

TRIPS AGREEMENT ARTICLE 31(B): THE NEED FOR REVISION

*Ann Marie Effingham**

I. INTRODUCTION

American pharmaceutical companies spend more than fifty billion dollars per year in research and development (“R&D”) in order to bring new drugs to market.¹ This immense investment is justified by the need to create a “blockbuster drug” that will solve a medical issue prevalent among millions of people.² These blockbuster drugs generate media attention, create hype among medical professionals, and generate enormous sales.³ The idea is that the revenue from several blockbuster drugs makes up for all the other disappointments in the R&D process.⁴

In addition to creating blockbuster drugs, American pharmaceutical companies rely on patent protection in order to safeguard their investments in R&D.⁵ While the American patent protection model is sufficient to protect domestic patents, it is disrupted when American patents are used outside of the United States.⁶

* J.D. Candidate, 2016, Seton Hall University School of Law; B.A., 2013, The College of New Jersey. Special thanks to Professor David Opderbeck for his guidance throughout the writing of this Comment.

¹ See PHARM. RESEARCH AND MFRS. OF AM., 2015 BIOPHARMACEUTICAL RESEARCH INDUSTRY PROFILE vi (2015), http://www.phrma.org/sites/default/files/pdf/2014_PhRMA_PROFILE.pdf [hereinafter Pharmaceutical Research].

² Neil F. Hazaray, Note, *Do the Benefits Outweigh the Risks? The Legal, Business, and Ethical Ramifications of Pulling a Blockbuster Drug Off the Market*, 4 IND. HEALTH L. REV. 115, 117–18 (2007) (defining “blockbuster drug”).

³ *Id.* at 118.

⁴ See David W. Opderbeck, *Patents, Essential Medicines, and the Innovation Game*, 58 VAND. L. REV. 501, 519 (2005) (explaining that pharmaceutical companies depend on blockbuster drugs to recoup R&D costs).

⁵ Pharmaceutical Research, *supra* note 1, at 28 (“IP-intensive manufacturing industries are defined as those industries that are more R&D-intensive than the average for all manufacturing sectors, and which rely heavily on patents to produce innovations.”).

⁶ Jamie Feldman, Note, *Compulsory Licenses: The Danger Behind the Current Practice*, 8 J. INT’L BUS. & L. 137, 141 (2009).

In an effort to standardize intellectual property protection across the world, the World Trade Organization (WTO), in the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”), set forth the minimum levels of protection that members of the WTO must enact.⁷ The TRIPS Agreement details minimum standards of protection for intellectual property rights including: copyrights, trademarks, geographical indications, industrial designs, and patents.⁸ Each of these elements is defined along with the rights afforded each element and the permissible exceptions.⁹ Likewise, the TRIPS Agreement provides guidelines for how member countries should enforce and settle disputes over intellectual property rights.¹⁰ The provisions also articulate the minimum duration of protection for each element.¹¹

Despite these minimum levels of protection with which WTO member countries must comply, the TRIPS Agreement provides exceptions in certain exigent circumstances. Specifically, Article 31(b) of the TRIPS Agreement allows for WTO members to use the subject matter of patents without the patent holder’s authorization in times of national emergency.¹² This compulsory licensing¹³ scheme has allowed less developed countries (LDCs)¹⁴ to obtain patent licenses to generic drugs that help solve national emergencies.¹⁵ In some ways, this

⁷ *Intellectual Property: Protection and Enforcement*, WTO, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Feb. 11, 2016).

⁸ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (1994), http://www.wto.org/english/docs_e/legal_e/27-trips.pdf [hereinafter TRIPS Agreement].

⁹ See also *Overview: The TRIPS Agreement*, WTO, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Feb. 11, 2016).

¹⁰ See *Intellectual Property: Protection and Enforcement*, *supra* note 7.

¹¹ *Id.*

¹² See TRIPS Agreement, *supra* note 8, at art. 31(b).

¹³ *License*, BLACK’S LAW DICTIONARY (9th ed. 2009) (defining “compulsory license” as “[a] statutorily created license that allows certain people to pay a royalty and use an invention without the patentee’s permission”).

¹⁴ The WTO differentiates between “developing countries” and “least developed countries.” Compare *The World Factbook*, CENTRAL INTELLIGENCE AGENCY, <https://www.cia.gov/library/publications/the-world-factbook/appendix/appendix-b.html> (last visited Feb. 11, 2016) (click “D” alphabetical tab and scroll to “developing countries”), with *The World Factbook*, CENTRAL INTELLIGENCE AGENCY, <https://www.cia.gov/library/publications/the-world-factbook/appendix/appendix-b.html> (last visited Feb. 11, 2016) (click “L” alphabetical tab and scroll to “less developed countries”). For purposes of this Comment, “LDCs” refers to both developing countries and least developed countries.

¹⁵ Riadh Quadir, Note, *Patent Stalemate? The WTO’s Essential Medicines Impasse*

compulsory licensing scheme has proven to be beneficial to LDCs that are affected by national health emergencies, but in other instances, LDCs are exploiting the availability of compulsory licenses.

For example, in the 1990s, the World Bank projected that 1.2 million Brazilians would be living with Human Immunodeficiency Virus and the Acquired Immunodeficiency Syndrome (HIV/AIDS) by the year 2000.¹⁶ In order to rid the country of its projected path of disease, Brazil negotiated with American pharmaceutical company Abbott Laboratories by threatening to obtain a compulsory license if the parties could not reach a reduced price settlement for antiretroviral medicines used to treat HIV/AIDS.¹⁷ This threat of a compulsory license was a way for LDCs to get developed countries to help them deal with national health crises.¹⁸

Conversely, there are instances in which LDCs have begun to exploit the Article 31(b) exception by obtaining generic patent information to treat diseases that are outside the scope of what many developed countries consider true national emergencies. For example, in late 2006, Thailand issued compulsory licenses for two antiretroviral drugs used to treat HIV/AIDS without trying to negotiate a lower price settlement as in the Brazilian example.¹⁹ Thailand then issued a compulsory license for a heart disease drug in 2007,²⁰ and in 2008 it issued four compulsory licenses for cancer-treating drugs.²¹ Although Thailand's usage of compulsory licenses in this way does not *per se* violate Article 31(b) of the TRIPS Agreement, using compulsory licenses in this manner does not align with the goal of the TRIPS Agreement: supporting public health during times of national emergencies.²² This is because identified cases of HIV/AIDS, cancer, and heart disease—albeit great in number—should not all be treated as national emergencies warranting the use of compulsory licensing.

between Pharms and Least Developed Countries, 61 RUTGERS L. REV. 437, 454 (2009).

¹⁶ *Brazil – AIDS & STD Control III – Result Story*, THE WORLD BANK, <http://go.worldbank.org/WTXL9OB2H0> (last visited Feb. 11, 2016).

¹⁷ Jennifer Bjornberg, Comment, *Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation?*, 27 NW. J. INT'L L. & BUS. 199, 224 (2006).

¹⁸ *Id.* at 210–11; see also Quadir, *supra* note 15, at 439, 459–60.

¹⁹ Tove Iren S. Gerhardsen, *Thailand Presents Report on Compulsory Licensing Experience*, INTELL. PROP. WATCH (Mar. 12, 2007), <http://www.ip-watch.org/2007/03/12/thailand-presents-report-on-compulsory-licensing-experience/>.

²⁰ *Id.*

²¹ Sinfah Tunsarawuth, *New Thai Minister May Review Compulsory Licenses on Cancer Drugs*, INTELL. PROP. WATCH (Feb. 8, 2008), <http://www.ip-watch.org/2008/02/08/new-thai-minister-may-review-compulsory-licences-on-cancer-drugs/>.

²² Quadir, *supra* note 15, at 452.

This Comment will cover how the TRIPS Agreement can be amended in order to make it function more effectively, thereby encouraging LDCs to take advantage of the Article 31(b) exception and simultaneously disallowing other LDCs from misusing the exception. Part II of this Comment discusses the historical development of international intellectual property rights and how it has evolved into the present-day understanding of the TRIPS Agreement. Additionally, Part III examines what, in particular, the TRIPS Agreement protects and how its shortfalls led to the Doha Declaration.²³ Part IV concludes with a discussion of the drafters' purposes and goals when authoring the TRIPS Agreement. Part V compares American pharmaceutical industries' interests in a for-profit business model with LDCs' interests in managing national health crises by using compulsory licenses. Part VI introduces instances in which Thailand has used compulsory licenses in ways that do not align with the goals of the TRIPS Agreement. Despite being a moderate-income developing country, Thailand is not further developing the domestic infrastructure needed to create its own medicines.²⁴ Instead, it is relying on compulsory licenses for medicines that treat illnesses and diseases that most would not consider to be national emergencies necessitating use of Article 31(b).²⁵ Part VII analyzes how American pharmaceutical companies can incentivize LDCs to take advantage of the TRIPS Article 31(b) exception by proposing two solutions: (1) a regulatory solution and (2) a patent lifespan extension solution. Part VII also analyzes how the WTO can discourage LDCs from exploiting the TRIPS Article 31(b) exception through the formation of an international committee to investigate allegations of countries' misuse of compulsory licensing. Part VIII concludes.

²³ The Doha Declaration confirmed and endorsed that the purpose of the TRIPS Agreement is to support public health by promoting access to medicines. The major change promulgated at the Doha Declaration was the Paragraph 6 Decision, which effectively allows LDCs that do not have the manufacturing capabilities to issue a compulsory license to a developed country that does have the capabilities to export such medicines. *See infra* Part III.

²⁴ Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921, 928 (2007), http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=2490&context=faculty_scholarship ("The growing ability of some middle-income developing countries to produce low-cost generic medicines under these regimes—notably in Argentina, Brazil, Chile, India, Thailand, Egypt, Indonesia, Taiwan and South Korea—made it increasingly possible for even poor states to obtain certain low-cost generic medicines on the world market, whether such products were on or off patents.").

²⁵ *See infra* Part IV.

II. FROM THE PARIS CONVENTION TO THE TRIPS AGREEMENT: THE ORIGIN OF COMPULSORY LICENSES

In 1883, one of the first international intellectual property treaties was formed: the Paris Convention for the Protection of Industrial Property (“Paris Convention”).²⁶ The treaty pioneered patent protection and has served as a foundation for future international intellectual property agreements.²⁷ Today, 167 countries participate in the Paris Convention.²⁸ In 1967, the United Nations (U.N.) created the World Intellectual Property Organization (WIPO), which supervises international intellectual property matters.²⁹ WIPO has also acted as the administrator to the Paris Convention as it has grown.³⁰ Despite WIPO’s general success, it is inadequate to deal with international patent policies due to its inability to effectively and efficiently adjudicate intellectual property disputes.³¹ As the leaders in patentable products, developed countries have tried to use WIPO to authorize strong protection for international patents.³² In contrast, LDCs pushed for a more malleable patent scheme that could work with their societies’ growth and innovation as their countries continued to develop.³³

To resolve WIPO’s inadequacies, the General Agreement on Tariffs and Trade (GATT) was formed as a treaty in 1947, but by the 1970s it evolved into an international trade organization.³⁴ The developed countries’ new method to get LDCs to comply with their international patents was to tie patent protection to trade policy.³⁵

²⁶ Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 (as last revised July 14, 1967), http://www.wipo.int/treaties/en/text.jsp?file_id=287556.

²⁷ Quadir, *supra* note 15, at 447.

²⁸ *WIPO-Administered Treaties*, WORLD INTELL. PROP. ORG., http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2 (last visited Feb. 11, 2016) (enumerating all contracting countries).

²⁹ Convention Establishing the World Intellectual Property Organization, July 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S. 3 (as amended Sept. 28, 1979), <http://www.wipo.int/treaties/en/convention>; see also Elaine B. Gin, *International Copyright Law: Beyond the WIPO & TRIPS Debate*, 86 J. PAT. & TRADEMARK OFF. SOC’Y 763, 780–81 (2004).

³⁰ See Gin, *supra* note 29, at 780–82.

³¹ *Id.* at 780; see also Monique L. Cordray, *GATT v. WIPO*, 76 J. PAT. & TRADEMARK OFF. SOC’Y 121, 131 (1994).

³² See Gin, *supra* note 29, at 780–82.

³³ *Id.* at 781–82.

³⁴ ROBERT E. HUDEC, ENFORCING INTERNATIONAL TRADE LAW: THE EVOLUTION OF THE MODERN GATT LEGAL SYSTEM 70–71, 73 (1993).

³⁵ See Vandana Date, *Global “Development” and Its Environmental Ramifications—The Interlinking of Ecologically Sustainable Development and Intellectual Property Rights*, 27

Because LDCs needed trade to fuel their economic and social growth, they were required to comply with this stricter view of patent protection.³⁶

In 1995, GATT developed into the WTO, which was charged with “reducing trade barriers and creating a robust international trading platform.”³⁷ This reorganization of the WTO further engrained the connection between trade and patent policy.³⁸ As part of the reorganization of GATT, the TRIPS Agreement was created.³⁹ The WTO is authorized to supervise the TRIPS Agreement and settle disputes between member countries using its Dispute Settlement Body (DSB).⁴⁰ Today, 162 countries are WTO members.⁴¹

All member countries must abide by the TRIPS Agreement, which established minimum levels of copyright, trademark, and patent protection.⁴² Despite the differences of opinion between LDCs and developed countries regarding intellectual property protection, the TRIPS Agreement has created a workable international intellectual property framework that has proven successful.⁴³ The TRIPS Agreement’s minimum standards of intellectual property protection are required to be upheld throughout all member countries regardless of their domestic laws.⁴⁴

A. Article 31(b) and Other Exceptions to the TRIPS Agreement

While this Comment focuses on the Article 31(b) exception, it is important to appreciate the various other exceptions to the TRIPS Agreement in order to best understand their interrelatedness. Article 7 stresses the importance of technological innovation in a manner

GOLDEN GATE U. L. REV. 631, 659–61 (1997).

³⁶ *Id.*

³⁷ Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1125, 1144 (1994), http://www.wto.org/english/docs_e/legal_e/03-fa.pdf; Quadir, *supra* note 15, at 448.

³⁸ Quadir, *supra* note 15, at 448.

³⁹ *Id.*

⁴⁰ Cynthia M. Ho, *A New World Order for Addressing Patent Rights and Public Health*, 82 CHI.-KENT L. REV. 1469, 1470 (2007).

⁴¹ *Understanding the WTO: The Organization: Members and Observers*, WTO, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Feb. 11, 2016).

⁴² See TRIPS Agreement, *supra* note 8; Samira Guennif & Julien Chaisse, *Present Stakes Around Patent Political Economy: Legal and Economic Lessons from the Pharmaceutical Patent Rights in India*, 2 ASIAN J. WTO & INT’L HEALTH L. & POL’Y 65, 67 (2007).

⁴³ See TRIPS Agreement, *supra* note 8; see also Guennif & Chaisse, *supra* note 42, at 67.

⁴⁴ CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 8 (2007).

conducive to social and economic welfare.⁴⁵ Article 8 generally allows member countries to take any action to protect the public that are “necessary” and “consistent” with the TRIPS Agreement,⁴⁶ and Article 27(2) acknowledges the balancing act between the need for public health and intellectual property protection.⁴⁷ Article 31(b) permits patent use without the authorization of the right and articulates the requirements of obtaining a compulsory license.⁴⁸

Article 7 of the TRIPS Agreement states:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and *in a manner conducive to social and economic welfare*, and to a balance of rights and obligations.⁴⁹

The enforcement of intellectual property protection seeks to uphold social and economic welfare. Arguably, this section implies that the TRIPS Agreement consists of more than rules and several exceptions that allow a country to issue a compulsory license and import medicines whenever exigent circumstances exist.⁵⁰ This section, when taken in tandem with other sections, encompasses the TRIPS Agreement’s broad scope to not only help a country use technological—in this case patent-related—advances to its advantage, but to also benefit the producers of the information.⁵¹

Article 8 states, “[m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”⁵² This broad language seems to indicate that members can take any action so long as it is “necessary” and

⁴⁵ See *infra* notes 49–50.

⁴⁶ See *infra* notes 52–53.

⁴⁷ See *infra* notes 54–56.

⁴⁸ See *infra* notes 58–61.

⁴⁹ TRIPS Agreement, *supra* note 8, at art. 7 (emphasis added).

⁵⁰ *Id.*; see also CARLOS M. CORREA & ABDULQAWI A. YUSUF, INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 12 (1998); Amir Attaran, *The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 859, 871 (2002).

⁵¹ TRIPS Agreement, *supra* note 8.

⁵² TRIPS Agreement, *supra* note 8, at art. 8.

“consistent” with the TRIPS Agreement.⁵³

Article 27(2) states:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.⁵⁴

This Article acknowledges the balancing between intellectual property protection and the need for public health.⁵⁵ Some argue that this Article should allow HIV/AIDS medicines to be exempt from the TRIPS Agreement.⁵⁶ Others argue that this Article simply prohibits hazardous inventions from being patentable.⁵⁷

Article 31(b) provides, in relevant part, that patent use without authorization of the right holder:

[M]ay only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly⁵⁸

This Article is the most controversial of the exceptions to the TRIPS Agreement.⁵⁹ In effect, it allows LDCs, under certain circumstances, to

⁵³ *Id.*; CORREA, *supra* note 44, at 106.

⁵⁴ TRIPS Agreement, *supra* note 8, at art. 27(2).

⁵⁵ *Id.*; *see also* Attaran, *supra* note 50, at 871.

⁵⁶ TRIPS Agreement, *supra* note 8, at art. 27(2); *see also* Attaran, *supra* note 50, at 871.

⁵⁷ TRIPS Agreement, *supra* note 8, at art. 27(2); *see also* Attaran, *supra* note 50, at 871.

⁵⁸ TRIPS Agreement, *supra* note 42, at art. 31(b).

⁵⁹ *See* CORREA, *supra* note 44, at 313.

use member countries' patents without consent.⁶⁰ This exception is commonly referred to as "compulsory licensing."⁶¹ The goal of Article 31(b) is to allow an LDC to manufacture a generic drug domestically for less than the cost of purchasing and importing it from the foreign pharmaceutical company.⁶²

B. When and How Compulsory Licenses Are Used

Article 31(b) articulates how a compulsory license is obtained.⁶³ It requires an LDC to negotiate with the patent holder to purchase pharmaceuticals at a reasonable price and within a reasonable amount of time.⁶⁴ This requirement may be waived if an LDC has a national emergency, is facing other circumstances of extreme urgency, or plans to use the pharmaceuticals for a public, non-commercial use.⁶⁵ These exceptions to the negotiation requirement allow LDCs to completely bypass bargaining with the patent holder and, instead, to issue compulsory licenses without prior notice.⁶⁶

Bypassing bargaining with the patent holder and issuing a compulsory license imposes on the LDC several requirements that must be met in order to obtain the patented information. To issue a compulsory license under the Article 31(b) list of exemptions, an LDC must first notify the patent holder.⁶⁷ Second, an LDC must be able to domestically manufacture the pharmaceutical for which it issues a compulsory license.⁶⁸ Domestic manufacturing requires a country to have sufficient industrial and technological bases, such as banking institutions, transportation, and other assets that are necessary to domestic industry.⁶⁹ Third, an LDC must reasonably compensate the

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

⁶³ TRIPS Agreement, *supra* note 8, at art. 31(b); *see also* Guennif & Chaisse, *supra* note 42, at 80.

⁶⁴ TRIPS Agreement, *supra* note 8, at art. 31(b); *see also* Guennif & Chaisse, *supra* note 42, at 80.

⁶⁵ TRIPS Agreement, *supra* note 8, at art. 31(b); *see also* Guennif & Chaisse, *supra* note 42, at 80.

⁶⁶ TRIPS Agreement, *supra* note 8, at art. 31(b); *see also* Guennif & Chaisse, *supra* note 42, at 80.

⁶⁷ TRIPS Agreement, *supra* note 8, at art. 31(b); *see also* CORREA, *supra* note 44, at 313.

⁶⁸ TRIPS Agreement, *supra* note 8, at art. 31(f); CORREA, *supra* note 44, at 313. *But see infra* note 79 (explaining that the Paragraph 6 Decision did away with this requirement in 2003).

⁶⁹ Zita Lazzarini, Essay, *Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil*, 6 YALE HUM. RTS. & DEV. L.J. 103, 134 (2003).

patent holder.⁷⁰ There is no precise formula to determine reasonable compensation.⁷¹ Adequate remuneration is determined by taking into account the economic value conferred upon the importing LDC by the developed country in granting the compulsory license.⁷²

III. THE DOHA DECLARATION

In 2001, several years after the TRIPS Agreement took effect, the Declaration on the TRIPS Agreement and Public Health (“Doha Declaration”) was promulgated in order to clarify and possibly amend the TRIPS Agreement.⁷³ The Doha Declaration reaffirmed that the TRIPS Agreement’s “interpretation should support public health by promoting access to existing medicines and the creation of new medicines.”⁷⁴ While the Doha Declaration helped promote the TRIPS Agreement’s overall purpose, it failed to shed light on the meaning of “national emergency” or “other circumstances of extreme urgency.”⁷⁵

One major change that the Doha Declaration effectuated was the Implementation of Paragraph 6 (“Paragraph 6 Decision” or “the Decision”). At the Doha Declaration, many LDCs voiced complaints that they could not take advantage of the Article 31 exception because it required domestic production—resources and infrastructure—to which LDCs did not have access.⁷⁶ This requirement, they criticized, inhibited their ability to access medicines through compulsory licenses.⁷⁷ In response to these complaints, the Council for the TRIPS Agreement issued the Paragraph 6 Decision.⁷⁸ The Paragraph 6

⁷⁰ TRIPS Agreement, *supra* note 8, at art. 31(h).

⁷¹ *See id.*

⁷² Edited by Sean D. Murphy, *Modification of WTO Rules on Protection of Pharmaceuticals*, 97 AM. J. INT’L L. 981, 982 (2003).

⁷³ WTO, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002), http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.pdf [hereinafter Doha Declaration].

⁷⁴ Quadir, *supra* note 15, at 453.

⁷⁵ Bjornberg, *supra* note 17, at 206.

⁷⁶ Abbott & Reichman, *supra* note 24, at 929–30.

⁷⁷ *Id.*

⁷⁸ *See* WTO, Declaration on the TRIPS Agreement and Public Health of 14 November 2001, para. 6, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002), http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf [hereinafter WTO Declaration]. As noted by the WTO:

We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

Id.

Decision waived the Article 31(b) domestic market requirement.⁷⁹ In effect, the Decision allows member countries that do not have an ability to domestically produce a drug to issue a compulsory license for pharmaceutical drugs and to issue a compulsory license to developed countries in order to export the pharmaceutical drugs.⁸⁰ It also requires the importing LDC to issue a compulsory license to import the pharmaceutical drugs.⁸¹ As of this Comment's writing, WTO members are deciding whether to make this waiver a permanent amendment to the TRIPS Agreement.⁸²

IV. THE PURPOSE OF THE TRIPS AGREEMENT

The WTO delegates' intent behind the TRIPS Agreement can be summarized in three main points: (1) to protect developed countries' R&D investments; (2) to promote industry in developing countries; and (3) to advance public health, especially in developing countries.⁸³ American pharmaceutical companies spend more than fifty billion dollars in R&D annually in order to bring new medicines to market.⁸⁴ If generic pharmaceutical companies in foreign markets are able to circumvent American patent protection by continuing to import these medicines, there is little incentive for American pharmaceutical companies to develop drugs that will help these developing countries. Thus, the WTO sought to promote R&D by instituting minimum levels of worldwide patent protection.⁸⁵

⁷⁹ Decision of the General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Doc. WT/L/540 (Sept. 1, 2003) [hereinafter Paragraph 6 Decision]; see also Abbott & Reichman, *supra* note 24, at 932.

⁸⁰ Paragraph 6 Decision, *supra* note 79; Abbott & Reichman, *supra* note 24, at 932.

⁸¹ Paragraph 6 Decision, *supra* note 79; Abbott & Reichman, *supra* note 24, at 932.

⁸² Paragraph 6 Decision, *supra* note 79; Abbott & Reichman, *supra* note 24, at 932.

⁸³ See CORREA & YUSUF, *supra* note 50, at 10–15; SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 121–62 (2003); Nabila Ansari, *International Patent Rights in a Post-Doha World*, 11 CURRENTS: INT'L TRADE L.J., no. 2, 2002, at 57, 58 (2002); Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 CHI. J. INT'L L. 47, 49 (2002); Grace K. Avedissian, Note and Comment, *Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of "Super-Terrorism,"* 18 AM. U. INT'L L. REV. 237, 251 (2002); *Understanding the WTO: The Agreements: Intellectual Property: Protection and Enforcement*, WTO, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Feb. 11, 2016) [hereinafter TRIPS Explanation].

⁸⁴ Pharmaceutical Research, *supra* note 1, at 58.

⁸⁵ See CORREA & YUSUF, *supra* note 50, at 10–15; SELL, *supra* note 83; Sykes, *supra* note 83.

Another goal of the TRIPS Agreement is to promote industry, especially in developing countries.⁸⁶ By protecting intellectual property, trade barriers should theoretically decrease, which, in turn, would increase developing countries' growth and development.⁸⁷ Thus, the WTO sought to promote industry by creating international patent protection.⁸⁸

The final, and arguably the most important, goal of the TRIPS Agreement is to advance public health.⁸⁹ In connection with the first goal that sought to protect R&D, this goal "attempts to strike a delicate balance between the short-term objective of providing access to existing medicines and the long-term objective of developing new medicines through incentives for future Research and Development."⁹⁰ Additionally, the TRIPS Counsel acknowledged the necessity of "maximum flexibility in the domestic implementation of laws and regulations in order to enable [the developing countries] to create a sound and viable technological base."⁹¹ Thus, while the WTO wanted to allow compulsory licenses to combat public health crises, it simultaneously wanted to promote developing countries' self-sustainability through the creation of their own medicines.⁹² These twin aims—self-sustainability and health crisis management—are clearly at odds with the way compulsory licenses are currently being used.⁹³

⁸⁶ Ansari, *supra* note 83, at 58–59 ("Poor international intellectual property protection has been analogized to trade barriers . . ."); TRIPS Explanation, *supra* note 83.

⁸⁷ Ansari, *supra* note 83, at 58–59.

⁸⁸ *Id.*

⁸⁹ See TRIPS Agreement, *supra* note 8, at art. 8.

⁹⁰ See CORREA & YUSUF, *supra* note 50, at 11 (citing Arnoldo Lacayo, Comment, *Seeking a Balance: International Pharmaceutical Patent Protection, Public Health Crises, and the Emerging Threat of Bio-Terrorism*, 33 U. MIAMI INTER-AM. L. REV. 295, 312 (2002)); Avedissian, *supra* note 83, at 251.

⁹¹ TRIPS Agreement, *supra* note 8, at preamble.

⁹² *Id.*

⁹³ See *infra* Part IV.

V. COMPETING INTERESTS BETWEEN AMERICAN PHARMACEUTICAL COMPANIES & LDCs

A. *American Pharmaceutical Companies' Interests*

Pharmaceutical companies research, develop, and market medicines.⁹⁴ The largest pharmaceutical companies are located in Germany, Switzerland, Japan, and the United States—all developed countries.⁹⁵ American pharmaceutical companies alone are responsible for bringing 300 new medicines that treat 150 conditions to market since 1990.⁹⁶ As such, they are partially responsible for the improvement of peoples' quality of life worldwide.⁹⁷

Pharmaceutical companies' incentive to bring new medicines to market is closely tied to policy—specifically, policy that promotes “effective use of intellectual property.”⁹⁸ Pharmaceutical companies have a strong interest in policy because intellectual property policy, more specifically patent protection, allows these companies to recover the considerable R&D costs expended before a drug hits the market.⁹⁹ The cost for creating a new drug can range from at least \$50 million to \$600 million.¹⁰⁰ This process includes “discovery, preclinical development, three phases of clinical trials, registration, and post-marketing studies.”¹⁰¹ And if the drug passes these phases, pharmaceutical companies may spend up to an additional \$200 million on marketing.¹⁰²

Pharmaceutical companies depend on patents in order to protect these large investments.¹⁰³ Predictable patent protection is especially important because it allows pharmaceutical companies the ability to determine in which markets advertising would most likely allow them

⁹⁴ See Bjornberg, *supra* note 17, at 209–10; see also Pharmaceutical Research, *supra* note 1, at 17; PHARMA. RESEARCH AND MFRS. OF AM., THE FACTS ABOUT PHARMACEUTICAL MARKETING & PROMOTION 17 (2008), http://www.phrma.org/sites/default/files/pdf/marketing_and_promotion_facts_071108_final.pdf.

⁹⁵ See Bjornberg, *supra* note 17, at 209–10; see also KEITH E. MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY 52 (2000).

⁹⁶ Quadir, *supra* note 15, at 441.

⁹⁷ *Id.*

⁹⁸ *Id.* at 441–42

⁹⁹ *Id.* at 443.

¹⁰⁰ *Id.* at 442.

¹⁰¹ *Id.*

¹⁰² Quadir, *supra* note 15, at 442.

¹⁰³ Pier DeRoo, Note, “Public Non-Commercial Use” Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs, 32 MICH. J. INT’L L. 347, 362 (2011).

to recover their large R&D investments.¹⁰⁴ Investments in R&D are largely profit-driven.¹⁰⁵ Therefore, if a pharmaceutical company is unlikely to recover the costs of R&D due to an unstable domestic or international patent regime, it is unlikely to make the initial investment.¹⁰⁶

Governmental support of pharmaceutical companies and their profit-driven business models account for much of the reason that some developed countries have threatened or resorted to retaliatory acts.¹⁰⁷ For example, the United States has put Thailand and Brazil on Section 301 of the Trade Act, a watch list for countries the United States believes to be noncompliant with U.S. intellectual property protection policies.¹⁰⁸

B. LDCs' Interests

Generally, LDCs are trying to increase their own economic growth.¹⁰⁹ The U.N. supports this endeavor by funneling significant resources toward developing LDCs.¹¹⁰ Many of these resources come from, and are the product of, developed countries' support of LDCs.¹¹¹ Notwithstanding developed countries' financial contributions, LDCs still lack the infrastructure needed to provide predictable patent protection.¹¹²

¹⁰⁴ Quadir, *supra* note 15, at 443.

¹⁰⁵ *See id.*

¹⁰⁶ *See id.*

¹⁰⁷ *See* Abbott & Reichman, *supra* note 24, at 980.

¹⁰⁸ *Id.*

¹⁰⁹ *See* U.N. Charter arts. 55–58, <https://treaties.un.org/doc/Publication/CTC/uncharter.pdf>; Vincent Chiappetta, *The Desirability of Agreeing to Disagree: The WTO, TRIPS, International IPR Exhaustion and a Few Other Things*, 21 MICH. J. INT'L L. 333, 334 (2000).

¹¹⁰ Quadir, *supra* note 15, at 443–44.

¹¹¹ *Id.*

¹¹² Maria L. Mellino, Note, *The TRIPS Agreement: Helping or Hurting Least Developed Countries' Access to Essential Pharmaceuticals?*, 20 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1349, 1352–53 (2010).

LDCs also have a strong interest in protecting the health of their citizens.¹¹³ The U.N. recognizes health as a fundamental right for all.¹¹⁴ In fact, many advocates of LDCs' accessing pharmaceutical drugs frequently cite this right in support of their objectives.¹¹⁵ Undoubtedly, there is a relationship between LDCs' level of health and their ability to create the necessary infrastructure and to grow economically.¹¹⁶ Unlike developed countries, LDCs do not have the monetary resources to address their countries' health epidemics.¹¹⁷ Yet several countries, including Brazil, India, Malaysia, and Thailand, offer national treatment programs to citizens for little or no cost.¹¹⁸ Thus, despite the developmental efforts LDCs make, the treatment of HIV/AIDS in these countries is still a hindrance to their overall economic success given the interrelatedness between health and economic growth.¹¹⁹

VI. THAILAND'S MISUSES OF THE TRIPS AGREEMENT ARTICLE 31 (B) EXCEPTION

Over the course of a short timespan, Thailand has issued compulsory licenses for a variety of different pharmaceutical drugs, including medicines that treat HIV/AIDS, heart disease, and cancer.¹²⁰ For example, in late 2006, Thailand issued compulsory licenses for two antiretroviral drugs used to treat HIV/AIDS.¹²¹ In 2007, Thailand

¹¹³ See David P. Fidler, *Neither Science Nor Shamans: Globalization of Markets and Health in the Developing World*, 7 IND. J. GLOBAL LEGAL STUD. 191, 191–92, 195 (1999) (explaining that the economic gap between developed and developing countries is linked to health of their respective populations, with the physical and economic burdens of poor health falling disproportionately on developing countries); James Thuo Gathii, *How Necessity May Preclude State Responsibility for Compulsory Licensing Under the TRIPS Agreement*, 31 N.C. J. INT'L L. & COM. REG. 943, 958–59 (2006) (explaining that the HIV/AIDS epidemic has slowed economic progress because the disease usually infects individuals during the productive periods of their lives, and the care of these individuals falls on the families of those infected—further detracting from economic growth); Madhavi Sunder, *IP*³, 59 STAN. L. REV. 257, 292 (2006).

¹¹⁴ WORLD HEALTH ORG. CONST. pmbl., *opened for signature* July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185, http://www.who.int/governance/eb/who_constitution_en.pdf; see also Fidler, *supra* note 113, at 194.

¹¹⁵ Quadir, *supra* note 15, at 444.

¹¹⁶ See Fidler, *supra* note 113, at 194–95.

¹¹⁷ See Sinfah Tunsarawuth, *Governments Urged to Use Compulsory Licenses to Boost Drug Access*, INTELL. PROP. WATCH (Nov. 23, 2007), <http://www.ip-watch.org/weblog/2007/11/23/governments-urged-to-use-compulsory-licences-to-boost-drug-access/>.

¹¹⁸ UNAIDS, GLOBAL REPORT: UNAIDS REPORT ON THE GLOBAL AIDS EPIDEMIC 2010 160–63 (2010), http://www.unaids.org/globalreport/documents/20101123_GlobalReport_full_en.pdf.

¹¹⁹ See Fidler, *supra* note 113, at 196–97; Gathii, *supra* note 113, at 961.

¹²⁰ See *infra* Part VI.

¹²¹ Gerhardsen, *supra* note 19.

issued a compulsory license for a heart disease drug,¹²² and in 2008, it issued four compulsory licenses for cancer-treating drugs.¹²³ These instances show Thailand's trend toward using compulsory licenses in ways that do not align with the goals of the TRIPS Agreement. First, in relation to HIV/AIDS medicines, Thailand began negotiating in 2006 with Merck & Co. for Efavirenz.¹²⁴ Nothing came of the negotiations, and in November 2006, Thailand issued a compulsory license for Efavirenz.¹²⁵ Around the same time, Thailand began negotiating with Abbott Laboratories ("Abbott") for Kaletra, an HIV/AIDS treatment.¹²⁶ After several months of negotiating, Thailand issued a compulsory license for Kaletra in 2007.¹²⁷ Subsequently, Abbott withdrew seven pending pharmaceutical applications in Thailand.¹²⁸ It is unclear what Abbott's rationale was for withdrawing the applications, but Abbott denied that the withdrawals were in response to Thailand's issuing the compulsory license.¹²⁹ Many, however—including the Thai government—argue that Abbott withdrew the applications as retaliation toward Thailand.¹³⁰ Abbott eventually reduced the price of Kaletra to the price that the Thai government commanded during negotiations.¹³¹

Second, in relation to heart disease, Thailand issued a compulsory license in 2007 to Sanofi-Aventis for Plavix, a blood thinner medicine used to treat heart disease.¹³² This was the first time that a compulsory license was issued for a chronic disease,¹³³ which therefore made the issuance even more controversial.¹³⁴

¹²² *Id.*

¹²³ Tunsarawuth, *supra* note 21.

¹²⁴ See David Cronin, *EU Split Arises Over Thai Effort to Obtain Cheaper Patented Drugs*, INTELL. PROP. WATCH (Sept. 5, 2007), <http://www.ip-watch.org/weblog/index.php?p=732>; see also Gerhardsen, *supra* note 19.

¹²⁵ See Gerhardsen, *supra* note 19.

¹²⁶ *Id.*

¹²⁷ See Cronin, *supra* note 124.

¹²⁸ *Abbott to Reduce Cost of Kaletra in Thailand, Other Developing Countries*, KAISER HEALTH NEWS (June 11, 2009), <http://kaiserhealthnews.org/morning-breakout/dr00044189/> [hereinafter *Reduce Cost of Kaletra*]; Martin Vaughan, *In Clash with Activists, Critics Charge Thailand Violation of Trade Rules*, INTELL. PROP. WATCH (Mar. 19, 2007), <http://www.ip-watch.org/weblog/index.php?p=569>.

¹²⁹ See Vaughan, *supra* note 128.

¹³⁰ See Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact from Fiction under TRIPS*, 34 N.C. J. INT'L L. & COM. REG. 371, 444 (2009) (noting that the intent may be inferred from American pharma's actions).

¹³¹ See *Reduce Cost of Kaletra*, *supra* note 128.

¹³² Gerhardsen, *supra* note 19.

¹³³ As opposed to an infectious disease like HIV/AIDS.

¹³⁴ JOANNA T. BROUGHER, INTELLECTUAL PROPERTY AND HEALTH TECHNOLOGIES:

Third, in relation to cancer-treating medicines, Thailand issued four more compulsory licenses in 2008.¹³⁵ It issued two to Novartis: one for Gleevec, a treatment for leukemia and gastrointestinal stromal tumors, and one for Femara, a treatment for breast cancer.¹³⁶ Thailand also issued one compulsory license to Sanofi-Aventis for Taxotere, a treatment for lung and breast cancer.¹³⁷ Finally, it issued one compulsory license to Roche for Tarceva, a treatment for lung cancer.¹³⁸ Thailand's continued issuance of compulsory licenses is creating immense tension between Thailand and pharmaceutical companies.¹³⁹ It seems as though Thailand is using compulsory licenses as its default mechanism for obtaining access to medicines, indicating a disconnect between the TRIPS Agreement's intended use and its actual use.¹⁴⁰

Thailand's use of compulsory licenses for more commonplace diseases is not in accord with the problems that Article 31(b) intended to solve. The TRIPS Agreement was implemented to strike a balance between providing access to medications for LDCs and developing new medicines through R&D.¹⁴¹ The delegates of the WTO that oversaw the TRIPS drafting process acknowledged that LDCs needed to create a sound technological base.¹⁴² By recognizing this as a goal, the drafters sought not only to provide immediate access to medicines for the short-term, but also to support LDC's development toward creating their own medicines over the long-term.¹⁴³

To reiterate, Article 7 states that intellectual property protections should be instituted "in a manner conducive to social and economic welfare."¹⁴⁴ This implies that the TRIPS Agreement was enacted for a larger goal than simply allowing LDCs to issue compulsory licenses anytime there is a public health emergency. Rather, it seeks to promote social and economic welfare for all member countries. Article 8(1) states that member countries should "promote the public

BALANCING INNOVATION AND THE PUBLIC'S HEALTH 182–83 (2014).

¹³⁵ Tunsarawuth, *supra* note 21.

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ See Gerhardsen, *supra* note 19.

¹⁴⁰ See *id.*

¹⁴¹ See CORREA & YUSUF, *supra* note 50, at 11.

¹⁴² *Id.*

¹⁴³ Jessica J. Fayerman, Comment, *The Spirit of TRIPS and the Importation of Medicines Made Under Compulsory License After the August 2003 TRIPS Council Agreement*, 25 NW. J. INT'L L. & BUS. 257, 268–69 (2004).

¹⁴⁴ TRIPS Agreement, *supra* note 8, at art. 7.

interest in sectors of vital importance to their socio-economic and technological development.”¹⁴⁵ While the TRIPS Agreement allows for compulsory licenses, one of its main goals at the time of adoption was to help bolster member countries’ economic and technological development.¹⁴⁶

Thailand’s continued use of compulsory licenses circumvents Articles 7 and 8, which call for intellectual property protection while also encouraging economic welfare. Rather than create its own infrastructure to complete the R&D process of its own pharmaceutical drugs, Thailand instead resorts to issuing compulsory licenses for the patent formula and then manufacturing them domestically, leaving developing countries to bear the R&D cost burden.¹⁴⁷

Article 31 does not expressly prohibit the types of activity in which Thailand engages.¹⁴⁸ Article 31(b) only applies in cases “of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.”¹⁴⁹ When taken in concert with Articles 7 and 8, however, Article 31(b) is meant to be a rare exception to the general, strict patent protection regime.¹⁵⁰ It is meant for situations

¹⁴⁵ *Id.* at art. 8.

¹⁴⁶ *Id.* at art. 7.

¹⁴⁷ See *Thai Health Ministry Breaks Patent, Issues Compulsory License for Abbott’s Antiretroviral Kaletra*, KAISER HEALTH NEWS (June 11, 2009), <http://kaiserhealthnews.org/morning-breakout/dr00042592/>; see also Dina Halajian, Note, *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, 1192–93 (2013).

¹⁴⁸ TRIPS Agreement, *supra* note 8, at art. 31.

¹⁴⁹ *Id.* at art. 31(b).

¹⁵⁰ *Id.* at arts. 7, 8, 31(b); Johanna Kiehl, *TRIPS Article 31(b) and the HIV/AIDS Epidemic*, 10 J. INTELL. PROP. L. 143, 164 (2002). Kiehl states:

According to Canada, Article 7 makes the balance between the intellectual property rights created by the Agreement and other important socio-economic policies of WTO Member governments one of the TRIPS Agreement’s key goals. Furthermore, Article 8 elaborates the socio-economic policies in question, with particular attention to health and nutritional policies. The European Communities, in comparison, viewed Articles 7 and 8 as statements that describe the balancing of goals that had already taken place in negotiating the final texts of the TRIPS Agreement.

Id. at 164 (footnotes omitted). See also Jennifer R. Andrew, *Swine Flu, Bird Flu, SARS, Oh My! Applying the Precautionary Principle to Compulsory Licensing of Pharmaceuticals under Article 31 of TRIPS*, 2011 MICH. ST. L. REV. 405, 435 (2011). Andrew reasons that, according to the plain terms of Article 8.1, public health measures adopted by Members must be consistent with the provisions of this Agreement (such as TRIPS Article 27.1 discussed below) and “necessary” to protect public health. A panel will find that TRIPS Article 31(b) public health emergency legislation is not consistent with TRIPS Article 27.1, that it is not “necessary” under Article 8.1, and that when the other terms of Article 31 are applied in the HIV/AIDS context, it upsets the basic balance of

where life-threatening epidemics hinder an LDC's economic growth.¹⁵¹ It is more acceptable to issue compulsory licenses for HIV/AIDS because the LDCs requesting them are usually impacted to the point where much of their populations are affected, and the countries do not have the wherewithal to stop the epidemic.¹⁵²

Thailand's current compulsory licenses have implicitly exceeded the scope of Article 31(b). What began as a way for the country to fight its HIV/AIDS crisis has evolved into a way for Thailand to escape developing its own infrastructure and technological base needed to create its own medicines. While heart disease and cancer may affect a large population of Thai citizens, these diseases do not rise to the level of epidemic proportions requiring the need for compulsory licenses.

VII. SOLUTIONS TO THE CURRENT PATENT REGIME

In order to incentivize LDCs to utilize the TRIPS Article 31(b) exception without exploiting it, this Comment proposes two domestic solutions: (1) a Regulatory Solution and (2) a Patent Lifespan Extension Solution. Alternatively, in order to discourage LDCs from exploiting the TRIPS Article 31(b) exception, this Comment proposes a Suspension Solution.

the Agreement. *Id.* at 435.

¹⁵¹ See WTO Declaration, *supra* note 78. It provides in relevant part:

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

5. (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

Id. See also Srividhya Ragavan, *The Jekyll and Hyde Story of International Trade: The Supreme Court in PhRMA v. Walsh and the TRIPS Agreement*, 38 U. RICH. L. REV. 777, 796 (2004).

¹⁵² See, e.g., Gathii, *supra* note 113, at 961 (“[T]he long term health interests of the population of African countries should be given more weight than the property rights interests that would be injured by compulsory licensing of essential medicines.”); see also Halajian, *supra* note 147, at 1192–93 (“Developing countries often lack the capabilities and infrastructure to create IP, such as patentable drugs, and are thus primarily IP importers, and lack an incentive to protect IP. These countries favor weaker IP rights, which allow market entry of generic drug manufacturers and increased market competition. Market entry and competition lower drug prices, resulting in increased availability of affordable medications.”).

A. Regulatory Solution

The Regulatory Solution would consist of the American Food and Drug Administration (FDA) pausing, or slowing down, the passage rate of new and developing American pharmaceuticals. This would take place until American pharmaceutical companies help LDCs by providing generic drug patent information, manufacturing medicines, and/or distributing medicines. This regulatory solution would prevent American pharmaceutical companies from bringing new drugs to market until they comply with the compulsory licenses issued to them.

Although it is uncommon for a pharmaceutical company to blatantly refuse to comply with compulsory licenses, there are instances where American pharmaceuticals are skirting, avoiding, or prolonging the process. For example, “Thailand issued compulsory licenses to achieve its mandate of providing access to essential drugs after years of negotiation with patent owners failed to yield price cuts beyond the level of currency appreciation.”¹⁵³ These lengthy negotiations, spanning a number of years without ultimately leading to a reduction in cost, give the impression that some companies are attempting to circumvent the compulsory license.¹⁵⁴

The Regulatory Solution would ensure a more direct form of compliance by promoting the use of compulsory licenses as an effective negotiation tool¹⁵⁵ when pharmaceutical companies are completely unresponsive to the drug needs of LDCs. Such a solution would also support the U.N.’s recognition that all people have a fundamental right to health¹⁵⁶ by more readily providing medicines to LDCs.

An impediment to this solution, however, is the FDA. With the ability to make its own rules and the ability to control which pharmaceutical drugs are brought to market, the FDA is the only regulatory body that could prevent American pharmaceutical companies from bringing new drugs to market. This regulatory body “has the authority to issue its own rules so long as they support the intent of the statutes and regulations which they are intended to

¹⁵³ See, e.g., Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1062 (2009).

¹⁵⁴ *Id.*

¹⁵⁵ Feldman, *supra* note 6, at 155 (“In the past, Brazil, for example has successfully used compulsory licenses as a tool to negotiate lower prices from both Merck and Roche.”).

¹⁵⁶ WORLD HEALTH ORG. CONST. pmb., *opened for signature* July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185, http://www.who.int/governance/eb/who_constitution_en.pdf; see also Fidler, *supra* note 113, at 194.

enforce.”¹⁵⁷ Additionally, no medicine can be sold in the United States without FDA approval.¹⁵⁸ In order for a medicine to obtain approval, the pharmaceutical company must complete the Investigational New Drug Application.¹⁵⁹ This application is supported by all of the research and clinical trials that the drug has undergone.¹⁶⁰ After successful completion of the application, the FDA deems the drug safe and effective.¹⁶¹ Because the FDA is able to make its own regulations, it *could* make rules to enforce such a solution.

The FDA, however, may not be able to make such a regulation. Professor Peter Schuck has stated that “[m]any critics denounce the agency’s enforcement activity as lax and inadequate,” and “some go so far as to claim that the regulated industries have ‘captured [the FDA],’” thus making it impossible for it to regulate effectively.¹⁶² He continued to explain that a recent examination of various industries’ influence over Congress found pharmaceutical companies to be the most influential over Congress.¹⁶³ Considering how much power pharmaceutical companies wield over the FDA, it is unlikely that such a solution could even be considered.

¹⁵⁷ Jennifer S. Bard, *What to Do When You Can’t Hear the Whistleblowing: A Proposal to Protect the Public’s Health by Providing Whistleblower Protection for Medical Researchers*, 9 *IND. HEALTH L. REV.* 1, 17 (2012) (citing Julia Kobick, *Negotiated Rulemaking: The Next Step in Regulatory Innovation at the Food And Drug Administration?*, 65 *FOOD & DRUG L.J.* 425, 434 (2010) (“FDA has never voluntarily convened a rulemaking negotiation, and Congress has never statutorily mandated that FDA establish an ad hoc negotiated rulemaking committee.”)).

¹⁵⁸ W. Christopher Matton & F. Scott Thomas, *The Continuing Balance: Federal Regulation of Biotechnology*, 44 *JURIMETRICS J.* 283, 293–96 (2004).

¹⁵⁹ *Id.* at 295.

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 *ROGER WILLIAMS U. L. REV.* 73, 112 (2008).

¹⁶³ *Id.*; see also Jennifer S. Bard, *Putting Patients First: How the FDA Could Use Its Existing Powers to Reduce Post-Market Adverse Events*, 10 *IND. HEALTH L. REV.* 495, 553 (2013) (“The most likely source of congressional power to regulate prescription drugs is found in the power the Constitution gives Congress in Article I, Section 8 to regulate commerce.”); Eric R. Claeys, *The Food and Drug Administration and the Command-and-Control Model of Regulation*, 49 *ST. LOUIS U. L.J.* 105, 118–21 (2004) (explaining how Congress initially conferred to the FDA, an executive agency, the power to enforce regulations and how its power has since expanded to include the rulemaking powers and the promulgation of procedural regulations); Kate Cook, *The Presidential FDA: Politics Meets Science*, *DIGITAL ACCESS TO SCHOLARSHIP AT HARVARD*, 5–6 <http://nrs.harvard.edu/urn-3:HUL.InstRepos:8852216> (last visited Feb. 11, 2016) (explaining the mechanisms Congress possess to control the FDA).

B. Patent Lifespan Extension Solution

The second domestic solution this Comment proposes is a Patent Lifespan Extension Solution. In this solution, the U.S. Patent Office would allow pharmaceutical companies that willingly participate in compulsory licensing to extend their patent lifespan by several months or a year. This solution would serve as a more “pharma-friendly” option to American pharmaceutical companies than the first proposed Regulatory Solution.

This patent lifespan extension could potentially be promulgated through the Hatch-Waxman Act.¹⁶⁴ Before the Hatch-Waxman Act, generic drug companies that wished to sell and market off-patent drugs needed to go through the same rigorous FDA approval process that new brand-name drugs went through.¹⁶⁵ The Hatch-Waxman Act effectively changed that and, among other patent protections for pharmaceutical companies, provided for patent term extensions averaging three years.¹⁶⁶ Given that a typical patent lifespan lasts twenty years, the patent term extensions were necessary since the term realistically only lasts about seventeen years because the patent application and FDA approval process take approximately three years.¹⁶⁷ Given the Hatch-Waxman Act’s existing ability to extend patent terms, the suggested patent lifespan extension solution is a cohesive and consistent addition to its already existing powers. The timeframe given to pharmaceutical companies that comply with compulsory licensing would be “inserted” after the time in which a patent is currently set to expire and the Hatch-Waxman Act’s extension term, immediately preceding the time in which a generic company may apply for the patent. While this solution may constrain domestic, generic pharmaceutical companies’ access to brand name drugs, it promotes the betterment of international public policy by advancing LDCs’ access to medicines—a primary goal of the TRIPS Agreement.¹⁶⁸

¹⁶⁴ See Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of 15, 21, 28, & 35 U.S.C.).

¹⁶⁵ Amanda Baltazar, *The Hatch-Waxman Act*, ABOUT MONEY, <http://pharmacy.about.com/od/Glossary/a/The-Hatch-Waxman-Act.htm> (last visited Feb. 11, 2016).

¹⁶⁶ *Id.*

¹⁶⁷ WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., R41114, THE HATCH-WAXMAN ACT: A QUARTER CENTURY LATER 3 (2012), http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/R41114_03132013.pdf.

¹⁶⁸ See TRIPS Agreement, *supra* note 8, at arts. 7, 8.

This solution may be workable given that pharmaceutical companies are largely driven by corporate profits.¹⁶⁹ In fact, the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) recognizes that profits drive pharmaceutical companies.¹⁷⁰ If pharmaceutical companies are able to dominate the American market for several months (or a year) longer by having their patent lifespans extended domestically, they have the ability to produce hundreds of millions, or even billions, of dollars in additional profit.¹⁷¹ The benefit of this is to recoup the millions of dollars lost in the R&D process.

Profits, however, are never guaranteed: “With the exception of a few blockbuster drugs, the commercial success rate of pharmaceuticals remains low. In fact, just two out of ten medicines ever produce revenues that match or exceed average R&D costs.”¹⁷² In order to make up for the low rates of return for many drugs, this Patent Lifespan Extension Solution would incentivize domestic pharmaceutical companies to help LDCs by providing generic drug information.

Generally, public policy wants to promote generic drug competition, and this solution is in conflict with that ideal.¹⁷³ A major factor in the promotion of generic drugs is that it can reduce public healthcare costs in one of three ways: (1) generic substitution of drugs for the therapeutically equivalent branded drug;¹⁷⁴ (2) therapeutic

¹⁶⁹ Jennifer A. Lazo, *The Life-Saving Medicines Export Act: Why the Proposed U.S. Compulsory Licensing Scheme Will Fail to Export Any Medicines or Save Any Lives*, 33 BROOK. J. INT’L L. 237, 270–71 (2007).

¹⁷⁰ *Id.*

¹⁷¹ See Anup Malani & Jonathan S. Masur, *Raising the Stakes in Patent Cases*, 101 GEO. L.J. 637, 675 (2013) (“[A] single patent—particularly a patent on a successful pharmaceutical—could be worth hundreds of millions or even billions of dollars per year.”).

¹⁷² Stuart R. Cohn & Erin M. Swick, *The Sitting Ducks of Securities Class Action Litigation: Bio-Pharmas and the Need for Improved Evaluation of Scientific Data*, 35 DEL. J. CORP. L. 911, 916 (2010) (citing Pharm. Research and Mfrs. of Am., *Pharmaceutical Industry Profile 2009*, 38–39 (2009)).

¹⁷³ Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 248 (2012) (“The Hatch-Waxman Act therefore promotes generic market entry by relieving almost all of the regulatory burdens for generic manufacturers, as well as by helping generic manufacturers challenge the validity of brand-name pharmaceutical patents that might be hindering such market entry.”).

¹⁷⁴ “Therapeutically equivalent” drugs are those that have the same active ingredient, strength, dosage form, and route of administration. Substitution can be made by either a prescriber or a pharmacist, according to state regulations and laws. OFFICE OF THE ASSISTANT SEC’Y FOR PLANNING AND EVALUATION, U.S. DEP’T OF HEALTH AND HUMAN SERVS., EXPANDING THE USE OF GENERIC DRUGS 2–3 (2010), <http://aspe.hhs.gov/sites/default/files/pdf/76151/ib.pdf>.

substitution;¹⁷⁵ and (3) reduction in the price of brand name drugs paid by consumers resulting from generic substitution.¹⁷⁶ The rate at which generic drugs are substituted (when there is a generic substitute available) is nearly ninety percent, which accounted for a savings of \$121 billion in 2008.¹⁷⁷ Therefore, a plan that delays generic drug competition would hinder the savings to the domestic market. It is likely the American public who would oppose this solution because the solution would suppress the free-flow of medicines in the domestic market by constricting who the manufacturers are for an even longer period of time than before.¹⁷⁸

When contrasted with the international public healthcare benefit, however, this patent lifespan extension scheme seems the most viable solution. Extending the patent lifespan for American pharmaceutical companies could generate revenue on their name-brand drugs, which in turn could offset the cost of participating in the compulsory license. The American generic market would be delayed slightly thereby hindering domestic savings but it would be at a cost that benefits international public health. Thus, this solution presents several hurdles but is more realistic than the first Regulatory Solution.

C. Suspension Solution

In order to discourage LDCs from exploiting the TRIPS Article 31(b) exception, this Comment proposes a Suspension Solution. The WTO can discourage or prohibit LDCs from exceeding the bounds of

¹⁷⁵ “Therapeutic substitution” is switching from a branded drug to a generic in the same therapeutic class. Only a prescriber may make this substitution; a pharmacist may not do this because the drugs are not therapeutically equivalent. *Id.* at 4.

¹⁷⁶ *Id.* at 3–4.

¹⁷⁷ ALAN SHEPPARD, GENETIC MEDICINES: ESSENTIAL CONTRIBUTORS TO THE LONG-TERM HEALTH OF SOCIETY, IMS HEALTH 3 (2010), http://www.sandoz.com/cs/www.sandoz.com-v4/assets/media/shared/documents/press_releases/100401_Generic_Medicines_GA.pdf.

¹⁷⁸ See, e.g., Brian J. Love, *An Empirical Study of Patent Litigation Timing: Could a Patent Term Reduction Decimate Trolls Without Harming Innovators?*, 161 U. PA. L. REV. 1309, 1314 (2013) (“On the issue of patent reform, a civil war of sorts divides the technology community. Battle lines are drawn largely between industries. Pharmaceutical companies, on one side, argue that strong patent rights are crucial to continued innovation. High-tech firms, on the other, view the patent system as more foe than friend.”); Thomas H. Kramer, *Proposed Legislative Solutions to the Non-Practicing Entity Patent Assertion Problem: The Risks for Biotechnology and Pharmaceuticals*, 39 DEL. J. CORP. L. 467, 479–81 (2014) (explaining that technology and pharmaceutical industries bitterly dispute more or less regulated patent regimes, with technology industries wanting more lax laws and pharmaceutical industries wanting more stringent protection).

Article 31 (b) by suspending member countries that violate it.¹⁷⁹ Under this solution, the WTO would create an international committee that could investigate allegations of misuse. The committee would have the authority to suspend countries from the WTO if found guilty of practices that do not conform with proper patent protection policy. This solution would serve to deter countries, like Thailand, from engaging in practices that are not necessarily initiated because of a national emergency.

The suspension solution may be a viable resolution because the WTO would not need to create another enforcement body to moderate these disputes. The TRIPS Agreement already has a dispute settlement process built into it—the DSB. The DSB has the authority to issue trade sanctions against member countries and serves as an enforcement mechanism for all WTO issues, including conflicts regarding the TRIPS Agreement.¹⁸⁰ It also settles most disputes within fifteen months, although countries can settle their dispute themselves at any stage.¹⁸¹ This enforcement mechanism could serve as the

¹⁷⁹ WTO, UNDERSTANDING THE WTO 58 (2007), http://www.wto.org/english/thewto_e/whatis_e/tif_e/understanding_e.pdf. Before trade sanctions are imposed, the complaining party (referred to as the “plaintiff” for purposes of this Comment) must bring a complaint before the DSB. *Id.* If the DSB finds that the opposing party (referred to as the “defendant” for purposes of this Comment) is in fact noncompliant, it will make recommendations for how the defendant can bring its policy up to the status quo. *Id.* If the defendant fails to do so within a reasonable period of time, it must enter into negotiations with the plaintiff to determine acceptable compensation—i.e., tariff reductions, etc. *Id.* And if no satisfactory compensation agreement is reached, the plaintiff may ask the DSB to impose limited trade sanctions. *Id.*

¹⁸⁰ *See id.* at 55–57.

¹⁸¹ *Understanding the WTO: Settling Disputes: A Unique Contribution*, WTO, https://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm (last visited Feb. 11, 2016). The website explains:

Dispute settlement is the central pillar of the multilateral trading system, and the WTO’s unique contribution to the stability of the global economy. Without a means of settling disputes, the rules-based system would be less effective because the rules could not be enforced. The WTO’s procedure underscores the rule of law, and it makes the trading system more secure and predictable. The system is based on clearly-defined rules, with timetables for completing a case. First rulings are made by a panel and endorsed (or rejected) by the WTO’s full membership. Appeals based on points of law are possible . . . However, the point is not to pass judgement [sic]. The priority is to settle disputes, through consultations if possible . . . If a case runs its full course to a first ruling, it should not normally take more than about one year—15 months if the case is appealed. The agreed time limits are flexible, and if the case is considered urgent (e.g. if perishable goods are involved), it is accelerated as much as possible.

Id.

tribunal to investigate practices of excessive compulsory licensing.

The advantage of this solution is that the DSB already exists as a functioning dispute resolution body. Therefore, this solution would require less of a drastic change compared to the other two proposed solutions. The disadvantages of this solution are twofold: (1) it may not serve public health goals and (2) actions that exceed the bounds of the TRIPS purpose are not easily defined. The first drawback is in conflict with Article 8 of the TRIPS Agreement, which encourages member countries to take measures necessary to protect public health and to promote socio-economic development.¹⁸² When compared to this purpose of the TRIPS Agreement, this solution may not be viable.¹⁸³

The second disadvantage of this solution is that it would require a consensus among member countries as to what constitute a practice that misuses the Article 31 (b) exception—a feat that may be easier said than accomplished. The DSB is currently set up in a way that establishes “panels” of well-qualified experts to consider a case, and panelists are typically chosen in consultation with the countries in dispute.¹⁸⁴ Since the DSB already chooses panelists with the help of the parties, there may be less of a dispute about what constitutes a practice that misuses the Article 31 (b) exception.

Furthermore, the DSB was marked at its inception as a kind of “Star Chamber” decision-making process, which gave rise to questions of its transparency.¹⁸⁵ Since the Seattle Ministerial of 1999, there have been three major changes to the WTO that have increased its transparency, which include: (1) public access to documentation through its website;¹⁸⁶ (2) acceptance of amicus curiae briefs in both panel and Appellate Body proceedings; and (3) public participation in the WTO adjudicating bodies, committees, and councils.¹⁸⁷ Despite these changes, much of the DSB’s activity remains confidential.¹⁸⁸ Therefore, in order for the suspension solution to be viable, the DSB

¹⁸² TRIPS Agreement, *supra* note 8, at art. 8.

¹⁸³ *Id.*

¹⁸⁴ *Understanding the WTO: Settling Disputes: A Unique Contribution*, *supra* note 181.

¹⁸⁵ Robert E. Hudec, *The New WTO Dispute Settlement Procedure: An Overview of the First Three Years*, 8 MINN. J. GLOBAL TRADE 1, 44–45 (1999).

¹⁸⁶ With regard to dispute settlement body, “the availability of documentation varies depending on the particular stage of the process” that a case is in. Most dispute-related documents, however, are not automatically made public in an effort to protect confidential information. Gabrielle Marceau & Mikella Hurley, *Transparency and Public Participation in the WTO: A Report Card on WTO Transparency Mechanisms*, 4 TRADE L. & DEV., no. 1, 2012, at 24, 24–25.

¹⁸⁷ *Id.* at 23, 28, 36.

¹⁸⁸ *Id.* at 43.

would need to overhaul its confidential process in order to further increase its transparency and legitimize its decision-making process.

VIII. CONCLUSION

Although Thailand's repetitive use of compulsory licensing is not considered a *per se* violation of the TRIPS Agreement, the country's actions seem suspicious. It is understandable and acceptable that an LDC seeks a compulsory license to treat its growing HIV/AIDS epidemic. Compulsory licensing for cancer and heart disease medicines, however, do not seem to constitute exigent circumstances, given that many other countries across the globe face similar health concerns. Undoubtedly, cancer and heart disease are leading causes of death, but they are not infectious. They do not spread rapidly through under-educated and destitute countries the way HIV/AIDS does. And while many people in Thailand may be suffering from cancer and heart disease, compulsory licensing should not be a means to an end.

Rather than resorting to compulsory licensing, Thailand should first divert more resources to increasing its infrastructure so it may complete its own R&D for new medicines. Alternatively, Thailand could manufacture and distribute off-patent generic drugs—a business model that many American generic pharmaceutical companies have, with lower cost being a driving factor. This solution is even more feasible given Thailand's moderate-income status.

Besides domestic steps that Thailand can take, WTO members internationally and the United States domestically can take initiatives to prevent the kinds of practices that Thailand is engaging in, namely through the Patent Lifespan Extension Solution and the Suspension Solution. The Patent Lifespan Extension Solution is a way to encourage domestic pharmaceutical companies to help LDCs that are in dire need of medicines. Alternatively, the Suspension Solution is a way to discourage countries like Thailand that exceed the reasonable bounds of compulsory licensing from misusing Article 31(b) to their own benefit. Admittedly, both of these solutions need to be examined and discussed further before implementation. They do, however, provide a basis to change the current patent regime that would further effectuate the overall purpose of the TRIPS Agreement—access to *necessary* medicines for all.