

**PRESCRIPTION DRUGS: INDIA VALUES
THEIR COMPULSORY LICENSING
PROVISION—SHOULD THE UNITED
STATES FOLLOW IN INDIA’S FOOTSTEPS?**

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I. INTRODUCTION

Americans struggle on an ongoing basis with the high prices of prescription drugs.¹ Prescription drug prices are generally higher in the United States than in any other country.² There are few signs of prices going down.³ Americans frequently hear stories about senior citizens who are forced to choose between food and their medications. Americans also frequently hear about the large profits drug manufacturers make from drugs under patent.⁴

Congress and the individual state legislative bodies are beginning to fight back against high prices. Proposals from state legislators include adjusting existing state subsidy plans; modifying drug discount plans; expanding the federal 340B drug pricing program;⁵ regulating pharmacy benefit managers (PBMs), restricting marketing and advertising by pharmaceutical companies, interagency purchasing in bulk, and requiring transparency from the pharmaceutical companies by

1. See Bill Schneider, *Lawmakers Rally Around Prescription Drug Bill*, CNN, Apr. 26, 2004, <http://www.CNN.com/2004/ALLPOLITICS/04/23/rx.drugs/index.html>.

2. Congressional Budget Office (CBO) estimates that other Western countries' prices are 35–55% lower. Colin Baker, *Would Prescription Drug Reimportation Reduce U.S. Drug Spending?*, CBO, Apr. 24, 2004, http://www.policyalmanac.org/health/archive/prescription_drug_reimportation.shtml. According to a Boston University School of Public Health study from October 2005, last year Americans paid 81% more than buyers in Canada and six western European countries. Sharon A. Treat, Executive Dir., Nat'l Legislative Ass'n on Prescription Drug Prices, Address at the National Conference of State Legislatures (NCSL) Annual Meeting, Filling in the Gaps: A Legislative Roundtable on State Prescription Drug Initiatives (Aug. 17, 2005), available at http://www.nlarx.org/present/docs/NCSL_Presentation8_17_05.ppt.

3. See Steven Reinberg, *Prescription Drug Prices Soaring Above Inflation*, HEALTHDAY REP., Apr. 12, 2005, <http://news.healingwell.com/index.php?p=news1&id=525089> (reporting most brand-name prescription drug prices increased at more than double the rate of inflation); see also Treat, *supra* note 2.

4. See, e.g., *Prescription Drugs: Right at Any Price?*, AARP RX WATCHDOG REP. (AARP, Washington, D.C.), Sept. 2004, at 2–4 [hereinafter *Prescription Drugs*].

5. Section 340B of the Public Health Service Act allows specific entities to pay less than the Medicaid net price for prescription drugs. Treat, *supra* note 2, at 28. In addition, these covered entities avoid dispensing fees and mark-ups that retail pharmacies charge. *Id.*

posting their clinical trials data.⁶ However, the pharmaceutical lobby (PhRMA) in the U.S. Congress remains strong. While states propose and pass various laws, no federal laws to dramatically impact drug pricing have gone into effect.⁷ The more high-profile solution to re-import drugs from other countries at lower prices via bussing and internet pharmacy remains illegal.⁸

Some state legislators have been trying a different tack, one that does not simply regulate, but that would fundamentally change the patent system. The tension between prices charged to consumers and property rights of patent holders is ever present. A few bills have been proposed that allow compulsory licensing of drugs by individual states.⁹ "Compulsory licensing is generally defined as the granting of a license by a government to a third party to use a patent without the authorization of the patent holder."¹⁰ Compulsory licensing has been used as a cost-cutting and access-assuring mechanism in many countries off and on for years.¹¹ This Comment will examine how it is used in

6. *Id.* at 13–14.

7. Although the law allowing re-importation of drugs passed again in 2003, it has not gone into effect because the Secretary of Health and Human Services (HHS) has not certified that safety and efficacy would not be compromised by re-importation. See Pharmaceutical Market Access Act of 2003, H.R. 2427, 108th Cong. (2003). The predominant view is that it is unlikely any Secretary will certify. Mark Moran, *Reimportation Law Won't End Furor Over Drug Prices*, 39 PSYCHIATRIC NEWS 7, 7 (2004).

8. See Michelle Meadows, *Imported Drugs Raise Safety Concerns*, FDA CONSUMER, Sept.–Oct. 2002, http://www.fda.gov/fdac/features/2002/502_import.html. There is also the question of whether a substantial number of consumers are even using internet pharmacies. See SUSANNAH FOX, PEW INTERNET & AMERICAN LIFE PROJECT, *PRESCRIPTION DRUGS ONLINE: ONE IN FOUR AMERICANS HAVE LOOKED ONLINE FOR DRUG INFORMATION, BUT FEW HAVE VENTURED INTO THE ONLINE DRUG MARKETPLACE* i–ii (2004), available at http://www.pewinternet.org/ppf/r/139/report_display.asp.

9. See Treat, *supra* note 2, at 19.

10. Grace K. Avedissian, 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, 243–44 (2002).

11. See CHRISTOPHER S. HARRISON, *THE POLITICS OF THE INTERNATIONAL PRICING OF PRESCRIPTION DRUGS* 168 (2004) (citing Canada as an example). Europe has a compulsory license provision to "protect the public health from the abuses of monopoly." See ESTES KEFAUVER, *IN A FEW HANDS: MONOPOLY POWER IN AMERICA* 233 (1965).

India and in what form it has been proposed in the United States.

India provides a useful example because it has many of the same issues of price and access to drugs as the United States, but, unlike the United States, its patent system contains a compulsory licensing provision. Although India's patent regime took effect in 1856,¹² India, just in the last year, increased its patent protection to be in line with that of the United States.¹³ As a compromise between the drug companies and the health organizations, India's legislation retains the compulsory licensing provision.¹⁴

The recent patent regime changes in India spotlight the constant tension on an international level between economic development and the idea of a right to health.¹⁵ This clash was arguably not only over patent rights but also between developed and developing nations.¹⁶ The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement tries to unify, perhaps artificially, countries around the world to establish basic ground rules for intellectual property rights in the modern global world.¹⁷ This tension was at the forefront of World Trade Organization (WTO) negotiations between countries leading up to India's adoption of the Amendments to the Patent Law Act of 1970 in 2005 (revised Act).¹⁸ Due to the current high prices of

12. See *infra* Part II.B.

13. See The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, available at <http://indiacode.nic.in/>.

14. See *infra* Part II.B.

15. Shubha Ghosh, *Pills, Patents, and Power: State Creation of Gray Markets as a Limit on Patent Rights*, 14 FLA. J. INT'L L. 217, 222–23 (2002).

16. Srividhya Ragavan, *Can't We All Get Along? The Case for a Workable Patent Model*, 35 ARIZ. ST. L.J. 117, 118–19 (2003). David Plank famously said that in mediation, one of the great truisms is that a problem is never what that problem is about, that is, in order to figure out what the real interests are, one must look beneath the surface. David Plank, *Judging Critique at the International Chamber of Commerce (ICC) International Mediation Competition Semi-Finals*, Paris, France (Jan. 16, 2006).

17. See Ragavan, *supra* note 16, at 118–19; World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights of 15 April 1994, LT/UR/A-1C/IP/1 (1994), available at <http://docsonline.wto.org> [hereinafter TRIPS].

18. See Ragavan, *supra* note 16, at 126–28. Some argue that one of the reasons the tensions were higher in these negotiations is because human and economic rights are more closely intertwined in developing countries than in the United States. See Ghosh,

prescription drugs in the United States, tension is also building between PhRMA and consumers.¹⁹ The U.S. consumer wants a less controlled market while manufacturers want exclusive control over their product in the market.²⁰

There is an inherent conflict between protecting patent rights and protecting a right to health (if such a right exists). In order to connect the two concepts, we need to find a concept that bridges the gap itself. Compulsory licensing is one way to alleviate the tension because it creates competition and “directly challeng[es] the exclusive rights granted to the patent owner.”²¹ Compulsory licensing has been effectively used in India and it is the contention of this Comment that it should be implemented in the United States in some form.

The second part of the Comment outlines the elements of India's compulsory licensing provision and provides a history of the revised Act. It discusses the United States' approach to compulsory licensing in the past. It then examines the recent proposals for compulsory licensing in the District of Columbia and Vermont. The third part analyzes India's pharmaceutical market and how it and the world market will be affected by the revised Act passed in 2005. The fourth part of the Comment evaluates the problems of the U.S. pharmaceutical market and determines what could be gained from a compulsory licensing provision. The Comment concludes with a recommendation to the United States using India's policy as a model.

II. RECENT PATENT LEGISLATION IN INDIA AND THE UNITED STATES

India and the United States have very different histories

supra note 15, at 254. In that sense, although the tensions between human and economic rights cannot be eliminated, the tensions between the United States and many third-world countries could be due to a mutual misunderstanding.

19. See *Prescription Drugs*, *supra* note 4, at 6–7.

20. See Ghosh, *supra* note 15, at 249.

21. *Id.* at 230. One cliché that comes to mind is that information wants to be free; so, there is an inherent conflict in giving patent rights. *Id.* at 228. Another example Ghosh gives of information freeing itself is in the gray markets of parallel trade. *Id.* The patent owner's ability to create a price differential creates incentive for the gray market to exist and take advantage of the price differential. *Id.* at 229.

with respect to prescription drugs and patent laws. The United States has recognized patents in one form or another since the 1790s.²² The pharmaceutical industry has been strong since the early 1900s.²³ In response to the exorbitant prices of prescription drugs, some legislators in the United States are now proposing compulsory licensing.²⁴ India's current industry and laws, however, are based largely on its law passed in 1970.²⁵ Unlike the United States, India has had a compulsory licensing provision in its system for almost as long as its system has been in place.²⁶ A closer look at the political history and provisions of India's revised Act and the political history and proposals in the United States can provide a helpful background with which to attack today's problems.

A. *International Agreements Leading to India's Revised Act*

The new Amendments to the Patent Act of 1970 have been the subject of much debate, from bloggers to legal scholars.²⁷ The resulting revised Act is the product of several international agreements.²⁸ Members of the WTO were under obligation to implement TRIPS provisions by 2000, 2005, or 2016, depending on the level of development of the member country.²⁹ India was given an extended period of time to bring its patent regime up to the standard—India's was implemented January 1, 2005.³⁰ The WTO had been working on implementing the TRIPS agreement

22. See United States Patent Act, ch. 7, 1 Stat. 109 (1790) ("An Act to promote the progress of useful Arts.").

23. See AM. CHEM. SOC'Y, *THE PHARMACEUTICAL CENTURY: TEN DECADES OF DRUG DISCOVERY* (2006) (on file with author).

24. See Treat, *supra* note 2, at 19.

25. See The Patents Act, 1970, No. 39, Acts of Parliament, 1970, available at <http://indiacode.nic.in/>.

26. See *id.* §§ 82–98.

27. See, e.g., J. Matthew Buchanan, Promote the Progress: Blogging Worldwide Patent Law and Policy, <http://www.promotetheprogress.com> (Oct. 22, 2005); Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L. L. 317, 320–22 (2005).

28. See Ragavan, *supra* note 16, at 142–48.

29. WTO.org, Intellectual Property: Protection and Enforcement, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Oct. 22, 2006).

30. See The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005.

since it was negotiated in the Uruguay Round of General Agreement on Tariffs and Trade (GATT) negotiations in 1988.³¹

In 2001, the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) clarified schedules and requirements of TRIPS for member countries.³² The Doha Declaration was a result of the Doha Ministerial Conference of the WTO meeting in Doha, Qatar, on November 14, 2001.³³ In paragraph six, the Doha Declaration expressly recognizes the difficulties countries with little or no manufacturing capabilities have in obtaining medicines.³⁴ This provision serves as an exemption clause for TRIPS to allow developing countries to obtain generic drugs in a health crisis.³⁵ Specifically, the Doha Declaration stipulates that, in Article 31(b) of TRIPS, compulsory licenses are available for commercial activity on reasonable terms and conditions.³⁶ The Doha Declaration fails in its goal to clarify the use of compulsory licensing because it still allows the Member States the right to determine what constitutes a “national emergency,” a term with vague meaning at best.³⁷ In September 2003, a Ministerial Conference meeting in Cancun, Mexico was necessary to further clarify the requirements for importation and exportation.³⁸

One problem that arises is that countries exporting the drug must supply most of the drug to their domestic market.³⁹ TRIPS Article 31(f) states that compulsory licenses “shall be authorized predominantly for the supply of the domestic market of the

31. B. K. Keayla, *Amended Patents Act: A Critique*, COMBAT L., June–July 2005, available at <http://www.indiatogether.org>.

32. See *id.*; WTO, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

33. Abbott, *supra* note 27, at 317.

34. *Id.* Paragraph six provided for more discussion on the issue. This led to the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, promulgated on August 30, 2003. *Id.*

35. Sarah Boseley, *Yusuf Hamied, Generic Drugs Boss*, GUARDIAN, Feb. 18, 2003, <http://www.guardian.co.uk/aids/story/0,,898056,00.html>.

36. Keayla, *supra* note 31.

37. Amit Gupta, *Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?*, 2 BUFF. INTEL. PROP. L.J. 127, 148–49 (2004).

38. *Id.* at 149–50; see *supra* note 34 and accompanying text.

39. See TRIPS, *supra* note 17, art. 31(f); Avedissian, *supra* note 10, at 265.

Member authorizing such use.”⁴⁰ This provision fails to recognize that the countries most in need of the drug are those without capacity to produce it.⁴¹ Fortunately, TRIPS Article 30 allows WTO members to export to a country that grants a compulsory license, allowing the importing country to not be completely dependent upon licenses from exporting countries.⁴² This is a blanket exception that allows deviation from the general rules.⁴³ Furthermore, the Doha Declaration states—albeit in vague language—that compulsory licenses should be implemented to support public health and to promote access to medicine.⁴⁴ Therefore, although TRIPS Article 31 could be interpreted to restrict which licenses are granted, TRIPS Article 30 and the Doha Declaration support a broader approach.⁴⁵

TRIPS Article 31 lays out the reasons for government compulsory licensing or government authorized third party licensing.⁴⁶ Specifically, four of the uses allowed are “(a) situations of national emergency or extreme urgency, (b) cases of public non-commercial use, (c) cases where there is a need to ‘correct anti-competitive practices,’ and (d) cases of dependent patents, where the exercise of one patent is dependent on the infringement of another.”⁴⁷ Prior attempted negotiations are implied requirements to obtain some of the licenses.⁴⁸

Like the requirement for previous negotiation attempts, TRIPS Article 31(h) also balances the need for the license with the rights of the patent holder. Article 31(h) is a remuneration provision⁴⁹ akin to “just compensation” in the takings context.

40. TRIPS, *supra* note 17, art. 31(f); Avedissian, *supra* note 10, at 264.

41. *See, e.g.*, Avedissian, *supra* note 10, at 266 (stating the poorer countries can only obtain medicines from countries with no patent protection).

42. *See* TRIPS, *supra* note 17, art. 30; Avedissian, *supra* note 10, at 268; *see* Gupta, *supra* note 37, at 142.

43. Gupta, *supra* note 37, at 140–41.

44. *See* Doha Declaration, *supra* note 32; Avedissian, *supra* note 10, at 268.

45. *See* Avedissian, *supra* note 10, at 267–69.

46. TRIPS, *supra* note 17, art. 31 (“including use by the government or third parties authorized by the government”).

47. Gupta, *supra* note 37, at 136l (citing TRIPS, *supra* note 17, art. 31(b), (k), & (l)) (citations omitted).

48. *Id.* at 136.

49. HOACHEN SUN, CTR. FOR INT’L DEV. AT HARVARD U., RESHAPING THE TRIPS

There is an inherent conflict between economic and social policy as expressed in international trade, treaties, and contracts.⁵⁰ TRIPS attempts to balance the interests of consumers and producers, for example, by allowing compulsory licensing.⁵¹ India attempts to balance interests in the same manner. However, TRIPS leaves ambiguity whether the country must declare a national health emergency to invoke it.⁵² In the shadow of these requirements and tensions, India passed its revised Act, effective January 1, 2005.⁵³

B. India's Compulsory Licensing Provision in the Revised Act

India's patent laws date back to 1856.⁵⁴ A compulsory licensing provision was added in the Patent Act of 1970—the first comprehensive patent rights regime—as a result of the need to procure medicines at a lower cost for the poor.⁵⁵ Some contend that countries like India use compulsory licensing benefits for the exporting country's commercial interests rather than simply in the name of public health.⁵⁶ Although India's market does profit from export, the government is ostensibly committed to the people's health interests.⁵⁷ India's National

AGREEMENT CONCERNING PUBLIC HEALTH—TWO CRITICAL ISSUES 14 (2002), <http://www.cid.harvard.edu/cidtrade/Papers/haochensun.pdf>.

50. See James Thuo Gathii, *Rights, Patents, Markets and the Global AIDS Pandemic*, 14 FLA. J. INT'L L. 261, 300 (2002).

51. *Id.* at 307. On the one hand, in May 2000, President Clinton ordered the United States Trade Representative (USTR) not to revoke any intellectual property laws or policies aimed at promoting access to AIDS medications even though they were not technically in compliance with TRIPS. *Id.* at 310. On the other hand, Gathii argues, and most agree that, the driving force behind TRIPS is the United States' and drug manufacturers' aim to maximize profit in the marketplace through stronger intellectual property rights. *Id.* at 308.

52. *Id.*

53. See The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005.

54. Ragavan, *supra* note 16, at 129.

55. See *id.* at 130–33.

56. Avedissian, *supra* note 10, at 247.

57. See Bruce Einhorn, *How India Could Export Drug Deflation*, BUSINESSWEEK ONLINE, Feb. 24, 2003, http://www.businessweek.com/technology/content/feb2003/tc20030224_5858_tc058.htm (discussing India's export growth). India allows the "manufacture and export of patented pharmaceutical products . . . to address public health problems . . ." The Patents Act, 1970, No. 39, Acts of Parliament, 1970, § 92A(1).

Pharmaceutical Pricing Authority (NPPA) was created in 1986 to control prices of a list of drugs, again to allow access to drugs to the poor.⁵⁸

The purpose of India's compulsory licensing provision is to provide anyone wishing to exploit a patent by obtaining a compulsory license if "a patent is not worked in India [for] three years after its grant"⁵⁹ In addition, two other circumstances must be present before the government will issue a compulsory license: "reasonable requirements of the public' are not satisfied" and "[the patented invention] is not available to the public at a 'reasonably affordable price'"⁶⁰

India's revised Act has many new provisions that will shape the country's pharmaceutical industry and those who deal with it. For this discussion, the revised Act's key provisions to strengthen the regime are: (1) the recognition of product patents, not just process patents; (2) a twenty-year term from the filing date of applications; and (3) the availability of patents for industrial application.⁶¹ To placate those concerned with access and price, the revised Act retains its compulsory licensing provision.⁶²

India's compulsory licensing provision is now more important than ever since India passed the revised Act. Part of the reason the Indian generic drug industry has grown is due to the lack of patent protection in India for products patented in other countries.⁶³ Indian drug manufacturers were able to capitalize on their ability to manufacture cheaper drugs.⁶⁴ India

58. Ragavan, *supra* note 16, at 133–34. Access to the poor is a real problem in India; in 1993, 37% of Indians were poor. *Id.* at 135. As the poverty numbers decreased so did the authority of the NPPA. *See id.*; *supra* note 25 and accompanying text; *infra* notes 153–55 and accompanying text.

59. Peter Nunn, *India Introduces Product Patents*, CHARLES RUSSELL, Apr. 1, 2005, <http://www.cr-law.co.uk/articles/viewarticle.asp?articleid=1038>.

60. *Id.*

61. *See* Jeffrey D. Hsi, *Patent Law in India Focuses Strongly on R & D*, 25 GENETIC ENG'G NEWS 9, 9–10 (2005).

62. *See id.* at 10.

63. Abbott, *supra* note 27, at 320.

64. *See, e.g., id.* (explaining how a country in Africa could import a low-priced generic version of a drug from an Indian producer).

needs to encourage the continued success of the generic drug industry by allowing compulsory licensing.

C. Patent Rights and Consumer Protection in the United States: Past Attitudes

This is not the first time Americans have complained about the high cost of prescription drugs in the United States.⁶⁵ The difference between now and forty years ago is simply that there are more consumers in the prescription drug market today.⁶⁶ Due to public outcry in the 1950s, Estes Kefauver led the Administrated Prices Hearings for the pharmaceutical industry from 1959–1962.⁶⁷ Kefauver's motive for setting up the Administered Prices Hearings was that only a few large companies in the industry were in control of the industry, causing prices to be "inordinately high."⁶⁸ Specifically in the pharmaceutical industry, two percent of U.S. pharmaceutical firms earned ninety percent of the two billion dollars in sales.⁶⁹ The drug companies earned an average twenty percent profit since 1957—more than any other industry; during the Depression, profits were thirty percent.⁷⁰ Not only was there

65. See HARRISON, *supra* note 11, at 47 (illustrating that the same issues of price, foreign prices, and prices relative to advertising costs exist today as they did when Kefauver ran the debate in 1959); see also Morton Mintz, *Still Hard to Swallow*, WASH. POST, Feb. 11, 2001, at B1 (noticing the same issues about the pharmaceutical industry that were examined by Kefauver, and suggesting that compulsory licensing should be put back on the legislative table to solve the problem).

66. This is also a main reason Medicare had no prescription drug provision when it was enacted in 1965. See Susan E. Cancelosi, *Revisiting Employer Prescription Drug Plans for Medicare-Eligible Retirees in the Medicare Part D Era*, 6 HOUS. J. HEALTH L. & POL'Y 85, 97 (2005).

67. Mintz, *supra* note 65; CHARLES L. FONTENAY, ESTES KEFAUVER: A BIOGRAPHY 362–63 (1980).

68. FONTENAY, *supra* note 67, at 383–84. In addition to the "inordinately high prices" and lack of competition, Kefauver worried about the safety of the drugs sold in the marketplace. *Id.* Notably, the safety provisions were the only ones that made it into law, not the price cutting provisions. See Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, 788 (1962).

69. FONTENAY, *supra* note 67, at 379.

70. KEFAUVER, *supra* note 11, at 40–41. This percentage has not changed significantly. See, e.g., MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 40–41 (2004) (describing high profit

little competition within the pharmaceutical industry, but sale prices of the same prescription drugs were much lower overseas.⁷¹ The years-long inquiry was speckled with testimony that “regularly toward the end of each month [social security patients] were faced with the stark alternative of choosing between food [and] medical treatment.”⁷²

Kefauver found several features that made the pharmaceutical industry structure exceptionally profitable and keep the industry profitable today.⁷³ Kefauver asserted that the structure of the patent system itself fostered imperfect competition.⁷⁴ He especially noted that government not only supports, but encourages market power through tariffs, patents, and tax breaks.⁷⁵ The long term of the patent encouraged physicians to keep prescribing the patented version of a drug that might have been available in generic and, therefore, cheaper form.⁷⁶ Small firms, the ones that should create competition by undercutting the price of the large pharmaceutical companies, were not able to break into the monopoly.⁷⁷

After several years of hearings, Kefauver proposed Senate

margins). *But see* Policy Council, Drug Pricing and Profits, <http://policycouncil.nationaljournal.com/EN/Forums/GlaxoSmithKline/e6290aa8-ec89-463a-bc12-5179946b5764.htm> (last visited Oct. 22, 2006) (stating that “profits of American pharmaceutical companies are comparable to those of companies in other major US industries,” although interestingly, this website is sponsored by GlaxoSmithKline, a leader in the pharmaceutical industry).

71. For example, in France, the same drug cost only 17% of the price in the United States. FONTENAY, *supra* note 67, at 379.

72. KEFAUVER, *supra* note 11, at 11.

73. First, the patient is a “captive consumer,” because the patient has no other option than to fill his prescription, whether it be a generic or patented. *See* E. Haavi Moreim, *Medicine Meets Resource Limits: Restructuring the Legal Standard of Care*, 59 U. PITT. L. REV. 1, 27 n.87 (1997). Second, although people think of the industry as regulated, the price charged is “predicated on what the traffic will bear.” KEFAUVER, *supra* note 11, at 16 (attributing the statement to Seymour Blackman, Executive Secretary for Premo Pharmaceutical Laboratories). Third, large pharmaceutical companies capture more of the market due to extensive advertising even when smaller companies can charge lower prices. *See id.* at 10.

74. *See id.* at 23–25.

75. FONTENAY, *supra* note 67, at 377.

76. KEFAUVER, *supra* note 11, at 24.

77. *Id.* at 191.

Bill 1552 on April 12, 1961, to solve the price problems as well as the safety concerns.⁷⁸ Kefauver's bill proposed to reduce the patent holder's exclusive control from seventeen to three years,⁷⁹ to require generic names on labels, to require federal licensing of drug firms—that is, the compulsory licensing provision—and to require a demonstration of the drugs' effectiveness and safety before they enter the market.⁸⁰ After the three year exclusivity period, Kefauver's bill required compulsory licensing from the patent holder upon the payment of a royalty up to eight percent of the total sales.⁸¹ Although Kefauver concluded that “there is no reason or justification for the excessive prices paid by Americans” for prescription drugs,⁸² the compulsory licensing and shortening of the patent protection was eliminated when the bill came up again in 1962 to make room for safety provisions.⁸³ Safety provisions have been as far as the United States has been willing to go to protect the consumer in the prescription drug market.

In the 1990s, the United States formed the Intellectual Property Committee (IPC) to make intellectual property rights protection a “central part of U.S. foreign trade policy” and to promote international minimum standards for intellectual property rights protection in the Uruguay Round of TRIPS.⁸⁴ The 1984 amendments to the U.S. Trade Act of 1974 had already authorized the President to “consider the adequacy of intellectual property protection in deciding whether a developing

78. Julia A. Grow, *The Legislative History of the 1962 Drug Amendments: A Failure to Forget or A Lesson to Learn From?*, (May 1, 1997), <http://leda.law.harvard.edu/leda/data/189/jgrow.pdf#search=%22%22april%2012%2C%201961%22%20kefauver%22>.

79. In 1961, a patent was only valid for seventeen years, instead of twenty. *See* 35 U.S.C. § 154(a)(2) (2002) (amended in 1994 to change seventeen years to twenty years).

80. FONTENAY, *supra* note 67, at 384.

81. KEFAUVER, *supra* note 11, at 24.

82. FONTENAY, *supra* note 67, at 391.

83. *Id.* at 385. The Patents Subcommittee took out the provisions affecting patent life in the spring of 1962. *See id.* at 384–85. President Kennedy had initially supported Kefauver's efforts, but his administration was only prepared to fully support the drug safety portion of Kefauver's bill; so, the price cutting mechanisms hit the cutting room floor. *See id.* at 385.

84. Gathii, *supra* note 50, at 313.

country should be granted tariff preferences under the United States Generalized System of Preferences.⁸⁵ In 1988, the Trade Act of 1974 was amended by Special 301, which identified countries with different intellectual property practices and allowed the USTR to investigate whether or not these policies violated trade agreements or were unreasonable.⁸⁶ India was one of the first countries to be on the Priority Watch List.⁸⁷ India subsequently agreed at TRIPS to bring its country's laws in line with the unilateralist U.S. position.⁸⁸

Since the Doha Declaration, the United States has continued to pursue an inflexible course to strengthen patent rights. Tom Allen, an advocate for lower prescription drug prices and better access to generics, argued in a 2002 speech that the United States' aim is to eliminate the rest of the world's ability to use compulsory licensing to access affordable medicines.⁸⁹ Allen points out that at the Cancun Ministerial Conference,⁹⁰ "the [USTR] proposed to limit compulsory licensing only to those diseases specifically mentioned in the [Doha Declaration], . . . only to those developing countries without manufacturing capacity, . . . [and, finally,] only to government or other non-commercial actors."⁹¹ By limiting compulsory licensing, drug

85. *Id.* at 315–16.

86. *Id.* at 316 (citing Trade and Tariff Act of 1984, Pub. L. No. 98-573, § 501, 98 Stat. 3001–3002 (1984) (codified as amended at 19 U.S.C. §§ 2461–2465 (2001))).

87. *Id.*

88. *Id.* at 316–17 (discussing the emerging tendency towards U.S. unilateralism and describing how the United States singled out countries like India, who opposed the TRIPS agreement for punitive action unless it complied with U.S. law and agreed to TRIPS).

89. Tom Allen, U.S. Rep., Address to the International Generic Pharmaceutical Association: Access and Innovation: Restoring Balance in U.S. Trade Policy (Apr. 11, 2002). Allen, representing the First District of Maine, advocates "assuring timely access of generics" by cosponsoring the McCain-Schumer-Brown Bill. *Id.* That bill does not use compulsory licensing, but its stated purpose is to "protect Medicare beneficiaries from discriminatory pricing by drug manufacturers." Prescription Drug Fairness for Seniors Act of 1999, H.R. 664, 106th Cong. § 2(b) (1st Sess. 1999). This bill, only dealing with Medicare beneficiaries, recognizes the need for lower prices to "significantly improve the health and well-being of older Americans and lower the costs to the Federal taxpayer of the Medicare Program." *Id.* § 2(a)(6).

90. *See supra* Part II.A.

91. Allen, *supra* note 89. In 2001, the Doha Declaration clearly demonstrated that

companies would have stronger patents with more probability of profit. Eliminating compulsory licensing would eliminate the risk of only obtaining a small royalty on the product.

Although the United States did not achieve its strict interpretation of the Doha Declaration,⁹² it has since engaged in bilateral and regional trade deals with intellectual property provisions that restrict TRIPS and the Doha Declaration.⁹³ For example, in several countries, registration of the product in the importing country by the patent holder is now necessary in order for the generic product to be manufactured or imported there.⁹⁴ This places the importing country at the mercy of the patent holder, goes against the spirit of TRIPS agreement, and prevents the practical use of compulsory licensing.⁹⁵

One of the United States' ideas—increasing transparency—was incorporated into the global agreements.⁹⁶ This incorporation was to force countries to be up front and jump through one more hoop before giving the license.⁹⁷ Ironically, this provision only highlights the lack of transparency in the U.S. pharmaceutical market.⁹⁸ It is hard to figure out an objective price for any prescription drug, and the pharmaceutical industry's numbers for research and development are shrouded

poorer countries depended on compulsory licensing to access drugs, and affluent countries like the United States supported the drug manufacturers who wanted stronger intellectual property rights. *See id.*

92. Abbott, *supra* note 27, at 348–49 (describing how the United States had to “ultimately . . . accept a result that it had not preferred” in the face of a consensus among developing nations).

93. *Id.* at 349–50.

94. *Id.* at 351 (listing Australia as an example).

95. *Id.*

96. *Id.* at 345. Importing and exporting countries must give notice to the TRIPS Council that they will import or export using compulsory licenses. *Id.*

97. Chakravarthi Raghavan, *Draft Declaration Work to be Moved Forward, Ignoring Objections*, THIRD WORLD NETWORK, Oct. 3, 2001, <http://www.twinside.org.sg/title/moved.htm>.

98. While the United States was in favor of this transparency provision, pharmaceutical companies were reluctant to reveal the real figures on spending and pricing, marketing and R & D costs. *See* Kathleen M. Sanzo & Stephen P. Mahinka, *US Pharmaceutical Pricing: System Changes and Global Effects* (Aug. 1, 2001), http://www.morganlewis.com/pubs/0DD7F699-C48C-4264-9AAC61BF81A42AE9_Publication.pdf.

in numbers for marketing and advertising instead of clearly separate figures.⁹⁹

D. Current Compulsory Licensing Proposals in the United States

Bills that incorporate compulsory licensing have been proposed in the District of Columbia and Vermont.¹⁰⁰ The National Legislative Association on Prescription Drug Prices (NLARx) has launched a campaign to incorporate its Model State Legislation on Pharmaceutical Eminent Domain in all the states of the Union.¹⁰¹

The authority for states to compel licensing of patents to generic manufacturers comes from two sources.¹⁰² Professor Kevin Outterson, a key proponent of the compulsory licensing movement, argues that states can extend eminent domain to intellectual property, and that the Supreme Court opinion *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*,¹⁰³ held the state's infringement of a patent for a public purpose is not itself unconstitutional, so long as the state gives compensation.¹⁰⁴ Such compensation would satisfy the Due Process Clause requirements.¹⁰⁵ Therefore, Outterson argues, there is nothing stopping all the states from passing compulsory licensing statutes.¹⁰⁶

The District of Columbia bill allows its mayor to issue a compulsory license to a generic manufacturer in a "health

99. See *infra* Part IV.A (discussing costs).

100. See Barbara Dreyfuss, *Patents Pending*, NAT'L LEGISLATIVE ASSOC. ON PRESCRIPTION DRUG PRICES, Feb. 23, 2005, <http://www.nlarx.org/policy/pages/dreyfusspatents.html>.

101. See generally NLARx Home Page, <http://www.nlarx.org> (last visited Oct. 22, 2006). NLARx and its website are devoted to lowering prescription drug pricing through any type of legislation.

102. Dreyfuss, *supra* note 100.

103. 527 U.S. 627, 643 (1999).

104. Dreyfuss, *supra* note 100.

105. See Kevin Outterson, Presentation to the National Legislative Association on Prescription Drug Prices: States May Reduce Drug Prices with an Eminent Domain Process for Pharmaceutical Patents (Oct. 5, 2005), <http://www.nlarx.org/present/modelstate%20pharm%20emin%20domain%20present.html>.

106. See *id.*

emergency,”¹⁰⁷ that is, the “public health and safety of the residents . . . would be served.”¹⁰⁸ It provides substantive and procedural due process assurances in the form of just compensation and default royalties of four percent, as well as notice, a hearing, and a promptly issued opinion.¹⁰⁹ The bill was proposed by Councilman David Catania on February 1, 2005.¹¹⁰ Unfortunately for Catania, it seems he actually believes his ultimate goal of discounted drugs can be achieved through proposing enough legislation to scare the industry into action.¹¹¹ He perceives that drug companies would rather negotiate prices than involve themselves in “long, drawn-out due process review and hearings.”¹¹² However, drug companies go through these investigations every so often and are always happy to do so instead of lowering prices.¹¹³ Furthermore, the large amount of litigation over patent infringement just to profit from one more year under patent exclusivity¹¹⁴ demonstrates the lengths to which drug companies will go rather than allow prices to fall. Companies also secure patent exclusivity for new formulations of the same drug in order to stall generic competition and price reductions.¹¹⁵

Catania was encouraged by the pharmaceutical reaction to the Cipro emergency in 2001.¹¹⁶ In that case, Bayer Corporation lowered its prices dramatically in response to Secretary of HHS

107. Dreyfuss, *supra* note 100.

108. Prescription Drug Manufacture License Act of 2005, B. 16-0114, Council Pd. 16 § 2(a) (D.C. 2005).

109. *Id.* §§ 2(b)(3), 3(a)–3(c).

110. Dreyfuss, *supra* note 100. The D.C. bill is supported by the NLRx. *Id.* Although the bill was originally a compulsory licensing bill, it was since amended to be a price-gouging bill instead. *Id.*

111. *See id.*

112. *See id.*

113. Mintz, *supra* note 65 (listing 1959 hearings led by Kefauver and a series of inquiries in 1967–77 led by Benjamin Gordon).

114. *See* Melissa Ganz, *The Medicare Prescription Drug, Improvement, & Modernization Act of 2003: Are We Playing the Lottery with Healthcare Reform?*, 2004 DUKE L. & TECH. REV. 11 (2004).

115. NAT'L INST. FOR HEALTH CARE MGMT RES. & EDUC. FOUND. (NIHCM), *PRESCRIPTION DRUGS AND MASS MEDIA ADVERTISING*, 2000 5 (2001) [hereinafter NIHCM].

116. *See* Dreyfuss, *supra* note 100.

Tommy Thompson's threat to allow generic manufacturers to make Cipro.¹¹⁷ Executive threat is simply not a solution, however. Senator Kefauver came to the same conclusion in 1962 that threatening pharmaceutical companies was not enough—it was too ad hoc—and the real solution lies in changing the system.¹¹⁸

In response to the Cipro crisis and Anthrax scare, two bills were introduced giving authority for the Secretary of HHS to grant compulsory licenses in specific circumstances, namely public health emergencies.¹¹⁹ The bills never passed out of committee.¹²⁰

The suggested Model State Pharmaceutical Eminent Domain Act provides a template for every state to propose compulsory licensing legislation.¹²¹ The Act allows the state official to declare licensure in the name of public health and safety of the residents of the state.¹²² It ensures that notice is given, a hearing is held, and an opinion is issued on whether the goal of public health and safety of the state residents would be improved.¹²³ These requirements fulfill procedural due process requirements. The license must be purchased, and the patent holder must be given a default rate of four percent royalty on the patent, which satisfies substantive due process requirements.¹²⁴ The Act also provides for cooperation between the states.¹²⁵

117. *Id.*

118. KEFAUVER, *supra* note 11, at 204–05.

119. Avedissian, *supra* note 10, at 261–62. The bills referred to are House Bill 1708 and House Bill 3235, both introduced in 2001. *Id.* at 261. Both believed the threat of compulsory licensing would compel manufacturers to lower drug prices. *Id.* at 262.

120. See GovTrack.us, H.R. 1708[107]: Affordable Prescription Drugs and Medical Inventions Act, <http://www.govtrack.us/congress/bill.xpd?bill=h107-1708> (last visited Oct. 22, 2006) (noting that Affordable Prescription Drugs and Medical Inventions Act, H.R. Res. 1708, 107th Cong. (2001) “never became law”); GovTrack.us, H.R. 3235[107]: Public Health Emergency Medicines Act, <http://www.govtrack.us/congress/bill.xpd?bill=h107-3235> (last visited Oct. 22, 2006) (noting that Public Health Emergency Medicines Act, H.R. Res. 3235, 107th Cong. (2001) also “never became law”).

121. NLARx, Model Act Pharmaceutical Eminent Domain Act, <http://www.nlarx.org/present/modelpharmEDbill.html> (last visited Oct. 22, 2005).

122. *Id.* § 2(a).

123. *Id.* § 2(b)–2(c).

124. *Id.* § 2(a)(ii).

125. *Id.* § 3.

The Vermont legislature looked at a bill similar to that of D.C. and the Model Act called Senate Bill 162.¹²⁶ The bill's purpose was to allow the state to exercise eminent domain in order to offer residents pharmaceutical drugs at lower prices.¹²⁷ The bill allows Vermont to "lower pharmaceutical prices for specific drugs needed for use by the state. . . . [The bill] could also be used by Vermont as an important economic development strategy."¹²⁸ The reasons the bill gives for approving the "declaration of necessity" include prohibitive price, comparatively high price, or a determination that the drug is essential for maintaining health or life.¹²⁹ Like the Model Act, the default royalty rate is four percent,¹³⁰ the same procedural due process assurances are given,¹³¹ and provisions for coordinating with other states exist.¹³² In addition, the bill prohibits anything in it from acting as a waiver of the state's sovereign immunity against claims of patent infringement, as was upheld in *Florida Prepaid*.¹³³

III. THE INDIAN PHARMACEUTICAL MARKET

Both developed and undeveloped nations see the outcome of India's revised Act as crucial for their interests.¹³⁴ Third-world countries are dependent on Indian generic drug manufacturers to supply them with vital medicines, like AIDS treatments for cheaper prices.¹³⁵ "[A]pproximately 70% of all patients currently

126. S.B. 162, 68th Biennial Sess. (Vt. 2005).

127. *See id.*

128. *Id.* § 1(D).

129. *Id.* § 2 (amending section 4801(b)(1) of title 18 of Vermont's Annotated Statutes).

130. *Id.* § 2 (amending section 4801(b)(3)).

131. *See id.* § 2 (amending section 4801(c)–4801(e)).

132. *Id.* § 2 (amending section 4804).

133. *Id.* § 2 (amending section 4805); *see Fla. Prepaid*, 527 U.S. at 642–43.

134. *See Prognosis: Short-term Relief, Long-term Pain: The Future of Generic Medicines Made in India*, DOCTORS WITHOUT BORDERS, Apr. 25, 2005, <http://www.doctorswithoutborders.org/publications/ideas/indiapatents2005.cfm> [hereinafter *Prognosis*]; *see Abbott, supra* note 27, at 349–50 (describing the United States' efforts to restrict the TRIPS Agreement and strengthen patent regimes as much as possible in developing nations).

135. *Prognosis, supra* note 134.

take generic [antiretroviral] ARV medicines [that are] made in India.”¹³⁶

On the other hand, multinational corporations such as Ranbaxy, the largest Indian drug manufacturer, have a strong interest in promoting longer patents.¹³⁷ Ranbaxy’s newsletter describes the new patent regime with the title “New Patent Regime: New Opportunities.”¹³⁸ Mr. Ramesh Adige, Whole-time Director, Corporate Affairs & Global Corporate Communications of Ranbaxy, writes, “A stronger Patent [sic] regime will attract opportunities in every area: discovery, process R & D, custom synthesis & [sic] contract manufacturing and clinical research.”¹³⁹

As a result of these competing interests between manufacturers and impoverished nations, the revised Act has provisions, according to the Indian Commerce Minister Kamal Nath, to “balanc[e] and calibrat[e] intellectual property protection with public health concerns and national security.”¹⁴⁰

A. Access and Administrative Struggles

The rapid enforcement of TRIPS could be one reason there are so many problems and tensions.¹⁴¹ The Patent Office was inundated with requests¹⁴² filed since India agreed to comply

136. *Id.*

137. *See New Patent Regime: New Opportunities*, BUILDING BLOCKS FOR THE FUTURE, (Ranbaxy Laboratories, Ltd., India) Aug. 2005, at 18, available at http://www.ranbaxy.com/newsroom/rworld_aug05/rworld_2005.pdf.

138. *Id.*

139. *Id.*

140. *Ordinance Introduces Product Patent Protection*, INDIA REVIEW, Feb. 1, 2005, at 10, available at http://www.indianembassy.org/India_Review/2005/Feb2005.pdf [hereinafter *Ordinance*].

141. *See* Ragavan, *supra* note 16, at 149–50. While the United States, for example, has had patent regimes in place for centuries, developing countries have not. *Id.* To enforce such a regime in the span of ten to fifteen years forces the country to change at a rate that does not allow for growth of proper sectors in time. *See id.* TRIPS has forced countries to proceed without the necessary technology in place. *See id.* at 150. Furthermore, the secondary effects on developing countries that lack infrastructure are potentially severe. *See id.* Ragavan writes, “[A] product patent regime cannot be blindly introduced unless there is an adequate understanding of the nuances.” *Id.* at 156–57.

142. By the close of 2004, just before the revised Act was implemented, the patent offices had received around nine thousand applications for general patents since 1995—

with TRIPS; these requests are part of the “mailbox” provision that allows applications filed before January 1, 2005 to take retroactive effect.¹⁴³ One estimate is that only thirty percent of Indians had access to medication before the revised Act was passed.¹⁴⁴ Furthermore, with the advent of the new patent protection, this thirty percent will have less access to medicines.¹⁴⁵ Due to the revised Act, generic drug costs will go up regardless of whether they are even allowed to be manufactured.¹⁴⁶ The revised Act provides that all companies “producing generic versions of drugs for which patent applications were submitted [after] the signing of the WTO agreement in 1995 . . . will be allowed to continue doing so only if they pay a ‘reasonable’ royalty to the patent holder.”¹⁴⁷

B. Poised Manufacturers and Potential Consumers

India fortunately has over twenty thousand licensed pharmaceutical manufacturers and “has emerged as a world leader in the production of several bulk drugs.”¹⁴⁸ With so many manufacturers, India is poised to take on new ventures and investment. Furthermore, more Indian manufacturers want to take advantage of patent protection in the booming biotech area.¹⁴⁹

There is an enormous potential market in India for pharmaceuticals, as the Organisation of Pharmaceutical

when India agreed to strengthen its property rights. Narayan Kulkarni, *Bio Pharma*, BIOSPECTRUM, Feb. 11, 2005, <http://www.biospectrumindia.com/content/features/pharma/10502111.asp>; see also Frederick M. Abbott et al., *The Draft Patent Law*, HINDU, Mar. 12, 2005, <http://www.hindu.com/2005/03/12/stories/2005031201151000.htm>. It will take two to three years to wade through the applications. Kulkarni, *supra*.

143. Abbott et al., *supra* note 142 (stating that due to the mailbox provision prices will likely rise); see *infra* Part III.D.

144. Ragavan, *supra* note 16, at 158.

145. *Id.*

146. Kranti Kumara, *India Adopts WTO Patent Law with Left Front Support*, WORLD SOCIALIST WEB SITE, Apr. 16, 2005, <http://www.wsws.org/articles/2005/apr2005/indi-a16.shtml>.

147. *Id.*

148. Ragavan, *supra* note 16, at 159.

149. See Kulkarni, *supra* note 142.

Producers of India (OPPI) has astutely realized.¹⁵⁰ While U.S. companies are spending at least twenty percent of gross revenues on R & D expenditure¹⁵¹—claiming the high cost as a reason for charging high prices—Indian companies are spending on average four to six percent on R & D.¹⁵² Only ten percent of the population has health insurance.¹⁵³ India contains sixteen percent of the world's population, yet has only one percent of the world's healthcare investment.¹⁵⁴ Furthermore, the per capita expenditure on medicines is only \$4.¹⁵⁵ The Organisation of Pharmaceutical Producers in India forecasts that an enormous market—three hundred million middle class persons—will begin using medicines in the years to come due to increased literacy and access to medicines.¹⁵⁶

150. See OPPI's Position on Trade Related Aspects of Intellectual Property Rights (TRIPS), <http://www.indiaoppi.com/pharmindia.htm> (last visited Oct. 22, 2006) [hereinafter Position on Trade Aspects].

151. Research and Development in the Pharmaceutical Industry, A CBO STUDY (Cong. Budget Office, Washington, D.C.), Oct. 2006, at 8.

152. OPPI Fact Sheet 2003 (2003), <http://web.archive.org/web/20041022182401/www.indiaoppi.com/keystat.htm> (last visited Oct. 22, 2006) [hereinafter 2003 Fact Sheet]. This could be because the generic market in India traditionally has been much larger than the research oriented pharmaceutical companies. See IndiaOPPI.com, Intellectual Property Rights, <http://www.indiaoppi.com/intelprop.htm> (last visited Oct. 22, 2006) [hereinafter Intellectual Property Rights]. Cipla, primarily a generic drug manufacturer, was the number one drug company in India in 2004. 2003 Fact Sheet, *supra*. In the past, India has been best known for exporting generic drugs to other third-world countries, not for patenting drugs. See Ghosh, *supra* note 15, at 248 n.114.

153. WHO, REGIONAL OVERVIEW OF SOCIAL HEALTH INSURANCE IN SOUTH-EAST ASIA 82 (2004), available at http://www.searo.who.int/LinkFiles/Social_Health_Insurance_HSD-274.pdf.

154. *Id.* at 80; 2003 Fact Sheet, *supra* note 152.

155. 2003 Fact Sheet, *supra* note 152. In contrast, U.S. citizens spent \$5,267 per capita for health care in 2002. Gerard F. Anderson et al., *Health Spending in the United States and the Rest of the Industrialized World; Examining the Impact of Waiting Lists and Litigation Reveals No Significant Effects on the U.S. Health Spending Differential*, 24 HEALTH AFF. 903, 904 (2005). Although these numbers evaluate slightly different things, the U.S. figure is still 53% greater than any other country. *Id.* Anderson's team argues the two main reasons are higher prices and higher incomes in the United States. *Id.*

156. See REED EXHIBITIONS, A GUIDE TO DOING BUSINESS IN THE PHARMACEUTICAL INDUSTRY IN INDIA 2 (2004), <http://www.myworldofexpo.com/interphex/ThePharmaceuticalIndustryinIndia.pdf>.

C. *International Respect*

Increased patent protection and stricter regulations may increase foreign investment.¹⁵⁷ By promoting a respectable image, foreign investors will see India as more of a solid opportunity instead of a risk-filled one. Concern about counterfeit drug production has been on the rise throughout the world.¹⁵⁸ The World Health Organization (WHO) reports that “developing countries bear the brunt of the problem,” and “[p]overty, and the lack of an official supply chain, are major factors in creating markets for counterfeit products.”¹⁵⁹ A recent case traced the production back to India, where two ex-Johnson & Johnson employees had started their own business producing fake surgical mesh.¹⁶⁰ By bringing India’s third-world patent system into line with the Western world, India will gain positive attention and legitimacy.

D. *Compulsory Licensing Effects on the Indian Pharmaceutical Market*

Many maintain that the compulsory licensing provision India enacted effectively has no teeth.¹⁶¹ The Act allows a challenge to the patent application, but the challenging process itself is very slow.¹⁶² This, many are worried, will tie up the licenses for years before they can be used to save lives in other

157. “The biotechnology industry is witnessing a rapid growth in investment” due to better infrastructure and increasing support from government. Editorial, *Scaling New Heights*, EXPRESS PHARMA, Feb. 15, 2006, <http://www.expresspharmaonline.com/20060215/bioasia2006special01.shtml> [hereinafter *Scaling New Heights*].

158. B.R. Kirupakar, *Countering Counterfeits*, EXPRESS PHARMA, Feb. 15, 2006, <http://www.expresspharmapulse.com/20060215/management04.shtml> (“According to a World Health Organization (WHO) report, counterfeit drugs increased by 400 percent [sic] during the 1990s. According to the FDA, counterfeits account for 10 percent [sic] of the global market.”).

159. WHO Fact Sheet No. 275, *Counterfeit Medicines*, Feb. 2006, <http://www.who.int/mediacentre/factsheets/fs275/en/index.html>.

160. Jan Sliva, *Counterfeit Drugs Deemed Threat in Europe*, ABC NEWS, Sept. 22, 2005, <http://www.sfgate.com/cgi-bin/article.cgi?file=/n/a/2005/09/22/international/i060651D47.DTL&type=printable>.

161. See *India/Africa: Threat to Generic Drugs*, AFRICAFOCUS BULL., Mar. 7, 2005, <http://www.africafocus.org/docs05/ind0503.php>.

162. *Id.*

countries as well as in India.¹⁶³ Additionally, compulsory licensing terms are vague, making it more difficult to use the provision.¹⁶⁴

With fewer compulsory licenses and fewer generic medicines available, many fear the price of drugs will rise.¹⁶⁵ Generic medicines have reduced the prices of antiretrovirals (ARVs) by 98%, and Indian companies have been crucial in that effort.¹⁶⁶ Dr. Yusuf Hamied, Chairman and Managing Director of Cipla, the largest Indian generic drug producer, announced at an AIDS meeting in September 2000 that he would sell ARVs at less than one-tenth the price of other drug companies.¹⁶⁷ This move helped bring brand-name companies' prices down.¹⁶⁸ Therefore, an increase in price potentially would be detrimental to countries counting on low prices for treatments like ARVs.

Another potential problem with the compulsory licensing law is that it restricts the export of medicines to countries where they are patented.¹⁶⁹ This excludes a large portion of the population from gaining access to the drugs. Dr. Hamied has stated that even though countries have the ability to use compulsory licensing, they are not doing so.¹⁷⁰ While Cipla's price is greatly reduced from that of the brand-name drug manufacturers' price, it is still not reduced enough to reach the poorest nations.¹⁷¹ The requirements for importing or exporting also make it difficult to use and perhaps cost prohibitive; even Canada had to import most of its drugs supplied by compulsory license.¹⁷² The import/export process is purposefully legally

163. Editorial, *AIDS Drugs Threatened*, N.Y. TIMES, Mar. 5, 2005, at A12. "Despite huge potential, complications and overlap in regulations [in the approval process and intellectual property rights arena] are major roadblocks." *Scaling New Heights*, *supra* note 157.

164. See *supra* Part II.A (discussing the difficulty of understanding the meaning of TRIPS and Doha Declaration language).

165. See *India/Africa: Threat to Generic Drugs*, *supra* note 161.

166. *Id.*

167. Boseley, *supra* note 35.

168. *Id.*

169. See *supra* Part II.A (discussing restrictions on exports).

170. See Boseley, *supra* note 35.

171. See *id.*

172. Gupta, *supra* note 37, at 138.

cumbersome; two compulsory licenses are necessary in most circumstances, and the WTO can question the grant of such licenses.¹⁷³

Many are worried that the revised Act will adversely affect the rest of the third world.¹⁷⁴ Especially in Africa, one single virus can wreak havoc on the economy.¹⁷⁵ Those concerned about access to medicines for the Third World name public health as the total welfare goal.¹⁷⁶ With this in mind, the revised Act's restrictions on compulsory licensing allow that goal to be tossed aside. The Doha Declaration does allow public health to be the number one concern,¹⁷⁷ but the Indian Parliament, in enacting the revised Act, pits R & D and business concerns against public health.

The technology gap between developing and Western countries is historically wide,¹⁷⁸ but the increase in patent protection in developing countries partially closes this gap. Developing countries have been dependent on Western economies and technologies for much of the twentieth century.¹⁷⁹ Because producers in Western countries have gained from having property rights, they have more incentive to produce.¹⁸⁰ New, stronger property rights have given the India Contract Research Organization (CRO) sector a boost as well.¹⁸¹ One, albeit optimistic, estimate is that the sector will triple in the

173. *Id.* at 150–51.

174. *See India/Africa: Threat to Generic Drugs, supra* note 161.

175. Boseley, *supra* note 35.

176. *See* WHO, INTERNATIONAL CONFERENCE ON PRIMARY HEALTH CARE, ALMA-ATA: TWENTY-FIFTH ANNIVERSARY PROVISIONAL 1 (Apr. 23, 2003), http://www.who.int/chronic_conditions/primary_health_care/en/wha56_27_eng.pdf.

177. *See* Doha Declaration, *supra* note 32; *see also supra* Part II.A (discussing the Doha Declaration and public health concerns).

178. J. Bradford DeLong, *Slouching Towards Utopia?: The Economic History of the Twentieth Century* (1997), http://www.j-bradford-delong.net/TCEH/Slouch_divergence5.html (last visited Oct. 22, 2006).

179. Gathii, *supra* note 50, at 276.

180. *See id.* at 307. Of course, the Western countries probably still want countries like India to be dependent on Western technology, placing them in a bit of a Catch-22.

181. Deepali Gupta, *Cracking the Clinical Research Market*, EXPRESS PHARMA, Feb. 15, 2006, <http://www.expresspharmaonline.com/20060215/market01.shtml> (“To the credit of the government, the TRIPs agreement protects organisations from patent infringement, and that has further aided the boost to the Indian CRO sector.”).

next five years.¹⁸² As the major drug pipeline slows, the CROs are poised to step in and help manufacture “me-too” drugs and promote more clinical research.¹⁸³ The challenge for that sector will be to keep its costs low enough to attract customers while also improving quality.¹⁸⁴ The Indian government recognizes the need to support industry—for example, the Department of Biotechnology will spend as much as 25% of their budget on spurring innovation in the small and medium-sized research industry.¹⁸⁵

The potential problem is that the TRIPS remuneration provision uses the cost of bringing the drug to market as a basis for calculating the remuneration.¹⁸⁶ This assessment should factor in the additional cost of stringent requirements by the patent owners to obtain a compulsory license for the developing country.¹⁸⁷

Blogger J. Matthew Buchanan, patent attorney in the United States, goes even further and sees the compulsory licensing provision as a direct threat to the integrity of the new patent provisions in India.¹⁸⁸ He cites the vague language allowing compulsory licensing and the fact that India already has a compulsory licensing provision in case a patent has not been “worked” in India as problems.¹⁸⁹ He argues the existing

182. *Id.*

183. *Id.*

184. *Id.* (discussing how “CROs have to tread the fine line of maintaining low cost and high quality”).

185. Sapna Dogra, *The Present System is Not Sufficiently Innovative*, EXPRESS PHARMA, Feb. 15, 2006, <http://www.expresspharmaonline.com/20060215/bioasia2006special02.shtml> (interviewing Dr. M.K. Bhan, India’s Secretary of the Department of Biotechnology, and discussing the potential and the need for innovation in India’s biotech industry as well as the new government partnership with the private sector).

186. See Jean O. Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: “Heartless Exploitation of the Poor and Suffering”?*, 4 (Yale U. & the NBER, Paper No. 6366, 1999), available at <http://www.oiprc.ox.ac.uk/JLWP0799.pdf>.

187. See Gathii, *supra* note 50, at 307.

188. J. Matthew Buchanan, *Pharmaceutical Patents in India – New and Old Compulsory License Provisions Cast Doubt on Their Value*, PROMOTE THE PROGRESS, Sept. 7, 2005, <http://promotetheprogress.com/archives/2005/09/pharmaceutical.html>.

189. *Id.*

provision was enough and the recent changes allow too much room for the provision's use.¹⁹⁰

One of the provisions to the revised Act is that both product patent and process patent applications are now accepted in India.¹⁹¹ Some are concerned that India's pharmaceutical market will follow the U.S. market and become overrun with patents for new dosages and new usages rather than new drugs.¹⁹² The opportunity to gain patent protection for a product could "discourage generic companies from trying to develop a competitive product" because that market would be saturated with copycats.¹⁹³ An already saturated generic market would not bring down prices.

The mailbox provision could have huge price implications due to the volume of patent applications collected in the past ten years.¹⁹⁴ Some generic drugs might not be available if old medicines receive patents, but most believe the Indian Controller of Patents will take a conservative approach to granting patents.¹⁹⁵ With India competing more with developed nations in the development of medicines for patent control, other developing nations without a patent regime could face a tougher battle to obtain medicines.¹⁹⁶ Abbott states that the availability of compulsory licensing, which has been in place since the system's inception, "has not undermined the system" and should be kept.¹⁹⁷

On the one hand, access remains a problem in India even

190. *See id.*

191. *Id.*

192. *See, e.g., id.* The CRO industry in India is poised for just such a development. *See supra* note 184 and accompanying text.

193. NAT'L INST. FOR HEALTH CARE MGMT. RES. & EDUC. FOUND., CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION 16 (2002), available at <http://www.nihcm.org/finalweb/innovations.pdf>. *But see supra* Part III.B (discussing the potential market for pharmaceuticals in India).

194. *See Abbott, supra* note 27, at 321.

195. *See id.* at 322. *But see* Intellectual Property Rights, *supra* note 152 (stating the mailbox provision will not have a large negative impact).

196. *See Abbott, supra* note 27, at 323–24.

197. *Id.* at 326. Abbott clarifies that there was never any doubt that the compulsory licensing provision would remain in the TRIPS Agreement, just doubt as to how it could be implemented. *See id.*

when low prices exist. Union Minister for Science and Technology in India, Kapil Sibal, contends that “[e]ven with over 10,000 manufacturers producing millions of doses of essential drugs at the lowest prices in the world for the last several years, access continues to remain abysmally low at about 35 per cent [sic].”¹⁹⁸ This, unfortunately, means that even while Indian manufacturers have the capability to use compulsory licensing and produce cheaper medicines, affordability does not solve the greatest problem in India: access. Compulsory licensing is likewise a balance between greater access to medicine and the insistence on intellectual property rights protection as promoted, to a large extent, by the United States.¹⁹⁹

On the other hand, compulsory licensing is a good attempt to solve some of the access problems. The direct effect is that more people can access medicines because they are a cheaper generic form licensed from a patent holder. Generic drugs cost less to produce because they have few sunk costs—that is, no R & D responsibility—and can be sold at a lower price.²⁰⁰ When companies sell more generics or other cheap substitutes, the patented medicines lose market share.²⁰¹ Governments, in turn, can use their bargaining power to buy in bulk and further reduce prices—for example, when purchasing for people in Medicaid programs.²⁰² Compulsory licensing allows many

198. *Drugs: Sibal Prefers Price-Monitoring*, SIFY, Sept. 25, 2005, <http://sify.com/finance/fullstory.php?id=13948052>.

199. See Gathii, *supra* note 50, at 313 (discussing that one of the United States’ major aims in TRIPS was to improve international intellectual property rights protection). The influence of the U.S. pharmaceutical industry is not only seen in trade regulations; OPPI compares itself constantly to the U.S. market and industry even in its basic description. For example, OPPI boasts that India has the “largest number of U.S. FDA approved manufacturing facilities outside the U.S.A.” 2003 Fact Sheet, *supra* note 152.

200. FDA, Generic Drugs, http://www.pueblo.gsa.gov/cic_text/health/genericdrugs/genericdrugs.htm (last visited Oct. 22, 2006).

201. See Eva von Schaper & Angela Cullen, *Cheaper Competition Threatens Top Medicines*, INT’L HERALD TRIBUNE, Feb. 15, 2006, available at <http://www.iht.com/articles/2006/02/15/bloomberg/bxdrug.php> (“High-priced drugs can only keep their sales with the help of patent protection.”).

202. See S.B. 111, 121st Leg. (Me. 2003) (providing an example of the Maine government program that does this without the addition of the compulsory licensing provision).

countries, not only those with more wealth or those with manufacturing capacity, to purchase drugs for their citizens.²⁰³

Although access remains a problem, some groups in India are optimistic about the future of pharmaceuticals due to the revised Act. OPPI writes that the revised Act signals the start of a new era for the Pharmaceutical Industry in India: "The new Act will boost R & D and will help to bring in foreign direct investment in the industry and contribute to improved healthcare."²⁰⁴

For OPPI, the importance of the revised Act seems to lie in the new perception of India as a supporter of patent rights.²⁰⁵ OPPI believes the revised Act is still not strong enough, but that it should also eliminate pre-grant opposition, curb the compulsory licensing provisions, and strengthen mailbox provisions.²⁰⁶ Specifically, OPPI wants to restrict compulsory licenses to national emergencies, public health crises, and antitrust situations rather than the current vague language that goes beyond the Doha Declaration.²⁰⁷ But OPPI contends the revised Act will have little effect on drug pricing.²⁰⁸ Not only will few drugs be affected, but OPPI cites several studies that demonstrate strengthening intellectual property rights has little effect on existing drugs.²⁰⁹ India will profit by attracting foreign investment, creating opportunities for Indian talent to reverse the "brain drain," and incentivising creativity and the creation of wealth.²¹⁰ OPPI's statements imply that compulsory licensing

203. Krishna Ravi Srinivas: *The World's Poor and Sick Have Not Been Forgotten*, YALEGLOBAL, Oct. 20, 2003, <http://yaleglobal.yale.edu/display.article?id=2648>.

204. E-Interview with Ranjit Shahani, President, Organisation of Pharmaceutical Producers of India (Mar. 2, 2005), <http://www.pharmabiz.com/article/detnews.asp?articleid=26475§ionid=42>.

205. See Position on Trade Aspects, *supra* note 150.

206. *Id.*; see Intellectual Property Rights, *supra* note 152.

207. Position on Trade Aspects, *supra* note 150.

208. Intellectual Property Rights, *supra* note 152.

209. *Id.* OPPI claims that of the drugs on the list of Essential Drugs from the WHO, over 95% of the drugs' patents expired. *Id.* Therefore, the current prices will remain in place, and if prices become excessive, the NPPA can control them. *Id.* The studies cited evaluated nine different countries and the effect of increased patent protection on six therapeutic categories. *Id.*

210. See Position on Trade Aspects, *supra* note 150.

may not be as important as creating a system to promote industry.

In addition to foreign confidence in the Indian system, patent protection spurs individual confidence. Increased patent protection stops free ridership by encouraging new research, and it removes the burden of proving infringement from the patent owner.²¹¹ Those praising the revised Act often dwell on the boost to industry and do not even complain about the compulsory licensing provision.²¹²

The success of the collaboration between the pharmaceutical industry and public health advocates, therefore, seems to depend on perception. Since the provision was enacted, India has barely used its compulsory licensing provision the way that industry fears.²¹³ Yet, the possibility of giving it up created uproar in the international community.²¹⁴ At the same time, pharmaceutical companies were reluctant to invest in India because of the compulsory licensing provision and lack of full patent protection as required by the TRIPS Agreement.²¹⁵ Now that both elements—full patent protection and the compulsory licensing provision—are incorporated into the patent regime, both public health advocates and industry perceive they have a stake in the regime.

IV. THE U.S. PHARMACEUTICAL MARKET

[A]ccording to the U.N. Development Program, 35% of the \$297 billion industry in 1998 was controlled by the top ten pharmaceutical companies. In 1999, the median return on equity for the twelve pharmaceuticals members of the Fortune 500 was 35.8%, which was more than double the median return of 15.2% for the Fortune 500 as a whole.²¹⁶

Yet for all this success, pharmaceutical companies continue

211. *New Patent Regime to Boost R & D*, REDIFF.COM, Nov. 17, 2004, <http://inhome.rediff.com/money/2004/nov/17patent.htm>.

212. *See, e.g., id.*

213. Ragavan, *supra* note 16, at 160.

214. *See id.* at 118–19.

215. *See id.* at 160–61.

216. Gathii, *supra* note 50, at 333–34 (footnote omitted).

to cite commercial objectives as reasons why they cannot provide AIDS drugs in countries without patent protection.²¹⁷

There are three broad market failures in the pharmaceutical industry today that could be positively affected by a compulsory licensing provision: imperfect competition, informational problems, and failure to allocate goods to consumers.

A. *Imperfect Competition*

In a study done by the Centers for Medicare & Medicaid Services (CMS), one-fifth of gross revenues of a typical drug manufacturer went to net profit.²¹⁸ Thirty-one of every one hundred dollars went to marketing, advertising, and administrative costs, and only thirteen dollars were allocated to research and development costs.²¹⁹

There is some argument over whether the private sector really is doing the bulk of the research and development the corporations claim they need profits to support. Merrill Goozner, Director of the Integrity in Science Project at the Center for Science in the Public Interest, clarifies this issue.²²⁰ He reports that the public sector primarily does the basic research—although it does some applied research projects—whereas the pharmaceutical industry does applied research and pays for the clinical trials.²²¹ The overlap remains unclear. The National Institute of Health (NIH) once had a clause attached to its research for therapies it developed requiring a “reasonable price.”²²² Due to increasing pressure from the pharmaceutical industry and NIH scientists presumably working with private

217. *Id.* at 271.

218. *Average Price Increase of Brand-Name Drugs More Than Doubles CPI: Generic Manufacturers' Average List Price Increase is Well Below Inflation*, AARP RX WATCHDOG REP. (AARP, Washington, D.C.), Aug. 2005, at 3 (citing *Health Care Industry Market Update: Pharmaceuticals*, CMS, Jan. 10, 2003).

219. *Id.*

220. *See Prescription Drugs*, *supra* note 4, at 2–4.

221. *Id.* Questioning this relationship, Richard Manning from Pfizer, Inc. notes that out of the top forty-seven drugs from the past thirty years, only four were directly related to NIH research. *Id.* at 3–4.

222. *Id.* at 4.

laboratories, the NIH rescinded this clause.²²³ Gozner argues that the Bayh-Dole Act²²⁴ actually has slowed down medical breakthroughs because patents are taken out long before an application has been found for the research. This, as a result, eliminates incentive to conduct research in that area.²²⁵

In 1960, Kefauver believed the pharmaceutical industry was akin to a natural monopoly that could be broken by encouraging competition through compulsory licensing and reducing the number of years of patent exclusivity.²²⁶ Today, the World Socialist Web Site, for example, accuses patent exclusivity—what the pharmaceutical industry uses to charge high prices—of being a “state and WTO-enforced monopoly.”²²⁷ The top one hundred firms in the industry earn eighty percent of the profits. The government drives the pharmaceutical market by providing government-granted patents that provide protection to the patentee for twenty years.²²⁸

Several high barriers to entry exist due to the oligopolistic structure of the market and the market power held by the patentee.²²⁹ Bringing a drug to market requires enormous capital; in order to recoup that expended capital, the manufacturer must enter the market on a large scale.²³⁰ A large manufacturer is able to enter on a large scale because its cost of production will decrease as production increases.²³¹ This economy of scale acts as a deterrent for a potential entrant that

223. *Id.*

224. Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2000) (stating a purpose to encourage invention and collaboration by federal government and private sector by supporting patent rights).

225. *Prescription Drugs*, *supra* note 4, at 5.

226. *See* KEFAUVER, *supra* note 11, at 8, 78, 237.

227. Kumara, *supra* note 146. The industry as it stands is actually an oligopoly, a market made up of a few sellers dominating the competition. *See* Hope Shand, *Oligopoly, Inc. 2005: New Report on Concentration in Corporate Power*, ON THE COMMONS, Dec. 12, 2005, <http://onthecommons.org/node/775>.

228. 35 U.S.C. § 154(a)(2) (2000).

229. *See* BIANCA PIACHAUD, *OUTSOURCING R & D IN THE PHARMACEUTICAL INDUSTRY* 35 (2004).

230. *See id.* at 35–36.

231. *See id.*

might not have the ability to pay the initial capital costs.²³² The average cost of bringing a drug to market has been estimated at \$611 million over twelve years.²³³

Some corporations can avoid the sunk costs of R & D and focus on profits. Corporations such as Forest Laboratories do not manufacture any drugs they sell from start to finish, but rather, they focus on identification, product development, and marketing of drugs.²³⁴ They can choose the drugs they market, analyzing in advance which ones will be most profitable. The problem with these companies, however, is that most of them never fully break into the market; only a few companies still take the drugs from beginning to end product on the shelf.

New entrants also have to contend with the difficulty of getting consumers to switch brands. Consumers identify their need with the first and only brand on the market,²³⁵ and getting them to switch brands is difficult.²³⁶ Encouraging consumers to switch based on product differentiation is costly and usually requires massive advertising.²³⁷ Since 1997, when the FDA allowed direct-to-consumer advertising, mass media advertising for prescription drugs went from \$1.1 billion to \$2.5 billion in 2000.²³⁸ In 2000, “[e]ach of the top seven most heavily advertised drugs . . . beat out Nike’s ad budget of \$78.2 million for its top shoes.”²³⁹ These statistics demonstrate the connection between advertising and revenue for prescription drugs that make initial costs so high for their launch.

In addition to the huge capital requirements necessary to enter the market, government regulations add another cost. The

232. *See id.*

233. *Id.* at 12–13. *But see* Mintz, *supra* note 65 (reporting cost from innovation to market to be \$500 million) *and* ANGELL, *supra* note 70, at 37–41 (reporting that drug companies claim it costs \$802 million per drug).

234. *See* Forest Laboratories, Exploring Promising Opportunities for Innovative Therapies, <http://www.frx.com/about/divisions.aspx> (last visited Oct. 22, 2006).

235. *See id.* at 43.

236. *See id.* at 42.

237. *See id.* at 36. In this statement, “consumers” refers to both physicians who prescribe the drugs and end user consumers, or laypersons.

238. NIHCM, *supra* note 115, at 3.

239. *Id.* at 5.

pharmaceutical industry is one of the most highly regulated, and, as Kefauver advocated, the government requires high standards for safety, efficacy, and efficiency before approval is given.²⁴⁰ Among other requirements, several phases of clinical trials take place over several years and must be completed on both laboratory animals and then on humans.²⁴¹ Although the FDA has expedited the process for approval of generic drugs, the extended patent protection and the goodwill that is attached to the trademark of a drug still make it difficult for generics to enter the market.²⁴² Regulation is slow, overly risk-aware, expensive, and rarely accepting of foreign data.²⁴³ Regulatory costs, therefore, are costs the company must internalize and account for in its budget to bring the product to market.²⁴⁴ For many small and new companies in the industry, however, sunk costs are simply too high to internalize in order to enter the market.²⁴⁵ When few companies are able to enter the market, competition decreases and the pharmaceutical oligopoly can thrive.²⁴⁶

B. Informational Problems

Informational asymmetries exist between consumers and manufacturers. The competition between brands is overrun by advertising and marketing.²⁴⁷ Drug companies are also reluctant to reveal any of their production costs.²⁴⁸

240. PIACHAUD, *supra* note 229, at 36–37; Michelle Meadows, *Promoting Safe and Effective Drugs for 100 years*, FDA CONSUMER, Jan.–Feb. 2006, available at http://www.fda.gov/fdac/features/2006/106_cder.html.

241. See Michelle Meadows, *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*, FDA CONSUMER, July–Aug. 2002, available at http://www.fda.gov/fdac/features/2002/402_drug.html (contains revisions made in Sept. 2002).

242. Ghosh, *supra* note 15, at 239–40.

243. See Gathii, *supra* note 50, at 340–44 (pointing to the length of clinical trials, the number of clinical trials required, and the stringent specifications of the clinical trials as factors that raise costs of regulation).

244. See Bryan C. Mercurio, *TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 211, 251–52 (2004).

245. See Gathii, *supra* note 50, at 263.

246. See *id.* at 264.

247. See *supra* text Part IV.A.

248. See Mintz, *supra* note 65.

With the advent of direct-to-consumer advertising and the internet making more information available to the public, the traditional physician-lay-person relationship changed.²⁴⁹ Traditionally, the patient was forced to purchase the drug prescribed by the physician, regardless of whether it was patented or generic.²⁵⁰ With more information, consumers are encouraged to play a greater role in the demand of drugs. There are generally two demands: demand for the latest drug and demand for the cheapest drug.²⁵¹ These demands support the patented medicines as well as the generic industry.²⁵² Generic competition is gaining market share.²⁵³ Within the United States, market penetration by generic drugs in the first year of patent expiration approaches fifty percent; after five years, it can penetrate the market as much as eighty percent.²⁵⁴ Consumer demand for cheaper and better products, however, drives up competition and increases information available to them in order to persuade their decision making.²⁵⁵

C. Access

Access concerns, intimately intertwined with health concerns, drive the tension over intellectual property rights. Although access is not usually considered a consumer or industry cost or benefit, it is a social cost.²⁵⁶ In many countries,

249. See NIHCM, *supra* note 115, at 5–6.

250. See KEFAUVER, *supra* note 11, at 8–9; NIHCM, *supra* note 115, at 5 (discussing a finding that “detailing” to physicians, giving away free samples of pharmaceuticals’ new drugs, encourages physicians to prescribe the drug because it is conveniently right there and they seem altruistic to patients by giving away drugs). Without patient demand for cheaper drugs, the physician will likely prescribe the brand-name one. *Id.*

251. NIHCM, *supra* note 115, at 6–7 (reporting that prescription drug advertising—mostly for new drugs—has led to increase in sales and brand recognition); see, e.g., NAT’L INST. FOR HEALTH CARE MGMT. RES. & EDUC. FOUND., A PRIMER: GENERIC DRUGS, PATENTS AND PHARMACEUTICAL MARKETPLACE 17–18 (June 2002), <http://www.nihcm.org/finalweb/GenericsPrimer.pdf> [hereinafter PRIMER] (showing quick consumer turnover from brand drug to generic drug when patent expired).

252. See *supra* note 253.

253. NIHCM, *supra* note 115, at 46.

254. *Id.*

255. See *id.* at 37, 39.

256. See, e.g., Bob Herbert, *The Machete Budget*, N.Y. TIMES, Jan. 2, 2006, at A13.

the lack of access due to high prices is the reason that governments step in to regulate the market.²⁵⁷

There are several reasons the drugs do not reach those in need. One is that they are too expensive. In the United States, drugs are not covered well on insurance—28% of consumers pay out of pocket for prescription drugs.²⁵⁸ Another reason is that drug companies target groups who can pay for drugs and produce drugs accordingly.²⁵⁹ It is less desirable and more risky to manufacture drugs for those who are too poor to pay for them, or for which they sell at a discounted rate, when there are those who will pay full patent protected rates.²⁶⁰

Industry argues it promotes total societal welfare over consumer welfare. In protecting the patent system and keeping prices and, therefore, profits high, the pharmaceutical industry argues that it can continue to innovate and spend money on research and development.²⁶¹ It is hard to tell whether Industry just balances profit with less profit, or really does promote societal welfare at the expense of direct consumer welfare.

D. Compulsory Licensing Effects on the U.S. Pharmaceutical Market

Compulsory licensing offers a way to lower these barriers to entry. A license preempts patent exclusivity, and generic drugs not only decrease prices but also allow newcomer's entry into the market without having to put up substantial capital costs.²⁶² Consumer loyalty would not be as strong due to the shortened patent exclusivity period. Substitutes would take over the

257. Most of the world, including Europe and Canada, regulates prices in some form or another. See *Prescription Drugs*, *supra* note 4, at 5.

258. STUART O. SCHWEITZER, PHARMACEUTICAL ECONOMICS & POLICY 97 (1997). The jury is still out on what effect Medicare Part D (prescription drugs) will have on insureds and costs.

259. *Id.* at 12.

260. *See id.*

261. *See Prescription Drugs*, *supra* note 4 (Richard Manning of Pfizer describing profits and spending necessary to bring a drug to market).

262. *See von Schaper & Cullen*, *supra* note 201 (reporting the introduction of generic drugs onto the market can cut sales of patented drugs by as much as seventy percent).

market easily and force the patented product's price down.²⁶³ This benefit is predicated on the frequent use of the compulsory licensing provision.²⁶⁴ Occasional use of the provision might not have a severe impact on the pharmaceutical industry.²⁶⁵ This is for two main reasons: (1) the industry is so lucrative that investors would not be scared off by the occasional license, and (2) the industry is supported in large part by public monies that would not disappear with the threat of compulsory licensing.²⁶⁶

American lawmakers generally seem willing to attack the symptoms of the problem by, for example, trying to reimport medicines, but they are not yet willing to change the system itself.²⁶⁷ The Canadian government actually repealed its compulsory licensing provision,²⁶⁸ proving to many Americans that measures such as this adversely affect the country's ability to innovate.²⁶⁹ However politically unsavory,²⁷⁰ the answer lies in using a combination of approaches to attack the system itself. Compulsory licensing, combined with a requirement for transparency in drug companies,²⁷¹ would give the market a chance to change and increase competition.

As more drug manufacturers are able to participate in the market by obtaining a license, some informational problems will decrease. The informational asymmetry between the physician and patient will decrease because of the increase in availability of generic medicines supported by the government and the

263. See PIACHAUD, *supra* note 229, at 39.

264. See generally Avedissian, *supra* note 10, at 250–51 (arguing that the provision would not be used much because, in the context of bio-terrorism, one hopes compulsory licensing for protection is not necessary).

265. *Id.* at 280.

266. *Id.*

267. HENRY J. KAISER FAMILY FOUND., KAISER HEALTHPOLL REPORT 1, 20 (2005), http://www.kff.org/healthpollreport/feb_2005/upload/full_report.pdf (stating that Americans surveyed recently agreed that the importation of medicines was important to make medicine affordable (69%) and also agreed (91%) that drug companies are important for drug R & D).

268. HARRISON, *supra* note 11, at 137 (referring to C-91 that eliminated compulsory licensing in Canada and changed the patent period to twenty years).

269. SCHWEITZER, *supra* note 258, at 148.

270. See Ghosh, *supra* note 15, at 230.

271. See Avedissian, *supra* note 10, at 288–89 (suggesting transparency).

increase in direct-to-consumer advertising.²⁷² Arguably, consumer demand for generic medicines will increase as patients hear they can pay less for the same product.

The procedural due process provisions afforded consumers and manufacturers in the proposed U.S. legislation will improve access to information. The legislation includes notice to interested parties, public hearings, and a published opinion.²⁷³ These procedures ensure informed government decisions on granting the license and allow parties in the industry to contribute.

V. PROPOSED PRESCRIPTION FOR THE UNITED STATES

Compulsory licensing is a tool that strikes at the heart of the patent system. It is an effective measure to restrict patent exclusivity. It also strikes a balance between health concerns or access and financial concerns of incentivizing innovation.

The recent fight over the revised Act in India brought compulsory licensing to the forefront, and the country fought for the provision to remain in effect.²⁷⁴ The generics industry has been strong for years now. Whether or not the provision is much used, the strategic compromise allowing it to remain in the revised Act, even with the restrictions, is crucial for both sides to claim success. World health bodies are assured their supply of cheaper drugs will not dry up. Industry is content because increased patent protection is anticipated to bring foreign investment to India, regardless of the existence of the compulsory licensing provision.

The United States can learn from India's compromise. The U.S. pharmaceutical industry is slowly becoming less efficient in its product development—spending more but producing drugs that are not much more effective.²⁷⁵ Consumer frustration with high prices of prescription drugs continues to increase.²⁷⁶

272. See FED. TRADE COMM'N & DEPT. OF JUST., IMPROVING HEALTH CARE: A DOSE OF COMPETITION 20 (2004), <http://ftc.gov/reports/healthcare/040723healthcarerpt.pdf>.

273. See *supra* text Part II.D.

274. See *supra* notes 140–41 and accompanying text.

275. ANGELL, *supra* note 70, at 47.

276. See, e.g., Wal-Mart Press Release, Wal-Mart Announces Accelerated Rollout of

Compulsory licensing would increase competition through lowering barriers to entry in the market. Increased competition could lead to lower prices, as in India where the generics market is strong. More substitutes would decrease the informational problems between consumers, physicians, and manufacturers.

Most importantly, a compulsory licensing provision in the United States would raise consumer confidence in the patent system, bridging the gap between consumer access and industry innovation. It adds an element of transparency that promotes cooperation between industry and consumers. Industry representatives in India are confident about future prospects due to increased patent protection and do not anticipate the compulsory licensing provision eliminating its chance of success.²⁷⁷ The United States should also adopt the view that a compulsory licensing provision will not destroy pharmaceutical industry profit ability but will promote competition and increase consumer confidence in the entire system.

*Katharine W. Sands**

\$4 Generic Prescription Program in 14 States (Oct. 19, 2006), <http://www.webwire.com/ViewPressRel.asp?aid=22360>.

277. *See supra* Part III.D (discussing how the increased patent protection and compulsory licensing grant both the pharmaceutical industry and public health advocates a stake in India's current patent regime).

* J.D. Candidate 2007, University of Houston Law Center; B.A. History 2002, Yale University. This Comment received the 2006 Beirne Maynard & Parsons Writing Award. I wish to thank Professors Darren Bush and Patricia Gray for helping me select this topic, and the editorial board of HJIL for their hard work on this Comment. I am especially indebted to Neil B. Mascarenhas for his thoughtful comments and unending love and encouragement.