

# PERMITTED USE OF PATENTED INVENTIONS IN THE UNITED STATES: WHY PRESCRIPTION DRUGS DO NOT MERIT COMPULSORY LICENSING

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## INTRODUCTION

On October 16, 2001, in the wake of several mail anthrax cases, Attorney General John Ashcroft and U.S. Senator Charles Schumer (D-NY) urged the federal government to sanction the generic manufacture of an antibiotic to combat the disease, despite existing patent rights on the drug.<sup>1</sup> Bayer AG manufactures ciprofloxacin, known commonly as Cipro, and has a patent on the drug. “One [sixty]-day supply of Cipro costs just under \$700 in the United States, while a [sixty]-day supply of generic ciprofloxacin—not allowed until 2003 in the United States—costs about \$20 in other countries . . . .”<sup>2</sup> Although Bayer pledged to increase production of this antibiotic threefold in response to the recent threats of bioterrorism, some public officials still insisted on more action.<sup>3</sup> Senator Schumer initiated talks with three generic drug manufacturers over the possible expedited approval of generic ciprofloxacin, believing that the federal government does have the power to override Bayer’s patent rights.<sup>4</sup> A spokesman for the Department of Health and Human Services, however, hesitated at such dramatic action, stating “[w]e have to be careful about patent protections—there’s a balance there.”<sup>5</sup>

In August 2001, the Brazilian government announced plans to disregard patent rights granted to the Swiss pharmaceutical company Roche for an AIDS drug.<sup>6</sup> Viracept, the brand name for nelfinavir, is an expensive drug often used in AIDS cocktail treatments. Brazil purportedly spends \$88 million annually on Viracept alone, which accounted for over a quarter of the country’s AIDS program budget.<sup>7</sup> Under mounting pressure to lower the cost of the drug and

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1. See *N.Y.’s Schumer Wants Anthrax Drug for Government Use Despite Patent*, CNNMONEY, Oct. 16, 2001, available at [http://money.cnn.com/2001/10/16/news/generic\\_cipro/](http://money.cnn.com/2001/10/16/news/generic_cipro/) [hereinafter *Schumer Wants Anthrax Drug*].

2. Julie Rovner & April Fulton, *Senate Panel Approves Bill On Generic Drug Availability*, NAT’L J.’S CONGRESSDAILY, Oct. 18, 2001, available at LEXIS, News Group File, <http://lexis.com>.

3. See *id.*

4. See *Schumer Wants Anthrax Drug*, *supra* note 1.

5. *Id.*

6. See *Brazil Plans to Ignore Patent on AIDS Drug*, THE GLOBE AND MAIL, Aug. 23, 2001, available at LEXIS, News File, <http://lexis.com>.

7. See Anthony Faiola, *Brazil to Ignore Patent on AIDS Drug*, WASH. POST, Aug. 23, 2001,

increased criticism from AIDS activists worldwide, Roche eventually reached an agreement with Brazil to lower the price to roughly thirty percent of the price in the United States.<sup>8</sup> Merck & Company, a U.S. pharmaceutical company, also reduced the price on two of its AIDS drugs, indinavir and efavirenz, by approximately sixty percent in anticipation of similar pressure.<sup>9</sup>

Brazil is not the only country to exhibit such a dismissive attitude toward international protection of intellectual property, particularly with respect to prescription AIDS drugs. Previously, South Africa faced the same situation with its own national AIDS crisis, in which approximately 70,000 HIV-positive children are born each year.<sup>10</sup> Pleas to pharmaceutical companies created a stir among intellectual property authorities and human rights activists alike.<sup>11</sup>

Due at least in part to events in Brazil and South Africa, U.S. Representative Sherrod Brown (D-OH) introduced The Affordable Prescription Drugs and Medical Inventions Act.<sup>12</sup> This legislation seeks to amend existing patent laws and allow compulsory licenses potentially applicable to “any invention relating to health care.”<sup>13</sup> That is, the government would permit the use of patented inventions, forcing those patent holders to either proactively negotiate licenses or claim reparations after the permitted use.

Although the United States has avoided similar proposals in the past and public health emergencies have been thought to be solely third-world concerns, the recent anthrax scare has revived compulsory licensing arguments with renewed vigor and urgency. On November 6, 2001, Representative Brown appropriately reintroduced his compulsory licensing proposal under a different title, The Public Health Emergency Medicines Act.<sup>14</sup> Deriving many of its provisions from H.R. 1708, this new bill marks an attempt to capitalize on the threat of bioterrorism and feared public health disaster to usher in a compulsory licensing scheme within the U.S. patent system. Public sentiment regarding the rising costs of health care brings prescription drug prices, pharmaceutical patent rights, and compulsory licensing to the forefront of medical, ethical, and economic debate.

This Note argues that compulsory licensing for prescription drugs under these proposed bills is not warranted. It further discusses the rationales that support compulsory licensing and how they are already addressed by other legislative and judicial means. Part I of this Note provides an overview of United

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at A20.

8. Jennifer L. Rich, Business/Financial Desk, *Roche Reaches Accord on Drug with Brazil*, N.Y. TIMES, Sept. 1, 2001.

9. *See id.*

10. Barnaby Phillips, *South Africa Sued Over Aids Drugs*, BBC NEWS, Mar. 15, 2001, at [http://news.bbc.co.uk/1/hi/english/world/africa/newsid\\_1502000/1502518.stm](http://news.bbc.co.uk/1/hi/english/world/africa/newsid_1502000/1502518.stm).

11. *See id.*

12. H.R. 1708, 107th Cong. (2001). Representative Brown introduced an earlier version of this bill, entitled the Affordable Prescription Drugs Act, H.R. 2927, 106th Cong. (1999).

13. H.R. 1708.

14. H.R. 3235, 107th Cong. (2001).

States patent law and the transactional interests of government and inventors in a patent system. Part II explores the general arguments regarding compulsory licensing within the United States patent system. Part III examines de facto compulsory licensing in the United States, including existing statutory exceptions such as the Drug Price Competition and Patent Term Restoration Act of 1984<sup>15</sup> and government use of intellectual property. Further, Part III will discuss judicial actions that, under special circumstances, essentially result in a compulsory licensing arrangement. Part IV compares U.S. legislation with current existing international treaties and agreements governing patented inventions, especially provisions therein that allow compulsory licensing. Finally, Part V addresses the motivation behind both The Affordable Prescription Drugs and Medical Inventions Act and the Public Health Emergency Medicines Act, analyzes the arguments for compulsory licensing of pharmaceutical drugs, and discusses why these reasons fail in light of other currently available avenues for the permitted use of patented inventions.

#### I. TRANSACTIONAL INTERESTS OF GOVERNMENT AND INVENTORS IN UNITED STATES PATENT LAW

United States patent law finds its roots in the Constitution, which empowers Congress “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>16</sup> When the U.S. government issues a patent, it includes “a grant . . . of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States . . . .”<sup>17</sup> In order to stimulate technological growth and advances, the government essentially grants a limited period of exclusivity to inventors who bring forth and disclose their work.<sup>18</sup> Government provides this as an incentive for inventors to invest time, resources, and money into the innovation process that is often costly. In theory, the public benefits from the introduction of this new and useful invention; inventors, on the other hand, benefit from a period of exclusivity during which they can seek to recoup their investments and profit from their rights.

##### A. *Contract Theory of Patent Law*

Many judges and scholars have regarded the modern U.S. patent systems as a type of contract between government and the inventor.<sup>19</sup> The inventor presents

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15. Pub. L. No. 98-417, 98 Stat. 1585 (codified at as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

16. U.S. CONST. art. I, § 8, cl. 8.

17. 35 U.S.C. § 154(a)(1) (2000).

18. See Lisa A. Huestis, *Patent and Antitrust Law: The Second Circuit Strives Toward Accommodation*, SCM Corporation v. Xerox Corporation, 48 BROOK. L. REV. 767, 773 (1982).

19. See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 489 (1974) (stating that a patent is a social contract or bargain, granting exclusive rights in return for public disclosure); see also *In*

to the public something that is useful,<sup>20</sup> novel,<sup>21</sup> and unobvious;<sup>22</sup> this public disclosure is his consideration in the bargain. In return, the government provides consideration of exclusive rights to the claimed invention for a limited time.<sup>23</sup> Under this construction, invoking theories of contract law, courts have found patents invalid on the grounds that inventors did not contribute to the public domain anything that was not already known, thus amounting to a failure of consideration.<sup>24</sup> As the inventor's part of the bargain is unsatisfied, courts effectively revoke the government's consideration and are unwilling to enjoin an allegedly infringing party based on the fatally deficient contract.<sup>25</sup> On the other hand, compulsory licensing has been viewed as a failure of consideration on the part of the government. So, even though the inventor satisfied the bargain by publicly divulging his invention, the government's consideration of patent exclusivity is revoked.<sup>26</sup>

Impliedly, however, a patent holder is under no obligation to make, use, sell, or import this invention. Neither the Constitution nor statutory law explicitly requires that the patentee make use of the invention or ensure that the invention is used to its fullest potential. However, some scholars argue that utilization and practical application of the invention is also part of the patent bargain, so that non-use would be a failure of the inventor's consideration in the patent bargain. They argue that strict enforcement of the patent right to exclude, in cases of non-use, does not truly further the spirit of the Patent Clause in the promotion of the useful arts.

### *B. Is Non-use a Failure of Consideration?*

Early in the Twentieth Century, the U.S. Supreme Court recognized the rights of patentees to exclude others even if the patentee himself was not using the invention.<sup>27</sup> At the time, circuit courts were split over the effect of patent non-use with regard to enforcement of a patentee's exclusive rights.<sup>28</sup> Some circuits insisted that use of the patented invention was an incumbent responsibility of the inventor; if an inventor did not use the invention, other parties were free to practice the invention without threat of an action for patent

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*re* Bayer, 568 F.2d 1357 (C.C.P.A. 1978); *In re* Tenney, 254 F.2d 619, 623 (C.C.P.A. 1958) (stating that an inventor must give to the public something it does not already have in consideration for exclusive patent rights). DONALD S. CHISUM, PATENTS (1997).

20. See 35 U.S.C. § 101 (2000).

21. See *id.* § 102.

22. See *id.* § 103.

23. Patents are generally subject to a grant of rights extending for a period of twenty years from first filing a patent application. See *id.* § 154(a)(1)-(2).

24. See *Tenney*, 254 F.2d at 622-24.

25. *Id.*

26. See *id.* at 622-23.

27. *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405 (1908).

28. See *id.* at 425-26.

infringement.<sup>29</sup> In *Continental Paper Bag Co.*,<sup>30</sup> the petitioner alleged that non-use of a patent was sufficient grounds to overcome the inventor's protection of exclusive rights. Writing for the majority, Justice McKenna disagreed with this premise, recognizing instead that a patent holder is under no obligation either to use the invention himself or license the invention to others.<sup>31</sup>

If he [a patentee] sees fit, he may reserve to himself the exclusive use of the invention or discovery. If he will neither use his device nor permit others to use it, he has but suppressed his own, . . . his title is exclusive, and so clearly within the constitutional provisions in respect to private property that he is neither bound to use his discovery himself or permit others to use it.<sup>32</sup>

The Court explained that the right to exclude others was independent of the patent holder's own use or non-use of the patented subject matter.<sup>33</sup> Furthermore, a patent holder is not obligated to license the invention to other interested parties should he choose not to make, use, sell, or import the invention himself.<sup>34</sup>

The Court did, however, acknowledge that some forms of non-use could be directed at wrongful purposes and that such non-use might merit revocation of exclusionary patent rights.<sup>35</sup> Although the Court did not expressly identify these situations at the time, several of these reasons have since developed as new and evolving technology continues to challenge the foundation of patent rights in U.S. law.

## II. ARGUMENTS FOR AND AGAINST COMPULSORY LICENSING IN THE UNITED STATES

This section will focus on two leading arguments supporting compulsory licensing of patented inventions: economic benefit and public interest. Advocates of compulsory licensing highlight the supposed economic advantages of compulsory licensing and the evils of perceived monopolistic and anticompetitive behavior that the patent system encourages. Additionally, with particular respect to prescription drugs, arguments in favor of compulsory licensing generally emphasize moral and ethical concerns, citing such circumstances as the crippling spread of certain diseases, unavailability of critical lifesaving medication, and high yet preventable mortality rates.

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29. *See id.*

30. 210 U.S. 405 (1908).

31. *Id.* at 427-29.

32. *Id.* at 425 (alteration in original) (quoting *Bement v. Nat'l Harrow Co.*, 186 U.S. 70, 90 (1902)).

33. *Id.* at 429. *See also* *Hartford-Empire Co. v. United States*, 323 U.S. 386, 432 (1945) (holding that a patent owner is under "no obligation . . . to use [the patented invention] or to grant its use to others.").

34. *Continental Paper Bag Co.*, 210 U.S. at 429. *See also* CHISUM, *supra* note 19.

35. *Id.* at 428-29.

### A. *Economic Rationale*

One aspect of exclusive patent rights that draws criticism is that a patent holder may be incapable of meeting demand for the invention. Although this reality may appear on its face to support the introduction of other suppliers in a market via compulsory licensing, the basis for this argument may be rebutted by exploring the economic impact of granted patent rights.

Allowing a competitor to enter a market destroys the fundamental principle of patent protection: exclusivity to compensate for innovation expenses. Theoretically, a “monopolist reduces output below the level that would be found in a perfectly competitive industry.”<sup>36</sup> A patent holder may intentionally undersupply goods to maximize profits. Introducing another competitor into a given market would reduce the patent holder’s incentive to undersupply and would thus more fully utilize and commercialize the invention.<sup>37</sup> However, increasing access to patented inventions to the detriment of patentees would undermine the incentive to innovate and would deter research. In fact, the mere possibility of compulsory licensing may reduce the incentive for innovation.<sup>38</sup> In high-risk areas of research and development, brand-name pharmaceutical companies (also referred to as “innovator” companies) often seek to recoup costs associated not only with the invention itself, but also with the many other ideas that require resources and fail. Diminishing the return on such research and development by the threat of compulsory licenses could potentially stifle investment in these areas.<sup>39</sup>

The term “monopoly” is used liberally in patent law to describe the position of a patentee in a given market. However, a more precise definition of the relevant market is necessary to understand a patentee’s market power. In one instance, Eli Lilly & Co. (Lilly), a pharmaceutical corporation in Indianapolis, Indiana, had exclusivity over the compound nizatidine (Axid®), a histamine H<sub>2</sub>-receptor antagonist useful for treating such gastrointestinal maladies as heartburn or stomach ulcers.<sup>40</sup> Lilly could be thought to have had a theoretical “monopoly” over the relevant market, but this market would be limited to nizatidine. Instead, a more practical analysis of the situation reveals that the relevant market cannot be defined simply as the nizatidine market, but rather as all histamine H<sub>2</sub>-receptor antagonists. This includes competitors’ drugs such as cimetidine (Tagamet®), famotidine (Pepcid®), and ranitidine (Zantac®). Shrewd adherence to monopolistic practices by any one of these competitors could likely have an adverse effect, dissuading consumers from one product and shifting market share

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36. P. SAMUELSON & W. NORDHAUS, *ECONOMICS* 166 (16th ed. 1998).

37. WARD S. BOWMAN, JR., *PATENT AND ANTITRUST LAW* 3 (1973).

38. *See id.*

39. *See* Kevin Rhodes, Comment, *The Federal Circuit’s Patent Nonobvious Standards: Theoretical Perspectives on Recent Doctrinal Changes*, 85 NW. U. L. REV. 1051, 1076 (1991).

40. *See* Axid®: nizatidine capsules, Axid® product label, available at <http://www.reliantrx.com/pdfs/AxidPI.pdf> (last visited Nov. 26, 2001).

to other available alternatives. Overly zealous exercise of a patentee's monopoly position in a competitive industry can actually encourage more aggressive "design-around" efforts by competitors.<sup>41</sup> This is one example in which the supposed "monopolistic" rights of a patent holder translate into a much less powerful economic force when viewed in context of a different "relevant market." Thus, a narrow perspective can easily overestimate the true economic power of a patent.

### B. Public Interest

The general premise behind this policy rationale is that patent rights, although important, are not absolute. The essential needs of the society as a whole may outweigh the exclusive rights of an individual patentee. Arguments for overriding patent rights in the public interest typically address matters of public health and welfare.<sup>42</sup> Also, matters of national security and defense are considered to impact the public at large and are often treated similarly.<sup>43</sup> For example, judicial determination of public interest has balanced the health and economic interests of citizens against the exclusive rights of a patent holder.<sup>44</sup>

The arguments allowing use of patented inventions for the public good are admittedly not without merit. As an analogy, an individual's *real* property rights, although generally respected and held in high regard, are not absolute. Throughout history, society has recognized certain situations in which the interests of the many outweigh the rights of the individual. For example, in early Seventeenth Century England, it was acknowledged that the King's intrusion on a citizen's private land to mine saltpeter was permitted.<sup>45</sup> Because the act was for the defense of the all the King's people, the right to enter the private land trumped the individual's interest in property.<sup>46</sup> Likewise, a large urban fire necessitated one city's fire department to destroy an individual's house to spare countless other homes and lives.<sup>47</sup> In that case, the court held that "[a]t such times [of emergency], the individual rights of property give way to the higher

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41. See Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 206-07 (1987).

42. See, e.g., Plant Variety Protection Act, 7 U.S.C. § 2404 (2000) (mandating a compulsory license if necessary to ensure an adequate supply of food); Clean Air Act, 42 U.S.C. §§ 7401-7626 (2000) (requiring licensing under reasonable terms of technology to prevent and control air pollution).

43. See, e.g., Atomic Energy Act, 42 U.S.C. § 2183 (2000) (citing the public interest as justification for licensing of patented atomic energy inventions).

44. See *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577 (7th Cir.), *cert. denied*, 293 U.S. 576 (1934).

45. See *The King's Prerogative in Saltpetre*, 12 Cl. 12 (Eng. 1607) (stating that the King's trespass onto private land was privileged and that no compensation was owed to the owner).

46. *Id.*

47. *Surocco v. Geary*, 3 Cal. 69 (1853).

laws of impending necessity.”<sup>48</sup> So, too, have intellectual property rights of the individual in limited circumstances yielded to the benefit of society.

However, an analogous application of a doctrine of necessity to intellectual property rights is not as straightforward. The immediate difficulty with this rationale is the inconsistency in establishing what is in the public interest. The definition of public interest may be subject to change, even within a given country, in light of economic and social values at any given time.<sup>49</sup> Variation in this definition among different courts is common, and among nations, the disparity is even more pronounced.<sup>50</sup> The recent events in the United States involving anthrax and Cipro are an excellent illustration of the susceptibility of the public interest argument to impulsive or irrational reactions to perceived emergencies. Although proponents of compulsory licensing are quick to point out the benefits of such a flexible measure, the more troubling outcome of compulsory licensing is the potential for abuse and manipulation of vague standards.<sup>51</sup> Governments intend compulsory licensing as a means for increasing access to critical patented inventions.<sup>52</sup> However, the consequence of such licensing may be the deterrence of companies to invest.

### III. DE FACTO COMPULSORY LICENSING IN THE UNITED STATES

Over the past century, several exceptions have been carved into the exclusivity that patentees enjoyed. In the United States, three broad categories permitting use of patented inventions have emerged: statutory exceptions, sovereign immunity for governmental entities under the Eleventh Amendment, and judicial remedies. This section details the erosion of patent rights and explains how competing interests of government, inventors, and the public are resolved by current U.S. laws. Furthermore, this section argues that these exceptions to exclusive patent rights are based upon factors that are outside the realm of the pharmaceutical industry and therefore are unnecessary for prescription drugs in the current U.S. patent system.

#### A. Statutory Exceptions

Congress has seized upon certain priorities that serve the public interest, passing legislation that provides for compulsory licensing of patents necessary to further efforts in designated fields of technology. For example, the Atomic Energy Act<sup>53</sup> deals with national defense and security in nuclear materials.<sup>54</sup>

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48. *Id.* at 73.

49. See generally Paul S. Haar, *Revision of the Paris Convention: A Realignment of Private and Public Interests in the International Patent System*, 8 BROOK. J. INT'L L. 77 (1982).

50. See *id.*

51. See *id.*

52. Cole M. Fauver, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*, 8 J. INT'L. L. BUS. 666, 671 (1988).

53. 42 U.S.C. § 2183 (2000).

54. This statute states, in pertinent part,



Enacted in 1954,<sup>55</sup> the law reflects the national importance of nuclear power in post-World War II times. A further instance is the Plant Variety Protection Act, which states that a compulsory license is mandatory if necessary to ensure an adequate supply of food.<sup>56</sup> A compulsory sale from farmers of saved seed to other farmers is mandatory.<sup>57</sup> Although Congress intended to preserve compelling societal interests—vital national security matters and humanitarian concerns—the effect and necessity of these statutory compulsory licensing provisions are still questioned today. Indeed, despite these examples, the debate surrounding statutory compulsory licensing is far from settled.

A leading example of the ambiguity of compulsory licensing statutes is the Clean Air Act,<sup>58</sup> passed in 1970 amid an escalating international fuel crisis and a rising trend of ecological awareness. Concerned about pollutants, increasing vehicle emissions, and overall air quality levels, Congress proposed “a national research and development program to achieve the prevention and control of air pollution.”<sup>59</sup> Additionally, if technology existed that was vital to an industry to meet the goals of the Act, as determined by government officials, a court order could be sought, “requiring the person who owns such patent to license it on such reasonable terms and conditions as the court, after hearing, may determine . . . .”<sup>60</sup>

At the time, the compulsory licensing provision in the Clean Air Act garnered very little attention.<sup>61</sup> It was believed that Congress had feared that companies could control important pollution control patents and strategically build monopolies by exercising patent rights in view of harsh penalties for violations.<sup>62</sup> Since its inception, however, the compulsory licensing provision has seen little litigation in the courts; arguments concerning its impact have generally been relegated to academia.<sup>63</sup> Unfortunately, lack of resolution in the courts has brought cries of victory from commentators of both sides of the debate. Advocates for compulsory licensing cite the compulsory licensing

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[w]hensoever any patent has been declared affected with the public interest, . . . (1) the Commission is hereby licensed to use the invention or discovery covered by such patent in performing any of its powers under this Act; and (2) any person may apply to the Commission for a nonexclusive patent license to use the invention or discovery covered by such patent . . . .

*Id.* § 2183(b).

55. Pub. L. No. 703, 68 Stat. 919 (1954).

56. 7 U.S.C. § 2404 (2000).

57. *See id.*

58. 42 U.S.C. §§ 7401-7626 (2000).

59. *Id.* § 7401(b)(2).

60. *Id.* § 7608.

61. *See* Jeffrey C. Gerber & Peter W. Kitson, *Compulsory Licensing of Patents Under the Clean Air Act of 1970*, 54 J. PAT. OFF. SOC'Y 650 (1972).

62. *See id.*

63. *See* Kenneth J. Nunnenkamp, *Compulsory Licensing of Critical Patents Under CERCLA?*, J. NAT. RESOURCES & ENVT'L. L. 397, 406 (1994).

provision as an example of a provision that ensures that future advances in pollution control are appropriately managed to avoid monopolistic control.<sup>64</sup> They assert that such a clause provides for adequate protection with no apparent adverse effects. On the other hand, critics point out that the immeasurable loss of research and development greatly outweigh any benefits of the licensing provision.<sup>65</sup> It is unclear how such a provision may have deterred investment in pollution control. Also untold are the number of settlements or voluntary licensing arrangements motivated by parties seeking to avoid compulsory licenses, which are usually less favorable to patentees.

In 1996, Congress enacted changes to the patent statutes entitled "Limitation on Patent Infringements Relating to a Medical Practitioner's Performance of a Medical Activity" that limited the enforceability of some medical procedures patents.<sup>66</sup> This statute severely limits the exclusivity of patents claiming medical or surgical procedures. The language of the statute is explicit: "[w]ith respect to a medical practitioner's performance of a medical activity that constitutes an infringement[,] . . . [certain remedial provisions] of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity."<sup>67</sup> In essence, patentees of such procedures are denied any remedy from infringing physicians or hospitals. Remedies that would enjoin practitioners from practicing the invention and enable patentees to recover damages are among those that this statute eliminates.<sup>68</sup> In approving this statutory exception, Congress was especially persuaded by the medical profession's argument that doctors have the ethical and professional duty to share knowledge of new, effective treatments with their patients.<sup>69</sup> Protecting medical procedures through the patent system, proponents argued, would encourage secrecy and inhibit the development of life-saving techniques.<sup>70</sup>

It is critical to note, however, that this statute targets only procedures. Congress expressly exempted pharmaceutical drugs and medical devices from the effects of this Act.<sup>71</sup>

[T]he term "medical activity" . . . shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation

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64. See Leroy Whitaker, *Compulsory Licensing—Another Nail in the Coffin*, 2 AM. INTELL. PROP. L. ASS'N Q. J. 155, 163-65 (1974).

65. See Nunnenkamp, *supra* note 63, at 406-07.

66. See Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208 § 616 (1996).

67. 35 U.S.C. § 287(c)(1) (2000).

68. *Id.* § 287(c).

69. Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601, 606 (2000).

70. See *id.*

71. 35 U.S.C. § 287(c)(2)(A) (2000).

of a biotechnology patent.<sup>72</sup>

Congress was careful to craft this exemption very narrowly around medical and surgical procedures. Patented new chemical entities (“NCEs”) and medical devices were outside the intended scope of the amendment. Lawmakers acknowledged that the pharmaceutical sector is unique in its reliance on investment-backed expectations.<sup>73</sup> Medical and surgical procedures are more likely to advance through dissemination to other physicians, hospitals, and universities.<sup>74</sup> On the other hand, the same reasoning does not apply to the exploratory and speculative nature of drug research. The highly competitive and costly industry of drug research and development is one that would not be as productive but for the patent incentive for innovation and investment.<sup>75</sup>

Perhaps the statutory reference most relevant to pharmaceutical drugs, experimental use, rests in the Hatch-Waxman Act.<sup>76</sup> This legislation was the direct congressional response to an infringement lawsuit before the Court of Appeals for the Federal Circuit. In *Roche Products, Inc. v Bolar Pharmaceutical Co.*,<sup>77</sup> a generic manufacturer used the innovator company’s approved compound in studies for its version of the drug to seek approval from the Food and Drug Administration (“FDA”).<sup>78</sup> The Federal Circuit acknowledged that the purely experimental use of a patented invention, independent of commercial gain, should be exempt from infringement liability.<sup>79</sup> However, despite recognition of this permitted “experimental use,” the court narrowly interpreted the statutory provisions that allowed for this type of experimentation.<sup>80</sup> The infringing act was to be independent of activities directed to commercial gain, and should have been limited “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”<sup>81</sup> Thus, under strict interpretation of the existing statute, the submission of data to regulatory agencies fell outside the scope of permitted use. The Federal Circuit reversed the district court decision for the generic company, holding that the use of a patented drug by a generic drug company regardless of purpose was an act of infringement.<sup>82</sup> Effectively, “innovator” companies

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72. *Id.* The term “composition of matter” is recognized as patentable subject matter under 35 U.S.C. § 101 (2000).

73. See Bloomberg et al., *Patenting Medical Technology: “To Promote the Progress of Science and Useful Arts,”* 317 NEW ENG. J. MED. 565, 566-67 (Aug. 27, 1987).

74. See Wendy W. Yang, Note, *Patent Policy and Medical Procedure Patents: The Case for Statutory Exclusion from Patentability*, 1 B.U. J. SCI. & TECH. L. 5, ¶ 51 (1995).

75. See *id.* ¶¶ 53-54.

76. Pub. L. No. 98-417, 98 Stat. 1585 (codified at as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

77. 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

78. *Id.* at 864.

79. *Id.* at 860-61. See also CHISUM, *supra* note 19, § 16.

80. See 733 F.2d at 864.

81. *Id.* at 863.

82. *Id.*

garnered an extended period of exclusivity because generic manufacturers were forced to wait until after a drug's patent expired before work could start on regulatory approval, a process that could take several years.<sup>83</sup>

Immediately following the *Roche* decision, Congress quickly enacted the Drug Price Competition and Patent Term Restoration Act of 1984, known commonly as the Hatch-Waxman Act.<sup>84</sup> As a compromise between the generic drug industry and innovator pharmaceutical companies, the amendment included provisions that would directly override the Federal Circuit holding. Congress changed the patent infringement laws to permit use of patented inventions "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."<sup>85</sup> Generic companies then were allowed to practice patented inventions, including patented drugs, in order to satisfy regulatory submission requirements.

The experimental use exception was based on two general principles intended to further technological advances. It was necessary to work patented subject matter 1) to test the feasibility of another's claimed invention, and 2) to continue to innovate and build upon others' work. In the spirit of "promoting the useful arts," Congress had weighed the innovator companies' interest in protection of drug research investment against the public interest of speeding generic drugs to market.<sup>86</sup> Through the Hatch-Waxman Act, Congress had chipped away at the protection of patented pharmaceutical drugs and lessened the effective period of exclusivity necessary to recoup the cost of years of drug research investment.

### *B. Federal and State Government Use of Intellectual Property*

A second general area of permitted use of patented inventions involves federal or state governmental action. If the federal government infringes a patent, the infringement may amount to a "taking" under the Fifth Amendment, and the patentee is entitled to compensation for the infringing use.<sup>87</sup> Because

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83. See Ralph A. Lewis, Comment, *The Emerging Effects of the Drug Price Competition and Patent Term Restoration Act of 1984*, 8 J. CONTEMP. HEALTH L. & POL'Y 361 (1992).

84. Pub. L. No. 98-417, 98 Stat. 1585 (codified at as amended in scattered sections of 15, 21, 28, and 35 U.S.C.). The Federal Circuit decided *Roche* in May 1994. In response to heavy pressure from the pharmaceutical industry, including both generic and innovator manufacturers, Congress quickly enacted the Hatch-Waxman Act in October 1994.

85. 35 U.S.C. § 271(e)(1) (2001).

86. See H.R. REP. NO. 98-857, pt. 2, at 30 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2714. It is important to note that the Hatch-Waxman Act was the product of much deliberation and compromise between innovator pharmaceutical companies and the generic drug industry.

87. See generally Lionel Marks Lavenue, *Patent Infringement Against the United States and Government Contractors Under 28 U.S.C. § 1498 in the United States Court of Federal Claims*, 2 J. INTELL. PROP. L. 389 (1995) (stating that the "takings" clause is an appropriate analysis for government infringement of patented inventions).

patent rights are conferred upon inventors by the United States government, a sovereign nation, these granted rights are subject to the eminent domain of the federal government. As an individual's *real* property rights are subject to eminent domain, so too are *intellectual* property rights in an analogous Fifth Amendment "takings" analysis.<sup>88</sup> In a suit against the federal government for unlicensed use of a patent, a patent holder may recover "reasonable and entire compensation."<sup>89</sup> However, absent from the statute is equitable injunctive relief; injunctions are not available to patent holders against the federal government.<sup>90</sup> The infringing use of patented inventions by the states presents a different problem for patent holders.

Recent Supreme Court cases have directly addressed the issue of sovereign immunity of states. In 1996, the U.S. Supreme Court in *Seminole Tribe of Florida v. Florida*<sup>91</sup> debated the limits on Congress' power to relinquish the sovereign immunity of the states. Invoking the Eleventh Amendment, Congress had attempted to regulate commerce between states and the Indian tribes under the Indian Commerce Clause.<sup>92</sup> The Court determined that Congress did not have the power pursuant to the Commerce Clause to abrogate states' sovereign immunity under its Article I powers. Unless a state consented to suit, it could claim sovereign immunity and avoid liability.<sup>93</sup> The Supreme Court did discuss, however, Congress' power under the Fourteenth Amendment to discharge state sovereign immunity.<sup>94</sup> The Court recognized that the Fourteenth Amendment "expand[ed] federal power at the expense of state autonomy, . . . alter[ing] the balance of state and federal power struck by the Constitution."<sup>95</sup>

The Court revisited this issue within a patent infringement context in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank and United States*.<sup>96</sup> In that case, College Savings Bank had patented a method of guaranteeing sufficient funds to cover college tuition costs.<sup>97</sup> It marketed this method in the form of certificates of deposit, named CollegeSure CDS, which were "essentially annuity contracts for financing future college expenses."<sup>98</sup> Florida Prepaid, a state-created entity, imitated the idea and created a comparable system for state universities. College Savings Bank initiated a lawsuit for patent infringement under the Patent and Plant Variety Protection Remedy Clarification Act,<sup>99</sup> and Florida Prepaid moved for dismissal on the grounds of state sovereign

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88. *Id.* at 393-94.

89. 28 U.S.C. § 1498(a) (2000).

90. *Id.* § 1498.

91. 517 U.S. 44 (1996).

92. *Id.* at 47.

93. *Id.*

94. *Id.* at 59.

95. *Id.*

96. 527 U.S. 627 (2000).

97. *Id.* at 630-31.

98. *Id.* at 630.

99. 35 U.S.C. §§ 271, 296 (1994).

immunity. The Supreme Court reversed the holdings of two lower courts in deciding that Congress had improperly annulled states' sovereign immunity by passing this act. As a rationale, the majority noted that the state use of immunity in federal suits was rare, and that it was similarly uncommon that a state would deprive a patent owner of property without a state remedy.<sup>100</sup>

Since the decision in *Florida Prepaid*, commentators have indicated that the holding will be problematic for patentees, as state jurisdictions remain the only surviving venue for patent infringement suits against state government entities.<sup>101</sup> For example, pharmaceutical research strategists may weigh the high-stakes risks of drug development, and indeed could turn away from universities and research institutions, as these entities derive partial funding from state governments. Not only would the holding of *Florida Prepaid* be applicable to the states themselves, but conceivably the argument could be extended to state actors and other peripheral organizations that derive their authority or funding from state governments. *Florida Prepaid* represents a culmination of High Court decisions that, in light of larger federalism and sovereign immunity ideals, opens the door for state use of patented inventions and further erode the sanctity of patentees' property rights.

### C. Judicial Action Resulting in Compulsory Licensing Arrangements

Even if an infringing party cannot find relief in statutory infringement exceptions or within sovereign immunity concerns, the federal court system may craft remedies for the patent holder that result in a compulsory licensing relationship. Although the United States Patent and Trademark Office determines patentability through the examination and prosecution process, validity is not finally decided until a matter is litigated before a federal court.<sup>102</sup> Federal judges have many options in the complex case of a patent infringement lawsuit. A patentee may ask for injunctive relief, that the defendant be enjoined from conducting the infringing acts. In such a prayer for remedy, the courts may consider aspects of equity. On the other hand, the patentee may seek monetary damages for infringement. The statutory provisions for patent infringement remedies are explicit, as permissive language surrounds injunctive relief,<sup>103</sup> while compensatory damages are written with imperative language.<sup>104</sup>

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100. *Florida Prepaid*, 527 U.S. at 647.

101. See Peter S. Menell, *Economic Implications of State Sovereign Immunity From Infringement of Federal Intellectual Property Rights*, 33 LOY. L.A. L. REV. 1399 (2000).

102. See Fauver, *supra* note 52, at 667.

103. The statute reads in pertinent part: "The several courts having jurisdiction of cases under this title *may* grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283 (2000) (emphasis added).

104. The law providing for compensatory damages is written differently: "Upon finding for the claimant the court *shall* award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the

1. *Injunctive Relief*.—Courts have exercised discretion by withholding injunctive relief in certain cases, even if infringement is found on the part of the defendant. The Federal Circuit has cautioned that injunctive relief is not necessarily granted once infringement is decided.<sup>105</sup> In determining remedies for injured patentees, courts sitting in equity have considered the rationale of economic concerns and public interest, as well as the equitable conduct of the patentee himself.

“A patent owner prevailing on the merits of a patent infringement claim will usually be granted a permanent injunction against future infringement unless the public interest otherwise dictates.”<sup>106</sup> Courts have weighed the public interest against interests of the patent holder. In *City of Milwaukee v. Activated Sludge, Inc.*,<sup>107</sup> the courts analyzed the impact of injunctive relief, balancing the health and economic consequences the public would suffer against the protection afforded a patent holder. The patentee in that case sought an injunction to stop the city from further working a patented method and apparatus for sewage purification. The appellate court affirmed the trial court’s findings, but refused to allow an injunction. That court considered the severe health risk caused by lack of sewage treatment should an injunction be enforced in reaching its decision.<sup>108</sup> Even today, *City of Milwaukee* represents the leading case in which public interest was found to be compelling in itself to justify denial of injunctive relief.<sup>109</sup>

Courts may also balance the detriment to the infringing party against the benefit to be gained by the patent holder when granting an injunction.<sup>110</sup> Furthermore, a compulsory license may be a possible remedy for an aggrieved plaintiff when the defendant is guilty of antitrust violations.<sup>111</sup> The nature of the

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infringer, together with interest and costs as fixed by the court.” 35 U.S.C. § 284 (2001) (emphasis added).

105. See *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 865-67 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

106. CHISUM, *supra* note 19, § 20 (footnote omitted).

107. 69 F.2d 577 (7th Cir.), *cert. denied*, 293 U.S. 576 (1934).

108. *Id.* at 593.

109. See also *Vitamin Technologists, Inc. v. Wis. Alumni Research Found.*, 146 F.2d 941, 945 (9th Cir. 1944) (concluding that the public interest of production of oleomargarine, the “butter of the poor,” outweighed the patent holder’s interest in retaining exclusive rights); *Hybritech, Inc. v. Abbot Labs.*, 4 U.S.P.Q.2d 1001 (C.D. Cal. 1987) (denying patentee injunctive relief despite infringement because it was in public interest to continue production of infringing medical test kits that patentee was not itself marketing). Cf. *Wis. Alumni Research Found. v. Gen. Elec. Co.*, 880 F. Supp. 1266, 1277 (E.D. Wis. 1995) (granting a permanent injunction because of the public interest in preventing infringement of valid patents). Courts have, however, construed the term “public interest” to include the guarantee of certainty and enforceability to patent holders.

110. See *Am. Safety Device Co. v. Kurland Chem. Co.*, 68 F.2d 734 (2d Cir. 1934).

111. See *United States v. U.S. Gypsum Co.*, 340 U.S. 76 (1950); *United States v. Hartford-Empire Co.*, 46 F. Supp. 541 (N.D. Ohio 1942) (granting compulsory licenses as a remedy for antitrust violations); see also Carlisle M. Moore, *A Study of Compulsory Licensing and Dedication*

claim of injunctive relief allows a court flexibility in deciding the most appropriate sanction in a successful infringement lawsuit. This equitable determination is a suitable measure for permitting use of patented inventions while avoiding the overly broad and generalized reach of a compulsory licensing statute.

2. *Damages in a Patent Infringement Action.*—In a patent infringement action, a plaintiff may elect to seek damages. Statutory provisions require “in no event less than a reasonable royalty” for infringement.<sup>112</sup> Beyond reasonable royalties, however, a patentee may seek lost profit damages for infringement.

To recover lost profits, “a patent owner must prove a causal relation between the infringement and its loss of profits.” The Federal Circuit stated that

a patentee receives a reasonable royalty for any of the infringer’s sales not included in the lost profit calculation. Thus, a patentee may obtain lost profit damages for that portion of the infringer’s sales for which the patentee can demonstrate “but for” causation and reasonable royalties for any remaining infringing.<sup>113</sup>

Moreover, during the damages stage of a patent infringement action, a judicial determination of de minimis infringement damages may further limit the relief to which a patentee is entitled. In *Embrex, Inc. v. Service Engineering Corp.*,<sup>114</sup> the defendant was accused of infringing a patented process for injecting a vaccine into an avian egg. After affirming the trial court’s finding of infringement, the Federal Circuit vacated the awarded damages of \$500,000. “Because the only cognizable infringement in this case [was] the testing and those tests were not shown to cause any loss of profits to Embrex,”<sup>115</sup> the Federal Circuit remanded the case to the trial court for a finding of reasonable royalties.<sup>116</sup> Therefore, in cases concerning mere testing, a patentee may find it difficult to establish sufficient evidence to compute a reasonable royalty. This holding furthers the patent system goal of promoting scientific inquiry by protecting and encouraging research.

#### IV. THE TRIPS AGREEMENT AND ITS COMPULSORY LICENSING PROVISIONS

Representative Brown’s compulsory licensing bills include reference to the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPs”).<sup>117</sup> This international treaty of the World Trade Organization

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*of Patents as Relief Measures in Antitrust Cases*, 24 GEO. WASH. L. REV. 223 (1955).

112. 35 U.S.C. § 284 (2000).

113. *Crystal Semiconductor Corp. v. Tritech Microelectronics Int’l, Inc.*, 246 F.3d 1336, 1353-54 (Fed. Cir. 1996) (quoting *BIC Leisure Prods., Inc. v. Windsurfing Int’l, Inc.*, 1 F.3d 1214, 1218 (Fed. Cir. 1993)).

114. 216 F.3d 1343 (Fed. Cir. 2000).

115. *Id.* at 1350.

116. *Id.*

117. AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS



(“WTO”) promotes uniformity among member nations by introducing standards for patent protection worldwide. This section details the compulsory licensing provisions of TRIPs and how the proposed legislation is unnecessarily redundant.

The TRIPs agreement does provide for compulsory licensing of patented inventions. The criteria for such compulsory licensing circumstances exist in Article 31 of the TRIPs document. Most notably, Article 31(b) allows compulsory licensing of patented inventions in situations of national emergency or extreme urgency.<sup>118</sup> Article 31(g) provides that use of the patented invention under the license may continue only so long as the original need exists.<sup>119</sup>

There exists an ongoing dispute between developed countries possessing key patented technology and those bearing “developing nation” status that typically claim the greatest need. Developed nations such as the United States generally possess advanced medical technology and resources, and they advocate a narrow interpretation of the TRIPs compulsory licensing provisions. Criticism of TRIPs compulsory licensing provisions centers on the ambiguity and latitude in interpretation. Terms such as “circumstances” and “purpose” could lead to inconsistent application.<sup>120</sup> Nations still may exercise sovereign power by declaring “national emergency.” There are few guidelines that indicate standards for such events, and this section of the TRIPs agreement has not been challenged to an authoritative body.<sup>121</sup> Developing nations, however, argue for an expansive reading of Article 31, and present humanitarian issues such as AIDS crises and other public health concerns as justification. Pharmaceutical companies are placed in the awkward position: on one hand, they want to avoid arguing that widespread diseases are not a matter of public interest, but on the other, they are wary of importation or foreign infringement that would result from enactment of compulsory licensing provisions.<sup>122</sup>

Article 31(c) of TRIPs limits licensing of patented inventions to the original purpose for which the license was granted.<sup>123</sup> This condition within the treaty addresses the concern of developed nations that appropriation of patented inventions may be abused beyond the national emergency or circumstances that created the justification for a compulsory license. Specifically, the concern is that even after the emergency need is met, rogue companies will inundate the international market illegally.

Clarification from the WTO regarding the terminology of TRIPs and the boundaries of the compulsory licensing provisions is needed to provide a

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[hereinafter TRIPs], available at [http://www.wto.org/english/docs\\_e/legal\\_e/final\\_e.htm](http://www.wto.org/english/docs_e/legal_e/final_e.htm) (last visited Jan. 3, 2003).

118. *Id.* Part II, sec. 5, art. 31(b).

119. *Id.* art. 31(g).

120. See 145 CONG. REC. H6027 (daily ed. July 21, 1999).

121. See Robert J. Gutowski, Comment, *The Marriage of Intellectual Property and International Trade in the TRIPs Agreement: Strange Bedfellows or a Match Made in Heaven?*, 47 BUFF. L. REV. 713, 720-24 (1999).

122. See 145 CONG. REC. H6027 (daily ed. July 21, 1999).

123. TRIPs, *supra* note 117, art. 31(c).

meaningful international agreement. For example, in the case of patented AIDS pharmaceutical drug therapies, the United States and South Africa argued over the precise application of the TRIPs agreement.<sup>124</sup> However, despite the weaknesses of TRIPs, it does present background for analysis of domestic compulsory licensing laws. The following section analyzes the current legislative proposals before the U.S. House of Representatives.

#### V. PROPOSED COMPULSORY LICENSING OF HEALTH CARE INVENTIONS

The proposed legislation sponsored by Representative Sherrod Brown seeks to “use market competition to bring down the cost of prescription drugs.”<sup>125</sup> Supporters of these bills eagerly cite the success of compulsory licensing provisions in the Clean Air Act.<sup>126</sup> They insist that the rising costs of health care may be curbed by licensing measures for expensive prescription drugs, prices of which “bear[] no resemblance to pricing norms for other industries.”<sup>127</sup> The broad sweeping language of this proposed legislation relates to “any invention related to health care,”<sup>128</sup> which encompasses any drug or device, any biological product, or any technology or process to the extent the technology or process is applied to health or health care.<sup>129</sup> It is unclear, however, whether Representative Brown’s bills strike the proper balance between public access to drug inventions and research incentive.

##### A. *H.R. 1708: The Affordable Prescription Drugs and Medical Inventions Act*

This bill bestows to both the Secretary of Health and Human Services and the Federal Trade Commission “the right to establish other use of the subject matter of the patent without authorization of the right holder”<sup>130</sup> for any invention

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124. See Office of the United States Trade Representative, Executive Office of the President, *United States-South Africa Understanding on Intellectual Property*, available at <http://www.ustr.gov/releases/1999/09/99-76.html> (last visited October 15, 2001). Interestingly, both nations agreed to resolve the dispute over intellectual property rights privately as opposed to seeking adjudication from the WTO’s Dispute Settlement Board, perhaps for concern of an unfavorable interpretation of the treaty provisions.

125. U.S. Representative Sherrod Brown (D-OH), *The Affordable Prescription Drugs Act*, Bill Summary, available at <http://www.house.gov/sherrodbrown/rxdrugsumm.htm> (last visited October 15, 2001).

126. Representative Brown refers to the precedent established in the Clean Air Act, discussed *supra*, which provides for compulsory licensing of patented pollution control devices deemed necessary by government to the success of the Act. *Medicare Prescription Drugs: Hearings Before the House Subcomm. on Health and the Environment*, 105th Cong. (1999) [hereinafter *Hearings*] (statement of Rep. Brown, Member, House Comm. on Energy and Commerce), available at <http://www.house.gov/sherrodbrown/medpresdrg.htm> (last visited Oct. 15, 2001).

127. *Hearings*, *supra* note 126.

128. H.R. 1708, § 2, 107th Cong. (2001).

129. *Id.*

130. *Id.*

related to health care. In order for the government agencies to invoke these licensing rights, such invention must fulfill at least one of five determinative factors.<sup>131</sup> The bill further provides for “adequate remuneration for the use of the patent,”<sup>132</sup> and claims consistency with existing international treaty provisions.<sup>133</sup>

The determinative factors in the proposed bill are directly analogous to existing theories supporting compulsory licensing. The first item relates to the argument that non-use of a patented invention may be grounds for compulsorily licensing the invention. If “[t]he patent holder . . . has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in a field of use,”<sup>134</sup> then the patented invention may be subject to a compulsory license under this bill. The proposition that licensing is mandated should the patent holder fail to use the patented invention himself is the very concept dismissed by the U.S. Supreme Court in *Continental Paper Bag Co.*<sup>135</sup> Non-use of patented inventions has not been upheld as a valid justification for compulsorily licensing subject matter of any kind, and the rationale should fail when targeting health care inventions specifically. Moreover, ambiguous terms such as “reasonable time,” “effective steps,” and “practical application” are subject to a wide range of judicial interpretations that could lead to deterring inconsistencies in enforcement.

Two additional factors invoke the public interest or public health argument. A compulsory license option may be triggered if “[t]he invention claimed in the patent is needed for research purposes that would benefit the public health, and is not licensed on reasonable terms and conditions,” or if “use of the subject matter of the patent is necessary to alleviate health or safety needs which are not adequately satisfied.”<sup>136</sup> This rationale could be extended to reach many different types of technologies so long as a tie to public health could be established. Furthermore, the impetus of “research purposes” was addressed directly in the experimental use provisions of the Hatch-Waxman Act.<sup>137</sup> Recent decisions from the Court of Appeals for the Federal Circuit have indicated that this argument is disfavored, deferring instead to respect of the patentee’s intellectual property rights. The limitation of reasonable licensing terms is also questionable. It is conceivable that new and unobvious innovations in a particular field may indeed merit terms favorable for the patentee; this is the nature of pioneer inventions. By regulating the terms by which parties seek licenses, Congress may very well inhibit the incentive to invest in an industry as costly and research-intensive as pharmaceuticals.

Another factor reflects the judicial denial of equitable relief in cases of

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131. *Id.*

132. *Id.*

133. *Id.* The bill refers to the TRIPs, discussed *supra*, and the Uruguay Round Agreements Act, § 101(d)(15).

134. H.R. 1708, § 2.

135. 210 U.S. 405, 429 (1908).

136. H.R. 1708, § 2, 107th Cong. (2001).

137. *See supra* Part III.A.

anticompetitive behavior. Traditionally, the United States has frowned upon antitrust-like behaviors, a paradigm often forced into conflict by the exclusionary nature of the patent system.<sup>138</sup> The bill permits compulsory licensing in the event that “the patented invention is priced excessively relative to the median price for developed countries or by other reasonable standards, and that such pricing contravenes the public interest.”<sup>139</sup> The United States is responsible for a great majority of the total costs for drug research and development. This portion of the proposed bill aims to target the perceived unfairness in pricing relative to other developed nations. However, advocates for the innovator pharmaceutical companies point out that the United States often reaps the benefit of life-saving therapies years ahead of other nations. They defend discrepancies in drug pricing compared to other industrialized nations by citing the advances of the U.S. health care system and the higher standard of living enjoyed by the average U.S. citizen. In fact, this type of pricing comparison would be difficult to weigh practically and even more difficult to implement.

The final factor permits compulsory licensing if “[a]n invention covered by a [second] patent . . . cannot be exploited without infringing upon the [first] patent . . . , insofar as the invention claimed in the second patent involves an important technical advance.”<sup>140</sup> This factor relates to the patent misuse doctrine, a common law principle raised during litigation. Patent misuse is available as an affirmative defense in a patent infringement action, as alleged patent infringers assert that the plaintiff-patentee has abused the patent grant. The allegation is that the patentee has overreached and attempted to extend its exclusivity to items that are not within the scope of the patent.<sup>141</sup> If successful, the affirmative defense can result in the denial of equitable relief.<sup>142</sup>

The determinative factors cited in The Affordable Prescription Drugs and Medical Inventions Act are wholly redundant and unnecessary. It may be argued that these considerations merely represent the codification of common law principles. However, application of these remedies under the aforementioned circumstances is by no means universal or automatic in patent infringement cases, and health care inventions do not merit special consideration of this option. H.R. 1708 presents a backwards step for pharmaceutical innovation and public health concerns.

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138. See Philip Girard, *Impact of United States Antitrust Laws on Territorially-Limited International Patent Licensing Agreements*, 11 U. S.F. L. REV. 640 (1977). Judges have, on occasion, considered the anticompetitive behavior of the patent holder in determining appropriate sanctions for the infringing party. See *United States v. U.S. Gypsum Co.*, 340 U.S. 76 (1950); *United States v. Hartford-Empire Co.*, 46 F. Supp. 541 (N.D. Ohio 1942) (granting compulsory licenses as a remedy for antitrust violations).

139. H.R. 1708, § 2.

140. *Id.*

141. See CHISUM, *supra* note 19, § 19.

142. See *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488 (1942). The Patent Act of 1952 revised the statutory law to limit the patent misuse doctrine to tying agreements involving staple products. See *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 209 (1980).

*B. H.R. 3235: The Public Health Emergency Medicines Act—  
An Even Broader Approach to Compulsory Licensing*

Less than two months following the tragic and shocking events of September 11, 2001, Representative Sherrod Brown introduced H.R. 3235, a statutory measure directed to the threat of bioterrorism.<sup>143</sup> This revised legislation also aspires to establish compulsory licensing of patented inventions, but in a much broader sense than H.R. 1708. The proposed statute reads:

In the case of any invention relating to health care[,] the Secretary of Health and Human Services shall have the right to authorize use of the subject matter of the patent without authorization of the patent holder or any licensees of the patent holder if the Secretary makes the determination that the invention is needed to address a public health emergency.<sup>144</sup>

Absent from H.R. 3235 are the determinative factors of H.R. 1708, which provided at minimum some measure of guidance for a reasonable assessment of applicability. In the case of the Public Health Emergency Medicines Act, however, *any* invention related to health care would be implicated provided that a public health emergency exists. It is not difficult to conceive of the multitude of patented inventions this includes, making this overly broad proposal unrealistic and infeasible.

Representative Brown remarked that his bill “would address the compensation issue [of use of patented inventions], precluding endless court battles and unnecessary government spending.”<sup>145</sup> He cited “[u]ncumbered access to drugs [as] an essential element in [the] response to bioterrorism.”<sup>146</sup> Yet, he also conceded that “[t]he links between antibiotic resistance and bioterrorism are clear. . . . We can only assume that anthrax, and other bacterial agents, could also be engineered to resist antibiotics—including drugs like Cipro.”<sup>147</sup> Under a compulsory licensing scheme as proposed by Representative Brown, the incentives under the current U.S. patent system are severely weakened so that the next generation of drug therapies may never arrive.

CONCLUSION

Compulsory licensing of patented inventions is not merited for pharmaceutical drugs. Proposed bills such as the Affordable Prescription Drugs and Medical Inventions Act and the Public Health Emergency Medicines Act do

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143. See H.R. 3235, § 2, 107th Cong. (2001).

144. *Id.*

145. U.S. Representative Sherrod Brown (D-OH), Remarks on the Public Health Emergency Medicines Act, *available at* <http://www.house.gov/sherrodbrown/bioterror1115.htm> (last visited Feb. 25, 2002).

146. *Id.*

147. *Id.*

not take into account the present range of legislative and judicial avenues for relief that are available. Existing remedies already satisfy arguments concerning the public interest and economic reasons. These arguments are too easily influenced by contemporary sentiment. The recent events in the United States involving Cipro and the threat of anthrax present a prime example of this phenomenon. Proponents of compulsory licensing are too quick to point to perceived health emergencies and urgent needs while ignoring the deterrence on innovation and the continued erosion of patent rights. In past legislation, Congress has correctly recognized the unique incentive-backed investment expectations of the pharmaceutical industry and should wisely avoid these broad, sweeping compulsory licensing bills. Without the preservation of exclusionary patent rights for pharmaceuticals, there may not be a next generation of critical drugs to meet future needs.