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Patrick Russo

CHINA'S HEALTHCARE REFORM: HOW PATENT LAWS AND GENERIC DRUGS CAN BENEFIT CHINA'S PUBLIC HEALTH

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CHINA'S HEALTHCARE ISSUES

Imagine a place where a sick or disabled child is quickly disowned by his parents and handed over to the government. Imagine a medical care system that forces a father to abandon his three-month-old daughter in front of an orphanage at six in the morning. Imagine a government that purposely establishes drop-off centers for medically adverse children because their parents are financially unable to care for them. Surely, no such place could exist, right? It just so happens that the world's most populous country, and the largest economy, is currently facing this dilemma.[1]

Late afternoon in the Sichuan province of China, a young, 21-year-old father holds his newborn son in one arm, and all the infant's cloths and belongings in a bag in the other arm.[2] The child has a rare medical condition that causes fluids to aggregate around the brain, causing severe brain damage, and possibly leading to death.[3] Due to China's healthcare system, this father is unable to afford the proper medical care for the child, and now attempts to leave his son at a newly opened "baby-hatch" in an orphanage.[4] A "baby-hatch" is an additional section affixed to an orphanage, where financially strained parents can abandon their children suffering from unique disorders.[5] Once the children are left, the government funded orphanages then presumably provides care for these abandoned babies.[6]

Since the opening of the first "baby-hatch" in China in 2011, more than 30

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[1] *Population, total*, THE WORLD BANK, http://data.worldbank.org/indicator/SP.POP.TOTL (last visited Oct. 08, 2015); *China's Population Set to Peak at 1.4 Billion Around 2026: Census Bureau Projects India to Become Most Populous Country in 2025*, U.S. CENSUS BUREAU (Dec. 15, 2009), http://www.census.gov/newsroom/releases/archives/international_population/cb09-191.html (discussing the population growth in China and how India will be surpassing China has the most populous country in about a decade); CARL J. DAHLMAN & JEAN-ERIC AUBERT, CHINA AND THE KNOWLEDGE ECONOMY: SEIZING THE 21ST CENTURY (The World Bank Institute Publ'n 2001), http://info.worldbank.org/etools/docs/library/137742/ChinaKE.pdf; *see generally* ANGUS MADDISON, CHINESE ECONOMIC PERFORMANCE IN THE LONG RUN (OECD Dev. Ctr., 2d ed. 2007) (discussing the economic emergence of China); CNN Staff, *CHINA: Sick Children Being Abandoned Because Parents Can't Afford Medical Care*, WDAY NEWS (June 30, 2014, 11:30 AM), http://www.wday.com/content/china-sick-children-being-abandoned-because-parents-cant-afford-medical-care.

[2] CNN Staff, *supra* note 1.

[3] *Id.*

[4] Connie Young, *China 'Baby Hatch' Inundated with Abandoned, Disabled Children*, CNN (June 30, 2014, 7:56 AM), http://www.cnn.com/2014/06/30/world/asia/china-baby-hatches-jinan/; Seth Doane, *A Look at China's "Baby Hatches" for Unwanted Infants*, CBS NEWS (June 27, 2014, 7:23 PM), http://www.cbsnews.com/news/a-look-at-chinas-baby-hatches-for-unwanted-infants/; Jing Gao, *Chinese City Sets Up Baby Hatch to Tackle Child Abandonment*, MINISTRY OF TOFU (Mar. 6, 2012), http://www.ministryoftofu.com/2012/03/chinese-city-sets-up-baby-hatch-to-tackle-child-abandonment/.

[5] Young, *supra* note 4.

[6] *Id.*

additional "baby-hatches" have been launched across the country.[7] According to the Chinese government, the amount of orphans in China is just north of 700,000.[8] Studies show, however, that the number is more likely in the millions, especially with the emergence of the hatches.[9] The majority of children left at these "baby-hatches" have disabilities or suffer from medical conditions (mostly rare medical disorders).[10] Staggeringly, China is now on the top 15 list of countries with the highest under-5 mortality rate, according to UNICEF, and this number has been steadily increasing since 1990.[11]

Many of these issues are negative effects of the poor healthcare system in China.[12] Over the past two decades, several major trends stand out as a result of the declining healthcare market.[13] One is the overall price increase in medical care, especially for a major illness or injury, and the increase in public "out-of-pocket" spending that coincides with this.[14] Since the 1970s, public spending on healthcare increased from 20% to 60%.[15] The quality of healthcare has also been inconsistent depending on location.[16] For instance, medical care and hospital quality are significantly better in urban areas than in the rural countryside.[17] Only 20% of China's health services are in rural areas.[18] This has led to civil unrest and instability as the citizens fight for better health services.[19] As part of the Healthy China 2020 program, the Chinese government is currently initiating a two-tiered reform of medical care and the health care system.[20] The government seeks to establish universal coverage of basic medical insurance, an essential drug system for increased generic drug use, health care infrastructure upgrades, greater health care equality between the urban and rural parts of China, and the facilitation of private investment for hospitals.[21] This note will focus on China's drug system, and propose a method for improving access and affordability of

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[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id.* (naming some medical conditions like congenital heart diseases, brain diseases, tumors, and breathing complications).

[11] *China: Statistics*, UNICEF: UNITED NATION'S CHILDREN FUND, http://www.unicef.org/infobycountry/china_statistics.html (Last visited November 13, 2014); *Mortality Rate, Infant (Per 1,000 Live Births)*, THE WORLD BANK: WORKING FOR A WORLD FREE OF POVERTY, http://data.worldbank.org/indicator/SP.DYN.IMRT.IN (Last visited November 13, 2014).

[12] *See generally* OFFICE OF WORLD HEALTH ORG. REPRESENTATIVE IN CHINA AND SOC. DEV. DEP'T OF CHINA STATE COUNCIL DEV. RESEARCH CTR., China: Health, Poverty and Economic Development (2005), http://www.who.int/macrohealth/action/CMH_China.pdf.

[13] Benjamin L. Liebman, *Essay: Malpractice Mobs: Medical Dispute Resolution in China*, 113 COLUM. L. REV. 181, 189-92 (2013).

[14] *Id.*

[15] *Id.* at 188.

[16] Thomas R. McLean, *Article: International Law, Telemedicine & Health Insurance: China as a Case Study*, 32 Am. J. L. and Med. 7, 17 (2006).

[17] *Id.*

[18] *Id.*

[19] Liebman, *supra* note 13, at 243.

[20] *See* Ian Lewis, *A Different Kind of Hospitality Opportunity in China*, LAW360 (Oct. 23 2014).

[21] SWEDISH AGENCY FOR GROWTH POL'Y ANALYSIS, CHINA'S HEALTHCARE SYSTEM: OVERVIEW AND QUALITY IMPROVEMENTS (2013), *available at* http://www.tillvaxtanalys.se/download/18.5f097bc113eacc3d6d513e/1369033621751/direct_response_2013_03.pdf; David Blumenthal & William Hsiao, *Privatization and its Discontents: The Evolving Chinese Health Care System*, N ENGL J. MED (2005), http://www.nejm.org/doi/full/10.1056/NEJMhpr051133.

pharmaceuticals. In the 1980s, the U.S. government implemented the Hatch-Waxman Act and the Orphan Drug Act, which helped reshape the country's drug system.[22] The former regulated and encouraged the manufacturing of generic drugs, and the latter sought to facilitate research and development of orphan drugs through various incentives.[23] Both acts have improved U.S. public health while protecting patent rights, and they continue to be effective three decades later.[24] This note proposes that the Chinese government adopt the guidelines presented in both the Hatch-Waxman Act and the Orphan Drug Act. Following the general protocol of these federal laws would fill the gap in a drug system that fails to address these issues, and help establish a foundation for the drug system sought by the government's current healthcare reform.

In Part I, this note first discusses the importance of having both patent protected pharmaceuticals and access to generic drugs, and how this relationship between the patent market and big pharma industry affects public health. Part II then examines global efforts to combat this issue of protecting and developing both public health and intellectual property rights, such as compulsory licenses and the Doha Declaration. The United States' involvement in these world efforts is discussed in Part III, along with an overview of the U.S. patent system, the Hatch-Waxman Act, and the Orphan Drug Act. Part IV provides a comparison between the U.S. and Chinese patent systems, and examines China's healthcare system reform and how the two U.S. laws could be implemented.

I. MEDICINAL DRUG PATENTS AND THE PHARMA INDUSTRY

There is an ongoing controversy between two giant players in the world economy. The intertwining relationship between the patent market and the pharmaceutical industry is complicated, and is the cause of much debate.[25] It affects individual nations, as well as the international landscape; private companies, as well as the public commercial sector; and the government, as well as public welfare.[26] When patents are issued to protect prescription drugs, private pharmaceutical companies usually own the rights to produce and sell these drugs.[27] This causes drastic price increases in medication, creating a financial barrier for suffering people who cannot afford medicine.[28] The availability of patent protected pharmaceuticals in developing and industrialized countries has become an issue, since many patients are unable to afford the proper medicine from the pharmaceutical companies.[29]

A major dilemma that demonstrated the importance of access to drugs, but also

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[22] Judy Vale, Article, *Expanding Expanded Access: How the Food and Drug Administration Can Achieve Better Access to Experimental Drugs for Seriously Ill Patients*, 96 GEO L. J. 2143, 2166-67 (2008).

[23] *Id.* at 2167.

[24] *See generally id.*

[25] *Pharmaceutical Pricing: The New Drugs War*, THE ECONOMIST (Jan. 4, 2014), http://www.economist.com/news/leaders/21592619-patents-drugs-are-interests-sick-well-industry-protection-should-not [hereinafter *Pharmaceutical Pricing*].

[26] *Id.*

[27] *The Controversy About Patents for Pharmaceuticals*, FEDCIRC.US PATENT LAW INFORMATION, http://www.fedcirc.us/the-controversy-about-patents-for-pharmaceuticals.php, (Last visited November 13, 2014) [hereinafter *Controversy About Patents for Pharmaceuticals*].

[28] H. David Banta, *Worldwide Interest in Global Access to Drugs*, 285 J. AM. MED. 22, 2844-46 (2001) [hereinafter *Banta*].

[29] Liebman, *supra* note 13, at 3.

reiterated the significance of intellectual property rights, was the HIV crisis in South Africa, which erupted in 1998.[30] At the time, South Africa became "the country with the highest absolute number of people living with HIV/AIDS."[31] According to the South African Department of Health, since the average annual income in the country was $2,600 and the cost of medicine for HIV was about $1,000 a month, most affected people could not afford the proper medication.[32] The South African legislature passed a statutory amendment that allowed the import and distribution of patented pharmaceuticals to combat the pandemic.[33] The pharmaceutical companies argued that the parallel imports violated patent holders' rights to their patents, while South Africa, and the public, pleaded the need for affordable medical care.[34]

A. Importance of Patents for Pharmaceuticals

A patent is the grant of exclusive rights by a government to the patent owner to exclude others from commercially using, making, or selling the patent owner's invention.[35] The invention must be novel, useful, and non-obvious in order to be granted a patent, and it could not have been sold, used, or published about before the inventor files for patent protection.[36] In order to gain exclusive patent rights, the inventor or owner must file an application with the government's patent office, which in the U.S. is the United States Patent and Trademark Office (USPTO).[37] Once an inventor is granted a patent, the invention is under patent protection for twenty years from the date of filing.[38]

There are many benefits that come from patent protection, including both economic and societal effects.[39] The main purpose of the patent system is to promote innovation while also protecting individuals' intellectual property.[40] Essentially being granted a monopoly

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[30] *Pharmaceutical Pricing*, *supra* note 25.

[31] William W. Fisher & Cyrill P. Rigamonti, *The South Africa AIDS Controversy: A Case Law Study in Patent Law and Policy*, HARV. L. SCH.: THE L. AND BUS. PAT. (Feb. 10, 2005), http://cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf; Steven Casper, *Between Free Market and Human Right: Government Policy, the Pharmaceutical Industry and the HIV/AIDS Crisis*, KECK GRADUATE INST., CLAREMONT C. (Oct. 2011), http://pacs.einaudi.cornell.edu/system/files/Casper-PKfestV2.pdf; *See generally* Lissett Ferreira, *Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations*, 71 FORDHAM L. REV. 3, 1132-80 (2002).

[32] Fisher & Rigamonti, *supra* note 31.

[33] *Id.*

[34] *Id.*

[35] Jehangir Choksi, Bereskin & Parr, *The Benefits and Costs of Patent Protection*, IEEE CAN. (1999), http://www.ieee.ca/canrev/canrev32/choksi.pdf; *Chapter 2: Fields of Intellectual Property Protection*, WIPO (2004), http://www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch2.pdf;
35 U.S.C. §102 (1952).

[36] Choksi et al., *supra* note 35.

[37] *Id.*

[38] United States Patent and Trademark Office, 2701 Patent Term, MANUAL OF PATENTING EXAMINING PROCEDURE (9th ed. Rev. 11.2013, Mar. 2014).

[39] James Yang, *Benefits of Patent Protection*, OC PATENT LAWYER, http://ocpatentlawyer.com/benefits-of-patent-protection/ (last visited Nov. 13, 2014) [hereinafter Yang]; Kristina Lybecker, *Promoting Innovation: The Economics of Incentives*, IP WATCHDOG (July 21, 2014), http://www.ipwatchdog.com/2014/07/21/promoting-innovation-the-economics-of-incentives/id=50428/; *Pharmaceutical Pricing, supra* note 25.

[40] Lybecker, *supra* note 39.

over an invention, being rewarded exclusive rights to exclude market competitors, serves as incentive for people to study new technology and to continue with research and development.[41] Patent protection prevents the theft of inventions and new ideas from those who initially conceived of the innovations.[42] Instead, it compensates those who have spent time and money researching, developing, and reducing their inventions to practice.[43]

Firstly, besides compensation for inventors' hard work, the economic and financial benefits for the patent owner include higher profit margins and expanded market share.[44] The increased profits are a result of higher prices for the invented product.[45] These prices are to recover for the large investments spent on research and development, as well as the high demand and sole responsibility of supply by the patent owners.[46] The need for the invented product in other states, or even countries, can lead the patent owner to license the product to companies abroad, therefore expanding the market share for the invention.[47]

Next, the community can greatly benefit from patents as well, because the products are marketed, sold, and used by society.[48] Specifically with pharmaceuticals, patent protection encourages inventors to continue their research and development, which in turn creates stronger, improved medicine.[49] These pharmaceuticals created by private pharma companies carry moral weight and create a public service.[50] People have a right to quality health and medical care, and are more productive members of society when healthy.[51] Medicine prevents diseases and the spread of epidemics, contributing to an effective and functioning society.[52]

B. Importance of Generic Drugs

A generic drug is a drug product that is deemed identical to the original, patented drug in "dosage form, safety, strength, route of administration, quality, performance characteristics and intended use."[53] When a patent term expires for a specific pharmaceutical, generic versions of that drug can be produced and sold.[54] Typically, when generic drugs are used or sold pre-patent term expiration, an infringement action is brought against the

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[41] *Id.*

[42] Yang, *supra* note 39.

[43] Banta, *supra* note 28, at 2845.

[44] Yang, *supra* note 39.

[45] *Id.*

[46] *Id.*

[47] *Id.*

[48] *Pharmaceutical Pricing*, *supra* note 25

[49] Jorg Schaaber, *Misguided Research*, DEVELOPMENT AND COOPERATION (November 1, 2010), http://www.dandc.eu/en/article/why-patents-often-stand-way-health-care (mentioning how revenue from patents intrigues inventors and promotes development for certain disease treatments) [hereinafter Schaaber].

[50] *Pharmaceutical Pricing*, *supra* note 25.

[51] *Id.*

[52] *Id.*

[53] *Understanding Generic Drugs,* U.S. FOOD AND DRUG ADMIN. (last updated Oct. 23, 2014), http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/.

[54] *Drugs: Facts About Generic Drugs*, U.S. FOOD AND DRUG ADMINISTRATION (last updated Sept. 19, 2012), http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm [hereinafter *Facts About Generic Drugs*].

infringers. There are, however, unique exceptions to this problem that will be addressed in a later section. Competition among drug production companies increases without patent protection, consequently reducing the price of the generic drugs.[55] The companies also do not need to pay for the clinical trials, marketing, and advertising that would be needed for new, brand named drugs.[56] This creates a more affordable version of the expensive medicine.[57] Generic drugs, on average, cost about 80-85% less than their brand name counterparts.[58] In one year, generic drugs can save U.S. consumers about three billion dollars a week.[59]

Many people are skeptical of generic drugs, and feel that they do not provide the same positive medical effects as the brand named versions.[60] The U.S. Food and Drug Administration has evaluated evidence from studies comparing particular brand named drugs with their generic counterparts, i.e. cardiovascular medicine, which showed no medically significant variability.[61] The FDA also ensures that the generic product will meet the same quality standards as the brand name drug, and will meet the same testing and manufacturing specifications as well.[62]

One of the most common, and most important, drugs is Ibuprofen.[63] This is an anti-inflammatory that helps relieve pain and lower fevers, originally patented in 1961.[64] Once the patent expired, pharmaceutical companies were able to produce and sell Ibuprofen independently. Since then, Ibuprofen has become quite popular, sold under different, well-known trade names like Advil, Motrin, and Nurofen.[65] Another similar pain relief medicine is acetaminophen, or paracetamol, which is an anti-inflammatory that is used to treat arthritis, as well as prevent heart attacks and strokes.[66] Like the patent for Ibuprofen, the patent rights for acetaminophen have long expired, thus there are a wide variety of trade names selling the generic version of this drug.[67] Common generic Acetaminophen trade names in the United States include Aspirin, Tylenol, and Panadol.[68] Millions of people take these drugs, many of

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[55] *Id.*

[56] *Id.*

[57] *Drugs: What Are Generic Drugs*, U.S. FOOD AND DRUG ADMINISTRATION (last updated May 12, 2009), http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm.

[58] *Savings: $1 Trillion Over Ten Years – Generic Drug Savings in the U.S. Fourth Annual Edition 2012*, GENERIC PHARMACEUTICAL ASSOCIATION (2012), http://www.gphaonline.org/media/cms/IMSStudyAug2012WEB.pdf.

[59] *Id.*

[60] *Facts About Generic Drugs*, *supra* note 54.

[61] Aaron S. Kesselheim, et al., *Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease: A Systematic Review and Meta-analysis*, 300 J. AM. MED. 21, 2514-26 (2008).

[62] *Facts About Generic Drugs*, *supra* note 54.

[63] *See generally*, World Health Org. [WHO], *WHO Model List of Essential Medicines: 18th List* (Apr. 2013), http://apps.who.int/iris/bitstream/10665/93142/1/EML_18_eng.pdf?ua=1.

[64] Gayle M. Halford, Marie Lordkipanidz & Steve P. Watson, *50th Anniversary of the Discovery of Ibuprofen: An Interview with Dr. Stewart Adams*, 23 PLATELETS 6, 415-22 (2012).

[65] *Ibuprofen (By Mouth)*, PRE MED HEALTH (July 1, 2015), http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0010648/?report=details.

[66] *Paracetamol*, DRUGS.COM, http://www.drugs.com/paracetamol.html (last visited Nov. 13, 2014) [hereinafter *Paracetamol*].

[67] Karan B. Thakkar & Gauri Billa, *The Concept of: Generic Drugs and Patented Drugs vs. Brand Name Drugs and Non-proprietary (Generic) Name Drugs*, PUBMED – U.S. NAT'L LIBRARY OF MED. (Sept. 12, 2013), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3770914/.

[68] *Paracetamol*, *supra* note 66.

which use the drugs on a daily basis, so it is easy to see the importance of accessibility to pharmaceuticals.[69]

II. WORLD EFFORTS TO INCREASE ACCESS TO ESSENTIAL MEDICINE

A. International Organizations

Efforts to regulate and improve international trade have long been part of the world economy.[70] After World War II, the General Agreement on Tariffs and Trade (GATT) was initiated by the United Nations as an initial basis to create mutually advantageous trade opportunities for its member states.[71] The goals of the GATT were to lower trade tariffs and barriers, and to promote trade relations between nations.[72] It set the foundation for a long-term, multilateral, international trade system, however after almost half a century, the system needed a makeover.[73] A more successful and efficient organization was established in 1995, the World Trade Organization (WTO), replacing the GATT.[74] The implementation of the WTO established the world's largest international trade agreement with the current involvement of 160 member states.[75] The World Trade Organization oversees all aspects of international trade, including: goods, services, intellectual property, negotiation, and dispute resolution.[76] Ensuring fair market competition is a cornerstone of the WTO, the WTO implements five main principles: non-discrimination, reciprocity, binding and enforceable commitments, transparency, and safety valves.[77] The last of these, safety valves, aims to protect and develop the public health, and concerns the proper use of patent protection.[78]

The Agreement on Trade-Related Aspects of Intellectual Property Rights, also known as TRIPS, is an international agreement founded by GATT in 1994 and currently administered by the WTO.[79] This agreement is a staple of the international intellectual property trade system, setting the standards for intellectual property regulation for WTO members.[80] The goal was to set guidelines for intellectual property protection, like

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[69] *Id.*

[70] *Modest Trade Recovery to Continue in 2015 and 2016 Following Three Years of Weak Expansion*, WORLD TRADE ORGANIZATION (April 14, 2015), https://www.wto.org/english/news_e/pres15_e/pr739_e.htm.

[71] *Timeline: World Trade Organization,* BBC (Feb. 2, 2012, 7:31 PM), http://news.bbc.co.uk/2/hi/europe/country_profiles/2430089.stm.

[72] Robert W. Staiger, *The Economics of GATT*, THE NAT'L BUREAU OF ECONOMIC RESEARCH, http://www.nber.org/reporter/spring99/staiger.html (last updated Jan. 7, 2015).

[73] *The GATT Years: From Havana to Marrakesh*, WTO, http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm (last visited Jan. 6, 2015).

[74] BERNARD M. HOEKMAN ET AL., WORLD BANK, DEVELOPMENT, TRADE, AND THE WTO: A HANDBOOK 41 (2002) [hereinafter Hoekman].

[75] *Members and Observers*, WORLD TRADE ORG. (Last visited January 6, 2015), http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.

[76] Hoekman, *supra* note 74.

[77] *Principles of the Trading System*, WTO (last visited January 6, 2015), http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact2_e.htm#seebox.

[78] *Id.*

[79] *WTO TRIPS Implementation*, INT'L INTELLECTUAL PROP. ALLIANCE, http://www.iipa.com/trips.html. (last visited Jan. 6, 2015).

[80] *Id.*

patentability requirements and the length of patent terms, during international trade.[81] TRIPS, however, has received heavy criticism from developing countries because of its heavy influence and protection of patents, which has negative effects on access to medicine.[82] The implementation of TRIPS causes not only increases in drug prices, but also decreases in research and development of treatments for rare diseases and diseases that predominantly affect developing countries.[83] This is a huge dilemma, especially since more than three-fourths of the world population lives in developing countries, yet they account for less than 10% of the pharmaceutical market.[84]

The World Trade Organization, along with the help of the World Health Organization (WHO), took drastic steps in initiating agendas aimed at alleviating this issue.[85] The outbreak of HIV/AIDS in both Africa and Brazil in the 1990s caused the necessity of medicine in order to combat the disease and help the ailing.[86] The patent protection afforded to pharmaceuticals spurred an outcry to circumvent the patents in order to provide easier access to medicine.[87] This caused a shift in the attitudes about patent protection among international agencies such as the WTO and WHO.[88] These organizations placed an emphasis on promoting public health over trade interests, which was controversial in the commercial pharmaceutical industry.[89]

B. Compulsory Licenses and NGOs

An example applying this movement to promote public health over commercial interests was the Brazilian AIDS Programme, established by the Brazilian government.[90] Like South Africa, Brazil was suffering from a widespread HIV/AIDS epidemic during the mid-1990s and needed access to medicine.[91] Half a billion people in Brazil are infected with HIV, but with the support of non-governmental organizations (NGOs), like Doctors Without Borders, Brazil was able to reduce its AIDS-related mortality rate by 50% in just three years and save almost half a billion dollars in treatment costs.[92] Two major reasons the Programme was so successful were the production of medicine locally and the implementation of compulsory licenses.[93] Compulsory licensing in this context is when the government allows

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[81] *Id.*

[82] Ellen F.M. 'T Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, 3 CHI. J. INT'L L. 27, 27 (2002) [hereinafter Hoen].

[83] *Id.*

[84] *Id.* at 28.

[85] *Id.* at 35.

[86] *Id.* at 32-33.

[87] Angela J. Anderson, *Global Pharmaceutical Patent Law in Developing Countries – Amending TRIPS to Promote Access for All*, BEPRESS LEGAL REPOSITORY (Mar. 9, 2006), http://law.bepress.com/cgi/viewcontent.cgi?article=5237&context=expresso.

[88] *See Id.*

[89] Hoen, *supra* note 82, at 35-36.

[90] *Id.* at 32.

[91] *Id.*

[92] *Id.* at 44-45.

[93] *Id.* at 32.

for the production of a patented product without the consent of the patent owner.[94] This is one of the flexibility propositions provided under the TRIPs Agreement, and was enacted into Brazilian patent law.[95] Under TRIPs, there are specific situations that allow for the use of compulsory licenses in order to circumvent strict patent restrictions.[96] Several of these include: inventions funded by the government; lack of research and development over a certain period of time in the territory of a patent; where the refusal of a license leads to the inability to exploit the important use of a patent, national emergency, or extreme urgency; and cases of non-public commercial use.[97] These last two listed situations where the factors used to justify implementation during the HIV/AIDS crises in Brazil and South Africa.[98] The generic copies of the drugs during periods of compulsory licensing are mainly for domestic use, not for export, which is why Brazil was so successful in the local production and distribution of medicine.[99]

Doctors Without Borders is part of a larger NGO, Médecins Sans Frontières, which has medical programs in 70 countries and aims to promote the access and affordability of medicine to anyone who needs.[100] This relief organization has collaborated with other NGOs and activist groups, such as Oxfam, Voluntary Service Overseas, and Action Aid, in order to advocate for affordable healthcare in developing nations.[101] These collaborations, along with participation of national governments, were the reasons for success in countering the negative effects of the TRIPs agreement, and battling diseases like HIV/AIDS, Ebola, and tuberculosis in developing countries.[102] Besides Brazil and South Africa, other countries that have been negatively affected by TRIPs, where NGOs continue to work, include Kenya, Guatemala, and Thailand – which has over 600,000 people infected with HIV/AIDS, but now has access to medicine 25 times cheaper than the brand name equivalent.[103] Drawing attention to the disparity between patent prices and the affordability of drugs continues to be a focus of these NGOs.[104]

C. The Doha Declaration

The WHO's initiative to put public health before intellectual property rights was highly controversial.[105] Western countries like the United States and a number of European

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[94] *Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORG. (Sept. 2006), http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm [hereinafter *Compulsory Licensing*].

[95] Hoen, *supra* note 81, at 32.

[96] *URUGUAY ROUND AGREEMENT: TRIPS, Part II – Standards Concerning the Availability, Scope and Use of Intellectual Property Rights*, WORLD TRADE ORG., http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm (last visited Oct. 8, 2015).

[97] *Id.*

[98] Hoen, *supra* note 82, at 32.

[99] *Compulsory Licensing*, *supra* note 94.

[100] *About MSF*, MEDECINS SANS FRONTIERES, http://www.msf.org/about-msf. (last visited Oct. 8, 2015).

[101] Nathan Ford, *Patents, Access to Medicines and the Role of Non-Governmental Organizations*, 1 J. GENERIC MED. 137, 139 (2004) [hereinafter Ford] (discussing the importance of the partnerships between NGO's like Medecins Sans Frontieres and other activist groups).

[102] *Id.*

[103] *Id.* at 141.

[104] *Id.* at 144.

[105] Hoen, *supra* note 82, at 48.

nations opposed this solution to the AIDS crisis and urged for the protection of patent rights.[106] The Directorate General of Trade for the European Commission even stated, "[n]o priority should be given to health over intellectual property considerations."[107] Other organizations like UNAIDS, the World Bank, and the United Nations voiced their opinions on the need for access to medicine.[108] After much debate, the WTO decided to organize a special council to address access to pharmaceuticals and public health at the Doha Conference in 2001.[109]

In Doha, Qatar, about twenty developing countries joined together and presented a text proposal for clarifications of the TRIPs Agreement and related topics, such as compulsory licensing.[110] They wanted industrialized countries to stop implementing trade pressures in order to protect their pharmaceutical industries.[111] The opposing side, consisting of more developed countries like the United States, Japan, Switzerland, Australia, and Canada, proposed an alternate draft that focused more on intellectual property rights and protection for research and development.[112] This side, along with the European Union, argued that intellectual property contributes to public health, and that inhibiting patent protection in favor of compulsory licensing and parallel imports would be counterproductive to the improvement of public health.[113] Patent owners and big pharma companies would lose both money on their pharmaceuticals, and the incentive to continue research and development for improvements.[114] This, in turn, would lead to less advanced pharmaceuticals and a lack of sufficient medicine accessible to the public.[115]

After several days of negotiation, a compromise was reached that would reaffirm much of the flexibility of the TRIPs Agreement, and make clear the boundaries between patent rights and access to medicine.[116] This compromise, the Doha Declaration, made clear that the TRIPs Agreement would not prevent any member state from protecting public health.[117] Each member of the agreement is allowed to create its own regime for "exhaustion of intellectual property rights," which means they are free to decide what constitutes a national emergency or extreme urgency in order to grant compulsory licenses to circumvent patent rights.[118] Member countries decide the grounds upon which compulsory licenses can

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[106] *Id.*

[107] *Id.* at 48.

[108] *Id.* at 49.

[109] *Id.*

[110] CARLOS M. CORREA, WHO, IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, at 3 (2002).

[111] Ford, *supra* note 101, at 143.

[112] Hoen, *supra* note 82, at 51.

[113] *Id.*

[114] Jon Matthews, *Renewing Healthy Competition: Compulsory Licenses and Why Abuses of the TRIPS Article 31 Standards Are Most Damaging to the United States Healthcare Industry*, 4 J. BUS. ENTREPRENEURSHIP & L. 118, 122 (2010).

[115] *Id.*

[116] Hoen, *supra* note 82, at 52.

[117] Vanessa Bradford Kerry & Kelley Lee, *TRIPS, the Doha Declaration and Paragraph 6 Decision: What are the Remaining Steps for Protecting Access to Medicines*, 3 GLOBALIZATION AND HEALTH 1, 2 (2007) (discussing the uncertainty of where the Doha clarifications about TRIPS would lead, and the undermining of developing countries' abilities to manufacture pharmaceuticals).

[118] *Declaration on the TRIPS Agreement and Public Health,* WTO (Nov. 20, 2001), http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

be granted within their borders, and what defines a national emergency, for instance epidemics like HIV/AIDS, tuberculosis, and malaria.[119] Big pharma industries and organizations like the United States Trade Representation protested the declaration and argued that it would have devastating effects on research and development.[120] TRIPs still provides protection for patent owners, however, it allows for developing countries to also protect their citizens, promote public health, and increase access to medicine.[121] The current status of the Doha Declaration remains mostly unchanged, but a new amendment has recently been proposed.[122] The proposal would allow for WTO member countries to export generic versions of drugs to countries that do not have the capability or capacity to manufacture for themselves.[123] In order for the amendment to be formally ratified, two-thirds of the 153 WTO members must agree.[124] As of now, only 53 members have accepted the agreement, and the deadline for acceptance has been extended to the end of December, 2016.[125]

III. U.S. PHARMACEUTICAL PATENT POLICIES

A. U.S. Guidelines in Accordance with WTO Guidelines

United States patent law is authorized and protected by Article One of the U.S. Constitution, and gives the patent holder the right to prevent others from making, selling, and using the invention during the patent term.[126] The term typically lasts for twenty years from the time of filing the patent application with the United States Patent and Trademark Office in Virginia.[127] The U.S. government has strongly defended patent rights, and all intellectual property rights, since the making of the Constitution and values the importance that patent protection contributes to society.[128] At the same time, the U.S. believes in protecting and promoting public health.[129] Thus, as a member state of the World Trade Organization, the U.S. adopted the 2001 Doha Declaration of the TRIPS Agreement and Public Health.[130]

Aside from following international organization guidelines, the U.S. has long sought to promote and advance public health and safety, not only abroad through the WTO and WHO, but also domestically.[131] This is evident through the establishment of government offices, such as the Department of Health and Human Services, and the Public Health Service

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[119] *Id.*

[120] Hoen, *supra* note 82, at 56.

[121] *Overview: The TRIPS Agreement*, WTO (last visited Jan. 6, 2015), http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm.

[122] *Members Accepting Amendment of the TRIPS Agreement*, WTO (last updated Sept. 10, 2014), http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm [hereinafter *Members Accepting*].

[123] *Members OK Amendment to Make Health Flexibility Permanent*, WTO (Dec. 6, 2005), http://www.wto.org/english/news_e/pres05_e/pr426_e.htm.

[124] *Members Accepting*, *supra* note 122.

[125] *Id.*

[126] U.S. CONST. art. I, § 8, cl. 8.

[127] *Chapter 2*, *supra* note 35.

[128] *See generally,* 35 U.S.C. § 154 (2013).

[129] *See generally*, LAWRENCE O. GOSTIN, Public Health Law: Power, Duty, Restraint 43 (2d ed. 2008).

[130] Hoen, *supra* note 82, at 51.

[131] *Global Health*, OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION (last visited December 1, 2015), http://www.healthypeople.gov/2020/topics-objectives/topic/global-health.

Act of 1944 that restructured the United States Public Health Service, which was founded in 1798.[132] The Department of Health was established with the goal of "improving the health, safety, and well-being of America," and originally included the now separate Department of Education.[133] It includes sub-departments and agencies, the primary division being the Public Health Service, which consists of most of these sub-compartments.[134] They include, but are not limited to, the Office of the Surgeon General, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, and National Institutes for Health.[135] Across these divisions, the Department of Health has issued many programs to further implement its goal of promoting public health; these programs include health and social science research, preventing disease and providing immunization, Medicare and Medicaid, health information technology, financial assistance, and medical preparedness for emergencies.[136] Altogether, the Department of Health and Human Services and its branches maintain an established network for developing and improving the nation's public health and well-being.

On top of protecting public health, the U.S. government also understands the need to protect intellectual property, and aims to establish a balance between the two ideas.[137] As a member state of the WTO and of the Doha Declaration, the United States agreed to the flexibility on the TRIPS Agreement for developing countries, but the U.S. also wants to prevent patent holders and the pharmaceutical business from being exploited.[138] Before the Doha Declaration, and even before the TRIPS Agreement, the U.S. has aimed to make sure its citizens' intellectual property rights are adequately and effectively protected abroad as well as at home.[139] Section 301 of the Trade Act of 1974 does just that.[140] The Office of the United States Trade Representative (USTR), a government agency that conducts and develops trade policy and negotiations, provides an annual report identifying those countries that inhibit the intellectual property rights of U.S. citizens and companies.[141] This report, known as the Special 301 Report, seeks trade barriers to U.S. products and creates a Watch List of countries that do not adhere to the USTR policies of "fair and equitable market access to United States

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[132] *About HHS*, U.S. DEP'T OF HEALTH AND HUMAN SERV., http://www.hhs.gov/about/ (last visited Jan. 27, 2015); *Public Health Service Act of 1944*, 59 Public Health Reports 916 (July 14, 1944).

[133] *Health Information Privacy*, U.S. DEP'T OF HEALTH & HUM. SERV. http://www.hhs.gov/ocr/privacy/ (last visited Jan. 27, 2015).

[134] *HHS Organizational Chart*, U.S. DEP'T OF HEALTH AND HUMAN SERV., http://www.hhs.gov/about/orgchart/ (last visited Jan. 27, 2015).

[135] *Id.*

[136] *HHS Programs and Services*, U.S. DEP'T OF HEALTH & HUMAN SERV., http://www.hhs.gov/about/programs/index.html (last visited Jan. 27, 2015).

[137] Victoria E. Hopkins, *Analysis of International Patent Protection and Global Public Health*, 17 PRINCETON J. OF PUB. INT'L AFF. 83, 84 (2006).

[138] Hoen, *supra* note 82, at 51.

[139] Letter from Steve Metalitz, Michael Schlesinger, Eric Schwartz, Amanda Wilson Denton, Counsel for Int'l Intellectual Prop. Alliance, to Susan F. Wilson, Dir. for Intellectual Prop. & Innovation, U.S. Trade Representative (Feb. 7, 2014).

[140] 19 U.S.C. § 2411 (2012); 19 U.S.C. § 2242 (2012).

[141] *Mission of the USTR*, OFFICE OF THE U.S. TRADE REPRESENTATIVE, https://ustr.gov/about-us/about-ustr (last visited Jan. 27, 2015).

persons that rely upon intellectual property rights."[142] Priority Foreign Countries on this list are those that "have the most onerous or egregious acts, policies, or practices" that deny fair trade to U.S. products.[143] If a country on this Watch List is not a member state of the WTO, the U.S. government can initiate unilateral trade sanctions.[144] Countries in agreement with the World Trade Organization, or other international unions like the North American Free Trade Agreement, may have dispute settlement proceedings initiated by the U.S. government against them.[145] As of the 2014 301 Special Report, 27 countries are on the Watch List, and 10 countries have been listed in the Priority Watch List.[146] Several countries have continually been listed every year, including China, India, and Thailand.[147] A majority of the reason these countries make the list is due to the issuance of compulsory licenses in emergency situations, which are part of the flexibility of the Doha Declaration.[148] Even though the U.S. is on alert for practices against U.S. intellectual property rights, the U.S. government continues to reaffirm its commitment to the Doha Declaration and promote public health.[149]

B. U.S. Government and Domestic Pharmaceuticals

Besides agreements with international organizations, the United States government has enacted reforms to bridge the gap between national public health and intellectual property rights.[150] The Orphan Drug Act and the Hatch-Waxman Act, passed in 1983 and 1984 respectively, were designed to influence the pharmaceutical industry to join the campaign for promoting public health.[151] The Hatch-Waxman Act, formally known as the Drug Price Competition and Patent Term Restoration Act, was an amendment to the Federal Food, Drug, and Cosmetic Act.[152] This law, forefronted by Congressmen Henry Waxman and Orrin

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[142] MICHAEL B.G. FROMAN, THE U.S. TRADE REPRESENTATIVE, 2014 SPECIAL 301 REPORT 59 (2014) [hereinafter Froman] (issuing the Special 301 Report for the 2014 year on behalf of the U.S. Executive Office); 19 U.S.C. § 2242, *supra* note 140.

[143] Froman, *supra* note 142.

[144] John T. Masterson, *Enforcement of Trademarks and Copyrights under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, in* INTERNATIONAL TRADEMARKS AND MANAGEMENT 1, 20 (John T. Masterson ed., Am. Bar Ass'n Publ'g 2004).

[145] *Id.* at 7.

[146] Froman, *supra* note 142.

[147] *Id.*

[148] Pier DeRoo, *"Public Non-Commercial Use" Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs*, 32 MICH. J. INT'L L. 347, 358 (2011).

[149] H.R. Res. 525, 110th Cong. (2007) (stating United States reaffirming its commitments to the 2001 Doha Declaration on the TRIPS Agreement).

[150] *See generally, Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, WORLD HEALTH ORGANIZATION, http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf.

[151] *See generally* Wendy H. Schacht & John R. Thomas, *The "Hatch-Waxman" Act: Selected Patent-Related Issues*, CONG. RESEARCH SERVICE (Apr. 1, 2002), http://congressionalresearch.com/RL31379/document.php?study=The+Hatch- Waxman+Act+Selected+Patent-Related+Issues (discussing the Hatch-Waxman Act); Enrique Seoane-Vazquez et al., *Incentives for Orphan Drug Research and Development in the United States*, ORPHANET JOURNAL OF RARE DISEASES (Dec. 16, 2008), http://www.ojrd.com/content/3/1/33 (discussing the Orphan Drug Act); Anton Leis Garcia, *Is the Copy Better than the Original? The Regulation of Orphan Drugs: a US-EU Comparative Perspective*, DASH HARVARD (Mar. 2004) http://dash.harvard.edu/bitstream/handle/1/8852101/Orphan_Drugs_RTF.pdf?sequence=1.

[152] Schacht et al., *supra* note 151.

Hatch, sought to regulate the manufacturing of generic drugs and encourage the pharmaceutical industry to produce these generic drugs.[153] It brought about significant changes to patent laws, specifically pharmaceutical patents.[154] These types of patents not only need to be approved by the USPTO, but must also attain market approval from the Food and Drug Administration (FDA), which promotes public health by supervising the safety of food and drug products.[155] This FDA approval typically causes delays in the patent term for the pharmaceutical, but the Hatch-Waxman Act extends the term life for these patents to reflect regulatory delays.[156] Another aspect of this act that caused significant patent law change (as well as controversy) is known as paragraph IV certification.[157]

Under this certification, when a generic drug product seeks to enter the market, the generic drug company must file an Abbreviated New Drug Application (ANDA) to gain approval from the FDA.[158] This certification process has two possible outcomes: either the FDA approves the generic drug once the last patent on the brand name drug expires, or the generic drug does not infringe the brand name drug and those patents are not enforceable against the generic product.[159] Once the generic product company files an ANDA and receives certification, the brand drug company is notified and has 45 days to file a patent infringement suit against the generic company.[160] If a suit is filed, the FDA cannot approve the generic ANDA until the suit is over, or until 30 months lapses, whichever comes first.[161] Filing an ANDA is still worthwhile for the generic company, because if the company is first to file the application and wins the infringement lawsuit, that generic drug product has market exclusivity for 180 days.[162] This allows for the generic product to mark prices well below the comparable brand name drug, acquire market share from the brand drug, and make a profit before other generic drugs enter the market, especially if the branded product is a "blockbuster" drug and in high demand.[163]

Like the Hatch-Waxman Act, the Orphan Drug Act also amended the Federal Food, Drug, and Cosmetic Act.[164] It aimed to promote public health while protecting patent rights at the same time.[165] An orphan drug is a pharmaceutical developed specifically for the purpose of treating orphan diseases, which are rare illnesses and medical conditions.[166] The Rare Disease Act of 2002 defines these orphan diseases as "any disease or condition that

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[153] *Id.*

[154] *Id.*

[155] *Paragraph IV Drug Product Applications: Generic Drug Patent Challenge Notifications*, U.S. FOOD AND DRUG ADMINISTRATION (Last updated March 27, 2014), http://www.fda.gov/drugs/developmentapproval process/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandagenerics/ucm147166.htm.

[156] Schacht et al., *supra* note 151.

[157] *Paragraph Four Explained*, PARRY ASHFORD PUBLICATIONS (Last visited January 27, 2015), http://www.paragraphfour.com/explained/process.html.

[158] *Id.*

[159] *Id.*

[160] *Id.*

[161] *Id.*

[162] *Id.*

[163] *Paragraph Four Explained, supra* note 157.

[164] Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049, 2049 (1983).

[165] *Id.*

[166] Sharma Aarti et al., *Orphan Drug: Development Trends and Strategies*, 2 J. PHARM. AND BIOALLIED SCI. 290, 290-99 (2010).

affects less than 200,000 people in the United States," which is about 1 in every 150,000 people.[167] These are the type of illnesses that doctors may encounter only once a year.[168] In the U.S. some of these diseases include Crohn's disease, cystic fibrosis, and tuberculosis.[169] What might be considered a rare disease in the United States might not be in other countries.[170] For instance, tuberculosis is much more prevalent in developing countries like India and China.[171] So an orphan drug may not only treat rare diseases, but also those diseases that would not be worth the time and effort for U.S. pharmaceutical companies to develop.[172] Developing new medicine can be costly and time consuming.[173] Because pharmaceutical companies can predict low return on manufacturing drugs for an orphan disease, they are less likely to spend the cost to develop them.[174] This causes many diseases to be ignored, which, although they might be considered rare, still affect thousands of people in the U.S.[175] Due to the poor economic potential of these drugs for the pharma industry, government intervention was necessary.[176]

The Orphan Drug Act aims to facilitate the research and development of orphan drugs through financial incentives.[177] Motivating factors for promoting this type of investment include tax breaks, increased patent protection and property marketing rights, research subsidies, and government-run programs to engage research and development.[178] The government established a 50% tax credit for expenses used during clinical and experimental trials for pharmaceutical testing, seven-year market exclusivity for the product, and about 15 grants awarded annually to researchers and companies.[179] Over the past three decades, the Orphan Drug Act has largely been a success.[180] As of 2010, more than 200 rare diseases have become treatable, and over 350 drugs and 2,000 drug compounds have been approved by the FDA.[181] The FDA even created its own department, called the Office of Orphan Product Development, to administer this development.[182] This devotion to developing orphan drugs and fighting rare diseases has sparked a global effort towards the manufacturing of these drugs as well.[183] Countries like Japan, Canada, and a host of European

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[167] H.R. 4013, 107th Cong. (2002).

[168] Aarti et al., *supra* note 166, at 290.

[169] Aarti et al., supra note 166.

[170] *Id.*

[171] *See Tuberculosis High-Burden Countries (HBCs)*, THE HENRY J. KAISER FAMILY FOUND., http://kff.org/global-indicator/tuberculosis-hbcs/ (last updated 2014).

[172] Aarti et al., *supra* note 166, at 290.

[173] *Id.*; Seoane-Vazquez et al., *supra* note 151.

[174] Seoane-Vazquez et al., *supra* note 151.

[175] Aarti et al., *supra* note 166, at 290.

[176] Seoane-Vazquez, *supra* note 151.

[177] *Id.*

[178] *Id.*

[179] *Id.*

[180] Mia Burns, *Report Projects Global Orphan Drug Market to Tap $112 Billion in 2017*, DRUGS.COM (2013), http://www.drugs.com/news/report-projects-global-orphan-market-tap-112-billion-2017-46803.html.

[181] Seoane-Vazquez, *supra* note 151, at 21.

[182] *Id.*

[183] Burns, *supra* note 180.

nations have joined the movement too.[184] It is predicted that the global orphan drug market will reach $112 billion by 2017, and $120 billion by 2018, with the U.S. accounting for a little more than half of the market.[185]

This movement toward increasing research and development affects the private sector as well as federal agencies.[186] Even though private industry based funds more than double the amount of government based funds, the private companies still benefit directly from the government tax breaks associated with research and development.[187] Companies also offer their own internal incentives to encourage their employees to participate in the invention process.[188] For instance, they may propose their own system of financial incentives, like a salary bonus or a patent royalty.[189] A company can also reward an employee/inventor with internal awards and recognition.[190] One first-hand, personal account of a patent agent's experience working for a company with such incentives comes from Russ Krajec, an attorney and engineer working in Colorado.[191] Before practicing as a solo attorney, Mr. Krajec worked as an engineer for Hewlett Packard, which operated its own patent incentive programs.[192] Mr. Krajec has discussed his experience working under one of these programs, which can offer up to $250 for submitting a patent disclosure to the USPTO, and up to $5000 when a patent issues.[193] He has submitted about 15 disclosures himself, with about ten issuing has independent patents.[194] The patent incentive programs were good motivational tools, he claims, but they would also lead to some controversy.[195] For instance, other employees would claim they were co-inventors on certain inventions they had no business being included in.[196] So while the incentive programs may cause tense competition intra-company, they also motivate employees, like Mr. Krajec, to work harder in research and development.[197] This shows how the Hatch-Waxman Act, the Orphan Drug Act, and the effects they have had in the U.S. are good illustrations of possible systems that developing countries can implement to promote public health.

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[184] Emmanuelle Lecomte, *Development of International Orphan Drug Policies*, EUROPEAN CONFERENCE ON RARE DISEASES (2014), http://www.rare-diseases.eu/wp-content/uploads/2014/05/0401_Emmanuelle_LECOMTE-BRISSET.pdf.

[185] Burns, *supra* note 180; Neeraj Chawla, *Global Orphan Drug Market to Reach US$ 120 Billion by 2018*, PR NEWSWIRE (Feb. 7, 2014), http://www.prnewswire.com/news-releases/global-orphan-drug-market-to-reach-us-120-billion-by-2018-244195511.html.

[186] Matthew S. Clancy & Giancarlo Moschini, *Incentives for Innovation: Patents, Prizes, and Research Contracts*, 35 APPLIED ECON. PERSP. AND POL'Y 206, 207 (2013).

[187] *Id.* at 207-208.

[188] *Id.*

[189] *Incentives for Inventors*, NAT'L INST. OF STANDARDS & TECH., http://www.nist.gov/tpo/collaborations/incentives-for-inventors.cfm (last updated Aug. 27, 2014).

[190] *Id.*

[191] Russ Krajec, *Patent Incentive Programs*, RUSS KRAJEC PAT. ATT'Y, http://krajec.com (last visited Jan. 27, 2015).

[192] *Id.*

[193] *Id.*

[194] *Id.*

[195] *Id.*

[196] *See Id.*

[197] *See generally* Krajec, *supra* note 191.

IV. CHINA'S MOVEMENT TO IMPROVE PUBLIC HEALTH

A. China's Healthcare Reform

China is currently undergoing a major healthcare system overhaul.[198] For decades, there has been a staggering difference in the quality, accessibility, and affordability of healthcare available between rural and urban parts of China.[199] Not only the disparity between the regions, but the overall inflated prices of drugs, and the denial of care to those without the ability to afford it no matter what part of China they were from, has sparked civil unrest.[200] Protests and even acts of violence have marred Chinese society throughout the country.[201] In 2009, the Chinese government finally released a two-tiered plan for a reform framework.[202] The more long-term plan is called the Framework Plan, or the State Council's Opinions on Deepening Healthcare System Reform, and aims to be established through the year 2020.[203] The Chinese Ministry of Health, now integrated into the National Health and Family Planning Commission in 2013 as part of the reforms, implemented a more detailed roadmap: the Ministry of Health's Implementation Plan for Immediate Priorities in Healthcare System Reform, or the Implementation Plan for short.[204] This plan was relatively short-term and aimed to be instituted from 2009-2011.[205] As a whole, the reform policy sought to cover five priority areas: providing universal coverage of basic medical insurance and increasing the value of the insurance coverage program benefits; establishing an essential drug system that would implement increased use in generic drugs and ensure a safe supply of medicine; upgrading the infrastructure for primary health care; creating greater equality between rural and urban public health access; and initiating a pilot reform policy for public hospitals, as well as policies to facilitate private investment for hospitals.[206]

China's government initially pledged to invest $124 billion into the healthcare reform, but as of early 2014, the total had already surpassed $371 billion.[207] This large amount of spending, however, has brought positive outcomes.[208] For instance, rural insurance coverage has reached its goal of a 90% coverage rate, and about 400 million urban citizens

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[198] *See generally* Winnie Chi-Man Yip et al., *Early Appraisal of China's Huge and Complex Health-care Reforms*, 379 THE LANCET 833 (2012).

[199] CHRISTINA S. HO, IMPLEMENTING HEALTH CARE REFORM POLICIES IN CHINA: CHALLENGES AND OPPORTUNITIES, CENTER FOR STRATEGIC AND INTERNATIONAL STUDIES 1, 1 (Charles W. Freeman II & Xiaoqing Lu Boynton eds. 2011), http://csis.org/files/publication/111202_Freeman_ImplementingChinaHealthReform_Web.pdf.

[200] *Id.*

[201] *Id.*

[202] James A.C. Sinclair, *China's Healthcare Reform, Reform Plans Promise Significant Change, But What Does That Mean for Foreign Healthcare Players?*, CHINA BUS. REVIEW (July 1, 2009), http://www.chinabusinessreview.com/chinas-healthcare-reform/.

[203] *Id.*

[204] *Id.*

[205] *Id.*

[206] Ho, *supra* note 199; Sinclair, *supra* note 202.

[207] Yanzhong Huang, *What Money Failed to Buy: The Limits of China's Healthcare Reform*, COUNCIL ON FOREIGN RELATIONS (Mar. 4, 2014), http://blogs.cfr.org/asia/2014/03/04/what-money-failed-to-buy-the-limits-of-chinas-healthcare-reform/.

[208] *Id.*

are enrolled in an insurance program.[209] In terms of private hospitals, the Ministry of Health sought an increase in private investments from 8% in 2012 to 20% by 2015.[210] As of 2014, the transaction to increase the amount of private investors in hospital management had driven in over $1.7 billion of capital.[211] Despite all of this, there is still much more ground for China's health department to cover.[212] For one thing, even with all the money the government spent, only one-third goes towards patients and consumers, while two-thirds is for healthcare providers (which may seem like a good thing, but less than 10% of the government's contributions reach public hospitals).[213] There are still about 300 million people living in urban areas without medical insurance coverage, and regardless of where people live, the price of medicine is still inaccessibly high and overcrowded hospitals deny care to the more indigent.[214]

B. China's Pharmaceutical Patent Industry

Patent laws in the People's Republic of China are quite similar to those in the United States.[215] China follows the Patent Cooperation Treaty, joined the World Trade Organization in 2001, and is a member state of the TRIPS Agreement.[216] China offers both utility and design patents and requires that patents are novel and incorporate prior art.[217] China's patent review system, however, does not require substantive examination as the USPTO does; therefore, it is easier to acquire patent rights in China.[218] The patent department does not have the necessary amount of patent examiners, nor the financial resources to hire enough, to conduct thorough examinations of patent applications.[219] Even though patent rights may be more easily granted in China, and patent protection lasts only 10 years instead of 20, this does not mean that patents are easier to invalidate.[220] Actually, it is quite the contrary, since China has implemented a discretionary review policy, which provides a more substantive examination of particular applications.[221] The Chinese system also enforces a maximum of two references to be used in an obviousness rejection of a patent

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[209] Ho, *supra* note 199.

[210] Benjamin Shobert, *China Taps Private Hospitals in Overhaul – Will it Work*, CNBC (Oct. 1, 2012), http://www.cnbc.com/id/49250873.

[211] Benjamin Shobert, *Concord Medical's China Growth Plans*, FORBES (Apr. 23, 2014), http://www.forbes.com/sites/benjaminshobert/2014/04/23/concord-medicals-china-growth-plans/.

[212] Huang, *supra* note 207.

[213] Shobert, *supra* note 210

[214] Ho, *supra* note 199.

[215] Gene Quinn, *Doing Business in China: Understanding China's Patent System*, IPWATCHDOG (Oct. 3, 2014), http://www.ipwatchdog.com/2014/10/03/doing-business-in-china-understanding-chinas-patent-system/id=51518/.

[216] *PCT Notification No. 81*, WIPO (October 1, 1993), http://www.wipo.int/treaties/en/notifications/pct/treaty_pct_81.html (discussing China's accession of the Patent Cooperation Treaty); *China*, WIPO (2008), http://www.wipo.int/wipolex/en/details.jsp?id=5484 (discussing China's Patent laws as up to the amended 2008 revisions).

[217] Quinn, *supra* note 215.

[218] *Id.*

[219] *Id.*

[220] *Id.*

[221] *Id.*

application.[222] Companies and independent investors in China will continue to pursue patent protection rights, because even though the examination process is quick and cheap, the validity of their patents are still strong.[223]

As China undergoes its healthcare reform, and the government tries to make medicine and drugs more affordable and accessible, there will be a larger push towards generic pharmaceuticals.[224] With a high demand for low cost drugs, companies in the big pharma industry that are issued dozens of patents on pharmaceuticals will be the most affected by this.[225] Large drug distributors in China, like SinoPharm Group and Shanghai Pharmaceutical Co., will not be able to handle this type of thin margin market, nor would they be willing to, especially when they have patent protection for the brand named medicine.[226] As a result of this reform, researchers will be more inclined to invest their time and money researching and developing drugs for the masses.[227] With many people receiving insurance program coverage, the economic potential for investing in popular, or "blockbuster," drugs will be worthwhile.[228] This, unfortunately, will leave those affected by rare medical conditions and orphan diseases relatively in the dark.[229] Companies are less likely to devote resources to developing medicine that would only be used by a small percentage of the population.[230]

The proposal introduced in the beginning of this note would substantially aid the Chinese government in overcoming many dilemmas they face amidst the healthcare reform. The government is developing certain measures and outlines, however, adopting two important, if not the most important, amendments to the U.S. Food, Drug, and Cosmetic Act – the Hatch-Waxman Act and the Orphan Drug Act – would provide an already established framework for this system. The Chinese government has published a National Essential Drug List to guide prices of the drug market, and has made the push towards a more generic drug market, which at the beginning of 2015 neared almost $82 billion.[231] China, however, has been accused of corruption, impropriety, and increased hostility towards foreign companies, especially in the big pharma industry.[232] This is evidenced by one of the largest generic drug manufacturers, Actavis, leaving the Chinese drug market.[233] China has also established its own definition of rare and orphan diseases and has attempted to create incentives for orphan drugs through procedures such as the New Drug Approval Regulation, the Drug Registration Regulation, and the Special Review and Approval Procedures for Drug Registration.[234] These

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[222] *Id.*

[223] Quinn, *supra* note 215.

[224] Sinclair, *supra* note 202.

[225] *Id.*

[226] *Id.*

[227] Ho, *supra* note 199.

[228] *Id.*

[229] Aarti et al., *supra* note 166, at 23.

[230] *Id.*

[231] Sinclar, *supra* note 202; Benjamin Shobert, *Why Did One of the World's Largest Generic Drug Makers Exit China*, FORBES (Feb. 3, 2014), http://www.forbes.com/sites/benjaminshobert/2014/02/03/why-did-one-of-the-worlds-largest-generic-drug-makers-exit-china/ (mentioning China's generic drug market).

[232] Shobert, *supra* note 210.

[233] *Id.*

[234] Peipei Song, et al., *Rare Diseases, Orphan Drugs, and Their Regulation in Asia: Current Status and Future Perspectives*, 1 INTRACTABLE & RARE DISEASES RES. 3, 4 (2012).

have established guidelines and criteria for accelerated approval of orphan drugs, but "detailed rules have yet to be implemented and further incentives have not been proposed."[235] According to a 2014 study by the European Committee of Rare Diseases, China has established neither an "orphan drug program nor special funding for orphan drug research."[236] Other players in the Asian drug market, however, like Japan and South Korea, have established their own orphan drug acts and regulations.[237]

With all of this still looming as China enters the sixth year of its healthcare reform, the joint implementation of the Hatch-Waxman Act and the Orphan Drug Act would create the solid foundation the reform needs to combat these issues.[238] The Hatch-Waxman Act would help establish a modern system for generic drug manufacturing that would not only protect intellectual property rights, but also provide a gateway that encourages the production of generic drugs in the pharmaceutical industry.[239] The Orphan Drug Act would establish funding and incentives for private sector companies to devote resources towards research and development of orphan drugs.[240] These two acts have been successful and influential in the United States for over thirty years.[241] Together, their implementation would protect pharmaceutical patent rights while also improving national and international public health, helping Chinese healthcare reform become that much more successful.

V. CONCLUSION

As discussed before, the United States and China have similar patent systems.[242] They also have similar drug administration systems, which, through implementation of this proposal, would make the transition of the drug system feasible and reasonable.[243] The Chinese government created the State Food and Drug Administration (SFDA), "influenced by the U.S. model," and passed the Drug Administration Law in 2001.[244] This established a regulatory system for drug approval and registration.[245] Just as U.S. drug makers have to seek authorization from the FDA, the SFDA also has to approve new drugs for market production and availability.[246] Like the U.S. Department of Health and Human Services, the Ministry of Health of the People's Republic of China oversees the laws, policies, and regulations related to public health, and would be the organization to undertake the implementation of the

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[235] *Id.*

[236] Lecomte, *supra* note 184.

[237] *Id.*

[238] Yip, *supra* note 198 (pointing out the starting year of China's healthcare reform).

[239] Schacht et al., *supra* note 151.

[240] Seoane-Vazquez et al., *supra* note 151.

[241] *Selected Amendments to the Federal Food, Drugs, and Cosmetic Act,* U.S. FOOD AND DRUG ADMIN., http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176580.htm (last updated June 19, 2015).

[242] *See generally* CHINA PATENT & TRADEMARK OFFICE, http://www.chinatrademarkoffice.com (last visited Oct. 8, 2015).

[243] Chenglin Liu, *Leaving the FDA Behind: Pharmaceutical Outsourcing and Drug Safety*, 48 TEX. INT'L. L.J. 1, 18 (2012).

[244] *Id.*

[245] *Id.*

[246] *Order of the President of the People's Republic of China No. 45*, CHINA FOOD AND DRUG ADMIN. (Feb. 28, 2001), http://eng.sfda.gov.cn/WS03/CL0766/61638.html.

proposal.[247] During the next phase of China's healthcare reform, the long-term Framework Plan, the Ministry of Health would be the governmental branch to implement the system frameworks of the Hatch-Waxman Act and the Orphan Drug Act in order to institute the new essential drug system.[248]

The world that once made it difficult for HIV/AIDS victims to receive the proper medicine, and turned its head on those suffering from rare medical conditions, is now making efforts to strive towards a more public-health conscientious global community.[249] With essential medicine more readily accessible and more time and money being invested in developing orphan drugs, the world may become a place where no one is denied access to necessary medicine.[250] China may follow in these footsteps and become a place where a father does not have to abandon his baby in order for it to receive proper medical care.[251] China can become a place where every child has access to the necessary care and pharmaceuticals.[252]

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[247] *Ministry of Health*, THE STATE COUNCIL OF THE PEOPLE'S REPUBLIC OF CHINA, http://www.gov.cn/english/2005-10/09/content_75326.htm (last updated Dec. 22, 2009).

[248] Sinclair, *supra* note 202.

[249] Hoen, *supra* note 82.

[250] *Id.*

[251] Young, *supra* note 4.

[252] Ho, *supra* note 199.