HISTORY, TRIPS, AND COMMON SENSE: CURBING THE COUNTERFEIT DRUG MARKET IN SUB-SAHARAN AFRICA

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I. INTRODUCTION

Imagine that you are an average citizen living in a sub-Saharan African country where almost half of the population survives on $1.25 U.S. dollars per day or less.[1] Day to day existence is hard enough to manage on this meager budget without added medical expenses. But, you, just as many other sub-Saharan Africans, succumb to the region's overwhelming disease burden and fall ill.[2] Accessing effective and affordable medication should be simple. Unfortunately, it is not. Unable to afford medications offered through a traditional pharmacy or medical facility, you buy your medications from a street vendor who sells medications at a price you can afford. You know that this medication may not be the same medication available at a hospital or pharmacy, but you buy it anyway. Buying what turns out to be a counterfeit drug, you could become one of the 100,000 sub-Saharan Africans who die each year from consuming these poor-quality counterfeits.[3]

The World Health Organization (WHO) estimates that in some developing countries up to 50% of the medications on the market are counterfeit.[4] These counterfeit medications generally are not the result of patent infringement as they are made to imitate legitimate, off-patent generic drugs. These drugs are typically made by criminal counterfeiters and often contain incorrect amounts of active ingredients or faulty formulations which make the drugs at best ineffective and at worse deadly.[5]

Understandably, sub-Saharan countries want to keep these dangerous products out of their countries and have passed legislation to achieve that

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[1] According to the World Bank, 46.8 % of sub-Saharan Africans lived on less than $1.25 U.S. dollars per day in 2011. *Poverty & Equity*, THE WORLD BANK, http://povertydata.worldbank.org/poverty/region/SSA (last visited Nov. 1, 2014).

[2] INSTITUTE FOR HEALTH METRICS AND EVALUATION ET AL., THE GLOBAL BURDEN OF DISEASE: GENERATION EVIDENCE, GUIDING POLICY, SUB-SAHARAN AFRICA REGIONAL EDITION 8 (2013), *available at* http://documents.worldbank.org/curated/en/2013/08/18187588/global-burden-disease-generating-evidence-guiding-policy-sub-saharan-africa-regional-edition.

[3] *See* Roger Bate, *The Deadly World of Fake Medicine*, CNN (July 17, 2012), http://www.cnn.com/2012/07/17/health/living-well/falsified-medicine-bate/index.html; Jocelyne Sambria, *Counterfeit Drugs Raise Africa's Temperature*, AFRICAN RENEWAL (May 2013), http://www.un.org/africarenewal/magazine/may-2013/counterfeit-drugs-raise-africa%E2%80%99s-temperature; Henry Miller, *Fake and Flawed Medicines Threaten Us All*, FORBES (July 25, 2012), http://www.forbes.com/sites/henrymiller/2012/07/25/fake-and-flawed-medicines-threaten-us-all/.

[4] Barbara Morgan, *Cracking Down on Counterfeit Drugs*, PBS NOVA NEXT (Aug. 20, 2013), http://www.pbs.org/wgbh/nova/next/body/uncovering-counterfeit-medicines/.

[5] *See infra* notes 19–21 and accompanying text.

aim.[6] However, these laws contain stringent intellectual property provisions aimed at protecting pharmaceutical patents even though the harmful products in question do not implicate intellectual property concerns.[7] As this Note will explain, anti-counterfeiting laws that implicate pharmaceutical intellectual property concerns often reduce access to legitimate generic medications.[8] These types of laws result from developed Western countries and Western pharmaceutical companies pressuring developing[9] and least-developed countries[10] into including intellectual property provisions.[11] These Western countries and pharmaceutical companies argue that increased

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[6] *See generally* The Anti-Counterfeit Act, No. 16 (2008), Kenya Gazette Supp. No. 512008, *available at* http://infojustice.org/wp-content/uploads/2012/04/Kenya-AC2008.pdf. On April 20, 2012, Kenya's High Court ordered the revision of the Anti-Counterfeit Act of 2008 because the Act would threaten access to affordable generic medicine. *See also* HAI AFRICA, THE PROLIFERATION OF ANTI-COUNTERFEITING LEGISLATION IN THE EAST AFRICAN COMMUNITY: ADDRESSING PUBLIC HEALTH, COPYRIGHT, AND DEVELOPMENTAL CONCERNS (2010, *available at* http://www.haiafrica.org/images/stories/pdf/others/Meeting_ReportFinal.pdf.

[7] THE PROLIFERATION OF ANTI-COUNTERFEITING LEGISLATION IN THE EAST AFRICAN COMMUNITY, *supra* note 6; *see infra* Part II.*A*.

[8] *See infra* Part III.*A*.

[9] There are no definitions of "developed" and "developing" countries according to the WTO. Member nations declare if they are developing or developed. However, other WTO members can challenge the decision of a member to make use of the provisions available to developing countries. Having the status of a developing country brings certain rights in the WTO. For example, WTO agreements provide developing countries with longer transition periods to implement required legislation than developed countries. This Note will focus on the WTO's Agreement on Trade Related Aspects of Intellectual Property. *Who Are the Developing Countries in the WTO*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/devel_e/d1who_e.htm (last visited Sept. 13, 2014). The World Bank classifies all countries it designates as low-income ($1,045 or less GNI per capita) or middle-income economies ($1,045–$12,746 GNI per capita) as developing countries but notes that this is a term of convenience and is not intended to indicate that all countries are experiencing a similar level of development. According to the World Bank's measure, *all* sub-Saharan countries are developing. *Country and Lending Groups*, THE WORLD BANK, http://data.worldbank.org/about/country-and-lending-groups (last visited Sept. 13, 2014).

[10] The WTO recognizes the category of least developed countries (LDCs). These countries have been designated as "least developed" by the United Nations. LDCs, like developing countries, are also granted longer transition periods in the WTO. *Least Developed Countries*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm (last visited Sept. 13, 2014). The United Nations Committee for Development Policy defines LDCs as countries "suffering from the most severe structural impediments to sustainable development." *LDC Information*: *The Criteria for Identifying Least Developed Countries*, U.N. DESA, http://www.un.org/en/development/desa/policy/cdp/ldc/ldc_criteria.shtml (last visited Jan. 12, 2014).

[11] *See generally* Trade Policy for Sub-Saharan Africa, 19 U.S.C. § 3703 (2012).

intellectual property protection will result in fewer counterfeit drugs and will also result in increased foreign investment. In reality, strict intellectual property laws in sub-Saharan developing and least-developed countries only serve as an additional barrier to affordable generic medications. This leads to continued reliance on the counterfeit market.

This Note cannot specifically address all the problems created by inadequate access to medicine in sub-Saharan Africa and the subsidiary problems arising from counterfeit drugs. However, there are opportunities to mitigate these problems through domestic legislation and World Trade Organization (WTO) action. This Note will explain those opportunities. Part II.*A* will present relevant background information on the access-to-medicine problem in sub-Saharan Africa and demonstrate how this problem significantly contributes to the success of the counterfeit drug market. Part II.*B* provides a historical overview of how similar access to medicine problems in the U.S. and India prompted the growth of these two countries' pharmaceutical industries. Part II.*C* will give a brief overview of the international agreement which sets the minimum intellectual property protection WTO member-countries must provide in their domestic laws and discuss the provisions within this agreement that pertain to public health and access to medicine. Part II.*D* will give the reader relevant information regarding sub-Saharan Africa's emerging pharmaceutical markets.

Following this background information, this Note will argue in Part III.*A* that the counterfeit drugs that are threatening the lives of sub-Saharan Africans are not patent-infringing drugs. Therefore, anti-counterfeiting laws must be drafted to clearly differentiate between drugs that are patent infringing and drugs that are made with the wrong amount of an active ingredient or with an incorrect formula. Part III.*B* argues that lower intellectual property protection will help sub-Saharan countries expand their pharmaceutical manufacturing capabilities, resulting in greater control of the quality and prices of the medications distributed to their citizens. This ultimately will enable these countries to take full advantage of the public health flexibilities afforded by the WTO's Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS).[12] To achieve this end, the

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[12] The WTO's TRIPS is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on April 15, 1994. Marrakesh Agreement Establishing the World Trade Organization, April 15, 1994, 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994).

WTO must extend the transition period, currently set to end in 2016, which developing countries and least-developed countries have to make their domestic laws TRIPS compliant. Sub-Saharan countries that are already TRIPS compliant must resist pressure by more developed countries to enact intellectual property laws that go beyond the protection required by TRIPS. In sum, this Note takes the position that intellectual property concerns must take a back seat to sub-Saharan Africa's pressing need to provide affordable, quality medications to its citizens. The best way to solve this problem is to increase domestic manufacturing of needed medications. In conclusion, Part IV discusses the consequences of allowing pharmaceutical intellectual property protection in sub-Saharan Africa to expand.

II. BACKGROUND

A. The Counterfeit Drug Market in Sub-Saharan Africa

The success of the counterfeit drug market in sub-Saharan Africa can be attributed to the lack of access to quality, affordable medications and a high disease burden. For example, 60% of the individuals infected with HIV/AIDS world-wide live in Africa, 24% percent of individuals infected with tuberculosis world-wide live in Africa, and 90% of the individuals infected with malaria world-wide live in Africa.[13] As a result of this high disease burden, sub-Saharan citizens must have access to quality medications.

The United Nations defines access as having affordable medicines continuously available at public health facilities, private health facilities, or medicine outlets that are located within a sixty-minute walk from an individual's home.[14] Affordability must be viewed from the patient's perspective and not the manufacturer's perspective.[15] This is because even if

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[13] WORLD HEALTH ORGANIZATION, THE HEALTH OF THE PEOPLE: THE AFRICAN REGIONAL HEALTH REPORT 44–51 (2006), *available at* http://www.who.int/bulletin/africanhealth/en/.

[14] United Nations Development Group, *Indicators for Monitoring the Millennium Development Goals*, at 89, U.N. Doc. ST/ESA/STAT/SER.F/95 (2003), *available at* http://mdgs.un.org/unsd/mdg/Host.aspx?Content=Indicators/Handbook.htm.

[15] *See generally* Leach, Paluzzi, Munderi, *UN Millenium Project 2005: Prescription for Healthy Development: Increasing access to Medicines: Report on the Task Force on HIV/AIDS, Malaria, TB, and Access to Essential Medicines, Working Group on Access to Medicines*, UNITED NATIONS DEVELOPMENT PROGRAMME (2005), *available at* http://www.unmillenniumproject.org/reports/tf_essentialmedecines.htm.

a medication's price is reasonable in the context of production costs, the medication will not be accessible if the patient cannot afford it.[16] The affordability of medications is a major concern in sub-Saharan countries where poverty is widespread. According to the World Bank, an average of 46.8% of the sub-Saharan population lives on less than $1.25 U.S. dollars per day.[17] This meager budget makes it difficult to afford expensive medications. For example, a 2012 study published by the U.N. found that a low-income family in the Democratic Republic of the Congo would need half a month salary of one family member to pay for even the lowest price medicines.[18] The disparity between income and the cost of medication allows the counterfeit medication market to flourish.

The dangerous counterfeit drugs sold in sub-Saharan Africa, for the most part, do not implicate intellectual property considerations. In reality, these drugs are sub-standard medications manufactured and sold with the intent to deceive consumers. In a 2012 survey of twenty-one sub-Saharan countries, 35% of the malaria drugs available for purchase were found to be of poor quality.[19] This study rejected the use of the term counterfeit and classified these poor quality drugs into three categories: (1) falsified; (2) substandard; and (3) degraded.[20] None of the categories included intellectual property considerations.[21]

Counterfeiters, both domestic and abroad, take advantage of the precarious situation caused by sub-Saharan Africa's high disease burden and

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[16] *Id.*

[17] *Poverty & Equity*, *supra* note 1. In the Democratic Republic of the Congo 87.72% of the population lives on $1.25 U.S. dollars per day. *Id.*

[18] UNITED NATIONS, MILLENNIUM DEVELOPMENT GOAL 8: THE GLOBAL PARTNERSHIP FOR DEVELOPMENT: MAKING RHETORIC A REALITY 64–65 (2012), *available at* http://www.un.org/en/development/desa/publications/mdggap2012.html (using the salary of the lowest paid government worker as the benchmark).

[19] A 2012 study, reported in *The Lancet Infectious Diseases Journal*, surveyed six classes of drugs from twenty-one countries in sub-Saharan Africa and found that 796 of 2,297 (35%) failed chemical analysis, 28 of 77 (36%) failed packaging analysis, and 79 of 289 (20%) were classified as falsified. Gaurvika M.L. Nayyar et al., *Poor-Quality Antimalarial Drugs in Southeast Asia and Sub-Saharan Africa*, 12 THE LANCET INFECTIOUS DISEASES 488–96 (2012).

[20] *Id.* at 488.

[21] *Id.* at 488–89. Falsified drugs are drugs manufactured with fake packaging that contain the wrong pharmaceutical ingredient or none of the asserted ingredient. Substandard drugs are products that result from poor manufacturing with no intent to deceive. Substandard drugs usually contain an inadequate amount of the active pharmaceutical ingredient or contain too much of the active ingredient. Degraded drugs are defined as drugs that had been of sufficient quality but are degraded by poor storage. *Id.*

widespread poverty. Counterfeiters are able to operate and distribute these medications with little fear of consequence.[22] Even in sub-Saharan countries that have criminalized trafficking in counterfeit medicines, political instability, weak governance, and weak law enforcement mechanisms make it difficult to enforce these laws.[23] As a result, there is little to deter counterfeiters from participating in what can be a very lucrative activity.[24]

It is estimated that counterfeit drug sales reached $70 billion U.S. dollars annually in 2010, a 90% increase from 2005.[25] Even small-scale vendors of counterfeit drugs stand to profit. For example, Marcel Olinga, a counterfeit drug vendor in Cameroon, makes an average of $40 U.S. dollars a day,[26] much more than the sub-Saharan daily average of $1.25 U.S. dollars.[27] Police have raided his operation before and seized his medications; however, he considers it a loss worth incurring because the raids are not regular and he never keeps the bulk of his supplies where he sells.[28]

Sub-Saharan African countries must find a way to meet their citizens' need for quality, affordable medication. Historically, the need for quality, affordable medications spurred the development of two of today's leading pharmaceutical markets: the United States and India. The development of these two pharmaceutical markets in the context of intellectual property protection will be discussed below.

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[22] UNITED NATIONS OFFICE ON DRUGS AND CRIME, ORGANISED CRIME AND TRAFFICKING IN EASTERN AFRICA 6 (2009), *available at* http://www.unodc.org/documents/easternafrica/regional-ministerial-meeting/Organised_Crime_and_Trafficking_in_Eastern_Africa_Discussion_Paper.pdf.

[23] *Id.*

[24] Counterfeiters can generally keep their production costs low. Many counterfeit medicines do not contain or contain a significantly reduced amount of the legitimate drug's active ingredient. Counterfeiters also do not have to invest in manufacturing infrastructure or practices that meet applicable regulations. *General Information on Counterfeit Medicines, Factors Encouraging Counterfeiting of Drugs*, THE WORLD HEALTH ORGANIZATION, http://www.who.int/medicines/services/counterfeit/overview/en/index1.html (last visited Sept. 11, 2014).

[25] BRIAN D. FINLAY, COUNTERFEIT DRUGS AND NATIONAL SECURITY 1 (2011), *available at* http://www.stimson.org/images/uploads/research-pdfs/Full_-_Counterfeit_Drugs_and_National_Security.pdf.

[26] Monde Kingsley Nfor, *Cameroonians "Dying" for Fake Drugs*, INTER PRESS SERVICE, Sept. 5, 2013, *available at* http://www.ipsnews.net/2013/09/cameroonians-dying-for-fake-drugs/.

[27] *Poverty & Equity*, *supra* note 1.

[28] Nfor, *supra* note 26.

B. From Patent Infringement to Pharmaceutical Growth: The United States and India

1. The United States

America's pharmaceutical industry developed as a result of weak intellectual property laws and deliberate intellectual property infringement.[29] Early pharmaceutical innovators chose not to patent their innovations and one company quickly copied the successes of another.[30] However, as German chemical companies gained an edge in the pharmaceutical market, they patented their important products like aspirin,[31] Salvarsan,[32] and Veronal.[33] By the end of the nineteenth century, German pharmaceutical manufacturers dominated the industry and their products were patent protected in the United States. As a result of the World War I blockades, U.S. chemists were forced to ignore German patents and replicate these needed medications.[34] The U.S. government also passed the Trading with Enemy Act in 1917 which allowed American firms to produce products that were patent protected by companies and individuals located in enemy territories.[35]

Facing a similar access-to-medicine crisis in World War II, America began to place a high priority on developing new processes to produce needed medications, effectively bypassing product patents.[36] This development was unhampered by stringent international intellectual property

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[29] Dennis B. Worthen, *American Pharmaceutical Patents From a Historical Perspective*, 8 INT'L J. PHARM. COMPOUNDING 36, 36–37 (2004).

[30] *Id.*

[31] German pharmaceutical company Bayer applied for a patent on aspirin in the United States in 1900. *Felix Hoffmann*, CHEMICAL HERITAGE FOUNDATION, http://www.chemheritage.org/discover/online-resources/chemisty-in-history/themes/pharmaceuticals/relieving-symptoms/hoffmann.aspx (last visited Sept. 4, 2014).

[32] In the early twentieth century Salvarsan was the most effective and most prescribed treatment for syphilis. The drug was manufactured by the German chemical company Hoechst. *See* Amanda Yarnell, *Salvarsan*, AMERICAN CHEMICAL SOCIETY, http://pubs.acs.org/cen/coverstory/83/8325/8325salvarsan.html (last visited Sept. 13, 2014).

[33] Veronal, a sedative used when treating battle wounds, was patented by the German chemist Emil Fischer in 1903. *See* Francisco Lopez-Muzoz et al., *The History of Barbiturates a Century After Their Clinical Introduction*, 1 NEUROPSYCHIATRIC DISEASE AND TREATMENT 332 (2005), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2424120/.

[34] Yarnell, *supra* note 32.

[35] Worthen, *supra* note 29, at 36.

[36] *Id.* at 37.

standards[37] like those that America and other developed countries now seek to impose on developing and least-developed countries in sub-Saharan Africa.[38]

2. India

India has a thriving generic drug industry and exports 67% of its generic drug output to developing and least-developed countries.[39] This successful generic drug market is a result of India's historically weak patent laws. After gaining independence from Britain in 1947, a Western patent regime stunted the growth of the pharmaceutical industry, and left India completely dependent on the West's high-price medicines.[40] In the 1970 Patents Act, India deliberately enacted a weak patent regime to enable the country to develop a strong domestic pharmaceutical industry.[41] Patent protection for drug products was not available at all in the 1970 Patents Act.[42] Only the process for making a particular drug could be patented for a period of five years from the date of the patent's issue or seven years from the date of the patent's application, whichever came first.[43] This restricted patent protection meant that drug developers could produce the same drug using a slightly different process.[44] The result was an explosion in the country's generic drug industry.[45] As discussed below, India's generic drug industry was put in jeopardy in 1995 when the WTO passed the TRIPS Agreement.

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[37] The TRIPS agreement will be discussed *infra* Part II.*C*.

[38] *See generally* Zinatul A. Zainol et al., *Pharmaceutical Patents and Access to Essential Medicines in Sub-Saharan Africa*, AFR. J. BIOTECH. 12376–88 (2011), *available at* http://www.academicjournals.org/ajb/PDF/pdf2011/30SepConf/Zainol%20et%20al.pdf.

[39] *See* MEDECINS SANS FRONTIERES, EXAMPLES OF THE IMPORTANCE OF INDIA AS THE "PHARMACY FOR THE DEVELOPING WORLD" (2007), *available at* http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_briefing_PharmacyForDevelopingWorld_India_ENG_2007.pdf.

[40] Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 504–09 (2007).

[41] The Patents Act, 1970, No. 39 of 1970, § 5, INDIA CODE, *available at* http://indiacode.nic.in [hereinafter 1970 Indian Patents Act].

[42] Susan Fyan, *Pharmaceutical Patent Protection and Section 3(D): A Comparative Look at India and the U.S.*, 15 VA. J.L. & TECH. 198, 205 (2010).

[43] *Id.* (citing 1970 Indian Patents Act § 53).

[44] *Id.*

[45] *Id.*

C. The World Trade Organization and the Agreement on Trade-Related Aspects of Intellectual Property

The World Trade Organization is an international organization that operates as a forum for governments to negotiate trade agreements and settle trade disputes.[46] WTO agreements are negotiated and signed by a majority of the world's trading nations and provide the legal ground rules for international commerce.[47] A majority of the WTO's 150 member nations are developing or least-developed countries.[48] WTO agreements include many provisions that give developing and least-developed countries extra time to fulfill their WTO commitments as they recognize that these countries have special developmental needs that require flexible implementation time frames.[49]

One of the most important WTO agreements is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS went into effect on January 1, 1995.[50] The agreement mandated that all WTO members implement or amend their domestic patent laws to include the TRIPS minimum requirements.[51] Before TRIPS, most countries had differing intellectual property rights protection,[52] and many developing and least developed nations concerned with access to medicines offered no form of patent protection for pharmaceuticals.[53] Strong protection was typically afforded in developed countries, like the U.S., to protect those countries' large, profitable pharmaceutical industries.[54] These developed countries argue that developing a new drug is a long, expensive process, and patent protection ensures that these investments are protected.[55] The TRIPS

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[46] *Understanding the WTO*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/who_we_are_e.htm (last visited Sept. 13, 2014).

[47] *Id.*

[48] *Understanding the WTO: Developing Countries*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/tif_e/dev1_e.htm (last visited Sept. 13, 2014).

[49] *Id.*

[50] TRIPS, *supra* note 12.

[51] Fyan, *supra* note 42.

[52] *See* Zainol et al., *supra* note 38.

[53] Fyan, *supra* note 42, at 202–03.

[54] P. BOULET ET AL., UNAIDS & WORLD HEALTH ORGANIZATION, PHARMACEUTICALS AND THE WTO AGREEMENT: QUESTIONS AND ANSWERS (2000), *available at* http://www.who.int/medicinedocs/pdf/whozip18e/whozip18e.pdf.

[55] Bruce Kuhlick, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93 (2004).

provisions reflect these interests.[56] Developing and least-developed countries signed TRIPS assuming that increased intellectual-property protection would lead to developed countries transferring technology and increasing their foreign investment.[57] In fact, Article 66 of TRIPS specifically states that "[d]eveloped country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base."[58]

TRIPS mandates that its members' domestic patent laws provide patent protection for a minimum of twenty years from the filing date of the patent.[59] Patent protection is afforded to both products and processes.[60] TRIPS provisions allow a patent to be issued for any invention, including a pharmaceutical product or process, as long as the process or product is either new or an inventive step and is capable of industrial application.[61]

Pharmaceutical companies use the "inventive step" provision to extend their patent protection, a practice known as "ever-greening."[62] Strategies for ever-greening include slightly changing a drug's chemical composition by combining formulas or making time-release versions.[63] This extends the life of the original patent, precluding generic drug manufacturers from manufacturing a generic, less expensive version.[64]

The drafters of TRIPS apparently recognized that the agreement's strong intellectual protections could result in negative consequences for public health and economic development. Article (8)(1) states that member states

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[56] Brook Baker, *Arthritic Flexibilities For Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the DOHA Declaration on the TRIPS Agreement & Public Health*, 14 IND. INT'L & COMP. L. REV. 613, 614 (2004).

[57] *See generally* Keith E. Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, 9 DUKE J. COMP. & INT'L L. 109 (1998) (arguing that increased intellectual property protections is only one factor multinational companies consider when deciding what countries to invest in).

[58] TRIPS, *supra* note 12, art. 66.

[59] *Id.* art. 33.

[60] *Id.* art. 27.

[61] *Id.*

[62] Brian Krans, *Pharmaceutical 'Evergreening' Raises Drug Costs, Study Says*, HEALTHLINE NEWS (June 4, 2013), *available at* http://www.healthline.com/health-news/policy-drug-companies-use-evergreening-to-extend-market-share-060413.

[63] *Id.*

[64] *Id.*

can "adopt measures necessary to protect public health and nutrition, and to promote the public interests in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of [TRIPS]."[65]

TRIPS originally granted an implementation extension period to developing and least-developed countries.[66] TRIPS drafters recognized that these countries needed additional time to create a viable technology and manufacturing infrastructure before they could effectively operate under stringent intellectual property requirements. Developing countries were given a five-year continuance.[67] If these developing countries did not already have a patent regime in place they were given an additional five years.[68] In Article 66 of the TRIPS agreement, least developed countries were given a ten-year implementation grace period.[69] Article 66 also provides that the WTO can extend this grace period.[70] The WTO has used this power to extend the implementation deadline twice. In the 2001 DOHA Declaration, least developed countries were given until 2016 to make their patent laws TRIPS compliant.[71] The WTO recently used this power again and granted LDCs an eight-year continuance from the 2016 deadline, but this implementation extension *does not* apply to pharmaceutical patents.[72] The continuance explicitly recognizes that least developed countries need more time to develop their technology and manufacturing capacities before they can participate in the global economy.[73]

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[65] TRIPS, *supra* note 12, art. 8.1.
[66] *Id.* arts. 65–66.
[67] *Id.* art. 65.
[68] *Id.*
[69] *Id.* art. 66.
[70] *Id.*
[71] Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/Dec/2 ¶ 4 (Nov. 14, 2001) [hereinafter DOHA Declaration]; *The DOHA Declaration Explained*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm (last visited Jan. 11, 2014).
[72] *The Least Developed Get Eight Years More Leeway on Protecting Intellectual Property*, WORLD TRADE ORGANIZATION (June 11, 2013), http://www.wto.org/english/news_e/news13_e/trip_11jun13_e.htm.
[73] ECONOMIC COMMISSION FOR AFRICA, UN DEVELOPMENT PROGRAMME, AFRICA REGIONAL PREPARATORY MEETING ON REVIEW OF THE IMPLEMENTATION OF THE BRUSSELS PROGRAMME OF ACTION 7, ¶¶ 32–34 (Mar. 8–9, 2010), *available at* http://www.un.org/wcm/webdav/site/ldc/shared/ARR%20Final%20document.pdf.

TRIPS is designed to be flexible in order to ensure that developing and least-developed countries have access to affordable medications. The compulsory licensing exception found in Article 31 is one of these "flexibilities."[74] A compulsory license allows a member state to break a patent by authorizing a third party to manufacture the product without the consent of the patent holder.[75] The TRIPS agreement allows compulsory licensing as part of the agreement's overall attempt to strike a balance between promoting access to existing drugs and promoting research and development of new drugs. While the term "compulsory licensing" does not appear in the TRIPS agreement, the phrase "other use without authorization of the right holder" appears in the title of Article 31.[76] The WTO defines the term to mean that a government allows "someone else to produce the patented product or process without the consent of the patent owner."[77] To utilize the exception, a third party must try to negotiate a voluntary license with the patent holder.[78] If these negotiations fail, then a compulsory license can be requested through the third party's government.[79] Member states facing "a national emergency or other circumstances of extreme urgency" are able to bypass the initial negotiations for a compulsory license if the product is manufactured primarily for domestic use.[80] Because many developing and least-developed countries do not have the infrastructure to manufacture these pharmaceuticals, they must import the needed medicines from other countries.[81] While these flexibilities may address the availability of needed medicines, they do not address affordability. If sub-Saharan citizens cannot afford to purchase these imported medicines, they will be forced to either forgo treatment or turn to the counterfeit market. In sum, the TRIPS flexibilities do not address the real issue.

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[74] TRIPS, *supra* note 12, art. 31.

[75] *Id.*

[76] *Id.*; Swarup Kumar, *Compulsory Licensing Provision Under TRIPS: A Study of* Roche v. Natco *Case in India vis-à-vis the Applicability of the Principle of* Audi Alteram Partem, 7 SCRIPTED, Apr. 2010, at 137.

[77] *TRIPS and Health: Frequently Asked Questions, Compulsory Licensing of Pharmaceuticals*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Sept. 13, 2014).

[78] *Id.*

[79] *Id.*

[80] TRIPS, *supra* note 12, art. 31(b); *see also* Dina Halajian, *Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access to Medicine Problem*, 38 BROOK. J. INT'L L. 1191, 1198 (2013).

[81] DOHA Declaration, *supra* note 71.

D. Sub-Saharan Africa's Emerging Pharmaceutical Markets

While sub-Saharan Africa continues to battle an overwhelming disease burden, its pharmaceutical markets are rapidly expanding.[82] Pharmaceutical spending in these countries is expected to reach over $30 billion U.S. dollars by 2016 and $45 billion by 2020.[83] This growth is a result of increased wealth, demographic changes, health-care investment, and a rising demand for drugs to treat non-communicable diseases.[84] Even though sub-Saharan countries still face political instability, political climates are beginning to stabilize.[85] As a result of this increased stabilization, many countries have enacted pro-business legislation to encourage foreign investment.[86] The U.N. predicted that foreign direct investment in Africa would double by 2014.[87]

In addition to political stability and increased foreign investment, sub-Saharan countries have a rising middle class that now accounts for 34% of the continent's inhabitants.[88] The urban populations in these countries is expected to exceed both China's and India's urban populations by 2050.[89] While these countries are dealing with overwhelming infectious disease burdens, they are also expected to experience an increase in death rates from cardiovascular disease, respiratory diseases, cancer, and diabetes. In the next ten years, the increase in these diseases in sub-Saharan Africa will be larger than any other region in the world.[90]

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[82] IMS HEALTH, AFRICA: A RIPE OPPORTUNITY, UNDERSTANDING THE PHARMACEUTICAL MARKET OPPORTUNITY AND DEVELOPING SUSTAINABLE BUSINESS MODELS IN AFRICA 2 (2012), *available at* http://www.imshealth.com/ims/Global/Content/Insights/Featured%20Topics/Emerging%20Markets/IMS_Africa_Opportunity_Whitepaper.pdf.

[83] *Id.*

[84] *Id.* at 2–3.

[85] *Id.* at 2, 10.

[86] *Id.* at 2.

[87] *Id.*

[88] AFRICAN DEVELOPMENT BANK, AFRICA IN 50 YEARS' TIME 13 (2011), *available at* http://www.afdb.org/fileadmin/uploads/afdb/Documents/Publications/Africa%20in%2050%20Years%20Time.pdf.

[89] IMS HEALTH, *supra* note 82, at 2.

[90] *Id.* at 3.

III. ANALYSIS

As discussed above, the dangerous counterfeit-drug problem in sub-Saharan Africa generally does not involve patent infringing products.[91] Therefore, anti-counterfeit legislation addressing pharmaceutical products imported into or manufactured in sub-Saharan Africa should not be focused on intellectual property considerations.

Currently, sub-Saharan countries must make their domestic pharmaceutical patent laws TRIPS compliant by 2016. The WTO should grant these countries a continuance on this deadline to allow them time to develop their technology and manufacturing capabilities. For those sub-Saharan countries already TRIPS compliant, they should actively resist entering into agreements with Western countries that will require higher intellectual property standards. They, like India, should also interpret TRIPS to require the least stringent protection acceptable to the WTO. By operating at a minimum standard under TRIPS, these countries will be better able to grow their domestic pharmaceutical production capabilities, with the ultimate goal of manufacturing and distributing the medications their citizens need. Once medicine supply chains are controlled and citizens have access to safe, affordable medication, the counterfeit drug market will shrink.

A. Anti-counterfeiting Legislation and Trade Agreements: A Guise for Increasing International Intellectual Property Protection

Curbing the counterfeit drug market in sub-Saharan Africa is of paramount importance. However, Western countries and Western pharmaceutical companies have exploited this problem for their own gain by using anti-counterfeiting legislation to expand global intellectual property protection even though there is no evidence to support the theory that increased protection results in a decrease in the sub-Saharan counterfeit drug market. In fact, the opposite may be true. Since India, a major exporter to sub-Saharan countries, updated its pharmaceutical patent laws to become TRIPS compliant in 2005, the sub-Saharan counterfeit drug market has increased by 90%.[92] This is because the sub-Saharan counterfeit drug market is not filled with patent-infringing products, but substandard products

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[91] *See supra* notes 19–21 and accompanying text.
[92] FINLAY, *supra* note 25.

manufactured to deceive customers into thinking that the products are legitimate, more affordable medicines.[93]

Some global actors have already suggested that intellectual property concerns have no place in the fight against counterfeit medication. For example, the Sixty-fifth World Health Assembly rejected intellectual property considerations in the battle against counterfeit medicines in 2012 when it decided to establish a new member-state mechanism for international collaboration to combat the counterfeit medicines.[94] This mechanism would operate from a public health perspective and exclude intellectual property concerns.[95] The exclusion of intellectual property considerations is warranted because a majority of dangerous counterfeit medications are not the result of intellectual property infringement but of fraudulent manufacturing or sub-standard manufacturing. When intellectual property considerations are a part of the battle against counterfeit medicines in sub-Saharan Africa, access to affordable medicines is jeopardized.

For example, in 2009, Dutch customs officials acting under European Union anti-counterfeiting regulations seized generic antiretroviral drugs bound for Nigeria.[96] These drugs were funded by UNITAID, an international agency that purchases drugs for the treatment of communicable diseases in developing countries.[97] These drugs were not patent infringing in India or Nigeria, but were counterfeit under the E.U. laws.[98] In fact, these drugs had been manufactured by an Indian generic pharmaceutical company.[99] A similar wrongful seizure of generic drugs prompted India and Brazil to file a complaint with the WTO in 2010.[100] India argued that the confiscated drugs were off-patent medication produced in India and that they were not meant for sale in the E.U. Rather, they were meant to be sold in

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[93] *See supra* notes 19–21.

[94] World Health Assembly, *Substandard/spurious/falsely-labeled/falsified/counterfeit Medical Products*, Res. WHA65.19 (May 26, 2012), *available at* http://apps.who.int/medicinedocs/documents/s19994en/s19994en.pdf.

[95] *Id.*

[96] *Nigeria: Seizure of Drug Shipment Threatens ARV Access*, IRIN, Mar. 13, 2009, http://www.irinnews.org/report/83459/nigeria-seizure-of-drug-shipment-threatens-arv-access.

[97] *Id.*

[98] *Id.*

[99] *Id.*

[100] Jennifer M. Freedman, *India, Brazil Complain at WTO Over Generic Drug Seizures by European Union*, BLOOMBERG, May 12, 2010, http://www.bloomberg.com/news/2010-05-12/india-brazil-complain-at-wto-over-generic-drug-seizures-by-european-union.html.

countries that did not have production capabilities, like those in sub-Saharan Africa.[101] After the E.U. promised to review its anti-counterfeiting regulations, India promised to refrain from taking further steps against the E.U. in the WTO.[102] On June 11, 2013 the E.U. Parliament approved new regulations known as the Customs IPR Regulation.[103] Under this new regulation, generic medicines in transit through the E.U. cannot be seized unless there is a concrete risk of diversion into the E.U. market.[104] While this is a step in the right direction, these regulations should also expressly prevent seizure even if the drug violates a patent in the seizing country.[105] This would ensure that more generic medications reach the sub-Saharan countries that desperately need them.

This external legislation is an important step to ensure that generic drugs reach sub-Saharan Africa from exporting countries like India. Internal sub-Saharan anti-counterfeiting legislation also must take generic medications out of anti-counterfeiting legislation that implicates intellectual property rights. The Kenyan Supreme Court realized this in 2012 when it declared the 2008 Kenyan Anti-Counterfeit Act unconstitutional and suspended the powers of the Kenyan Anti-Counterfeit Agency to interfere with the importation and distribution of generic medications in Kenya.[106] The Court found that the Act failed to clearly distinguish between medicines that were patent-infringing counterfeits and medicines that were legitimate generic medications.[107] The Court ordered that "[it] is incumbent on the state to reconsider" Section 2 of the Act in order to clear up ambiguities that in

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[101] *EU Agrees to Stop Confiscation of Indian Generic Drugs*, ECON. TIMES, July 29, 2011, http://articles.economictimes.indiatimes.com/2011-07-29/news/29829346_1_customs-regulations-indian-generic-drugs-international-intellectual-property-agreement.

[102] Ministry of Commerce, *India EU Reach an Understanding on the Issue of Seizure of Indian Generic Drugs in Transit*, PRESS INFORMATION BUREAU OF INDIA, July 28, 2011, http://pib.nic.in/newsite/erelease.aspx?relid=73554.

[103] *See* Van Bael & Bellis, *European Union: Anti-Counterfeit: European Parliament Approves New Customs IPR Regulation*, MONDAQ, July 17, 2013, http://www.mondaq.com/x/251548/Trademark/European+Union+AntiCounterfeit+European+Parliament+Approves+New+Customs+IPR+Regulation.

[104] *Id.*

[105] Because India does not allow "ever-greening," generic drugs produced with similar processes could be patented in the transit company but not in India. *See infra* note 139 and accompanying text.

[106] Reji K. Joseph, *Policy Reforms in the Indian Pharmaceutical Sector since 1994: Impact on Exports and Imports*, ECON. & POL. WKLY. 6–7, May 5, 2012 (LEXIS).

[107] *Id.*

retrospect have resulted in the seizure of legitimate generic or off-brand medications.[108]

This ambiguity was not the result of poor drafting. It was the result of unwarranted guidance. The 2008 Kenyan Anti-Counterfeiting Law was influenced by a 2006 World Customs Organization (WCO) intellectual property seminar where the WCO's model law was introduced and discussed. The seminar was sponsored by the U.K. pharmaceutical company GlaxoSmithKline and U.S. based Procter and Gamble.[109] The 2008 Kenyan Anti-Counterfeiting Law contains aspects of the WCO's model law concerning intellectual property protection.[110] The WCO created the model law to help countries draft national legislation to implement anti-counterfeiting laws in compliance with TRIPS.[111] However, because the dangerous counterfeit medicines in Kenya are not the result of patent infringement, the law was not targeting the real issue: counterfeit medications that are of substandard quality.

This is not the first time Western pharmaceutical companies or their home countries have pushed for greater IP protection at the cost of access to medicine. In 1997, South Africa voluntarily became TRIPS compliant[112] and passed the Medicines and Related Substances Control Amendment.[113] This amendment introduced a legal framework to increase affordable medicines within the country, including generic substitutions for off-patent medications, transparent pricing, and parallel importation—all allowable measures under TRIPS.[114] The following February, the South African Pharmaceutical Manufacturers Association and forty multinational pharmaceutical manufactures sued the South African government claiming that the act violated TRIPS.[115] These multinational pharmaceutical

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[108] *P.A.O. v. Attorney General*, (2012) eKLR (Kenya), *available at* http://kenyalaw.org/case law/cases/view/79032.

[109] Wambi Michael, *East Africa: Global Players Behind Anti-Counterfeit Law Campaign*, INTER PRESS SERVICE, May 21, 2010, *available at* http://www.ipsnews.net/2010/05/east-africa-global-players-behind-anti-counterfeit-law-campaign.

[110] *Id.*

[111] *Id.*

[112] Rene Loewenson, *Essential Drugs in Southern Africa Need Protection From Public Health Safeguards Under TRIPS*, 4 Bridges Between Trade and Sustainable Development, no. 7, 2000, at 2.

[113] Ellen Hoen, *Trips, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 30 (2002).

[114] *Id.*

[115] *Id.*

manufacturers were relying on the support of their home countries, like the U.S., to pressure the South African government to repeal the Amendment.[116] These countries threatened withholding trade benefits and levying further trade sanctions.[117] Public outrage over the litigation eventually resulted in the suit's dismissal, but the threat of litigation caused many to question whether or not the TRIPS flexibilities designed to ensure public health and access to medicines needed to be clarified.[118]

After this, the World Health organization, led by its African members, began to advocate for a "Revised Drug Strategy" that would call on member states to (1) ensure that public interests were given substantial weight in any new pharmaceutical or health polices, and (2) explore options under relevant international agreements to safeguard access to essential medicines.[119] These concerns were brought to the WTO in 2001 and led to negotiations that summer with respect to TRIPS and access to affordable medicines.[120] The events of September 11, 2001 changed the dynamics of these negotiations.[121] Shortly after 9/11, a series of anthrax attacks prompted the U.S. and Canadian governments to stockpile an adequate supply of Cipro, an antibiotic to treat anthrax.[122] To do this, the Bush administration threatened to override the drug's patent and allow for generic production using a compulsory license.[123] The international community accused the U.S. government of following double standards by threating the use TRIPS flexibilities when it had used its international clout to prevent developing countries from doing the same.[124] A few weeks later, in response to international criticism and in hope of gaining international support for an invasion into Afghanistan,[125] the U.S. assented to an agreement known as the

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[116] *Id.*
[117] *Id.*
[118] *Id.* at 31.
[119] James Love, *What the 2001 Doha Declaration Changed*, KNOWLEDGE ECOLOGY INT'L, Sept. 16, 2011, *available at* http://keionline.org/node/1267.
[120] *Id.*
[121] *Id.*
[122] Haochen Sun, *The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health*, 15 EUR. J. INT'L L. 123, 133 (2004).
[123] Jill Carroll & Ron Winslow, *Bayer Agrees to Slash Prices for Cipro Drug*, WALL ST. J., Oct. 25, 2001, at A3; *see also* Keith Bradsher & Edmund L. Andrews, *U.S. Says Bayer Will Cut Cost of Its Anthrax Drug*, N.Y. TIMES, Oct. 24, 2001.
[124] Sun, *supra* note 122, at 134.
[125] Love, *supra* note 119.

DOHA Declaration, which attempted to address the public health concerns TRIPS left open.[126]

The DOHA Declaration recognized the gravity of the public health problem affecting citizens in developing and least-developed countries resulting from diseases like HIV/AIDS, tuberculosis, malaria, and other epidemics.[127] The agreement also stressed that TRIPS should be viewed as a part of the international effort to address public health issues,[128] and that TRIPS should be interpreted and implemented in a manner supportive of members' right to protect public health and promote access to medicine for their citizens through the use of TRIPS "flexibilities."[129]

Despite these WTO assurances, developed countries like the U.S. have continued to pursue expanded international intellectual property protections beyond TRIPS through bilateral trade agreements and by threatening developing countries with trade sanctions.[130] For example, the U.S.'s African Growth and Opportunity Act extends trade benefits to eligible African countries based on how far these countries' domestic IP laws go beyond TRIPS requirements.[131] The Act states in the "Eligibility Requirements" section that "the President is authorized to designate a sub-Saharan African country as an eligible [country] if the President determines that the country has established, or is making continual progress toward establishing . . . the elimination of barriers to United States trade and investment, including by . . . the protection of intellectual property."[132]

Many sub-Saharan countries may expand their intellectual property protection under the guise that increased domestic intellectual property protection will spur U.S. companies to invest in their domestic economies.[133] However, Western pharmaceutical companies do not invest their resources into the development of new medicines for diseases that predominately affect sub-Saharan African countries because of the region's current low-purchasing power.[134]

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[126] Sun, *supra* note 122, at 135–36.
[127] DOHA Declaration, *supra* note 71.
[128] *Id.* ¶ 2.
[129] *Id.* ¶¶ 4–5.
[130] *See* Baker, *supra* note 56.
[131] Trade Policy for Sub-Saharan Africa, *supra* note 11.
[132] *Id.*
[133] *Id.*
[134] *See generally* Baker, *supra* note 56.

Even in countries that are TRIPS compliant, the U.S. continues to push for more intellectual property protection. For example, the U.S. is extremely critical of India's interpretation and implementation of the TRIPS agreement.[135] Because India remains committed to manufacturing affordable medications, it continues to resist efforts by more developed countries, like the U.S., to pressure the country into enacting TRIPS-plus patent laws.[136] India updated its patent laws in 2005 to make their laws TRIPS compliant.[137] Major international pharmaceutical companies hoped that these more stringent intellectual property laws would grant them greater patent protection and thus curb India's flourishing generic industry.[138] However, India has used a TRIPS ambiguity over the definition of "inventiveness" to set a relatively high bar for drug companies to meet before obtaining patents on new innovations, effectively eliminating ever-greening practices.[139] For example, in January 2013, India's Supreme Court rejected a patent on a Novartis leukemia drug because the active ingredient had been available for years. The Court held that the application for a new patent did not constitute a legitimate innovation.[140] The decision is regarded by many as a victory for the developing world because it serves to prevent pharmaceutical companies from impeding the production of generic medicines.[141] In an interview with *Al Jazeera*, James Love, the director of Knowledge Economy International, said, "This is a huge victory for patients around the world, including those living in developing countries. It does not solve all of the concerns about

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[135] Stefan Kirchanski, *Protection of U.S. Patent Rights in Developing Countries: U.S. Efforts to Enforce Pharmaceutical Patents in Thailand*, 16 LOY. L.A. INT'L & COMP. L.J. 569, 569 (1994).

[136] Timothy Bazzle, *Pharmacy of the Developing World: Pharmacy of the Developing World: Reconciling Intellectual Property Rights in India with the Right to Health: TRIPS, India's Patent System and Essential Medicines*, 42 GEO. J. INT'L L. 785, 799 (2011).

[137] *Id.* at 787.

[138] James Politi & Amy Kazmin, *U.S. Groups Accuse India of IP Protectionism*, FIN. TIMES, Mar. 13, 2013, *available at* http://www.ft.com/cms/s/0/364155ea-8be7-11e2-b001-00144feabdc0.html#axzz2iYPOO9U6.

[139] *See* The Indian Patents Act, 1970, No. 39 of 1970, § 5, INDIA CODE, amended by Patents (Amendment) Act, 2005 *available at* http://indiacode.nic.in; *see also* Bazzle, *supra* note 136, at 799.

[140] Zach Carter, *Obama Administration, Congress Intensify Opposition to Global Generic Drug Industry*, HUFFINGTON POST, June 28, 2013, http://www.huffingtonpost.com/2013/06/28/obama-generic-drugs_n_3513011.html.

[141] *Id.*

patents on health-related inventions, but it clears out many of the patents that have been used to inappropriately extend monopolies."[142]

India's intellectual property laws also allow generic drug manufacturers, not just the Indian government, to apply for compulsory licenses to override restrictive patents.[143] In March of 2013, India's Intellectual Property Appellate Board in Chennai upheld the grant of a compulsory license to a generic manufacturer producing a generic version of the patented drug Nexavar.[144] The court reasoned that TRIPS allows compulsory licenses to be issued in the "public interest,"[145] and Indian law specifically makes the availability of affordable medication a factor to consider when determining what is needed to serve the public's interest.[146]

The U.S. and pharmaceutical companies based in the U.S. are extremely critical of India's intellectual property laws and TRIPS interpretations. For example, the chief intellectual property attorney at Pfizer testified at a 2013 congressional hearing in opposition of India's intellectual property regime stating that India's "issuance of unwarranted compulsory licenses, the unfair revocation of valid patents, and the denial of patentability of inventions in India are critical areas of concern."[147] He also stated that India's patent laws had significantly impeded innovation in the pharmaceutical industry, and recommended that the U.S. raise the issue of stronger IP protection at every bilateral and multilateral trade negotiation.[148] The reasoning for this aggressive call is simple: pharmaceutical companies located in the U.S. and other developed countries want to ensure that they can exploit India's rapidly

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[142] *Q&A: Landmark Patent Ruling in India: Drug Policy Expert Says Refusal to Patent Novartis Cancer Drug was meant to "Promote Access to Medicines for All,"* AL JAZEERA, Apr. 2, 2013, *available at* http://www.aljazeera.com/indepth/features/2013/04/201341195136614868.html.

[143] Bazzle, *supra* note 136, at 799.

[144] Eva von Schaper, *Drugs for Indian Poor Spark Pfizer Anger at Lost Patents*, BLOOMBERG, Mar. 27, 2013, http://www.bloomberg.com/news/2013-03-27/drugs-for-indian-poor-spark-pfizer-anger-at-lost-patents.html; Sivarmajani Thambisetty, *Compulsory Licenses for Pharmaceuticals: An Inconvenient Truth?*, LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIENCE, Mar. 25, 2013, *available at* http://blogs.lse.ac.uk/indiaatlse/2013/03/25/compulsory-licenses-for-pharmaceuticals/.

[145] Thambisetty, *supra* note 144.

[146] *Id.*

[147] Politi & Kazmin, *supra* note 138.

[148] *Id.*

expanding pharmaceutical market.[149] As India develops, the opportunity to profit from middle and upper-income consumers willing and able to pay for branded medications expands.[150] To ensure that their branded products are the only ones available, U.S. drug companies want to stifle any domestic generic competition.[151] This same reasoning applies by extension to the emerging sub-Saharan pharmaceutical markets. With a rising prevalence of Western diseases due to an expanding middle class, Western pharmaceutical companies want to ensure before they invest that their investments into these potentially lucrative markets will be protected. But, this rationale proves insufficient in the face of the access-to-medicine crises facing many sub-Saharan countries. Patent protection must take a back seat to expanding access to medicines.

For now, sub-Saharan countries must do everything possible to protect the flow of generic medications into their countries and work to build their own generic manufacturing capabilities. If the U.S. government and U.S. pharmaceutical companies can pressure larger, more developed countries like India into enacting stronger patent laws, the Indian generic industry that sub-Saharan and other developing countries rely on will likely begin to shrink, further reducing access to needed medicines. Additionally, TRIPS compliant sub-Saharan countries will be much more likely to enact a Western-style intellectual property regime, rather than requiring TRIPS-minimum protection.[152]

B. The Case for a TRIPS Implementation Extension for sub-Saharan LDCs and TRIPS Minimum Intellectual Property Protection for sub-Saharan Developing Countries

At this time, sub-Saharan least-developed countries do not have to make their pharmaceutical patent laws TRIPS compliant until 2016.[153] As discussed above, the WTO recently granted least developed countries a compliance extension until 2021 for all patents except for pharmaceutical

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[149] *See* Brook Baker, *US Pharma v. India Patent Act: Myths Abound*, INFOJUSTICE, Oct. 14, 2013, *available at* http://infojustice.org/archives/30947.
[150] *Id.*
[151] *Id.*
[152] *See id.*
[153] DOHA Declaration, *supra* note 71.

patents.[154] This extension was granted after the WTO realized that least-developed countries need more time to create a "sound and viable technological base and overcome their capacity constraints."[155] The extension may allow time for developed countries and their companies and institutions to transfer some necessary technology.[156] This reasoning harkens back to the original TRIPS agreement that realized that intellectual property concerns vary according to a country's developmental stage.[157]

Developed countries, like the U.S., now take the position that increased intellectual property protection in developing and least-developed countries will spur development by increasing the transfer of technology, increasing foreign investment, increasing research and development in problems unique to these countries, and increasing domestic innovation.[158] However, this position fails to reflect the realities of history.[159] When the U.S. faced its own access-to-medicine problem, it deliberately infringed patents. When India faced this problem, it enacted lower intellectual property protection.[160] As a result, their pharmaceutical industries flourished.[161] A similar result is encouraged by the TRIPS agreement because it deliberately allows implementation extensions until a country has sufficient technology and manufacturing capabilities. When countries are developing, they must appropriate some intellectual property from more developed countries.[162] Once the country has sufficiently grown its technology and manufacturing sectors, the country will begin to produce original products and processes.[163] The same country will then have an incentive to protect its domestic intellectual property from being used in other countries.[164] While it is understandable that developed countries like the U.S. want to protect their

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[154] *The Least Developed Get Eight Years More Leeway on Protecting Intellectual Property*, *supra* note 72.
[155] *Id.*
[156] *Id.*
[157] *See* TRIPS, *supra* note 12, art. 66.
[158] Dru Brenner-Beck, *Do as I Say, Not as I Did*, 11 UCLA PAC. BASIN L.J. 84, 94–95 (1992).
[159] *See supra* Part II.*B*.
[160] *Id.*
[161] *Id.*
[162] Llewellyn Joseph Gibbons, *Do As I Say (Not As I Did): Punitive Intellectual Property Lessons for Emerging Economies from the Not So Long Past of the Developed Nations*, 64 SMU L. REV. 923, 931 (2011).
[163] *Id.* at 935.
[164] *Id.*

domestic products, developing and least-developed countries must be afforded the same intellectual property freedom that allowed the U.S. to meet its access to medicine problem during the World Wars and India to meet its access to medicine problem after independence from the United Kingdom.[165]

Indian pharmaceutical companies seem to see the potential in sub-Saharan Africa's emerging pharmaceutical markets more clearly than Western companies and have already begun investing in these markets and transferring technology. This dynamic is exactly the type of action foreseen by the drafters of TRIPS when they granted developing and least-developed countries the original implementation extension.[166] The phenomenon may be attributable to India's continuing need to continue providing affordable generic drugs to its own citizens, which requires it to resist global intellectual property expansion. As others have argued, extending the TRIPS implementation period for pharmaceuticals will likely make sub-Saharan African countries "attractive to generic drug manufactures from countries like India and will enable [African countries] to continue developing regional production and supply of generic pharmaceutical products without hindrances from Patent owners."[167]

Cipla, an Indian based pharmaceutical company, took advantage of this situation in 2004 and bought a minority stake in Quality Chemical Industries Limited (QCIL), a Ugandan pharmaceutical manufacturer.[168] Founded to reduce the communicable disease burden in Uganda by providing safe, effective, and low cost-medicines, QCIL is the first Ugandan manufacturer of antimalarial and antiretroviral drugs.[169] This partnership brought down the prices for first-line antiretroviral drugs sold in Uganda.[170] QCIL conforms to the most stringent manufacturing practices that are globally accepted and the company has obtained pre-qualification by the World Health Organization as a manufacturer of antiretroviral and anti-malarial

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[165] *See supra* Part II.*B.1*.

[166] *See* TRIPS, *supra* note 12, art. 66.

[167] Joan Akello, *LDCs Lobby for TRIPS extension*, INDEPENDENT, Feb. 25, 2013, http://www.independent.co.ug/news/news/7509-ldcs-lobby-for-trips-extension.

[168] Laurence Capron & Will Mitchell, *The Company Outsmarting Big Pharma in Africa*, HARV. BUS. REV. (Aug. 17, 2012), http://blogs.hbr.org/2012/08/into-africa-big-pharmas-growth/.

[169] *IGD Interview: Emmanuel Katongole, CEO, Quality Chemical Industries Ltd.*, INITIATIVE FOR GLOBAL DEVELOPMENT (June 20, 2013), http://www.igdleaders.org/igd-interview-emmanuel-katongole-ceo-quality-chemical-industries-ltd/.

[170] Raymond Baguma, *Quality Chemicals to List on the Stock Market*, ALLAFRICA GLOBAL MEDIA (Aug. 21, 2013), http://allafrica.com/stories/201308211203.html.

drugs.[171] Looking to further expand into the Ugandan market, Cipla bought an additional 14.5% stake in QCIL in November of 2013. Cipla's chief financial officer, Rajesh Garb stated that the company "see[s] an increased momentum in favor of generic drugs . . . and it's time to leverage our reputation as a trusted generic drug maker to tap that opportunity globally."[172]

Further extending least developed countries' grace period with respect to pharmaceutical patents will lead to more foreign investment in these countries' domestic pharmaceutical manufacturing. The need for a further implementation extension has already been recognized by associations in the industry. For example, the United Kingdom and the International Federation of Pharmaceutical Manufactures have called for the implementation period to be extended.[173] However, there is cause for great concern that the U.S. Trade Representative and the European Commission will oppose such an extension.

An extension is vital to the expansion of domestic manufacturing capabilities in sub-Saharan Africa. If this expansion occurs, domestic supply of generics will increase and both private and public distributors can directly purchase these quality medications at a lower cost than if they were imported. When individuals have access to quality affordable medications, they will be less likely to turn to alternative markets and less likely to receive dangerous counterfeit medications.

Sub-Saharan countries that are already TRIPS compliant must resist efforts by Western countries and pharmaceutical companies to enact agreements that will further expand intellectual property protections. If they continue to cave to this pressure, their pharmaceutical markets will remain underdeveloped and dependent on imported medicines from foreign

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[171] *Quality Chemical Industries: Ensuring Access to Quality Antiretrovial and Antimalarial Drugs through Local Manufacturing*, INDEPENDENT (Oct. 13, 2013), http://www.independent.co.ug/supplement/117-supplement/8330-quality-chemical-industries.

[172] C.H. Unnikrishnan, *Cipla Plans Bigger Global Presence*, LIVE MINT (Nov. 22, 2013), http://www.livemint.com/Companies/bq3ERyT9N6rODg1luuPSQN/Cipla-plans-bigger-global-presence.html.

[173] UNAIDS, IMPLEMENTATION OF TRIPS AND ACCESS TO MEDICINES FOR HIV AFTER JANUARY 2016: STRATEGIES AND OPTIONS FOR LEAST DEVELOPED COUNTRIES 4 (2011), *available at* http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief_TRIPS-access-medicines-LDC_en.pdf.

countries.[174] Enforcing only minimum standards under TRIPS will encourage countries like India to willingly transfer generic manufacturing technology and invest in sub-Saharan domestic manufacturing plants.[175]

When foreign pharmaceutical companies invest in domestic sub-Saharan pharmaceutical industries, they will have an incentive to produce quality products. Sub-standard medicines damage the brand image and reputation of pharmaceutical companies.[176] When a consumer purchases what they believe to be a quality medication and the medication is less than effective, the patient will blame the manufacturer if they never discover they were in fact deceived by a counterfeit medication.[177] To maintain their reputation in these sub-Saharan emerging markets, foreign companies and governments will have an incentive to work within these regions to eliminate the presence of counterfeit medications. This action could involve funding domestic and international organizations to enable them to effectively enforce criminal counterfeit penalties or forming direct distribution channels between the domestic manufacturers and domestic medical facilities. Increasing the domestic supply of affordable, quality medications will reduce the need of sub-Saharan citizens to turn to alternative markets for their medicine supply.

IV. CONCLUSION

Allowing pharmaceutical intellectual property protection to expand into sub-Saharan countries under the guise of anti-counterfeiting legislation, trade agreements, or TRIPS implementation could have extreme consequences. If these countries remain unable to meet the medical needs of their citizens, sub-Saharan African development will continue to be stunted in all areas. Even if aid to these countries is increased, without adequate human resources, i.e., a healthy workforce, these countries will not be able to

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[174] This situation is analogous to India's situation after independence from Britain where a Western patent regime made them dependent on importing high priced medicines from Western countries. *See supra* notes 39–45 and accompanying text.

[175] *See supra* notes 167–73 and accompanying text.

[176] THE ECONOMIC IMPACT OF COUNTERFEITING AND PIRACY, EXECUTIVE SUMMARY, ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT 18 (2007), *available at* http://www.oecd.org/industry/ind/38707619.pdf.

[177] *See id*.

effectively absorb and utilize this aid.[178] Allowing sub-Saharan African countries the intellectual property freedom to grow their domestic pharmaceutical industries will not only help solve the access to medicine problem and the counterfeit drug problem by lowering prices and giving these countries control over their medication supply chains, it will also provide employment and contribute to economic growth.[179] Sub-Saharan African countries need many solutions to solve the problems that years of disease, poverty, and political instability have caused; however, increased pharmaceutical intellectual property protection is not the answer.

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[178] *See, e.g.*, *Alliance Collaborates with Africa Public Health to Develop African Health Workforce Scorecards*, GLOBAL HEALTH WORK FORCE ALLIANCE, http://www.who.int/workforcealliance/media/news/2012/afrohrhnetworks/en/ (last visited Sept. 14, 2014).

[179] BERGER M. MURUGL ET AL., AFRICAN UNION, STRENGTHENING PHARMACEUTICAL INNOVATION IN AFRICA 85 (2009), *available at* http://www.nepad.org/system/files/str.pdf.