

**PATENT STALEMATE?
THE WTO'S ESSENTIAL MEDICINES IMPASSE
BETWEEN PHARMAS AND LEAST DEVELOPED COUNTRIES**

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“If it is to your advantage, make a forward move; if not, stay where you are. Anger may in time change to gladness; vexation may be succeeded by content.”

Sun Tzu, *The Art of War*¹

I. INTRODUCTION

Imagine that you operate a research-based pharmaceutical company. You have spent millions of dollars attempting to develop a medicine that helps treat a fatal disease that afflicts millions, though a majority of the infected resides in the world's most impoverished countries. You ultimately do develop a medicine that proves effective at treating this disease, but you record dozens of failed attempts in the process—which cost millions. It is critical that you sell the successful medicine for enough money, to not only recover the millions spent on the development process, but also to continue developing new medicines that respond to the disease when it mutates into resistant strains. To further this goal, you patent the medicine—to keep others from making and selling it—and sell it to sick people around the world.

Now imagine that you are the leader of a poor country, with millions of citizens dying from that same fatal disease, who cannot afford the available medicine. You attempt to negotiate a low bulk-rate price directly with the pharmaceutical company that developed the medicine, even though there is a legal means of taking the company's “formula” and manufacturing the medicine domestically at a very low cost—which would result in the company receiving little or no money. Unfortunately, negotiations stretch on for months and become adversarial. All the while, many perish from the disease. Eventually, when the negotiations are hopelessly deadlocked, you take the free-formula option, which allows you to provide the

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1. SUN TZU, *THE ART OF WAR* 35 (Lionel Giles trans., Wilder Publications 2008).

medicine to many of your sick citizens.

This decision proves effective at addressing your country's health crisis immediately, but is ultimately disastrous. At some point, the disease becomes resistant to the medicine. You would like to repeat your previous action of taking the company's formula for some *new* medicine, but unfortunately, no such medicine has been developed. The pharmaceutical company, sensing the economic futility of developing medicines for diseases that disproportionately impact poor countries, has stopped developing such medicines. Now, your country, which lacks the resources to develop new medicines, is beset by a disease that has no treatment. Hundreds are dying every day and no one is working on a cure.

Though a greatly simplified model, this scenario reflects a potential international crisis. Pharmaceutical companies (Pharmas),² which operate primarily in developed countries (DCs),³ inherently rely on patent protection to recover the significant cost of research and development (R&D)⁴ of medicines.⁵ In recent years, Pharmas like Merck & Co.,⁶ Abbott,⁷ and Roche⁸ have encountered difficulties in relying on the current international patent regime (IPR)⁹ to recover R&D costs for certain types of medicines.¹⁰ These difficulties are

2. For the purposes of this Note, the term "Pharmas" refers only to research-based pharmaceutical companies that innovate new medicines, and not generic-based pharmaceutical companies that manufacture medicines innovated by others.

3. Developed countries (DCs) have well-developed economies driven by the service and research and development (R&D) sectors. See The World Bank, Glossary, <http://go.worldbank.org/K2CKM78CC0> (last visited Feb. 20, 2009). DCs generally have a per capita income (an individual's annual income) over \$10,000 in U.S. currency. UNITED STATES CENTRAL INTELLIGENCE AGENCY [CIA], THE 2008 WORLD FACTBOOK, <https://www.cia.gov/library/publications/the-world-factbook/appendix/appendix-b.html>.

4. In 2006, U.S. Pharmas invested \$55.2 billion in R&D. PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA [PHRMA], 2007 ANNUAL REPORT 4 [hereinafter PHRMA REPORT].

5. See *id.* at 5-6.

6. Merck & Co. holds the patent for the HIV/AIDS treatment STOCRIN (efavirenz). Merck & Co, STORCIN Country-by-Country Registration Status, Aug. 2008, http://www.merck.com/corporate-responsibility/docs/access/STOCRIN_registration_status.pdf.

7. Abbott holds the patent for the HIV/AIDS treatment "Kaletra." See Kaletra Home Page, <http://kaletra.com> (last visited Feb. 20, 2009).

8. Roche holds the patent for the influenza treatment "Tamiflu." Roche, Product Details - Tamiflu, http://www.roche.com/home/products/prod_details.htm?type=product&id=92 (last visited Feb. 20, 2009).

9. The international patent regime (IPR) exists within a broader intellectual property system, which includes copyrights and trademarks. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994 [hereinafter TRIPS Agreement]. This Note deals only with patent protection.

10. In March 2007, Abbott withdrew seven pending applications to market new

especially true for medicines that treat the Human Immunodeficiency Virus and the Acquired Immunodeficiency Syndrome (HIV/AIDS), two diseases that disproportionately affect less developed countries (LDCs).¹¹

LDCs with high incidences of HIV/AIDS like Malaysia, India, Brazil, and Thailand have been increasingly reliant on ambiguous and unpredictable flexibilities in the IPR to increase their access to medicines for use in government subsidized HIV/AIDS treatment programs—typically to the dismay of Pharmas.¹² Most recently, Thailand, after failing to negotiate a price for Kaletra with Abbott, invoked a highly controversial legal mechanism known as a compulsory license.¹³ The compulsory license allowed Thailand to entirely circumvent purchasing the medicine from Abbott, despite the reasonable final price offered by Abbott after repeated concessions.¹⁴ Thailand, upon issuing the compulsory license, began manufacturing the medicine domestically at a low cost.¹⁵ Thailand's action is one example of the emerging trend among LDCs that are issuing compulsory licenses, whereas previously, LDCs typically used the *threat* of issuing a compulsory license as an effective bargaining chip in price negotiations with Pharmas.¹⁶

Thailand's actual use of the IPR's compulsory license flexibility

medicines in Thailand, possibly in reaction to a patent dispute. See Tove Iren S. Gerhardsen, *Thailand Compulsory License on AIDS Drug Prompts Policy Debate*, INTELL. PROP. WATCH, Dec. 22, 2006, <http://www.ip-watch.org/weblog/index.php?p=499>.

11. The United Nations distinguishes between "least developed countries" and "developing countries." Least developed countries have 1) "low-income criterion, based on a three-year average estimate of the gross national income per capita (under \$750 for inclusion, above \$900 for graduation)," 2) a low score on an index based on indicators of nutrition, health, education, and adult literacy, and 3) economic vulnerability, whereas a "developing country" is one that has developed beyond "least developed country" status but has not attained "developed" country status. United Nations Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing States [OHRLLS], *The Criteria for the Identification of the LDCs*, <http://www.un.org/special-rep/ohrls/lde/lde%20criteria.htm> (last visited Jan. 14, 2009). This Note will use "Least Developed Countries" (LDCs) to refer to both "developing countries" and "least developed countries."

12. See Tove Iren S. Gerhardsen, *Brazil Takes Steps to Import Cheaper AIDS Drug Under Trade Law*, INTELL. PROP. WATCH, May 7, 2007, <http://www.ip-watch.org/weblog/index.php?p=614>.

13. See *infra* note 118.

14. *Thai Health Ministry Breaks Patent, Issues Compulsory License for Abbott's Antiretroviral Kaletra*, KAISER NETWORK, Jan. 30, 2007, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=42580.

15. *Id.*

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

to increase its access to Abbott's Kaletra, however, has revealed some new, potentially far-reaching implications. For example, Abbott's immediate reaction was to withdraw pending applications to market several other medicines in Thailand.¹⁷ There is considerable debate whether these withdrawals were a retaliatory measure to punish Thailand or a legitimate business decision to protect Abbott's other patents from being undermined.¹⁸ Abbott's action may be an indication of Pharmas' overall frustration with the current IPR, especially its vague flexibilities. With this precedent in mind, other Pharmas may also withdraw marketing applications in LDCs, especially for medicines for which patents are consistently subjected to compulsory licenses or the threat of compulsory licenses. Ultimately, LDCs may find themselves home to diseases that have no treatment.

Other exchanges relating to such flexibilities, involving Malaysia, India, Taiwan, and Brazil, further highlight inadequacies in the current IPR. Most scholarship on the issue assumes that Pharmas' interests in patent protection are fundamentally incompatible with LDCs' ability to access necessary medicines.¹⁹ Scholars tend to take sides, with a majority arguing for greater access to medicines at the expense of patent observance.²⁰

This Note presents a novel approach to a situation that can be seen as a stalemate, where neither side has any move that will improve the other's situation. This Note argues for modifying the existing international legal framework for medicine patents, in such a way that allows the competing interests to coexist, and ultimately, develop into a symbiotic relationship. Part II provides the necessary background by discussing Pharmas' and LDCs' interests, the history of the IPR, and the current legal framework. Part III analyzes recent situations involving various Pharmas and LDCs and how they individually and collectively highlight inadequacies in the current IPR. Part IV proposes a solution that involves a conceptual paradigm shift, and outlines a multi-step process that strives to better balance the competing interests of Pharmas and LDCs.

17. See Martin Vaughan, *In Clash with Activists, Critics Charge Thailand Violation of Trade Rules*, INTELL. PRO WATCH, Mar. 19, 2007, <http://www.ip-watch.org/weblog/index.php?p=569>.

18. See *id.*

19. See, e.g., Brittany Whobrey, Note, *International Patent Law and Public Health: Analyzing TRIPS' Effect on Access to Pharmaceuticals in Developing Countries*, 45 BRANDEIS L.J. 623 (2007).

20. See, e.g., Bradley Condon & Tapen Sinha, *Global Diseases, Global Patents and Differential Treatment in WTO Law: Criteria for Suspending Patent Obligations in Developing Countries*, 26 NW. J. INT'L L. & BUS. 1, 32-41 (2005) (proposing a method to balance rights of Pharmas and LDCs).

II. BACKGROUND

A. *Pharmas' Interests*

Pharmas research, develop, market, and sometimes distribute medicines.²¹ The largest and most innovative Pharmas are concentrated in a few DCs including Germany, Switzerland, Japan, and the United States.²² Since 1990, United States Pharmas alone have “discovered and brought to market over 300 completely new biopharmaceutical medicines that treat over 150 conditions.”²³ Internationally, Pharmas are currently developing 7,000 compounds for potential therapeutic use and, on average, release thirty-five new medicines each year.²⁴ Pharmas have played an important role in improving quality of life worldwide and increasing life expectancy.²⁵ It is worth noting that Pharma-innovated medicines have contributed to the 70% reduction in the HIV/AIDS death rate in the United States since the mid-1990s.²⁶

Pharmas' ability to innovate and deliver effective medicines relies heavily on national and international policy.²⁷ Specifically, governmental policies that promote “successful health care systems,” “efficient markets,” “effective use of intellectual property,” and “adequate and predictable regulatory requirements” provide a positive environment for Pharma innovation.²⁸

Pharmas are especially concerned with policies related to intellectual property protection, specifically patent protection, because such policies most directly impact Pharmas ability to recover massive R&D costs.²⁹ In the United States, the R&D costs for

21. PHRMA REPORT, *supra* note 4, at 8-9.

22. Bjornberg, *supra* note 16, at 209-10. Many U.S. Pharmas are based in New Jersey—home to \$15 billion of medicine R&D annually, or 50% of the nation's gross R&D expenditure. The largest New Jersey Pharmas include Merck & Co. and Wyeth, which are two companies involved in the impasse between Pharmas and LDCs. Pharmaceuticals, Industry Profiles, http://www.locationnj.com/NJ_Pharmaceuticals_Profile.asp (last visited Feb. 20, 2009).

23. PHRMA REPORT, *supra* note 4, at 4.

24. INT'L FED. OF PHARM. MFRS. & ASS'NS [IFPMA], THE PHARMACEUTICAL INNOVATION PLATFORM: MEETING ESSENTIAL GLOBAL HEALTH NEEDS 7 (2007), <http://www.ifpma.org/issues/fileadmin/templates/ifpmaissues/pdfs/IFPMA-PIP-NOV2007-FINAL-EN.pdf> [hereinafter IFPMA REPORT]. In the United States, there are “more than 2,000 medicines in development: 646 for cancer, 146 for heart disease and strokes, 77 for AIDS, and 56 for diabetes.” PHRMA REPORT, *supra* note 4, at 4.

25. IFPMA REPORT, *supra* note 24, at 11. “Average life expectancy in the most industrialized countries has increased from “47 years in 1900 to 79 years.” *Id.*

26. *Id.*

27. *Id.* at 8.

28. *Id.*

29. *Id.* at 30. “Intellectual Property protection helps transform the intangible capital generated by pharmaceutical companies during the process of R&D into

creating a new medicine range from \$50-\$600 million.³⁰ The process is incredibly elaborate and includes discovery,³¹ preclinical development,³² three phases of clinical trials,³³ registration,³⁴ and post-marketing studies.³⁵ If a medicine is approved, Pharmas then may spend up to \$200 million on its marketing.³⁶

U.S. Pharmas have a powerful lobbying force—the Pharmaceutical Research and Manufacturers of America (PhRMA), which exerts considerable effort to influence legislation that affects the industry.³⁷ PhRMA has engaged in extensive litigation against both public and private entities, on issues ranging from state Medicaid preferred drug lists to mandatory pricing schemes.³⁸ The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) represents Pharmas on the international plane.³⁹

Pharmas, like companies in any patent-based industry, depend on a robust, predictable patent regime.⁴⁰ Predictability is especially

financial flows which enable the cyclical process of innovation to continue.” *Id.* U.S. Pharmas claim that their ability to produce 70% of the new drugs that enter the worldwide market each year is a direct result of strong domestic intellectual property laws. PHRMA REPORT, *supra* note 4, at 5.

30. See Donald W. Light, *Misleading Congress About Drug Development*, 32 J. HEALTH, POL’Y & L. 895, 897 (2007).

31. Discovery involves “[d]rawing on basic exploratory research to identify targets,” and then carrying out “initial research on new compounds . . . in the laboratory . . . to select the most promising compounds.” IFPMA REPORT, *supra* note 24, at 18.

32. Preclinical development involves testing selected compounds for toxicity and safety in animals. *Id.*

33. Phase I involves testing for “safety . . . and tolerability in healthy volunteers,” phase II involves testing for “safety, efficacy and bioequivalence studies in small groups of patients,” and phase III involves “large trials with different populations to demonstrate proof of efficacy, safety and value.” *Id.*

34. Registration involves presenting a regulatory dossier to “regulatory authorities for approval.” *Id.*

35. Postmarketing studies begin after a medicine is released, and track “thousands of patients . . . to identify any previously unforeseen side effects.” *Id.*

36. See Light, *supra* note 30, at 904.

37. See Frederick M. Abbott, *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, 962 (2007).

38. See PhRMA v. District of Columbia, 406 F. Supp. 2d 56 (D.C. Cir. 2005) (successfully challenging D.C.’s Prescription Drug Excessive Pricing Act); PhRMA v. Meadows, 304 F.3d 1197 (11th Cir. 2002) (challenging a Florida law requiring drug manufacturers to give a 10% discount on individual drugs to qualify for a preferred drug list); PhRMA v. Concannon, 249 F.3d 66 (1st Cir. 2001) (challenging a Maine law imposing mandatory pricing structures).

39. See Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT’L L. 317, 318 n.8 (2005).

40. See BRUCE A. LEHMAN & MICHAEL A. EINHORN, TWELFTH ANNUAL

important for Pharmas because it allows them to make better-informed business decisions, like what medicines to R&D and where to market them.⁴¹ Considering the investment necessary to bring just one medicine to market, the ability to recover R&D and marketing costs *and* make a profit are significant concerns for all Pharmas.⁴² In summary, a Pharma will likely avoid spending the time and money to develop a medicine if national and international patent regimes cannot effectively secure its underlying investments.⁴³

B. LDCs' Interests

The United Nations (U.N.) exerts significant resources and efforts toward the development of LDCs.⁴⁴ It develops policies and implements initiatives that promote, among other things, LDC economic growth and political stability.⁴⁵ Such measures generally call on DC Members to collectively support progress in LDCs.⁴⁶ The United Nations Educational, Scientific and Cultural Organization (UNESCO),⁴⁷ the United Nations Industrial Development Organization (UNIDO),⁴⁸ the International Fund for Agricultural

CONFERENCE ON INTERNATIONAL INTELLECTUAL PROPERTY LAW AND POLICY: INTELLECTUAL PROPERTY AND COMPULSORY LICENSING: PHARMACEUTICALS AND THE DEVELOPING WORLD (2004).

41. *See id.*

42. *See id.*

43. *See id.*

44. *See* Sonia E. Rolland, *Developing Country Coalitions at the WTO: In Search of Legal Support*, 48 HARV. INT'L L.J. 483, 511 (2007).

45. *See* U.N. Charter art. 55 [hereinafter U.N. Charter]. Article 55 reads in full: With a view to the creation of conditions of stability and well-being which are necessary for peaceful and friendly relations among nations based on respect for the principle of equal rights and self-determination of peoples, the United Nations shall promote: a. higher standards of living, full employment, and conditions of economic and social progress and development; b. solutions of international economic, social, health, and related problems; and international cultural and educational cooperation; and c. universal respect for, and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion.

Id.; *see also* Kimberly Carlson, *When Cows Have Wings: An Analysis of the OECD's Tax Haven Work as it Relates to Globalization, Sovereignty and Privacy*, 35 J. MARSHALL L. REV. 163, 180 (2002).

46. *See* U.N. Charter, *supra* note 45, arts. 55-58.

47. UNESCO's mandate includes "promoting collaboration among the nations through education, science and culture in order to further universal respect for justice, for the rule of law and for the human rights and fundamental freedoms which are affirmed for the peoples of the world, without distinction of race, sex, language or religion . . ." United Nations Educational, Scientific and Cultural Organization [UNESCO] Const. art. 1, para. 1, <http://unesdoc.unesco.org/images/0012/001255/125590e.pdf>.

48. UNIDO's mandate is to "[e]ncourage and extend, as appropriate, assistance to the developing countries in the promotion and acceleration of their industrialization,

Development (IFAD),⁴⁹ and the World Bank are all specialized U.N. agencies mandated to stimulate cooperation toward advancing LDCs' interests.

One fundamental right recognized by the United Nations—the fundamental right to health—is especially relevant to LDCs and is frequently cited by proponents of facilitating LDCs' access to medicines.⁵⁰ LDCs, especially those struggling with pandemic infectious diseases like HIV/AIDS, are keenly aware of the consequences of being deprived of this right.⁵¹ In Sub-Saharan Africa, for example, the HIV/AIDS epidemic over the past fifteen years has effectively reversed the notable economic, political, and social progress achieved in several countries during the 1980s, a time when there was generally a high level of health.⁵² Despite the Sub-Saharan LDCs' developmental momentum, the incidence of HIV/AIDS outpaced governments' treatment capacities, and millions were, and continue to be, deprived of their fundamental right to health.⁵³ Arguably, the plight of LDCs in Sub-Saharan Africa reveals the codependent relationship between LDCs' level of overall health, and their ability to advance economically, politically, and socially.⁵⁴

Generally, LDCs overwhelmed by HIV/AIDS have limited financial resources to address such health crises.⁵⁵ Some LDCs, like Malaysia, India, Brazil, and Thailand, have subsidized and implemented national treatment programs that offer ongoing treatment to their citizens, at no or minimal charge.⁵⁶ Such

in particular in the development, expansion and modernization of their industries” United Nations Industrial Development Organization [UNIDO] Const. art. 2, para. A.

49. IFAD's mandate is to mobilize "resources to be made available . . . for agricultural development in developing Member States . . . [.] taking into consideration . . . the importance of improving the nutritional level of the poorest populations in developing countries and the conditions of their lives." Agreement Establishing the International Fund for Agricultural Development [IFAD] art. 2, <http://www.ifad.org/pub/basic/agree/e/!01agree.pdf>.

50. See Madhavi Sunder, *IP*, 59 STAN. L. REV. 257, 292 (2006); 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 (1999).

51. Fidler, *supra* note 50, at 195.

52. See 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).

53. *Id.*

54. See Fidler, *supra* note 50, at 192.

55. WORLD TRADE ORG. AND WORLD HEALTH ORG. [WTO & WHO], WTO AGREEMENTS & PUBLIC HEALTH: A JOINT STUDY BY THE WHO AND WTO SECRETARIAT 87 (2002) [hereinafter JOINT REPORT].

56. See Sinfah Tunsarawuth, *Governments Urged to Use Compulsory Licences 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->

governmental programs are not viable, however, if the newest, most efficacious medicines can only be obtained at full-market price.⁵⁷ Between 2001 and 2006, Brazil repeatedly negotiated with several Pharmas—using the threat of issuing compulsory licenses—and successfully received significant price reductions for HIV/AIDS medicines, which it then used to effectively treat its citizens.⁵⁸

Brazil's approach to negotiating medicine prices laid a blueprint, which other LDCs could follow when attempting to increase their access to medicines for use in national treatment programs.⁵⁹ In 2007, Thailand pushed the bounds of Brazil's negotiation model to its outer limits, which resulted in its relationship with Abbott becoming increasingly adversarial over the course of several separate transactions; ultimately, Thailand issued a compulsory license.⁶⁰ Thailand's actions effectively summarize LDCs' interests regarding the IPR—when push comes to shove, an LDC will choose the well-being and health of its people over patent observance.

C. *The Rise of the IPR*

Two important purposes of patents and their enforcement are to spur scientific development and stimulate innovation.⁶¹ They accomplish this by giving property rights to individuals and businesses for their qualifying intellectual efforts.⁶² In the United States, patents⁶³ give inventors of new, useful, and non-obvious items the exclusive right to exclude others from making, using, or selling their inventions for a limited time.⁶⁴ This right allows patent holders a limited monopoly on qualifying inventions, and the ability to appropriate them to recover development costs and collect any

drug-access/.

57. *See id.*

58. Bjornberg, *supra* note 16, at 208-09.

59. *Id.* at 210-11. Brazil has issued compulsory licenses on several occasions. *Id.* at 212.

60. *See* Tove Iren S. Gerhardsen, *Thailand Presents Report on Compulsory Licensing Experience*, INTELL. PROP. WATCH, Mar. 12, 2007, <http://www.ip-watch.org/weblog/index.php?p=563>.

61. *See* Melissa Feeney Wasserman, *Divided Infringement: Expanding the Extraterritorial Scope of Patent Law*, 82 N.Y.U. L. REV. 281, 282-83 (2007).

62. *See id.* at 293.

63. Patents are often conflated with other types of intellectual property rights. In the United States, property rights are afforded to different types of intellectual goods—primarily by using patents, trademarks, and copyrights. A trademark is any name, symbol or device that is used by an individual to indicate the source of his or her goods and to distinguish such goods from those of others. 15 U.S.C. §1127 (2006). A copyright gives legal protection to the authors of original works of authorship, including literary, dramatic, musical, and artistic works. Copyright Act of 1976, 17 U.S.C. §101 (2006).

64. *See* 35 U.S.C. §§ 103, 154 (2000).

potential profits.⁶⁵

Patent laws range widely from country to country.⁶⁶ Generally speaking, DCs have well-established patent regimes that offer a great deal of protection through elaborate legislation and proactive enforcement mechanisms.⁶⁷ The United States, for example, has a “relatively experienced patent office, excellent trial courts, a specialized appellate court, and a Supreme Court poised to add a generalist perspective,” and thus “possesses the kind of institutional infrastructure needed to build and maintain a strong patent law system.”⁶⁸ Conversely, many LDCs have weak patent regimes, as they often lack the resources necessary to develop them.⁶⁹ Many LDCs are far behind DCs in their ability to innovate, and struggle to catch-up technologically.⁷⁰ LDCs, especially those consumed with addressing national health crises, are simply not able to develop strong patent regimes.⁷¹

In the late nineteenth century, the nations of the world sensed the need to develop an international patent regime.⁷² In 1883, eleven countries concluded one of the first international intellectual property related treaties, the Paris Convention for the Protection of Industrial Property (Paris Convention).⁷³ The Paris Convention

65. See Wasserman, *supra* note 61, at 283.

66. Jerome H. Reichman & Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 DUKE L.J. 85, 87 (2007).

67. 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, 343-44 (2000). “The laws of developed countries . . . as net producers of intellectual products, tend[] to favor IP creators. They generally [have] created a broad variety of highly protective regimes . . . coupled with robust enforcement.” *Id.*; see Vandana Shiva & Radha Holla-Bhar, *Intellectual Piracy and the Neem Tree*, 23 THE ECOLOGIST 223, 226 (1993).

68. Reichman & Dreyfuss, *supra* note 66, at 103.

69. Chiappetta, *supra* note 67, at 344. LDCs, “as net consumers of intellectual products, [have] tended to favor freer access to [intellectual property] as a vehicle for continued economic growth. Their regimes [have] offered much narrower protection, if any, and substantially more limited enforcement.” *Id.*; see also Daniel J. Gervais, *Intellectual Property, Trade & Development: The State of Play*, 74 FORDHAM L. REV. 505, 523 (2005).

70. See Reichman & Dreyfuss, *supra* note 66, at 91.

71. See *id.*

72. Faryan Andrew Afifi, Comment, *Unifying International Patent Protection: The World Intellectual Property Organization Must Coordinate Regional Patent Systems*, 15 LOY. L.A. INT'L & COMP. L. REV. 453, 453 (1993).

73. 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.org>. The Paris Convention is presently administered by the World Intellectual Property Organization (WIPO). World Intellectual Property Organization, *Paris Convention for the Protection of Industrial Property*, <http://www.wipo.int/treaties/en/ip/paris> (last

offered several innovative provisions for patent protection, including “priority right,”⁷⁴ and formed a foundation for subsequent international intellectual property related patent agreements. Currently, one hundred seventy-three countries are party to the convention.⁷⁵

In 1967, the United Nations created a specialized agency, the World Intellectual Property Organization (WIPO).⁷⁶ WIPO’s mandate includes handling international intellectual property matters and administering the Paris Convention.⁷⁷ Though WIPO is generally considered successful in terms of its mandate, international politics rendered it inadequate in certain contexts.⁷⁸ DCs tried to use the WIPO forum to push for strong international patent policies—a self-serving move, as they were and continue to be, home to much of the world’s patentable innovation.⁷⁹ LDCs, however, had little incentive to accede to a rigid patent regime—they insisted on a more flexible system that would better suit their needs to develop innovation capacities.⁸⁰ This difference in approach may be seen as the seed of the IPR issues that has since grown into the modern impasse between Pharms and LDCs.⁸¹

This standoff led DCs to shift the forum for their international patent agenda to the *General Agreement on Tariffs and Trade* (GATT).⁸² Though it began in 1947 as only a treaty, GATT had evolved into a de facto international trade organization by the

visited Feb. 20, 2009).

74. Priority right allows an applicant that has filed a patent first in his or her own country, to use that filing date when filing for the underlying invention’s patent abroad. *See id.* art. 4(a). This prevents other individuals from attempting to use pending patent applications in one country and applying internationally for the same patent in his or her own name. *Id.*

75. WIPO, *Paris Convention Contracting Parties*, http://www.wipo.int/treaties/en/statistics/StatsResults.jsp?treaty_id=2&lang=en (last visited Feb. 20, 2009).

76. 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> (last visited Feb. 20, 2009).

77. *Id.*

78. *See* Elaine B. Gin, *International Copyright Law: Beyond the WIPO & TRIPS Debate*, 86 J. PAT. & TRADEMARK OFF. SOC’Y 763, 780-82 (2004). DCs found it difficult to enforce the protection of their patents internationally because WIPO did not have the authority to issue binding sanctions. *Id.*

79. *Id.* DCs tried to push for stronger protection for all forms of intellectual property, but were especially concerned about patent protection. *Id.*

80. *Id.* at 789.

81. *See* Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 LOY. L.A. L. REV. 323, 357 (2004).

82. *Id.*

1970s.⁸³ The DCs' new strategy for encouraging LDCs to compromise their patent regime needs was to attach trade policy to patent policy.⁸⁴ LDCs viewed favorable trade conditions as having the potential to more directly further their overall economic, social, and cultural needs, and they were coerced into sacrificing their prior patent stance.⁸⁵

In 1995, GATT was transformed into the World Trade Organization (WTO).⁸⁶ The WTO's mandate includes improving member nations' welfare by reducing trade barriers and creating a robust international trading platform.⁸⁷ This transformation reaffirmed and solidified the DC-inspired linkage between trade policy and patent policy.⁸⁸ This is evident in the name of the intellectual property treaty created as part of the WTO negotiations—the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).⁸⁹ In 1995, international trade and patent regimes became inseparable. Generally, the WTO is empowered to oversee TRIPS and resolve Member disputes via its Dispute Settlement Body.⁹⁰ The Council for TRIPS is the actual body that administers the treaty.⁹¹ At present, 151 countries are WTO Members, of which a significant number are LDCs.⁹²

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

84. *Id.*

85. *Id.* at 73.

86. Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1125 (1994).

87. *Id.* at 1144.

88. *See id.*

89. TRIPS Agreement, *supra* note 9.

90. Cynthia M. Ho, *A New World Order for Addressing Patent Rights and Public Health*, 82 CHI.-KENT L. REV. 1469, 1470-71 (2007).

91. TRIPS Agreement, *supra* note 9, art. 68. "The Council [for TRIPS] shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights." *Id.*

92. WTO, *Members and Observers*, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Feb. 20, 2009). The process for joining the WTO is as follows:

Any state or customs territory having full autonomy in the conduct of its trade policies may join ("accede to") the WTO, but WTO members must agree on the terms. Broadly speaking the application goes through four stages: [1] . . . The government applying for membership has to describe all aspects of its trade and economic policies that have a bearing on WTO agreements; [2] . . . When the working party has made sufficient progress on principles and policies, parallel bilateral talks begin between the prospective new member and individual countries; [3] . . . Once the working party has completed its examination of the applicant's trade regime, and the parallel bilateral market access negotiations are complete, the working party finalizes the

TRIPS created minimum international standards for WTO Members regarding the protection of, among other things, copyrights, trademarks, and patents—and has proved successful overall.⁹³ Importantly, it established a solid international intellectual property framework despite the divergent interests at stake in its negotiation, such as those between DCs and Pharmas.⁹⁴ LDCs had a substantial presence at TRIPS negotiations and did in fact influence its ultimate form.⁹⁵

D. A Closer Look at TRIPS

TRIPS and its subsequent clarifying instruments comprise the core relevant law for a legal analysis of the impasse between Pharmas and LDCs.⁹⁶ A reading of its preamble reveals TRIPS's emphasis on the previously discussed linkage between trade and intellectual property:

Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade[.]⁹⁷

TRIPS established minimum standards for different forms of intellectual property and obliged all WTO members, irrespective of their level of development, to apply the same standards to their domestic laws.⁹⁸ This one-size-fits-all approach, with “[n]o specialized and differential treatment for [LDCs] . . . except for the possibility of applying transitional periods,” has been widely criticized—including

terms of accession; [4]) . . . The final package, consisting of the report, protocol and lists of commitments, is presented to the WTO General Council or the Ministerial Conference. If a two-thirds majority of WTO members vote in favour, the applicant is free to sign the protocol and to accede to the organization.

WTO, *Membership, Alliances and Bureaucracy*, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org3_e.htm#join (last visited Feb. 20, 2009).

93. TRIPS Agreement, *supra* note 9.

94. *See id.*

95. *See* 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. & POLY 65, 67 (2007).

96. World Health Organization, *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights Innovation and Public Health* 83 (2006). One relevant document besides the TRIPS Agreement is the Doha Declaration. *Id.* at 22, 126, 136.

97. TRIPS Agreement, *supra* note 9, pmb1.

98. *Id.* art. 1, para. 1. WTO Members did have flexibility to “determine the appropriate method of implementing the provisions of this Agreement within their own legal system an practice.” *Id.*

by the World Bank.⁹⁹ It is worth noting, though, that TRIPS did recognize “the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.”¹⁰⁰ However, this recognition, with its technology focus, seems to overlook LDCs’ need for flexibilities “in implementing the TRIPS obligations to protect public health, improve nutrition, alleviate poverty, or achieve other essential objectives”¹⁰¹

Also notable is TRIPS’s enforcement mechanism, which involves a dispute settlement process administered by the Dispute Settlement Body (DSB).¹⁰² The DSB handles all disputes between WTO Members, and ultimately, with the power of trade sanctions, functions as the enforcement mechanism for all WTO matters including those related to TRIPS.¹⁰³ Members who feel fellow Members have violated WTO agreements must approach the DSB with their disputes instead of acting unilaterally.¹⁰⁴ “Although much of the [DSB] procedure does resemble a court or tribunal, the preferred solution is for the countries concerned to discuss their problems and settle the dispute by themselves.”¹⁰⁵ Thus, consultations between Members are encouraged and well integrated in to the DSB’s procedures.¹⁰⁶ Based on DSB rulings, Members that have violated WTO agreements may “bring [their] policy [in]line with the ruling,” offer compensation such as “tariff reductions in areas of particular interest to the complaining side,” or ultimately bear

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

100. TRIPS Agreement, *supra* note 9, pmbl.

101. CORREA, *supra* note 99, at 13.

102. See WTO, UNDERSTANDING THE WTO 55-57 (2007), http://www.wto.org/english/thewto_e/whatis_e/tif_e/understanding_e.pdf. The DSB is a session, or a meeting, of all WTO Members. *Id.*

103. *Id.* at 55 (“Without a means of settling disputes, the rules-based system would be less effective because the rules could not be enforced.”).

104. *Id.* at 55-57.

105. *Id.* at 56.

106. *Id.* at 56-59. In brief, the dispute settlement-enforcement process is as follows: 1) *consultation* – members have sixty days to resolve the dispute among themselves; 2) *panel appointment* – if members fail to resolve the dispute, then the complaining member may ask the DSB to appoint a panel, which, if the DSB decides to do, must be done within forty-five days; 3) *panel process* – the panel has six months to hear the dispute, and ultimately, submit a final report indicating the existence or absence of a violation; 4) *report ruling* – the DSB has sixty days to accept the panel’s report and make it a ruling; 5) *appeals* – members may appeal the ruling to three members of an Appellate Body established by the DSB, which then has a maximum of ninety days to “uphold, modify or reverse the panel’s legal findings and conclusions”; 6) *appeals report ruling* – the DSB has thirty days to accept or reject the appeals report. *Id.* at 56-57.

limited trade sanctions.¹⁰⁷

Regarding patents, TRIPS requires that WTO Members must provide protection for other Members' qualifying inventions for a minimum of twenty years, whether the inventions are products or processes.¹⁰⁸ However, there are some exceptions.¹⁰⁹

TRIPS Article 8 states that "Members 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."¹¹⁰ Article 8's wording is broad, and seems to only limit Members' actions by requiring them to be "necessary" and "consistent" with TRIPS.¹¹¹ It seems to indicate that Members may use Article 8 as the legal basis to experiment with patented subject matter to better understand its underlying technologies.¹¹²

TRIPS Article 31, entitled "Other Use Without Authorization of the Right Holder," is the source of TRIPS most elaborate and controversial exceptions.¹¹³ Though addressed to all Members, Article 31 is effectively aimed at allowing LDCs, under a few different circumstances, to use other Members' medicine patents without permission—with the ultimate goal being to manufacture the medicine domestically as a generic for less cost than would be incurred if the medicine was purchased directly from the patent-holding Pharma.¹¹⁴ This mechanism is widely referred to as "compulsory licensing," and at the time of TRIPS negotiations, existed in some form in the laws of most countries of the world.¹¹⁵

TRIPS Article 31(b) details the procedure for using compulsory licenses.¹¹⁶ An LDC may issue a compulsory license for a medicine

107. *Id.* at 58.

108. See TRIPS Agreement, *supra* note 9, art. 33; see also Ho, *supra* note 90, at 1473-74.

109. See TRIPS Agreement, *supra* note 9, arts. 8, 31.

110. *Id.* art. 8.

111. CORREA, *supra* note 99, at 106.

112. See TRIPS Agreement, *supra* note 9, art. 8, ¶ 1.

113. *Id.* art. 31.

114. See *id.* art. 31(b).

115. CORREA, *supra* note 99, at 313. Through Article 31, "industrialized countries tried to limit the room for the use of the compulsory licensing system, even though its actual application has been rather limited in the past, except in the United States" where it has been "used as a remedy in more than 100 antitrust case settlements" *Id.*

116. TRIPS Agreement, *supra* note 9, art. 31(b). This provision reads in full:

[S]uch use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable

patent if it cannot obtain a reasonable price, within a reasonable amount of time, from the patent holder.¹¹⁷ This negotiation requirement, however, may be waived if the LDC has a national emergency, or other circumstance of extreme urgency, or if it plans to use it for a public non-commercial use.¹¹⁸ These three negotiation exemptions—“national emergency,” “circumstances of extreme urgency,” and “public non-commercial use,”—because of their ambiguity, have collectively played a significant role in the development of the impasse between Pharmas and LDCs. All three have been invoked by different LDCs to circumvent negotiations before issuing compulsory licenses.¹¹⁹

If an LDC chooses to issue a compulsory license, it must first notify the patent holder, use the medicines produced pursuant to a compulsory license primarily in the domestic market (which means that only a country with a domestic pharmaceutical manufacturing capacity may issue a compulsory license), and finally, give reasonable compensation to the patent holder.¹²⁰

TRIPS Article 6 contains a provision that is relevant to an LDC wishing to import medicines from countries that have surpluses of medicines purchased from patent-holding Pharmas.¹²¹ Article 6

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 promptly.

Id.

117. *Id.*

118. *Id.* The WTO, in its subsequently released Doha Declaration, established that individual countries may define “national emergency” and “other circumstances of extreme emergency” as they see fit. World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration]; see *infra* note 125. Despite this clarification, the terms are still ambiguous and have resulted in much of the conflict related to compulsory licensing. See Vaughan, *supra* note 17.

119. Guennif & Chaisse, *supra* note 95, at 80. “[T]he lack of a clear definition of these scenarios and the resultant legal insecurity have led developing countries to demand a specific statement on this matter.” *Id.*

120. TRIPS Agreement, *supra* note 9, art. 31. The domestic market requirement was subsequently waived. See *infra* note 131.

121. Article 6 of the TRIPS Agreement states that “[f]or the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.” TRIPS Agreement, *supra* note 9. This effectively leaves the long-standing principle of exhaustion intact. See *id.*

entails the doctrine of exhaustion, which generally states that once a patent holder sells a supply of some product based on that patent, that patent holder no longer has any rights to that supply.¹²² In the context of the impasse between Pharmas and LDCs, Article 6 provides the legal basis for a company or government that has purchased medicines from Pharmas to resell its surpluses to a “parallel importing” LDC for profit, if such opportunities exist.¹²³ This provides a LDC an alternative, or a complementary method to issuing compulsory licenses—for the purpose of increasing its access to medicines.

After TRIPS had been in effect for several years, WTO Members realized that it needed clarification and possibly modification—this led to the *Declaration on the TRIPS Agreement and Public Health* (Doha Declaration) in 2001.¹²⁴ The Doha Declaration offered some clarification for TRIPS flexibilities, and established that TRIPS interpretation should support public health by promoting access to existing medicines and the creation of new medicines.¹²⁵ Clarifications for the previously discussed negotiation exemptions,

122. See *id.*; Donald P. Harris, *Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion*, 27 U. PA. J. INT'L ECON. L. 681, 739 (2006) (stating that the doctrine of exhaustion allows for parallel importation, which occurs when one country shops among numerous countries for the lowest price for a particular product).

123. See *id.*

124. Doha Declaration, *supra* note 118.

125. The Doha Declaration, in relevant part, provides:

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.

...

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

...

TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

...

Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

...

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. ¶¶ 1, 3-5(c).

“national emergency” and “other circumstances of extreme urgency,” were less than satisfactory.¹²⁶ The Doha Declaration also acknowledged a major issue raised by many LDCs—in particular, by those with no domestic drug production capacity.¹²⁷ These LDCs felt that the domestic production requirement for Article 31 compulsory licensing prevented them from utilizing this flexibility to increase their access to medicines.¹²⁸ The Doha Declaration gave the Council for TRIPS a time frame in which to establish a solution for these LDCs.¹²⁹

In response, the Council for TRIPS issued the *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (Paragraph 6 Decision), which is the final component of the IPR relevant to the impasse between Pharms and LDCs.¹³⁰ This decision waived the TRIPS Article 31(b) domestic market requirement, and in effect, now allows a Member that *does have* a domestic drug production capacity to issue a compulsory license and export medicines made under such a compulsory license to a LDC that *does not have* a domestic production capacity, which must issue a separate compulsory license to import such medicines.¹³¹ Currently, WTO members are deciding whether to make this waiver a permanent amendment to TRIPS.¹³²

126. See Bjornberg, *supra* note 16, at 207.

[T]he WTO has not provided a precise definition of what constitutes a “national emergency” for purposes of the compulsory licensing exception. This type of imprecision may be an inherent byproduct of the relative newness of the TRIPS Agreement, but it is likely to lead to disparate application and general confusion until such vagueness is cured.

Id. (citations omitted).

127. Doha Declaration, *supra* note 118, art. 6.

128. 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, 929-30 (2007).

129. Doha Declaration, *supra* note 118, ¶ 6. Paragraph 6 reads:

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.

130. 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].

131. See *id.* The Paragraph 6 Decision, in relevant part, reads: “The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s). . . .” *Id.* ¶ 2.

132. Abbott & Reichman, *supra* note 128, at 932.

Looking back over the long-term development of the IPR, it becomes clear that it is a significant accomplishment. The IPR evolved over the past 125 years, and incrementally grew in response to needs perceived collectively by nations of the world. In contrast, looking back over the relatively recent, short-term development of the WTO, TRIPS, and TRIPS's subsequent clarifying instruments, it becomes clear that the current legal framework is undergoing growing pains, and has inadequacies that have only recently been revealed. The IPR is trying to establish itself as bona-fide, legitimate international law, while simultaneously trying to adapt to Members' newly realized, competing interests—through the use of minimally helpful declarations and decisions that fail to offer necessary clarification and resolution. The IPR's inadequacies are brought to life in the following examples from around the world.

III. ANALYSIS

A. *Recent Situations that Highlight the Inadequacies of the IPR*

1. Malaysia

In 2004, Malaysia issued a compulsory license for HIV/AIDS medicines patented by GlaxoSmithKline and Bristol-Myers Squibb, after lengthy, failed price negotiations.¹³³ Though these Pharmas had offered thirty to forty percent discounts, the Malaysian government chose to pursue issuing a compulsory license to “meet the needs” of its national HIV/AIDS treatment program.¹³⁴

Malaysia's use of this TRIPS flexibility expanded its program's treatment capacity from 1500 to 4000, by reducing the cost of three patented medicines by eighty-one percent.¹³⁵ However, there were a few notable undesirable consequences.

First, the patent holder Pharmas immediately filed complaints with the Malaysian government, which prompted concerns about “negative implications for foreign investment.”¹³⁶ These kinds of potential Pharma reactions and broader economic consequences may discourage other LDCs from even considering issuing compulsory licenses. LDCs may feel forced to sacrifice utilizing this flexibility to increase their access to medicines, in the hopes of possible new or continued foreign investment. Second, though the Malaysian Ministry of Health offered a four percent remuneration pursuant to TRIPS Article 31(h), the patent holders “refused compensation . . . for

133. Sara Germano, *Compulsory Licensing of Pharmaceuticals in Southeast Asia: Paving the Way for Greater Use of the Trips Flexibility in Low- and Middle-Income Countries*, 76 UMKC L. REV. 273, 286-87 (2007).

134. *Id.* at 287.

135. *Id.* at 288.

136. *Id.* at 287.

fear of creating an international precedent.”¹³⁷ This response indicates that TRIPS’s remuneration principle, though equitable in theory, is not meaningful in fact. An LDC that issues a compulsory license has complete discretion to determine a reasonable remuneration, and generally, the token amounts offered are purely symbolic.¹³⁸ Third, it took three years of “negotiations and discussions within governmental agencies” for Malaysia to increase its access to the medicines using the compulsory licensing mechanism.¹³⁹ This fact reveals that TRIPS’s compulsory licensing mechanism, and the domestic legal procedures that it requires, are cumbersome and not expeditious. Considering TRIPS’s repeated, express commitments to promoting LDCs’ abilities to react to health crises, Malaysia’s compulsory licensing experience indicates an unacceptable timeline. Finally, Malaysia’s use of compulsory licensing led the United States to approach Malaysia directly—outside the collective WTO framework—and successfully discourage it from future compulsory license issuance through a bilateral free trade agreement.¹⁴⁰

2. India

At the time of TRIPS’s conclusion, India had a relatively weak patent system, the modern form of which had been in place since 1970.¹⁴¹ When India joined the WTO in 1995, it had a “flourishing generic drug industry” due in part to this weak patent system.¹⁴² India had until 2005 to bring its domestic patent laws into compliance with TRIPS requirements.¹⁴³

In that ten-year span, however, Indian Pharmas produced significant amounts of generic HIV/AIDS medicines, and sold them for low cost to the government of India and the governments of various countries in Sub-Saharan Africa.¹⁴⁴ In some instances, Indian Pharmas were able to reduce monthly medicine costs from \$395 per

137. *Id.* at 288.

138. TRIPS Agreement, *supra* note 9, art. 31(h). “[T]he right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.” *Id.*

139. Germano, *supra* note 133, at 288.

140. *Id.* at 289.

141. Pooja Van Dyck, *Importing Western Style, Exporting Tragedy: Changes in Indian Patent Law and Their Impact on Aids Treatment in Africa*, 6 NW. J. TECH. & INTELL. PROP. 138, 141 (2007). India’s original patent system was considered weak because it offered protection only for processes, and not for substances. *Id.* This allowed Indian pharmaceutical companies to legally manufacture others’ medicines by slightly altering the method of manufacture. *Id.*

142. *Id.*

143. *Id.*

144. *Id.* at 143.

month to \$20 per month.¹⁴⁵ India (which in 2003 was home to 5.1 million people with HIV, or 12.6 percent of the world's HIV population) and countries in Sub-Saharan Africa (which in 2003 were home to 25.8 million people living with AIDS, or approximately 66 percent of the world's AIDS cases), were situated such that this kind of a price differential had the potential to make a significant difference in saving lives.¹⁴⁶

By 2005, India had updated its domestic patent laws to comply with TRIPS requirements.¹⁴⁷ One impact of these changes is that Indian Pharmas now have a narrower range of medicines that they may legally produce as generics.¹⁴⁸ In particular, they may not produce generics of the newest "second- and third-generation" HIV/AIDS medicines, whose patents must now be respected.¹⁴⁹ The net result of this is that the role Indian Pharmas have played since 1995, in reducing costs for the most needed HIV/AIDS medicines, will be curtailed. Though India's current TRIPS-compliant patent law allows it to play a role in the post-Paragraph 6 Decision compulsory licensing scheme (which waived TRIPS Article 31(f)'s domestic market requirement), Sub-Saharan African LDCs will likely have difficulty in utilizing compulsory licensing.¹⁵⁰ "[M]any African countries have unstable or ruthless governments that may not follow the process laid out by the WTO. People in these countries may continue to suffer even if drugs are available for people in other countries whose governments are willing to use the TRIPS process."¹⁵¹

Ultimately, it seems that the current IPR, despite its continued emphasis on promoting health, will indirectly—through the patent law restructuring it demands of countries like India—diminish the ability of Sub-Saharan LDCs (with 66 percent of the world's AIDS cases) to increase their access to necessary medicines.

Another situation in India that highlights the IPR's inadequacies involves litigation initiated by a Pharma. Recently, the Swiss Pharma Novartis brought an action in India's High Court claiming that India's domestic patent law breached TRIPS when it rejected a

145. *Id.* at 143-44.

146. *See id.* at 142.

147. *Id.* at 141.

148. *Id.*

149. *Id.* at 142.

150. *Id.* at 145.

151. *Id.* at 149. Though most "African countries have the legal right to produce generic drugs under compulsory licenses for their AIDS crises . . . most of them do not have the resources to create a domestic generic pharmaceutical industry [and therefore] will have to resort to the cumbersome TRIPS procedures." *Id.* at 148.

patent application for Glivec, an anti-cancer drug.¹⁵² Novartis argued that India's patent laws over-narrowly define patentable subject matter, in a way incompatible with TRIPS.¹⁵³ Underlying Novartis's claim, though, is its fear—and likely the fear of other Pharmas—that the application was rejected so that Indian manufacturers may freely create generic versions of Glivec.¹⁵⁴ As previously discussed, India is home to a large generic medicine manufacturing industry, and has little innovation capacity.¹⁵⁵

Two Indian High Court judges dismissed the case, holding that the High Court did not have the jurisdiction to determine whether its domestic patent law is incompatible with TRIPS provisions.¹⁵⁶ This decision effectively passed the dispute to the WTO.¹⁵⁷ The net effect of the Indian High Court's decision is that Novartis, through the Swiss government, must now initiate the lengthy and resource intensive WTO dispute settlement process.

3. Taiwan

In November 2005, Taiwan issued a compulsory license pursuant to TRIPS Article 31, for the Roche avian influenza drug "Tamiflu."¹⁵⁸ Taiwan claimed that the potential for an outbreak of bird flu constituted a national emergency and that it was necessary to ensure sufficient stockpiles of Tamiflu.¹⁵⁹ Here, Taiwan's broad interpretation of "national emergency" caused considerable alarm among Pharmas.¹⁶⁰ Though the TRIPS council had attempted to clarify "national emergency" in Doha Declaration Article 5(c), Pharmas' reaction to Taiwan's compulsory license indicates that "national emergency" is still too vague, and will likely be the source of future disputes between Pharmas and LDCs.¹⁶¹

152. Tatum Anderson, *Rejected Novartis Cases Leave India's TRIPS Compliance Unchallenged*, INTELL. PROP. WATCH, Aug. 7, 2007, <http://www.ip-watch.org/weblog/index.php?p=712>.

153. *Id.*

154. *See id.*

155. Guennif & Chaisse, *supra* note 95, at 82-83 (explaining that India's classification as a developing country required it to comply to TRIPS agreement).

156. Anderson, *supra* note 152.

157. *Id.*

158. Kathrin Hille, *Taiwan Employs Compulsory Licensing for Tamiflu*, FINANCIAL TIMES, Nov. 25, 2005, http://search.ft.com/ftArticle?queryText=compulsory+license&y=0&aje=true&x=0&id=051125005602&ct=0&nlick_check=1. The Taiwanese Department of Health assured Roche that it would pay the appropriate compulsory licensing remuneration pursuant to TRIPS Article 31(b). *Id.*

159. *Id.*

160. *Id.*

161. Doha Declaration, *supra* note 118, art. 5(c). "[P]ublic health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent

4. Brazil

Brazil has extensively utilized TRIPS flexibilities, more than any other LDC.¹⁶² A thorough analysis of Brazil is important because Brazil is seen as a pioneer in developing and implementing a successful national HIV/AIDS treatment program.¹⁶³ Unfortunately, it is problematic that other LDCs view Brazil's national treatment program as a model to follow because many LDCs have dramatically different economic, political, and social circumstances than Brazil.¹⁶⁴

In 2001, Brazil successfully used the threat of issuing compulsory licenses to receive significant discounts for Merck & Co. and Roche medicines.¹⁶⁵ In June 2005, Brazil threatened Abbott with compulsory license issuance for the HIV/AIDS drug Kaletra.¹⁶⁶ On the verge of Brazil actually issuing the compulsory license, Abbott granted Brazil its requested price.¹⁶⁷ Less than two years later, in May 2007, Brazil used the threat of issuing a compulsory license again, this time against Merck & Co. for its HIV/AIDS drug Efavirenz.¹⁶⁸ Over the course of negotiations related to this transaction, Merck & Co. made significant price concessions, but Brazil ultimately demanded the price that had been previously offered a few years earlier to Thailand.¹⁶⁹ It is worth noting that the price Merck & Co. had offered Thailand was based on Thailand's economic standing—a standing that Brazil far surpasses.¹⁷⁰

Ultimately, Merck & Co. refused to offer Brazil the price that it had offered Thailand, and Brazil officially issued a compulsory license for Efavirenz.¹⁷¹ Once Brazil actually issued the compulsory license, however, Merck & Co. gave Brazil the Thailand price.¹⁷² This rendered the compulsory license moot, and may have mitigated the undermining effect that the compulsory license would have had on the Efavirenz patent. This action indicates that Merck & Co.—and likely other Pharmas—would prefer to lose a pricing battle, but not the patent war.

a national emergency . . .” *Id.*

162. Abbott, *supra* note 37, at 950-52.

163. *Id.* at 951.

164. *See id.* at 953-54.

165. Peggy B. Sherman & Ellwood F. Oakley, III, *Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 AM. BUS. L.J. 353, 389 (2004).

166. *Id.* at 383.

167. *Id.*

168. Gerhardsen, *supra* note 12.

169. *Id.*

170. *Id.*

171. *Id.*

172. *Id.*

Based on these three instances, it is clear that Brazil, over the past few years, has used an increasingly aggressive approach with regard to compulsory licensing to increase its access to medicines. There are at least two potential negative consequences to Brazil's actions. First, LDCs in Sub-Saharan Africa, in desperation, may attempt to follow Brazil's negotiation model and approach Pharms with the threat of a compulsory licensing in hand. As previously discussed, most of these LDCs lack the resources necessary to make such a threat credible, and may ultimately lose precious time in trying to increase their access to medicines and treat their citizens. Also, Brazil's aggressive approach may lead Pharms, disillusioned with the futility of good-faith pricing negotiations, to discontinue their long-standing dialog with LDCs.

5. Thailand

Thailand, in the past few years, has utilized compulsory licenses, or at least the threat of issuing compulsory licenses to its advantage.¹⁷³ In 2006, Thailand entered into extensive negotiations with Merck & Co. for Efavirenz, but in November of the same year, issued a compulsory license.¹⁷⁴ In January 2007, it issued a compulsory license for the Abbott HIV/AIDS drug "Kaletra" after months of price negotiations.¹⁷⁵

Abbott, upon receiving notice of this compulsory license, withdrew pending applications to market seven other medicines in Thailand.¹⁷⁶ Abbott denied that these withdrawals were directly related to Thailand's compulsory licensing of Kaletra, but many, including the Thai government and non-governmental organizations, have argued that the withdrawals were retaliatory.¹⁷⁷

Ultimately, and for reasons unclear, Abbott reduced Kaletra's price to that which Thailand had demanded.¹⁷⁸ Arguably, this was an attempt by Abbott to salvage some of Kaletra's patent's integrity, much as Merck & Co. had done with Brazil for Efavirenz. Regardless, Abbott did not resubmit applications for the medicines it had

173. See Brent Savoie, *Thailand's Test: Compulsory Licensing in an Era of Epidemiologic Transition*, 48 VA. J. INT'L L. 211, 242-45 (2007).

174. Gerhardsen, *supra* note 60.

175. *Id.*; see David Cronin, *EU Split Over Thai Effort to Obtain Cheaper Patented Drugs*, INTELL. PROP. WATCH, Sept. 5, 2007, <http://www.ip-watch.org/weblog/index.php?p=732> (discussing different opinions within the European Union regarding Thailand's compulsory license for Abbott's Kaletra).

176. *Abbott to Reduce Cost of Kaletra in Thailand, Other Developing Countries*, KAISER NETWORK, Apr. 11, 2007, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=44162 [hereinafter *Kaletra Cost*].

177. Vaughan, *supra* note 17.

178. *Kaletra Cost*, *supra* note 176.

previously withdrawn.¹⁷⁹ Within a year of its successful price wrangling with Abbott, Thailand issued compulsory licenses for several more medicines from various Pharmas.¹⁸⁰ Presently, there is a great deal of tension between Pharmas and Thailand.¹⁸¹ Thailand's compulsory licensing experiences seem to indicate that this IPR flexibility is becoming a default mechanism for LDCs wishing to increase their access to medicines, and that Pharmas are becoming increasingly disillusioned in relying on the IPR to recover their R&D costs.

6. United States

The United States, propelled by Pharma lobbying efforts, has reacted to the current state of the IPR and LDCs' use of its flexibilities, by engaging in one-on-one negotiations with individual LDCs.¹⁸² These negotiations have resulted in bilateral agreements where the United States gives favorable trade incentives to LDCs for engaging in behavior that furthers medicine patent protection, above and beyond what is required by TRIPS and its subsequent clarifying instruments.¹⁸³ Critics of this recent trend have argued that it undermines the collective bargaining power that LDCs have within the WTO framework.¹⁸⁴ So far, the United States has used bilateral trade agreements with countries like Malaysia, Chile, and Singapore to successfully increase medicine patent protection internationally.¹⁸⁵

B. *The Big Picture*

These recent situations highlight several inadequacies of the current IPR. One phenomenon that has resulted from the IPR is the downward spiral of price point for certain HIV/AIDS medicines, accompanied simultaneously by the dilution of these medicines' underlying patents.¹⁸⁶ Since TRIPS came into force, Pharmas have

179. *Id.*

180. Nicholas Zamiska, *Thai Ministry to Recommend Ignoring Patents on Cancer Drugs*, WALL ST. J., Mar. 11, 2008, at A16. Thailand issued compulsory licenses for "Novartis's imatinib, also known as Gleevec; Novartis's breast-cancer drug letrozole, whose brand name is Femara; Sanofi-Aventis's docetaxel, marketed as Taxotere and used to fight lung and breast cancer; and Roche's erlotinib, whose trade name is Tarceva." *Id.*

181. Gerhardsen, *supra* note 60.

182. See Robert Galantucci, *Data Protection in a U.S.-Malaysia Free Trade Agreement: New Barriers to Market Access for Generic Drug Manufacturers*, 17 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1083 (2007).

183. *Id.* at 1087-89.

184. *Id.* at 1120-21.

185. *Id.* at 1121.

186. See Sinfah Tunsarawuth, *Governments Urged to Use Compulsory Licenses to Boost Drug Access*, INTELL. PROP. WATCH, Nov. 23, 2007, <http://www.ip->

consistently made significant price concessions in hopes that LDCs would not issue compulsory licenses. Merck & Co.'s and Abbott's repeated compromises in negotiations with Malaysia, Brazil, and Thailand indicate that they were willing to reduce prices in efforts to maintain the integrity of their patents—which is undermined by compulsory licenses. Under the current IPR, Pharmas are effectively forced to set pricing precedents through negotiations which may or may not prevent compulsory licensing. It is likely that Pharmas would not set these precedents if they knew that LDCs would ultimately resort to issuing compulsory licenses. This is because the pricing precedents potentially lower the starting point prices in subsequent negotiations with other LDCs.

A related phenomenon that has resulted from the IPR is that LDCs are demanding prices offered to other, differently situated LDCs. Pharmas like Merck & Co. and Abbott have negotiated in good-faith with individual LDCs like Malaysia, Thailand, and Brazil, and ultimately offered prices based on individual LDCs' abilities to pay.¹⁸⁷ LDCs, however, are aware of the prices other LDCs receive, and as was the case where Brazil sought Thailand's Efavirenz price, have been demanding the lowest price offered any LDC—irrespective of the economic standing on which the price is based.¹⁸⁸ Under the current IPR, there is the potential for better situated LDCs, like Brazil, to insist on paying for medicines according to the pricing precedents set by Pharmas in negotiations with truly impoverished LDCs, like those in Sub-Saharan Africa. This seemingly abusive use of pricing precedents may result in better-situated LDCs receiving prices disproportionately low compared to their ability to pay. Also, it may provide an easy way for better-situated LDCs to satisfy TRIPS Article 31(b)'s "prior negotiation" requirement. For example, Brazil could take an extremely low pricing precedent for a Sub-Saharan LDC and demand that price at the beginning of negotiations with a Pharma, knowing that the Pharma is unlikely to accede to such a demand.

The most apparent phenomenon that has resulted from the IPR is the overall increased issuance of compulsory licenses. Until recently, compulsory licenses provided a backstop to be used only as a last resort if Pharmas and LDCs failed to negotiate mutually satisfactory prices.¹⁸⁹ Both sides knew that the backstop was there but avoided relying on it. Pharmas seemed to prefer sacrificing

watch.org/weblog/index.php?p=838.

187. See, e.g., *Brazil Requests Voluntary Licensing for AIDS Drugs to Treat More Patients, Reduce Costs of Importing Patented Drugs*, KAISER NETWORK, Mar. 16, 2005, http://www.kaisernet.org/daily_reports/rep_index.cfm?hint=1&DR_ID=28706.

188. See Tunsarawuth, *supra* note 56.

189. Bjornberg, *supra* note 16.

revenue to maintain their patents' integrity, and LDCs seemed to prefer staying on good terms with the innovators of medicines that saved millions of their citizens' lives.¹⁹⁰ At present, it seems that LDCs are poised to avoid the pricing strike zone altogether, and instead, aim straight for the backstop by issuing compulsory licenses.¹⁹¹ This "automatic" approach to compulsory licensing seems to contravene a key element of TRIPS, which in its preamble, recognized "the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives."¹⁹²

The IPR should be reevaluated and modified, to avoid potential undesirable consequences for both Pharmas and LDCs. If Pharmas are forced to continue setting unfavorably low pricing precedents (that may be inappropriately demanded by LDCs for which they are not devised) *and* have their patents consistently undermined by automatic issuance of compulsory licenses, they may reduce their R&D resources channeled into medicines for diseases that disproportionately affect LDCs. Also, as Abbott did to Thailand, Pharmas may stop marketing newer, more effective medicines in LDCs. The overall undesirable consequence to Pharmas is that they may be demonized internationally for playing any role in reducing LDCs' access to medicines, irrespective of their legitimate business reasons.¹⁹³

If LDCs in legitimate need of increasing their access to medicines continue to engage Pharmas in adversarial negotiations, demand other LDCs' pricing precedents, and increasingly issue compulsory licenses, they may find that the medicines they need most are unavailable.¹⁹⁴ The overall undesirable consequence to LDCs is the widespread, tragic, and preventable loss of life. The following proposal is an attempt to better address the needs of both Pharmas and LDCs, and avoid these undesirable consequences.

IV. EVALUATION

A. *Discriminatory Pricing Index*

The WTO and the World Health Organization (WHO)¹⁹⁵ should

190. *See id.*

191. *See* Gerhardsen, *supra* note 12; Cronin, *supra* note 175.

192. TRIPS Agreement, *supra* note 9, pmb1.

193. Generally, Pharmas are heavily criticized for any decision that negatively impacts LDCs' access to drugs. *See, e.g.,* Tove Iren S. Gerhardsen, *OECD Meeting Highlights New Drug Purchasing Model Despite NGO Doubts*, INTELL. PROP. WATCH, June 27, 2007, <http://www.ip-watch.org/weblog/index.php?p=671>.

194. Bjornberg, *supra* note 16, at 214-15.

195. The World Health Organization (WHO) is the United Nation's specialized agency dedicated to directing health care internationally. Obijiofor Aginam,

create a joint council that can pool each respective organization's resources and areas of expertise.¹⁹⁶ These two organizations have been previously commissioned to produce a report related to LDCs' access to medicines.¹⁹⁷ The WTO/WHO joint council should aggregate existing data on various economic and health dimensions to devise a Discriminatory Pricing Index (DPI). The DPI, effectively, will be a list of prices that countries can afford to pay for various essential medicines,¹⁹⁸ like those for HIV/AIDS. The DPI should reflect that DCs and their individual citizens can pay more for medicines, and that LDCs and their individual citizens can pay less.

The WTO/WHO joint council, to derive the DPI, could create a formula that incorporates well-established and widely-used economic and health related measures like Gross Domestic Product,¹⁹⁹ Human Development Index,²⁰⁰ incidence of HIV/AIDS and other pandemic diseases, Foreign Direct Investment (FDI),²⁰¹ and domestic pharmaceutical manufacturing capacity.²⁰² Depending on the

Globalization of Health Insecurity: The World Health Organization and the New International Health Regulations, 25 MED. & L. 663, 665 (2006). See generally WORLD HEALTH ORGANIZATION, BASIC DOCUMENTS (39th ed. 1992).

196. The WTO has expertise in areas including the dynamics between trade and economics, settling disputes, and imposing sanctions judiciously. See WTO, *supra* note 102. "The [WHO] has . . . expertise with regard to disease, and it is the world's repository of information on outbreaks of epidemics" Barry Kellman, *An International Criminal Law Approach to Bioterrorism*, 25 HARV. J.L. & PUB. POL'Y 721, 739-40 (2002).

197. JOINT REPORT, *supra* note 55.

198. Essential medicines include those for the treatment of "acute respiratory infections, HIV/AIDS, malaria, diarrhoeal diseases, tuberculosis and the complications of measles." WHO, WHO MEDICINES STRATEGY: FRAMEWORK FOR ACTION IN ESSENTIAL DRUGS AND MEDICINES POLICY 1 (2000).

199. "Gross Domestic Product [is] the total value of all 'goods and services produced' by labor and property within a territory, usually on yearly basis. GDP is the broadest measure of the wealth of a country." Rosa Giovanna Barresi, *The Impact of Monetary Union and the Euro on European Capital Markets: What May Be Achieved in Capital Market Integration*, 28 FORDHAM INT'L L.J. 1257, 1258 n.2 (2005).

200. The Human Development Index includes "such variables as life expectancy at birth and adult literacy enrollment in primary, secondary and tertiary education, in addition to per capita assessments of GDP, to increase sensitivity to the non-economic, and particularly distributional, dimensions of development. Rajesh Swaminathan, *Regulating Development: Structural Adjustment and the Case for National Enforcement of Economic and Social Rights*, 37 COLUM. J. TRANSNAT'L L. 161, 179-80 (1998); see Press Release, World Trade Org., Trade and Foreign Investment 2 (Oct. 9, 1996), http://www.wto.org/english/news_e/pres96_e/pro057_e.htm.

201. The WTO broadly defines foreign direct investment as occurring "when an investor based in one country (the home country) acquires an asset in another country (the host country) *with the intent to manage that asset*." RICHARD BLACKHURST & ADRIAN OTTEN, TRADE AND FOREIGN DIRECT INVESTMENT: NEW REPORT BY THE WTO 6 (1996).

202. This proposed DPI is in certain respects a greatly elaborated hybrid of two

ultimate utility of the DPI, the Council for TRIPS should consider creating a permanent agency to monitor and update the DPI as countries' conditions evolve.

WTO Members should then draft a protocol to TRIPS or fashion a new treaty that obliges Pharmas in WTO Member states to price their sale of essential medicines according to the DPI, and to sell only those quantities documented necessary for individuals, health-care professionals, hospitals, and governments. Also, it will be important for the DSB to have the authority to enforce adherence to this arrangement through the use of its remedies and limited trade sanctions.²⁰³ A mandatory, enforceable DPI schema will potentially have a threefold preemptive effect on the previously discussed undesirable consequences that may result from the current IPR.

First, because the DPI will have been devised within the collective bargaining framework of the WTO and WHO, LDCs may feel that the prices they are required to pay are truly equitable, and accurately reflect their individual circumstances. The WTO/WHO joint council, in devising the DPI, should make certain that LDCs' interests and concerns are sufficiently represented and considered. Second, Pharmas and LDCs will be able to bypass the time-consuming and frequently adversarial process of price negotiation. As seen in the Malaysia, Brazil, and Thailand examples, price negotiations can take years and yet prove ineffective at avoiding compulsory license issuance. Third, Pharmas may be better able to recover their R&D costs because of the higher prices they can charge to DCs and their citizens.²⁰⁴ Related to R&D recovery, is the likelihood that Pharmas will not have to worry about potential revenues lost to parallel exporting and importing (when WTO Members sell medicine surpluses to other Members for profit)

different indices previously proposed. One such index is also for obligatory pricing, but is compiled exclusively from GDP. See Whobrey, *supra* note 19, at 639-40. The other proposed index allows LDCs to waive adherence to TRIPS based on disease rate, per capita income, and poverty rate. See Bradley Condon & Tapan Sinho, *Global Diseases, Global Patents and Differential Treatment in WTO Law: Criteria for Suspending Patent Obligations in Developing Countries*, 26 NW. J. INT'L L. & BUS. 1, 33-40 (2005). Neither article that proposes an index addresses compulsory licensing or enforcement.

203. See *supra* note 106 and accompanying text.

204. The WTO and WHO have indicated the benefit of differential pricing on Pharmas' ability to recover R&D costs:

Where patent protection confers pricing power for drugs of vital public health or life-saving importance, differential pricing is one way of ensuring that prices in poor developing countries are as low as possible while higher prices in rich countries continue to provide incentives for R&D. Also called "tiered" or "equity" pricing, differential pricing involves charging lower prices in poorer countries and thus spreading the burden of providing incentives for research and development more equitably.

JOINT REPORT, *supra* note 55, at 101.

because controlled sales quantities, based on documented needs, will preclude substantial surpluses. Some may argue that Pharmas will disfavor legal obligations to sell medicines at low-costs to LDCs, but even low-priced sales represent revenue that otherwise would be, and has been, lost to compulsory licensing and parallel importing and exporting.²⁰⁵

In summary, a mandatory, DSB-enforced DPI schema has the potential to successfully address several inadequacies in the current IPR, and presents a win-win solution for both Pharmas and LDCs. Pharmas may benefit from greater revenue and patent predictability, and LDCs may have increased, faster access to medicines for diseases that disproportionately affect them. To fully actualize the potential benefits of such a DPI schema, however, it will be necessary to modify TRIPS's compulsory licensing provision, and clarify TRIPS's exhaustion provision.

B. Compulsory Licensing

WTO members should amend TRIPS to eliminate compulsory licensing, for both importing and exporting Members. If the DPI schema proves effective through careful devising and administering, there will be no legitimate need for compulsory licensing of medicine patents. Eliminating compulsory licensing by LDCs will restore integrity to medicine patents, and likely ease Pharmas' apprehensions related to innovating medicines that are most needed in LDCs. Also, restoring patent integrity and reliability may quell the potentially emerging trend of Pharmas withdrawing pending marketing applications for medicines in LDCs for fear of patents being undermined by compulsory license issuance.²⁰⁶

As an alternative to eliminating compulsory licensing, WTO Members can amend TRIPS with new provisions that disincentive its use. Such disincentives would be especially necessary for LDCs dissatisfied with the DPI schema. For example, LDCs like Brazil, which would likely pay more for medicines than most LDCs under the DPI, would need such disincentives to discontinue issuing compulsory licenses for manufacturing medicines for domestic use.

One possible disincentive for an LDC that has a domestic production capacity *and* plans to domestically use a medicine manufactured pursuant to a compulsory license is to require it to pay a percentage of its own DPI price for the particular medicine to the patent-holding Pharma. For example, if Brazil has a DPI price of ten dollars per pill for Medicine A, and domestically manufactures Medicine A pursuant to a compulsory license for five dollars per pill,

205. Whobrey, *supra* note 19, at 640.

206. *See* Vaughan, *supra* note 17.

then it would have to pay Medicine A's patent holder a royalty of four dollars per pill—a "40 percent of DPI" royalty. A DPI-based royalty provision has two potential benefits. It would guarantee medicine patent holders some portion of otherwise lost revenues, and it prevents this class of compulsory license issuer (better situated LDCs, with domestic manufacturing capacities, issuing compulsory licenses for domestic use of medicines) from continuing to abuse the concept of remuneration.²⁰⁷ The ultimate goal of a provision like this would be to render the money saved—by a better-situated LDC like Brazil through compulsory license issuance—marginal, and ultimately encourage full acceptance of the DPI.

A similar disincentivizing provision could be used to deter a different class of compulsory license issuer. India for example, has issued compulsory licenses to manufacture medicines domestically, but sell them to other LDCs that have no domestic manufacturing capacity. The potential provision would be to require a manufacturing and exporting Member to 1) charge the destination LDC its DPI price for a particular medicine, and then 2) pay the medicine's patent holder a royalty based on the profit margin. For example, if India domestically manufactures Medicine B pursuant to a compulsory license for four dollars per pill, and it wants to sell Medicine B to another LDC—which has a DPI price for Medicine B of six dollars per pill, then India must sell Medicine B to that LDC for six dollars per pill, and finally, pay Medicine B's patent holder a royalty of one dollar per pill—a "50 percent of profit" royalty. A profit-based royalty provision aims to allow Pharmas to recover some profit lost from compulsory licensing, render compulsory license exporter profits marginal, and ultimately, encourage full acceptance of the DPI schema. Also, it may encourage LDCs like India to focus on manufacturing generic versions of medicines that are no longer protected by patents, but that are still in demand.

In summary, the DPI schema will likely be more effective if compulsory licensing is either eliminated or disincentivized. Either compulsory licensing arrangement may further the DPI schema's objectives of meeting the needs of both Pharmas and LDCs.

C. *Exhaustion*

WTO Members should amend TRIPS to clarify that sales of medicine surpluses, which are allowed by Article 6's exhaustion provision, must be priced according to the DPI.²⁰⁸ If the DPI schema's requirement that medicine sales be carefully controlled (and based on documented need) is successful, there will likely be limited surpluses.

207. *Id.*

208. TRIPS Agreement, *supra* note 9, art. 6.

However, there is still the possibility that an enterprising Member, in an attempt to amass a sizeable and potentially profitable surplus of some particular medicine, will reach out to other Members and purchase their minimal surpluses. If all Members are required to price all surplus sales according to the DPI, this large-scale arbitrage behavior may be discouraged. This is because better-situated LDCs, like Brazil (which are financially capable of engaging in arbitrage), will have to pay for surpluses based on their relatively high DPI prices—which in the end will undermine the profit potential of arbitrage behavior.

There is an additional potential benefit if the DPI schema is applied to surplus sales. Individual Members, that legitimately need a particular medicine that is available in other Members' surpluses, will be assured of uniform pricing based on their ability to pay, regardless of where they ultimately purchase the medicine.

V. CONCLUSION

This proposed solution, comprised of the DPI schema and TRIPS amendments, aims to reconcile the competing interests of Pharmas and LDCs. This modified IPR strives to create an environment conducive to Pharma and LDC coexistence, with the hope that ultimately, they work in tandem for mutual benefit. This solution, if effective, will further Pharmas' intrinsic revenue and innovation objectives. Also, it will further LDCs' ability to address national health concerns, both directly and indirectly.

The proposed solution will directly benefit LDCs, as previously discussed, by increasing and expediting their access to medicines. The potential indirect benefit, which could manifest in the long-term, is that Pharmas in DCs may increase their FDI into LDCs. As a bookend to complement the scenario that this Note began with, consider the following greatly simplified scenario. Pharmas, no longer worried about exposing their patented medicines to a weak IPR, may be inclined to develop manufacturing capacities in LDCs, motivated in particular by low-cost labor. This infusion of capital, in turn, may spur economic growth in LDCs. LDCs could then channel their new financial resources into developing comprehensive disease treatment programs. These programs, in turn, could utilize a multi-dimensional approach to addressing health crises by subsidizing preventative education and treatment monitoring mechanisms, as opposed to relying solely on increasing access to medicines.

An ideal situation like this would indicate that the stalemate between Pharmas and LDCs is patently resolved. Not by one side winning, but by both sides being able to move forward for mutual advantage because the underlying rules have been changed to reflect the true nature of current circumstances.

