage its use.¹²⁴ Furthermore, the United States should create new incentives, through legislation, for U.S. pharmaceutical companies to produce and manufacture more affordable essential medicines for markets in developing countries.¹²⁵

Specifically, developed countries, such as the United States should put the strongest emphasis possible on incentivizing the research and development of vaccinations for diseases plaguing developing countries.¹²⁶ The availability of immunizations is one of the most important factors in improving public health and can save millions of lives, and prevent suffering, death, and illness related medical expenses.¹²⁷ Vaccines are extremely cost effective because they are prophylactic.¹²⁸ Thus, incentivizing research and development for vaccines for prominent illnesses in developing countries could decrease the amount of future contributions developed countries would have to make towards treating and controlling the spread of infectious disease.¹²⁹ In order to avoid the possible threats posed by poor health in developing countries to the health, economy, and national security of developed countries, it is imperative that the United States utilize intellectual law and policy as a tool to increase access to essential medicines and vaccinations in developing countries.¹³⁰

¹²³ See Gostin, *Basic Survival Needs*, *supra* note 20, at 367–369.

¹²⁴ See Greenbaum, *supra* note 19, at 161.

¹²⁵ See *id.* at 162.

¹²⁶ See Gostin, *Basic Survival Needs*, *supra* note 20, at 334, 342–46, 367–69 (explaining that it is in the interest of wealthy states to help provide for the “basic survival needs” of those who live in underdeveloped states, by providing for vaccines, essential medicines, and any necessary research and development).

¹²⁷ See *id.* at 367–68.

¹²⁸ *Id.* at 367.

¹²⁹ See *id.* at 367–69.

¹³⁰ See Gostin, *Basic Survival Needs*, *supra* note 20, at 354–62 (explaining the impact that global health has on the national security and economy of developed countries); Greenbaum, *supra* note 19, at 161–62 (explaining how developed states can change their intellectual laws and policies to increase the access that developing states have to essential medicines and vaccines).

A. *Encouraging & Promoting The Use of TRIPS Compulsory Licensing Scheme*

The lack of utilization of the TRIPS compulsory licensing scheme by developing countries evidences the fact that the mere act of formally accepting the Paragraph 6 Waiver is insufficient.¹³¹ Developed countries, specifically the United States, should actively encourage the use of the TRIPS compulsory licensing scheme, attempt to alleviate possible fears of sanctions or retaliation caused by the United States actions against Brazil in 2001, and discourage developed countries from seeking stronger protections than those provided by TRIPS with respect to essential medicines.¹³²

First, developed countries should make a public commitment to developing countries, reiterating that the public health of developing countries is of utmost importance and will be taken into consideration when enforcing international intellectual property law.¹³³ Developed countries should both publicly reaffirm the ability of developing countries to request compulsory licenses under the appropriate circumstances and reassure those countries that such a request will not be followed by any form of sanctions, trading retaliation, or decreased financial support.¹³⁴ Second, developed countries should back their proposed public commitment by promulgating national guidelines regarding the implementation of the Paragraph 6 Waiver and outlining means of effective cooperation for companies exporting under a compulsory license.¹³⁵ Furthermore, at their discretion, developed countries could offer rewards, such as additional funding or tax incentives, to companies for timely cooperation and voluntary granting of compulsory licenses for essential medicines in developing countries suffering a health crisis.¹³⁶

¹³¹ See Greenbaum, *supra* note 19, at 161–62, 164–65.

¹³² See *id.* at 155–57, 161–62.

¹³³ See *id.* at 161 (“A specific commitment by developed countries like the United States should be issued so that those countries facing health crises can feel safe in their ability to use the TRIPS compulsory licensing schemes.”).

¹³⁴ See *id.* at 161–62; Dutfield, *supra* note 121, at 123; Bird & Cahoy, *supra* note 121, at 330 (pointing out that collective action among developing countries might insulate them from decreased financial support).

¹³⁵ See Greenbaum, *supra* note 19, at 162.

¹³⁶ See Donald Harris, *TRIPS After Fifteen Years: Success or Failure, As Measured By Compulsory Licensing*, 18 J. INTELL. PROP. L. 367, 390–91 (2011) (discussing how the lack of incentives and a complicated process discouraged a Canadian company from continuing to enter into compulsory licensing agreements); James Love & Tim Hubbard, *Prizes for Innovation of New*

Lastly, the WTO should act to ensure that member states are complying with the Paragraph 6 Waiver and not discouraging developing countries from requesting compulsory licenses.¹³⁷ The WTO should promulgate sample guidelines for member states to adopt, and should propose legislation that would assess penalties on any developed country (member state) who actively discourages the use of the compulsory licensing scheme through inappropriate measures.¹³⁸ Such inappropriate measures should include, but not be limited to, seeking sanctions where they are not provided for under TRIPS as a tactic to deter future requests for compulsory licensing or retaliation by means of trade or withdrawal of foreign direct investment.¹³⁹

However, in the case that pharmaceutical companies are willing and able to offer essential medicines at an affordable rate to markets in developing countries, there would be no need to grant a compulsory license under TRIPS. Thus, this approach should be incentivized and rewarded, as the next section will discuss.¹⁴⁰

*B. Means for Incentivizing the Production of Affordable
Essential Medicines*

The United States has implemented intellectual property law that could improve pharmaceutical access in developing countries in the form of an early working exception, known as the Bolar Exception.¹⁴¹ The Bolar Exception affords generic producers the opportunity “to import, manufacture and test a patented product prior to” the expiration of the patent term for the purposes later fulfilling generic marketing regulatory requirements imposed by

Medicines and Vaccines, 18 ANNALS HEALTH L. 155, 162–67 (2009) (suggesting that the government reward pharmaceutical companies with cash prizes instead of exclusive property rights for successfully developing a new medicine).

¹³⁷ See Greenbaum, *supra* note 19, at 161–62 (stating that the WTO should threaten sanctions against developed countries that retaliate against developing countries that utilize compulsory licenses).

¹³⁸ See *id.*

¹³⁹ See *id.* at 161; Dutfield, *supra* note 121, at 123; Bird & Cahoy, *supra* note 121, at 330.

¹⁴⁰ See Yu, *supra* note 7, at 843–46 (describing why pharmaceutical companies might refuse to make drugs available to the markets of developing countries at reduced prices); Love & Hubbard, *supra* note 136, at 162–63 (discussing different strategies to lower drug prices and encourage innovation in drug development).

¹⁴¹ Yu, *supra* note 7, at 903–04.

a particular country.¹⁴² However, allowing generic companies based in developing countries such early access to pharmaceuticals, or even granting a compulsory license for an essential medicines, unless imported under the license, in many cases may prove to be essentially useless.¹⁴³

The granting of early access or compulsory licenses can be insufficient due to the fact that many developing countries lack the technical expertise, financial resources, and manufacturing capacity necessary to develop and manufacture pharmaceuticals on a large scale.¹⁴⁴ Given the potential production and manufacturing problems in developing countries, and the trend of developed countries to disfavor requests to import under a compulsory license, it is arguable that promoting the use of the TRIPS compulsory licensing scheme by developing countries is not the most effective means of increasing the affordability of essential medicines.¹⁴⁵

Arguably, a more effective approach would be to change national intellectual property laws and policies in order to create incentives for pharmaceutical companies to innovate and manufacture certain essential medicines at an affordable cost for markets in developing countries.¹⁴⁶ Currently, under the U.S. Patent Act, an inventor filing for a patent is guaranteed “no more than [a] 3-year application pendency” with an extension for each day of delay (not caused by the filing party).¹⁴⁷ Upon approval by the U.S. Patent and Trademark Office (USPTO), the patent holder is entitled to rights for 20 years from the appropriate filing date.¹⁴⁸ This section proposes two significant changes to the U.S. patent law, relating to both the amount of time taken for application pendency and the duration of patent rights, in order

¹⁴² *Id.*; 21 U.S.C.A. § 355(j) (West, Westlaw through P.L.112-28 approved 8/12/11).

¹⁴³ Yu, *supra* note 142, at 846, 848–49.

¹⁴⁴ *Id.* at 846–49.

¹⁴⁵ *See id.*; Greenbaum, *supra* note 19, at 156–58, 160–62.

¹⁴⁶ *See* Pamela Das, Comment & Case Note, *Innovation, Access and the Public's Health: Intellectual Property Rights in Mexico & the TB Epidemic*, 15 L. & BUS. REV. AMERICAS 405, 422–23 (2009) (suggesting that potential negative effects of patents could be negated by creating a financial reward system for pharmaceutical companies which would reward positive healthcare outcomes); Love & Hubbard, *supra* note 136, at 162–64.

¹⁴⁷ United States Patent Act, 35 U.S.C.A. § 154(b)(1)(B) (West, Westlaw through P.L. 112-28 approved 8/12/11).

¹⁴⁸ United States Patent Act, 35 U.S.C.A. § 154(a)(2)(West, Westlaw through P.L. 112-28 approved 8/12/11).

to create the desired incentives.

First, this section proposes the implementation of a fast track examination program for qualifying pharmaceuticals, in order to allow for shorter application pendency in the USPTO. In 2009, the USPTO implemented a pilot program to accelerate the examination of green technology patent applications which will reduce the average application pendency to one year for qualifying applications.¹⁴⁹ Under this pilot program, qualifying applications relating to green technology “will be advanced out of turn for examination without meeting all of the current requirements of the accelerated examination program (e.g., examination support document).”¹⁵⁰ This section proposes that a fast track examination program, likened to the pilot program for green technology, be adopted for qualifying pharmaceuticals. The proposed program would allow for companies to get their product to the market faster, which could in-turn yield increased profits, thus incentivizing companies to innovate products that qualify for the fast track program.¹⁵¹

Furthermore, this section proposes that the USPTO establish formal guidelines regarding the determination of qualifying pharmaceuticals. The formal guidelines should require that applications for the fast track program be examined in light of the following non-exhaustive list of criteria: (1) whether the drug would treat a globally neglected disease, or disease which disproportionately affects developing countries; (2) whether the drug is preventative (immunizations given highest priority) or for treatment; (3) the severity of the illness prevented or treated by the drug; (4) the potential global impact on public health resulting from the disease to be treated or prevented; (5) the reasonableness of the price the company is willing to offer to markets of developing countries; and (6) the willingness of the company to file a certification binding them to offer the drug for a price that is fair and reasonable in developing countries, as compared to a comparable generic price, for the duration of the

¹⁴⁹ Notice of Pilot Program for Green Technologies Including Greenhouse Gas Reduction, 74 Fed. Reg. 234 (Dec. 8, 2009).

¹⁵⁰ *Id.*

¹⁵¹ See Immediate Release, U.S. Patent & Trademark Office [USPTO], USPTO Will Pilot a Program to Accelerate the Examination of Certain Green Tech. Patent Applications (Dec. 7, 2009), available at http://www.uspto.gov/news/pr/2009/09_33.jsp (“[The pilot program will be an] incentive to fuel further innovation of clean technology and a terrific mechanism to speed the dissemination of these patented technologies throughout the world.”).

patent term.¹⁵²

Second, the United States Congress should pass legislation providing an essential medicines patent term extension for pharmaceuticals specific to their use to prevent or treat diseases causing public health crises in developing countries. The proposed legislation would extend the patent term for qualifying medicines, in a similar fashion as the patent term extension created by the Hatch-Waxman Act.¹⁵³ However, unlike the Hatch-Waxman Act, which principally extends the patent term for qualifying patents by the appropriate amount of time in order to offset a delay resulting from agency approval, the proposed legislation would extend a patent term by a set amount of time (recommended one to three year extension) as a reward and incentive, by adding a critical extension which could thus increase profits.¹⁵⁴

The proposed legislation should include similar guidelines to those mentioned above for determining qualifying medicines under the fast track program, with the goal being to grant extensions to pharmaceuticals aimed at improving public health conditions in developing countries. An emphasis should be placed on the treatment and prevention of infectious diseases with the potential to cause the type of health, economic, and national security threats discussed in part II. Furthermore, a mandatory requirement to be considered as a qualifying pharmaceutical patent for the proposed extension should be a signed and binding certification requiring the patent holder to offer their drug for a price that is fair and reasonable in developing countries, as compared to a comparable generic price, for the duration of their patent term.

V. CONCLUSION

“Prevention of infectious diseases requires detection, reduction, and elimination at the sources of these diseases, which in turn requires improvements in basic health services and conditions for

¹⁵² See Das, *supra* note 146, at 422–23 (suggesting the implementation of a system that rewards drug companies for developing drugs based upon a public health need).

¹⁵³ See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 201, 98 Stat. 1585, 1598–1602 (1984) (codified as amended at 35 U.S.C.A. § 156).

¹⁵⁴ See *id.* (disclosing the terms for extension whereby after the allowance of the patent application, the extension of time is equal to the length of time the regulatory agency takes to review post allowance).

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all peoples.”¹⁵⁵ Poor health in developing countries results in suffering and fatalities within the borders of those countries, and has broad-reaching effects to the global community, to which developed countries are not immune.¹⁵⁶ The HIV/AIDS pandemic and spread of other infectious diseases may have disproportionate direct effects on developing countries; however, these health crises have, and will continue to have, a significant impact on the health, economy and national security of developed countries.¹⁵⁷ Access to immunizations and essential medicines is a critical factor in improving and maintaining public health in developing countries.¹⁵⁸ Thus, it is imperative that developed countries strive to improve access, if not for humanitarian reasons or based on the notion of a right to health, then to protect their own country’s health, economy, and national security.¹⁵⁹

Developed countries must continue to safeguard global public health, not only by providing funding and support to developing countries, but also by increasing access to essential medicines through altering national intellectual property laws and policy.¹⁶⁰ This article has proposed effective changes to intellectual law and policy, including encouraging the use of the TRIPS compulsory licensing scheme and the adoption national legislation to incentivize innovation and production of affordable essential medicines for developing countries. These proposals must be adopted to ensure global access to essential medicines and to promote and safeguard global public health and thus to promote increased global stability.

¹⁵⁵ Allyn L. Taylor, *Controlling the Global Spread of Infectious Diseases: Toward a Reinforced Role for the International Health Regulations*, 33 HOUS. L. REV. 1327, 1361 (1997).

¹⁵⁶ See *id.* at 1332–34; Gostin, *Basic Survival Needs*, *supra* note 20, at 355–56.

¹⁵⁷ See Gostin, *Basic Survival Needs*, *supra* note 20, at 355–56; Gostin, *World Health Law*, *supra* note 10, at 420–21.

¹⁵⁸ See Gostin, *Basic Survival Needs*, *supra* note 20, at 367.

¹⁵⁹ See *id.* at 355–56; Gostin, *World Health Law*, *supra* note 10, at 420–21.

¹⁶⁰ See Gostin, *Basic Survival Needs*, *supra* note 20, at 419–21.