

# CHEAP DRUGS AT WHAT PRICE TO INNOVATION: DOES THE COMPULSORY LICENSING OF PHARMACEUTICALS HURT INNOVATION?

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## ABSTRACT

The patent system is built on the premise that patents provide an incentive for innovation by offering a limited monopoly to patentees. The inverse assumption that removing patent protection will hurt innovation has largely prevented the widespread use of compulsory licensing—the practice of allowing third parties to use patented inventions without patentee permission. In this Article, I empirically test this assumption. I compare rates of patenting and other measures of inventive activity before and after six compulsory licenses over drug patents issued in the 1980s and 1990s. As reported below, I observe no uniform decline in innovation by companies affected by compulsory licenses and find very little evidence of a negative impact, which is consistent with earlier empirical work. While anecdotal, these findings suggest that the assertion that licensing categorically harms innovation is probably wrong. Based on the data, I comment on the use of compulsory licensing to reduce the price of AIDS and other drugs for developing countries. I suggest that, based on past experience, compulsory licenses need not result in a decline in innovation and that this policy option for increasing access to medicines deserves greater exploration.

## I. INTRODUCTION

The international AIDS crisis has posed an acute challenge to the robustness of the patent system. Critics contend that the basic bargain between patentees and the public, namely innovation in exchange for a lim-

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ited monopoly, is irreparably skewed in favor of drug companies.<sup>1</sup> Defenders of strong patent rights, on the other hand, insist that any weakening of existing protections would undermine the potential for future innovation.<sup>2</sup>

Compulsory licensing, the practice of authorizing a third party to make, use, or sell a patented invention without the patentee's consent,<sup>3</sup> has long provided an antidote to the perceived ills of the patent system.<sup>4</sup> In the context of the AIDS crisis, compulsory licensing offers one way to lower drug prices and increase access to patented medicines in developing countries in which pharmaceuticals have chosen to secure patent protection and the markets supplied by these countries.<sup>5</sup> Under the Agreement on Trade-

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1. See, e.g., PASCALE BOULIN ET AL., MÉDECINS SANS FRONTIÈRES, DRUG PATENTS UNDER THE SPOTLIGHT: SHARING PRACTICAL KNOWLEDGE ABOUT PHARMACEUTICAL PATENTS 2 (2003) ("Patents are not god-given rights. They are tools invented to benefit society as a whole, not to line the pockets of a handful of multinational pharmaceutical companies."), available at [http://www.accessmed-msf.org/documents/patents\\_2003.pdf](http://www.accessmed-msf.org/documents/patents_2003.pdf) (last visited July 19, 2003); Larry Elliot, *Evil Triumphs in a Sick Society*, GUARDIAN, Feb. 12, 2001 (criticizing global patent law for favoring large pharmaceutical companies), available at 2001 WL 11917250.

2. See, e.g., Gregory J. Glover, Statement on Behalf of Pharmaceutical Research and Manufacturers of America Before the Federal Trade Commission and the Department of Justice-Antitrust Division, Competition in the Pharmaceutical Marketplace 6 (Mar. 19, 2002) ("[C]ompanies would not be able to invest the huge amount of time and money it takes to discover and develop a new medicine if they did not have a sufficient opportunity to make a sufficient return before generic competitors copy and market the drug at greatly reduced cost."), available at <http://www.ftc.gov/opp/intellect/020319gregoryjglover.pdf>; Richard Tren, *Free Industry, Not the Drugs*, WALL ST. J. EUR., July 11, 2002, at A10.

3. F.M. SCHERER & JAYASHREE WATAL, POST-TRIPS OPTIONS FOR ACCESS TO PATENTED MEDICINES IN DEVELOPING COUNTRIES 13 (Comm'n on Macroeconomics & Health, Working Paper No. WG4:1, 2001), available at [http://www.cmhealth.org/docs/wg4\\_paper1.pdf](http://www.cmhealth.org/docs/wg4_paper1.pdf) (last visited Aug. 27, 2003).

4. Compulsory licensing was a component of a late nineteenth-century English patent reform bill. See Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1, 4 (1950). The United States instituted a compulsory licensing provision as early as 1910. Act of June 25, 1910, ch. 423, 36 Stat. 851, 853 (current version at 28 U.S.C. § 1498).

5. Other options include price regulation and improved health infrastructure. See, e.g., Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa*, 286 JAMA 1886, 1890 (2001) (noting that numerous drugs are not patented or are off-patent in a number of developing countries, arguing that the absence of patent protection neither guarantees nor increases access to drugs, and suggesting that factors such as political will and poverty levels restrict access more than patent protection does); Tobias Buck, *EU Acts to Speed up Flow of Cheap AIDS Drugs*, FIN. TIMES, May 27, 2003, at 6 (describing a proposal by the European Union to cap the price of AIDS, malaria, and tuberculosis drugs sold to developing countries).

Related Aspects of Intellectual Property Rights (“TRIPS”),<sup>6</sup> compulsory licensing is authorized under certain circumstances, such as public health emergencies. However, few if any compulsory licenses have actually been issued under TRIPS.<sup>7</sup> One of the most important reasons for this, and the one this Article focuses on, is the perception that compulsory licenses harm the incentive for innovation. In the words of one pharmaceutical executive: “[T]hreatening compulsory licensing . . . will only act as [a] disincentive[] to the development and marketing of new drugs.”<sup>8</sup> The twin goals of increasing access to existing medicines and promoting research and development of new medicines are perceived by some as competing with each other.

This Article questions this fundamental assumption. It explores whether compulsory licenses have actually been accompanied by a reduction in innovation, drawing upon past research efforts and the results of an empirical analysis that I performed on six cases of compulsory drug licenses issued in the United States by the Department of Justice (“DOJ”) in the 1980s and 1990s. The analysis compares rates of innovation within a therapeutic area, measured by patent counts and other indicia, before and after compulsory licenses were issued.

In five of the six cases I studied, I observed no measurable decline in innovation. This finding is consistent with earlier work. By available measures, the companies affected by licenses continued to perform research and development (“R&D”) in the therapeutic areas targeted by the license. Even in the case of forward-looking compulsory licenses that

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6. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND, vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

7. Nonetheless, the threat of compulsory licensing under TRIPS arguably encourages pharmaceutical companies to voluntarily reduce prices. See JEROME H. REICHMAN & CATHERINE HASENZAHN, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS: HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS, AND AN OVERVIEW OF THE PRACTICE IN CANADA AND THE UNITED STATES OF AMERICA 13 nn.92-93 (2002) (describing the experiences of Brazil and the United States in using the threat of compulsory licensing to drive down the prices of AIDS drugs), available at [http://www.ictsd.org/iprsonline/unctadictsd/docs/reichman\\_hasenzahl.pdf](http://www.ictsd.org/iprsonline/unctadictsd/docs/reichman_hasenzahl.pdf) (last visited July 19, 2003); *Patent Remedies*, ECONOMIST, Oct. 25, 2001 (stating that the U.S. Department of Health used the specter of domestic compulsory licensing to obtain a half-price discount on Cipro from Bayer), 2001 WL 7320684; Tina Rosenberg, *Look at Brazil*, N.Y. TIMES, Jan. 28, 2001 (detailing how Brazil effectively used the threat of compulsory licensing to leverage discounted prices on AIDS drugs), <http://www.nytimes.com/library/magazine/home/20010128mag-aids.html> (last visited July 19, 2003).

8. See Tren, *supra* note 2, at A10.

spanned several years, the decline in R&D that advocates for strong patent rights might predict was not observed. While limited and anecdotal, this and past work suggest that concerns about compulsory licensing are overstated and that the blanket assertion that licensing categorically harms innovation is probably wrong.

This Article also discusses how the structure and implementation of compulsory licenses affects R&D. Based on past research and common sense, I postulated that two factors are extremely important—the degree to which a company can predict that a compulsory license will be taken on a patent (“predictability”) and the relative importance of the markets affected by the license (“importance”).<sup>9</sup> In the six cases analyzed, licenses that were either unpredictable or did not affect important markets had no discernable impact on R&D, all other things being equal. In all cases but one, the license was either unpredictable or did not impact a developed, existing product market. I observed no reduction in R&D activity in these cases. However, in the one case where licensing was both predictable and impacted a developed market for a drug, there was some evidence of a decline in R&D. Although too few in number to be conclusive, these cases and earlier work provide hope that compulsory licensing and innovation do not necessarily conflict. They also underscore that the manner in which compulsory licensing is structured and implemented affects innovation and suggest that the factors of predictability and market impact deserve special attention.

Part II of this Article provides an overview of compulsory licensing. Part III explores the role of patents in pharmaceutical innovation and discusses the compulsory licensing of drugs. Part IV discusses the existing literature on the impact of compulsory licensing on innovation. Part V reports the results of empirical analyses performed on six case studies of pharmaceutical compulsory licensing. Part VI offers suggestions for further research and policymaking based on the results discussed in this Article.

## II. COMPULSORY LICENSING OVERVIEW

Compulsory licenses are generally defined as “authorizations permitting a third party to make, use, or sell a patented invention without the

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9. An important factor not addressed in this analysis is the royalty level at which the license is set. *See infra* note 95 and accompanying text. The licenses studied ranged in compensation rate from zero to “reasonable” levels, and although this factor did not directly correlate with outcomes in innovation impact, it nonetheless represents an important variable in compulsory license design. *See infra* Table 1.

patent owner's consent."<sup>10</sup> Because they limit the power conferred by patents, compulsory licenses have long been controversial.<sup>11</sup> This part briefly reviews the origins of compulsory licenses, the arguments for and against them in both the United States and developing countries, and the record of their implementation in the United States.

### A. General Overview

The current debate over compulsory licensing is nothing new. In the United States Senate in 1790, in the House of Lords in Britain in 1851, and in Germany in 1853,<sup>12</sup> policy makers discussed compulsory licensing as a way to preserve the benefits of the patent system while minimizing its evils. On the one hand, patents created positive incentives for innovation and the disclosure of inventions, granted "just rewards" to inventors, demonstrated society's recognition of the "natural" property rights of inventors, and generally addressed the public goods problems associated with creation of knowledge.<sup>13</sup> On the other hand, these benefits came at a cost, including the potential abuse of monopoly power by patentees, the use of patents to block inventive activity by third parties, the diversion of productive activity disproportionately towards patentable activity, and the substantial administrative costs of operating a patent system.<sup>14</sup>

With these benefits and costs in mind, patent critics and advocates accepted compulsory licensing as a "strategic compromise" in 1873 at the Patent Congress in Vienna.<sup>15</sup> In order to preserve the incentive for innova-

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10. See SCHERER & WATAL, *supra* note 3, at 12.

11. Although this Article focuses on compulsory licenses in the patent context, these licenses also arise in the context of other intellectual property, such as copyrights. See ROBERT A. GORMAN & JANE C. GINSBURG, COPYRIGHT 498-505 (6th ed. 2002) (describing the introduction of compulsory licensing into U.S. copyright law in 1909 and discussing 17 U.S.C. § 115, which permits the taking of licenses to publicly distributed phonorecords without the permission of the copyright holder).

12. See FRITZ MACHLUP, STAFF OF SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE SENATE COMM. ON THE JUDICIARY, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM 5 (Comm. Print 1958) [hereinafter ECONOMIC REVIEW OF THE PATENT SYSTEM].

13. See, e.g., Machlup & Penrose, *supra* note 4, at 10-11.

14. See, e.g., Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998) (describing the problem of "blocking" patents in biomedical research); Machlup & Penrose, *supra* note 4, at 23-28 (discussing general critiques of the patent system); James Love, *Paying for Health Care R&D: Carrots and Sticks*, Consumer Project on Technology, Oct. 19, 2000, (articulating perceived abuses of the patent system), at <http://www.cptech.org/ip/health/rnd/carrotsnsticks.html> (last visited Aug. 27, 2003).

15. A battle occurred between the anti-patent movement of the 1850s through 1870s and the patent advocates of the 1870s through 1910s: "The strategic compromise was the

tion while increasing access to innovations themselves, the Congress adopted a requirement that licensees pay patent holders reasonable compensation for their licenses.<sup>16</sup> With the subsequent adoption of compulsory licensing by the 1883 Paris Convention,<sup>17</sup> the world's foremost international patent agreement, compulsory licensing became a fixture in almost all patent systems.<sup>18</sup>

While specific provisions vary, compulsory licenses are generally authorized in the event of undesirable behavior by the patentee, such as anti-competitive, non-working, or blocking behavior; in the event of "public need," such as government infringement or national emergency; or in the context of food and drugs.<sup>19</sup> Licensees are commonly required to pay adequate compensation to a patentee in exchange for use of a patent. The required amount is generally more than a "reasonable royalty," the floor for infringement compensation in the United States,<sup>20</sup> but less than "lost profits," another basis for calculating infringement damages.<sup>21</sup> The amount of compensation varies among countries; commentators have observed that "the United Kingdom has provided the most generous compensation in its drug patent licensing decisions; the United States the least generous compensation in key antitrust decisions."<sup>22</sup>

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acceptance of the principle of compulsory licensing—of compelling all patentees to license others to use the invention at reasonable compensation . . . . The patent advocates and the free traders compromised on this general limitation on the patentees' monopoly power." See ECONOMIC REVIEW OF THE PATENT SYSTEM, *supra* note 12, at 5.

16. *Id.*

17. See Paris Convention for Protection of Industrial Property, Mar. 20, 1883, art. 5A, 21 U.S.T. 1583 (last revised at Stockholm, July 14, 1967).

18. As of Feb. 13, 2002, 163 states, including most industrialized countries, had ratified the Convention. See World Intellectual Property Organization [hereinafter WIPO], *Paris Convention for the Protection of Industrial Property*, at <http://www.wipo.int/treaties/documents/english/word/d-paris.doc> (last visited July 18, 2003).

19. See, e.g., FREDERICK M. ABBOTT, COMPULSORY LICENSING FOR PUBLIC HEALTH NEEDS: THE TRIPS AGENDA AT THE WTO AFTER THE DOHA DECLARATION ON PUBLIC HEALTH (Quaker United Nations Office, Occasional Paper No. 9, 2002); Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349, 349-55 (1993).

20. 35 U.S.C. § 284 (2000) (stating that the damages for patent infringement "shall [be] . . . adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer").

21. ROBERT P. MERGES, PATENT LAW AND POLICY 1038-84 (2d ed. 1997).

22. SCHERER & WATAL, *supra* note 3, at 28.

## B. United States v. Developing Country Perspectives on Compulsory Licensing

Within the general framework of compulsory licensing, however, there has been little consensus on the best way to implement compulsory licensing. In modern times, nowhere has the divergence in views been more pronounced than in the context of the compulsory licensing provisions of TRIPS. This was particularly evident during the negotiations behind these provisions. While the United States viewed these provisions with distrust and suspicion, developing countries claimed them to be an essential part of a workable patent system.<sup>23</sup> Commentators have noted that the resulting provisions, discussed below, were left intentionally vague, reflecting the parties' inability to come to an agreement.<sup>24</sup>

The contrast in views on patents between the United States and developing countries is driven in part by differences in economic status. In developing countries, foreigners file most of the patents.<sup>25</sup> As a result, the

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23. During TRIPS negotiations in 1989, the U.S. representative characterized compulsory licensing as prone to "mischievous use," and favored a more restrictive, exceptional regime in which licensing would be permitted only for "legitimate purposes." *Note by the Secretariat, Meeting of Negotiating Group of 12-14 July 1989*, 14.doc, ¶ 83.2, available at WTO, [http://www.wto.org/english/tratop\\_e/trips\\_e/trips\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/trips_e.htm) (download derestricted official document archive under heading *History: Derestricted Uruguay Round Negotiating Documents on TRIPS*) (last visited Aug. 20, 2003). In contrast, India's representative stated that compulsory licensing should be viewed as a means for balancing the rights and obligations of patent holders; compulsory licenses should not be narrowly circumscribed, particularly since they are vital to the transfer of technology. *Id.* ¶ 83.3. This difference in views led to competing draft legislation in 1990. The version supported by the United States and other developed nations narrowly defined the basis for licenses, whereas the version supported by developing countries was much more open-ended. See generally ABBOTT, *supra* note 19.

24. See JEAN O. LANJOUW, *INTELLECTUAL PROPERTY AND THE AVAILABILITY OF PHARMACEUTICALS IN POOR COUNTRIES* 25 (Ctr. for Global Dev., Working Paper No. 5, 2002). *But see* REICHMAN & HASENZ AHL, *supra* note 7, at 12-13 (stating that the resulting language ultimately vindicated the stance of developing countries over that of the United States).

25. Consider, for example, Brazil and South Africa. These are two developing countries against which U.S. government and industry have initiated significant patent disputes over compulsory licensing. Brazil held less than 0.1% of the U.S. patents issued in 1998, while the United States captured nearly 40% of the patents issued in Brazil that same year. In South Africa, foreigners applied for over 99% of the patents in 1999 (issued patent data is not available), and 40% of those applications were from the United States. In contrast, South African inventors captured less than 0.1% of U.S. patents issued in 1998. See 1 NAT'L SCI. BD., *SCIENCE & ENGINEERING INDICATORS—2002*, source data for 6-21 fig.6-23, source data for 6-25 fig.6-27 [hereinafter NAT'L SCI. BD. SOURCE DATA], at <http://www.nsf.gov/sbe/srs/seind02/pdf/volume1.pdf> (last visited Aug. 24, 2003) (source data for fig.6-23, at <http://www.nsf.gov/sbe/srs/seind02/c6/fig06-23.xls>;

patent system facilitates the transfer of monopoly rents to foreigners outside the country, although it is also true that companies may choose not to patent inventions in markets they regard as too small to be significant.<sup>26</sup> Furthermore, the high price of products covered by patents can put needed technology out of the reach of developing country consumers, who are generally required to pay for drugs out of pocket due to the lack of health-care infrastructure.<sup>27</sup> To compensate for these patent system costs, permissive compulsory licenses are used to widen distribution of and increase access to patented technologies. The situation is different in the United States since U.S. inventors capture a large share of patents both domestically and abroad.<sup>28</sup> Patent profits from both domestic and international markets reward and support research performed locally by U.S. inventors.

Another basic reason for the difference in perspectives derives from the rationales behind each country's patent system. Generally, countries with relatively few patents view the patent system as a means to promote the transfer of technology from other countries.<sup>29</sup> Compulsory licensing provides an important safeguard to ensure that technology transfer happens in the event of non-working or high prices. In contrast, countries

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source data for fig.6-27, at <http://www.nsf.gov/sbe/srs/seind02/c6/fig06-27.xls>; U.S. PAT. & TRADEMARK OFF., PATENTING TRENDS CALENDAR YEAR 1999, at [http://www.uspto.gov/web/offices/ac/ido/oeip/taf/pat\\_tr99.htm](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/pat_tr99.htm) (last visited Aug. 24, 2003); WIPO, WIPO INDUSTRIAL PROPERTY STATISTICS 1999, WIPO Doc. IP/STAT/1999/B (1999), at <http://www.wipo.org/ipstats/en/publications/b/1999/i/pattab1.pdf> (last visited Aug. 24, 2003).

26. See Attaran & Gillespie-White, *supra* note 5, at 1890.

27. See WORLD HEALTH ORG. & WORLD TRADE ORG. SECRETARIATS, REPORT OF THE WORKSHOP ON DIFFERENTIAL PRICING AND FINANCING OF ESSENTIAL DRUG [sic] 6 (2001) (reporting that 90% of the population in developing countries buys medicines out-of-pocket, whereas only 20% of the population does so in high income countries), at [http://www.who.int/medicines/library/edm\\_general/who-wto-hosbjor/wholereporthosbjorworkshop-fin-eng.pdf](http://www.who.int/medicines/library/edm_general/who-wto-hosbjor/wholereporthosbjorworkshop-fin-eng.pdf) (last visited Aug. 24, 2003).

28. In the United States, a thin majority (54%) of patents were granted to U.S. residents in 2001. U.S. PAT. & TRADEMARK OFF., 2001 PERFORMANCE AND ACCOUNTABILITY REPORT 115, 118 (2001), at <http://www.uspto.gov/web/offices/com/annual/2001/01performreport.pdf>. Most of the remaining patents were granted to inventors from developed countries. *Id.* Because U.S. inventors capture an extensive share of the patents in these developed countries, the costs of foreign patenting are counterbalanced by the benefits to U.S. inventors of obtaining patents abroad. In 1998, for instance, the United States captured 45%, 28%, 28%, and 30.4% of the patents awarded to foreigners in Japan, Germany, France, and the United Kingdom, respectively, while the same countries each captured 46%, 14%, 5%, and 5%, respectively, of the patents awarded by the United States to residents of foreign countries. See NAT'L SCI. BD. SOURCE DATA, *supra* note 25.

29. See Edith Penrose, *International Patenting and the Less-Developed Countries*, 83 ECON. J. 768, 771 (1973).

such as the United States claim a relatively large share of the world's patents and look to the patent system primarily as an incentive to innovate and a means to stimulate technology creation.<sup>30</sup> This innovation-based focus leads to the selective application of compulsory licensing to cases where patents hinder rather than advance innovation.

### C. Compulsory Licensing in the United States

Consistent with a focus on innovation, the U.S. government has used compulsory licenses to curb anti-competitive behavior.<sup>31</sup> By 1977, the Federal Trade Commission ("FTC") and DOJ had issued approximately 125 decrees over thousands of patents and a wide range of technology.<sup>32</sup> Recently, such decrees have been ordered in the context of mergers, price-fixing, and the abuse of monopoly or market power.<sup>33</sup> Compulsory licensing has also been proposed as a solution to the problem of patent thickets, wherein broad or multiple patents over technology areas prevent follow-on research. Voluntary or compulsory patent pools, in which the rights to use multiple patents are exchanged among patentees have been proposed as a way to overcome the refusal of patentees to license an invention and the administrative burden associated with licensing.<sup>34</sup>

However, compulsory licensing has also been used to further public interests, primarily by enabling the U.S. government to use patented inventions without permission. Although courts have emphatically resisted issuing compulsory licenses merely because a patentee chooses not to use

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30. See Clarisa Long, *Patents and Cumulative Innovation*, 2 WASH. U. J.L. & POL'Y 229, 231 (2000).

31. See, e.g., *United States v. Nat'l Lead Co.*, 332 U.S. 319 (1947); *Hartford-Empire Co. v. United States*, 323 U.S. 386, 417 (1945); see also Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 297 n.46 (2003) (noting the role of the U.S. military in ensuring cross-licenses between the Wright Brothers and follow-on innovators).

32. See F.M. SCHERER, *THE ECONOMIC EFFECTS OF COMPULSORY PATENT LICENSING* 47-48 (1977).

33. See, e.g., *Compulsory Licensing as Remedy to Anticompetitive Practices*, Consumer Project on Technology, at <http://www.cptech.org/ip/health/cl/us-at.html> (last visited July 18, 2003) (reporting that of 25 compulsory licenses issued since the mid-90s, roughly half resulted from mergers and acquisitions, while the remainder resulted from other forms of anticompetitive behavior).

34. See generally JEANNE CLARK ET AL., U.S. PAT. & TRADEMARK OFF., *PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS?* 8-12 (2000) (discussing the use of patent pools as a solution to the problems associated with biotechnology patents), available at <http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf> (last visited July 19, 2003).

her invention,<sup>35</sup> the U.S. government routinely relies on 28 U.S.C. § 1498 to immunize its use of inventions without the patentee's permission. The statute limits a patentee's remedy for infringement by the government or a government contractor to "reasonable and entire compensation."<sup>36</sup> By not allowing for injunctive relief, the statute effectively strips patentees of the right to prevent others from using their inventions.

Although the statute was originally conceived with wartime urgency in mind,<sup>37</sup> the government has used it in a wide range of circumstances. Since 1948, the year of the statute's enactment in its current form,<sup>38</sup> the Court of Federal Claims and its predecessors have decided almost 300 cases, involving a wide variety of technologies, under § 1498.<sup>39</sup> Although this figure is surprisingly large, it arguably understates the use of compulsory licenses by the government because it excludes cases resolved without litigation and infringement that goes unnoticed by the patentee. In infringement suits against the government that have been decided on the

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35. See, e.g., *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 429 (1908) (holding that "it is the privilege of any owner of property to use or not to use it, without question of motive"); see also 35 U.S.C. § 271(d)(4) (2000) (confirming by amendment under the Patent Misuse Reform Act of 1988 that the refusal to license or use one's patents rights does not by itself constitute misuse for which compulsory licensing would be a remedy).

36. 28 U.S.C. § 1498(a). The subsection states:

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his *reasonable and entire compensation* for such use and manufacture

. . . .

*Id.* (emphasis added).

37. In *Richmond Screw v. United States*, the Supreme Court commented about the statute:

The intention and purpose of Congress . . . was to stimulate contractors to furnish what was needed for the war, without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents . . . . To accomplish this governmental purpose, Congress exercised the power to take away the right of the owner of the patent to recover from the contractor for infringements.

275 U.S. 331, 345 (1928).

38. See 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, 415 (1995).

39. *Id.* at 496 n.563 (noting that there have been 240 cases from 1949 to Apr. 1, 1994); LEXIS search, Genfed Library, FED File (Apr. 2, 1994 through Aug. 10, 2002) using search terms "28 U.S.C. § 498", "government", and "patent".

merits, plaintiff patentees have won just over one-third of the time,<sup>40</sup> as compared to a 58% success rate of patentees against accused infringers in general.<sup>41</sup> Outside the context of § 1498, compulsory licenses have been authorized for public policy reasons, but on a more limited scale.<sup>42</sup>

### III. THE COMPULSORY LICENSING OF DRUGS

Against the backdrop of compulsory licensing, this part discusses the role of patents in drug innovation and the compulsory licensing of drugs both in the United States and under TRIPS.

#### A. Patents and Drug Innovation

Drugs have been singled out for special treatment both in terms of patenting and compulsory licensing primarily because of their role in promoting public health. For many years product patents were not awarded over pharmaceuticals. In the developed world, Japan did not introduce product patents for drugs until 1976, and pharmaceutical powerhouse Switzerland waited until 1977 to introduce patents covering pharmaceutical products.<sup>43</sup> Spain, Portugal, Greece, and Norway introduced product patents over drugs as recently as 1992.<sup>44</sup> At the end of the 1980s, at least forty developing countries, including the most populous, provided no patent protection for pharmaceuticals.<sup>45</sup> The rationale behind this policy of

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40. This figure is based on an analysis of cases from 1982 to 1993. *See* Lavenue, *supra* note 38, at 502.

41. Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 385 (2000).

42. *See* 42 U.S.C. § 2183 (2000) (allowing the Atomic Energy Commission to compel licensing of certain “public interest” patents); *id.* § 7608 (allowing compulsory licenses if use of the patented invention is required to meet emission requirements, no reasonable alternative is available to meet the requirements, and the lack of availability of the patentee would tend to lessen competition). In several cases, courts have *de facto* authorized compulsory licensing by awarding damages but refusing to enjoin infringement for public interest reasons. *See* *Vitamin Technologists v. Wis. Alumni Research Found.*, 146 F.2d 941 (9th Cir. 1945) (stating that the partial refusal to license production of vitamin D in oleomargarine amounted to patent misuse and suggesting that an injunction could be denied if the refusal to license was against public interest); *Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577 (7th Cir. 1934) (declining to issue an injunction against a patent infringing sewage plant because it would cause lake pollution), *cert. denied*, 293 U.S. 576 (1934).

43. JEAN O. LANJOUW & IAIN COCKBURN, *DO PATENTS MATTER? EMPIRICAL EVIDENCE AFTER GATT 1 n.2* (Nat’l Bureau of Econ. Research, Working Paper No. 7495, 2000).

44. *Id.*

45. *Id.* at 1. However, all WTO members are obligated to offer pharmaceutical patent protection by 2016. *See* ABBOTT, *supra* note 19, at 11.

non-protection was that drugs are too important to patent and leave vulnerable to monopoly abuses.

However, a competing rationale has stimulated the recent trend toward granting patent protection for drugs. Drug development is enormously time-consuming, risky, and expensive,<sup>46</sup> intensifying the importance of the patent incentive. In addition, drug patents tend to be more effective in securing commercial advantage because, once invented, drugs are relatively easy to copy, and because a few key patents usually cover a single drug product.<sup>47</sup> Accordingly, surveys published in 1986 and 2000 all concluded that the pharmaceutical, biotechnology, and chemical industries rely more heavily on patents than other industries.<sup>48</sup> Pointing to these facts, critics of compulsory licensing have concluded that drugs are too crucial *not* to be protected by patents.

The U.S. system reflects this inherent tension, extensively regulating drug development on one hand and providing special incentives for drug innovation on the other. In terms of regulation, pharmaceutical companies must undergo a lengthy drug approval process administered by the

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46. Precisely how expensive is highly contested. Researchers at Tufts estimate the cost of developing a new drug to be \$802 million. Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003). However, roughly half of this figure reflects opportunity costs within the industry. *Id.* Using data from PhRMA, Public Citizen estimates the cost of development to be between \$114 million and \$150 million. PUBLIC CITIZEN, RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY'S R&D "SCARE CARD" 7 (2001), available at <http://www.citizen.org/documents/acfdc.pdf> (last visited Aug. 27, 2003). The Boston Consulting Group, who estimates a development cost of \$880 million, suggests that \$165 million is spent in target identification, \$205 million is spent on target validation, \$40 million is spent on screening, \$120 million is spent on optimization, \$90 million is spent on pre-clinical development, and \$260 million on clinical development. The time expended in each of these phases is estimated at 1, 2, 0.4, 2.7, 1.6, and 7 years, respectively. See PETER TOLLMAN ET AL., THE BOSTON CONSULTING GROUP, A REVOLUTION IN R&D: HOW GENOMICS AND GENETICS ARE TRANSFORMING THE BIOPHARMACEUTICAL INDUSTRY 12 (2001), available at [http://www.bcg.com/publications/files/eng\\_genomicsgenetics\\_rep\\_11\\_01.pdf](http://www.bcg.com/publications/files/eng_genomicsgenetics_rep_11_01.pdf).

47. See F.M. Scherer, *The Pharmaceutical Industry and World Intellectual Property Standards*, 53 VAND. L. REV. 2245, 2247 (2000) (estimating that it costs only \$1 million to copy a drug); cf. DiMasi, *supra* note 46 (estimating the development cost of a new pharmaceutical to be \$802 million).

48. This difference in reliance on patents is decreasing. See WESLEY M. COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) 11-14 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000), available at <http://papers.nber.org/papers/w7552.pdf> (last visited Aug. 27, 2003); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 175 (1986).

Food and Drug Administration (“FDA”) prior to selling a new drug to the public. Companies must prove the efficacy and safety of the new drug. Direct-to-consumer drug advertising, liberalized in 1997, remains heavily regulated.<sup>49</sup> The government has occasionally authorized or ordered the compulsory licensing of patented drugs as well, as discussed below.

In terms of incentives, the Orphan Drug Act of 1983 provides marketing exclusivity, tax incentives, and research grants for companies engaging in research on rare “orphan” diseases that affect a small share of the population.<sup>50</sup> Similarly, the Hatch-Waxman Act of 1984 extends the period of exclusivity granted by drug patents in order to compensate for time lost in FDA approvals.<sup>51</sup> These extensions are meant to encourage not only the initial R&D that leads to the discovery of patentable drug inventions, but the expensive and time-consuming testing and commercialization of inventions after their discovery. In fact, according to one estimate, close to 50% of expenditures take place post-patenting.<sup>52</sup> Although post-patenting development activities are highly worthwhile and for all practical purposes required in order for the public to benefit from the patented innovation, they are not necessarily “innovative” in the sense typically thought of, especially given that they are carried out downstream from the patentable invention, often by parties other than the inventor.<sup>53</sup>

## **B. Compulsory Licensing of Drugs in the United States**

To date, Congress has resisted enacting specific provisions authorizing the compulsory licensing of drugs, although pharmaceutical-specific

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49. See Tamar V. Terzian, *Direct-to-Consumer Prescription Drug Advertising*, 25 AM. J.L. & MED. 149 (1999) (describing the FDA’s in-depth regulations of prescription drug broadcast advertisements).

50. See, e.g., F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97 (1993) [hereinafter Scherer, *Pricing*].

51. See THE BOSTON CONSULTING GROUP, *SUSTAINING INNOVATION IN U.S. PHARMACEUTICALS: INTELLECTUAL PROPERTY PROTECTION AND THE ROLE OF PATENTS* 16-18 (1996).

52. TOLLMAN ET AL., *supra* note 46 and accompanying text. In the Boston Consulting Group model, it is assumed that there are eleven years of patent protection after clinical development. *Id.* at 59-60. Based on a patent life of twenty to twenty-three years, after Hatch-Waxman extensions, this means that patents are issued nine to twelve years before FDA approval, before the time consuming clinical and development phases, which consume 45% of total expenditures. See The Boston Consulting Group, *supra* note 51, at 35 (stating that average extensions are two to three years in length).

53. See generally DATAMONITOR, REP. NO. DMHC1554, *CREATING WIN-WIN BIOTECHNOLOGY AND PHARMACEUTICAL DEALS* 22 (Oct. 2000) (describing the various ways in which biotechnology firms may license their inventions to pharmaceuticals in the development phase and estimating that 30% of pharmaceuticals use portfolio management, a strategic tool that specifically contemplates drug development partnerships).

price regulation has been contemplated intermittently since the 1950s. In the late 1950s and early 1960s, the Kefauver hearings turned public scrutiny on the industry's above-average profit levels, price markups, false and misleading advertising, and general lack of price competition.<sup>54</sup> In 1962, Congress enacted the Kefauver-Harris amendments, which increased the FDA's involvement in the development and advertising of drugs.<sup>55</sup> U.S. lawmakers again addressed price control mechanisms in 1972 with the proposal of the Public Health Price Protection Act, which was ultimately unsuccessful.<sup>56</sup>

During the 1990s, several trends came together to focus attention on drug pricing, the most prominent being the "relentless escalation" of health care costs.<sup>57</sup> By 1992, the United States devoted 14% of its Gross National Product to healthcare costs, more than any other industrialized country.<sup>58</sup> Prices rose much faster on drugs than on other goods, and pharmaceutical profitability levels topped those of all other industries.<sup>59</sup> The unsuccessful Hart Bill of 1993 and Affordable Prescription Drugs Act of 1999 proposed compulsory licensing of health related patents in various circumstances, such as unreasonable pricing.<sup>60</sup> In 2000 and 2002, President Clinton and President Bush, respectively, blocked the implementation of bills that would have enabled prescription drug wholesalers to import drugs from countries where they are cheaper.<sup>61</sup>

As another form of price regulation, compulsory licenses over drug patents have been granted in two contexts—under 28 U.S.C. § 1498 and under antitrust consent decrees. Although few in number, drug licenses taken pursuant to the statute have involved deliberate infringement by the

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54. See Mary T. Griffin, *AIDS Drugs & the Pharmaceutical Industry: A Need for Reform*, 17 AM. J.L. & MED. 363, 377 (1991).

55. *Id.*

56. *Id.* at 404.

57. Scherer, *Pricing*, *supra* note 50, at 97.

58. *Id.*

59. *Id.* at 98.

60. See Joseph A. Yosick, *Compulsory Patent Licensing for Efficient Use of Inventions*, 2001 U. ILL. L. REV. 1275, 1278 (2001).

61. See Mason Essif, *Prescription Drugs are Crossing Borders to Buyers*, CNN.COM, Mar. 12, 2001, at <http://www.cnn.com/2001/HEALTH/03/12/prescription.drugs> (last visited Aug. 1, 2003); Robert Pear, *Plan to Import Drugs From Canada Passes In Senate, but Bush Declines to Carry It Out*, N.Y. TIMES, July 18, 2002, available at 2002 WL 24463223. *But see Import Drug Bill Clears House*, CBSNEWS.COM, July 25, 2003, at <http://www.cbsnews.com/stories/2003/07/25/politics/main565066.shtml> (last visited Aug. 11, 2003) (describing House passage of a bill that allows for importation of drugs from Canada and the European Union and that, unlike past bills, specifically avoids presidential oversight of the drug approval process).

government to produce drugs for public health purposes. In the 1960s and 1970s, the U.S. government made and used tetracycline<sup>62</sup> and meprobamate<sup>63</sup> for the military without permission from patent holders. Similarly, in the fall of 2001, the threat of a compulsory license was used to drive down the price of the patented drug Cipro by almost 50%.<sup>64</sup>

Antitrust orders have generated many more compulsory licenses, and have been issued to remedy patent misuse and the use of patents in price-fixing, entry-restricting cartels, and market concentration schemes.<sup>65</sup> One of the most notable early cases involved the licensing of tetracycline, ampicillin, and related products as part of a judgment against Pfizer, American Cyanamid, and other pharmaceutical companies, in response to an antibiotic price-fixing scheme.<sup>66</sup>

In the 1970s, the FTC created a division, staffed with thirty-five lawyers and investigators within the Bureau of Competition, to work exclusively on health care antitrust issues.<sup>67</sup> In the second half of the 1980s and early 1991, in response to the rising number of pharmaceutical mergers, the division issued twelve consent decrees. Five decrees involved horizontal mergers between direct competitors, three involved mergers between potential competitors, and four involved the proposed combination of R&D “innovation” markets.<sup>68</sup> Six of the twelve decrees ordered the compulsory licensing of patented drugs; these form the basis of the analysis in Part IV.

Although all antitrust licensing orders seek to address antitrust concerns, their provisions have varied, depending on whether the objective is to increase access to existing competitors, facilitate entry of new competitors, or redress past wrongs by the patentee. Under a decree, remuneration for licenses may be negotiated by the parties, set by the court, or set at

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62. See SCHERER & WATAL, *supra* note 3, at 26.

63. *Carter-Wallace, Inc. v. United States*, 496 F.2d 535 (Ct. Cl. 1974).

64. See Kavaljit Singh, *Anthrax, Drug Transnationals, and TRIPs*, FOREIGN POLICY IN FOCUS NEWSLETTER, Apr. 29, 2002, at 1-3, available at <http://www.fpip.org/pdf/gac/OUS0204trips.pdf> (last visited Aug. 8, 2003); Press Release, U.S. Dep’t Health & Human Servs., HHS, Bayer Agree To Cipro Purchase (Oct. 24, 2001), available at <http://www.hhs.gov/news/press/2001pres/20011024.html> (last visited Aug. 8, 2003).

65. SCHERER & WATAL, *supra* note 3, at 17.

66. See *In re Am. Cyanamid Co.*, 63 F.T.C. 1747 (1963); Peter Temin, *Technology, Regulation, and Market Structure in the Modern Pharmaceutical Industry*, 10 BELL J. ECON. 429, 435-41 (1979).

67. See HEALTHCARE SERVS. & PRODS. DIV., FED. TRADE COMM’N, FTC ANTI-TRUST ACTIONS IN HEALTHCARE SERVICES AND PRODUCTS 1-2 (Apr. 2003), available at <http://www.ftc.gov/bc/hcupdate030401.pdf>.

68. *Id.*

zero (royalty-free). Most often, orders call for reasonable royalties and let the parties decide on the price. The court only intervenes if the parties cannot agree. Some orders indicate specific monetary licensing terms, while others authorize cross-licenses as an alternative.<sup>69</sup> Royalty-free licenses are issued more rarely—usually in cases of misconduct.<sup>70</sup>

Additionally, to ensure that the license issues to a viable or prospective competitor, the DOJ or FTC approval of the licensee and additional license terms is sometimes required.<sup>71</sup> Also, to increase the likelihood that patents will be used efficiently, the license may cover know-how, manufacturing capability, or other tangible or intangible assets in addition to the patents. Special precautions are often taken in the case of pharmaceutical licenses because of the special challenges posed by the time-consuming and expensive drug development process.<sup>72</sup> This has led to the creation of additional obligations for the patentee, such as providing ongoing support until the licensee's product is approved, and the possibility of a continuing relationship with the licensee.

### C. Compulsory Licensing of Drugs under TRIPS

TRIPS contains a comprehensive framework for the compulsory licensing of patented inventions. The agreement also makes clear that, for public health reasons, countries may suspend patent protection over drugs.

The primary provision for compulsory licensing is Article 31, which is entitled "Other Use without Authorization of the Right Holder."

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69. See, e.g., *Hartford-Empire Co. v. United States*, 323 U.S. 386, 414-17 (1945).

70. See, e.g., Lawrence Schlam, *Compulsory Royalty-Free Licensing as an Antitrust Remedy for Patent Fraud: Law, Policy and the Patent-Antitrust Interface Revisited*, 7 CORNELL J.L. & PUB. POL'Y 467 (1998).

71. See *In re Institut Merieux S.A.*, 113 F.T.C. 742 (1990).

72. See BUREAU OF COMPETITION, FED. TRADE COMM'N, A STUDY OF THE COMMISSION'S DIVESTITURE PROCESS 40-41 (1999), available at <http://www.ftc.gov/os/1999/08/divestiture.pdf> (last visited Aug. 28, 2003). The study stated that:

The pharmaceutical orders played an important role in the development of the divestiture remedies because they posed, in a more obvious form, some of the difficulties found in the Study. . . . Foremost among them is the fact that divestiture is not possible unless the Food and Drug Administration authorizes the buyer to produce the drug or health product. Until approval is obtained, the most that the buyer could expect to do under FDA rules is to market and distribute the products made by the respondent. In the meantime, the buyer would be required to build and replicate exactly the respondent's production facilities. The orders had to reflect these realities through provisions requiring interim supply agreements and technical assistance for a substantial period of time.

*Id.*

This provision permits WTO member countries to authorize compulsory licenses for use by the government or third parties subject to certain restrictions. Under all circumstances, patentees are to receive “adequate remuneration . . . taking into account the economic value of the authorization.”<sup>73</sup> Before licenses are granted, the proposed user must try unsuccessfully for a reasonable amount of time to secure a license on reasonable terms.<sup>74</sup> However, this requirement is waived if there is “a national emergency” or a “circumstance[] of extreme urgency,” or if the patented invention is used for “public noncommercial use.”<sup>75</sup> Such use must be non-exclusive and non-assignable.<sup>76</sup> Additionally, unless the patentee has engaged in anticompetitive behavior, the use must predominately supply the domestic market.<sup>77</sup> Finally, the scope and duration of use is limited to the purpose authorized with a license subject to termination “if and when the circumstances which led to it cease to exist and are unlikely to recur.”<sup>78</sup> Article 30 authorizes general exceptions to patent protection, presumably including compulsory licensing, but states that these exceptions must neither “unreasonably conflict with a normal exploitation of the patent” nor “unreasonably prejudice the legitimate interests of the patent owner.”<sup>79</sup>

While Articles 30 and 31 apply to patents in all fields, Articles 8 and 27, as well as the Doha Declaration on the TRIPS Agreement and Public Health (“Doha Declaration”), explicitly address the relationship between TRIPS and public health. Article 8 states that “[m]embers may . . . adopt measures necessary to protect public health,” but adds the requirement that “such measures are consistent with the provisions of this Agreement.”<sup>80</sup> Article 27 allows member countries to exclude from patentability inventions needed to protect public health.<sup>81</sup> The Doha Declaration on TRIPS, adopted in October 2001 by the WTO Ministerial Conference, affirms that countries may undertake compulsory licensing for public health reasons. Heralded as a major step forward in paving the way for cheap drugs for the poor,<sup>82</sup> it states in part:

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73. TRIPS Agreement art. 31(h).

74. *Id.* art. 31(b).

75. *Id.*

76. *Id.* art. 31(d)-(e).

77. *Id.* art. 31(f), (k).

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

79. *Id.* art. 30.

80. *Id.* art. 8(1).

81. *Id.* art. 27(2).

82. See, e.g., Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 28 (2002) (describing

We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate declaration.<sup>83</sup>

In addition, the Doha Declaration clarifies that member countries may define for themselves “what constitutes a national emergency or other circumstances of extreme urgency.”<sup>84</sup> When a country declares an emergency in good faith, this waives the obligation to negotiate under Article 31(b) before issuing a compulsory license. Finally, the Declaration acknowledges the problems imposed by Article 31’s requirement that manufacturing be done primarily to service the domestic market, which prevents countries without generic drug manufacturing capabilities from making use of the provision.<sup>85</sup>

While developing countries have pressed for a broad interpretation of the Doha Declaration, and thus a large list of diseases for which patent rules will be relaxed, drug companies and their respective governments have advocated for a narrow interpretation of the Declaration.<sup>86</sup> Despite the Declaration’s requirement that the TRIPS Council find an “expeditious

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the Declaration as an “important achievement” that “broke new ground in guaranteeing Members’ access to medical products”).

83. WTO, Ministerial Declaration, Fourth Ministerial Conference in Doha, Qatar, ¶ 17 (adopted Nov. 14, 2001).

84. See WTO, Declaration on the TRIPS Agreement on Public Health, Fourth Ministerial Conference in Doha, Qatar, ¶ 5(c) (adopted Nov. 14, 2001) [hereinafter Doha Declaration].

85. *Id.* ¶ 6. The Doha Declaration states  
[w]e recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

*Id.*

86. See, e.g., Sarah Boseley & Charlotte Denny, *Prescription for World’s Poorest Stays Unwritten: WTO Conference Deadlock as US Shows no Sign of Loosening Veto on Pharmaceutical Patent Rights*, GUARDIAN, Feb. 20, 2003, available at [http://www.economist.com/agenda/displayStory.cfm?story\\_id=1589657](http://www.economist.com/agenda/displayStory.cfm?story_id=1589657) (last visited July 19, 2003); *Negotiators Meet Again; Minds Don’t*, ECONOMIST, Feb. 19, 2003, available at [http://www.economist.com/agenda/displayStory.cfm?story\\_id=1589657](http://www.economist.com/agenda/displayStory.cfm?story_id=1589657) (last visited July 19, 2003).

solution” to these issues by the end of 2002;<sup>87</sup> by August 2003, no such solution had been devised.

#### IV. EMPIRICAL BACKGROUND (LITERATURE REVIEW)

One major obstacle to the widespread use of compulsory licenses has been the perception that licenses reduce the incentive for innovation offered by the patent system.<sup>88</sup> Insofar as patents are needed to induce innovation, the argument goes, weakening patents through compulsory licenses will reduce innovation. This notion has special import for the drug industry.

First, it is often repeated that drugs, due to the costs and risks associated with drug development, are different than other inventions, and that the drug industry relies on patents more than other industries.<sup>89</sup> Because of this unique dependence on patents, more is at stake for the drug industry than for other industries when measures that reduce patent protection such as compulsory licensing are contemplated.

Second, in light of the current public health crisis, relaxation of patent rules will likely take place to some degree, regardless of any potential effect on innovation.<sup>90</sup> In the context of the AIDS crisis and public health generally in developing countries, at least two kinds of incentives are relevant—those that prompt research in diseases of common interest to developed and developing countries (e.g., AIDS), and those that encourage research in areas specifically relevant to developing countries (e.g., malaria).<sup>91</sup> Particularly problematic could be a negative impact on R&D specific to the developing countries, the growth of which is anxiously anticipated with the introduction of stronger patent protection.<sup>92</sup> In light of

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87. Doha Declaration, *supra* note 84, ¶ 6.

88. *See* Tren, *supra* note 2.

89. *See* Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 1987 BROOKINGS PAPERS ON ECON. DEV. 783, 796-98 (1987); *supra* note 48.

90. *See infra* note 81 and accompanying text.

91. *See* Jean O. Lanjouw, A Patent Policy Proposal for Global Diseases (Apr. 2001), at [http://econ.worldbank.org/files/1733\\_lanjouw.pdf](http://econ.worldbank.org/files/1733_lanjouw.pdf) (last visited July 14, 2003).

92. *See generally* CARSTEN FINK, HOW STRONGER PATENT PROTECTION IN INDIA MIGHT AFFECT THE BEHAVIOR OF TRANSNATIONAL PHARMACEUTICAL INDUSTRIES (World Bank Group, Policy Research Working Paper No. 2352, 2000) (modeling the impact of stronger patent rights on the pharmaceutical industry in India), at [http://www-wds.worldbank.org/servlet/WDSContentServer/WDSP/IB/2000/06/27/000094946\\_00060905463269/Rendered/PDF/multi\\_page.pdf](http://www-wds.worldbank.org/servlet/WDSContentServer/WDSP/IB/2000/06/27/000094946_00060905463269/Rendered/PDF/multi_page.pdf) (last visited July 28, 2003); LANJOUW & COCKBURN, *supra* note 43, at 3-4 (establishing for future reference the current baseline of research efforts devoted to those diseases specific to developing countries).

these incentives, the challenge for policy makers will be to implement patent-weakening schemes that increase access but cause minimal harm to the patent innovation incentive.

#### A. Compulsory License Design

The impact of a license on the licensor's innovation depends on a variety of factors. The following paragraphs identify possible factors that might determine how much a compulsory license impacts innovation.

It is clear that the price at which a compulsory license is set will determine whether and how much innovation is affected. If a compulsory license price is set essentially at what a patentee demands, there is no real reason to anticipate that innovation will be substantially harmed. On the other hand, a compulsory license whose price is set at a level far below market could operate to effectively strip the patentee of its right to any monopoly profits.<sup>93</sup> Besides price, two factors that deserve special attention are "market significance," or the extent to which a licensee actually threatens the patentee's markets, and "predictability," or the extent to which a licensor anticipates a compulsory license.

As to market significance, compulsory licenses can vary in degree as to the competitive threat they pose to licensors. If a compulsory license covers a known product in a licensor's target market, the licensor and the licensee will have to share the same market. Under the above definition, the market significance of this license is high because the licensor's market is directly threatened. Conversely, if the license covers a market that is unimportant to the licensor, or it covers a product that has yet to be proven or for which the market is immature or untested, there is a good chance that the licensee and licensor will not compete head to head. The significance of this license may be relatively low.

Whether a license is predictable is also an important characteristic. Unpredictable licenses that cover only existing technologies are more limited in scope than those that are predictable and cover future inventions. Although the unanticipated loss of exclusivity that accompanies an unpredictable compulsory license may influence a company's decisions about investing in follow-on innovation, development, and commercialization, the licensing event may come at a point that is too late for the company to change course. This is not the case with an order that requires licensing of

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93. For a deeper analysis of the ethical and economic issue of what developing countries should contribute to innovation, see WILLIAM JACK & JEAN O. LANJOUW, FINANCING PHARMACEUTICAL INNOVATION: HOW MUCH SHOULD POOR COUNTRIES CONTRIBUTE? (Ctr. for Global Dev., Working Paper No. 28, 2003), at [http://www.cgdev.org/wp/cgd\\_wp028.pdf](http://www.cgdev.org/wp/cgd_wp028.pdf) (last visited Aug. 8, 2003).

future patents. The licensor may choose to redirect R&D investment, put off inventive activity until the license has expired, or choose trade secret over patent protection.

## B. Literature Review

For some time, researchers have not focused on compulsory licensing and the more general phenomenon of weakening patent protection, presumably because changes to the patent system over the last several decades have been in the direction of strengthening patent protection.<sup>94</sup> Nevertheless, major studies conducted in the 1960s and 1970s on compulsory licensing regimes concluded that, as implemented, licensing had no long-term negative impact on licensor innovation.<sup>95</sup> The most thorough study to date, that focused on U.S. antitrust consent decrees issued during the 1950s and 1960s, found that licensing had no measurable impact on future innovation in any of the industry segments studied, including pharmaceuticals.<sup>96</sup> Another major study that focused on Canada's extensive general compulsory licensing program similarly concluded that Canada's program had no negative impact on pharmaceutical innovation.<sup>97</sup>

However, research on related questions suggests that some forms of compulsory licensing could be detrimental to innovation. From 1967 to 1968, the Harbridge House conducted a study of civilian utilization of inventions created for the government. The study demonstrated that the loss of exclusivity due to the compulsory licensing of some of the inventions negatively affected utilization rates of those inventions.<sup>98</sup> In addition, there is a perception that compulsory licensing can discourage R&D. A survey of British pharmaceutical executives suggested that they believed that, in some extreme forms, licensing could harm innovation.<sup>99</sup>

Like the study in this Article, these studies focused exclusively on licensor innovation, and largely ignored the impact of compulsory licensing on the licensee. The licensee often benefits from the "spillover" effects

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94. See LANJOUW & COCKBURN, *supra* note 43.

95. See SCHERER, *supra* note 32; Donald G. McFetridge, *Intellectual Property, Technology Diffusion, and Growth in the Canadian Economy*, in COMPETITION POLICY AND INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE BASED ECONOMY 65 (Robert D. Anderson & Nancy T. Gallini eds., 1998).

96. See SCHERER, *supra* note 32, at 67-75.

97. See McFetridge, *supra* note 95.

98. See SCHERER, *supra* note 32, at 78-82.

99. C.T. TAYLOR & Z.A. SILBERSTON, THE ECONOMIC IMPACT OF THE PATENT SYSTEM 198-99 (1973) (study results further described in SCHERER, *supra* note 32, at 60-62).

of the original innovation.<sup>100</sup> Indeed, follow-on innovation by competing licensees or by potential entrants is often the very aim of licensing orders in the antitrust context.<sup>101</sup> The question of whether a potential tradeoff between increased licensee innovation and decreased licensor innovation exists, however, is beyond the scope of this Article.

### C. Compulsory Licensing under U.S. Antitrust Consent Decrees

In 1977, F.M. Scherer conducted a major study of antitrust, consent-related compulsory licenses. His study focused on nearly seven hundred companies, forty-two of which had been subject to compulsory licenses.<sup>102</sup> Scherer calculated the ratio of each company's R&D expenditures to its sales for the year 1975, and compared ratios between companies that had been subject to significant compulsory licensing decrees and those that had not. Scherer further modeled the relationship between compulsory licensing and R&D, and found a slight positive correlation between licensing and high R&D-to-sales ratios. On average, companies subjected to compulsory licensing actually spent more on R&D than similar firms in their industry that had not been subjected to compulsory licenses.<sup>103</sup> This was true for all industries, including pharmaceuticals. Because Scherer only had data from one year, he was not able to determine whether the R&D expenditures of the firms affected by compulsory licensing had fallen from previously higher levels.<sup>104</sup> Nevertheless, he concluded that compulsory licensing had not forced firms to invest in R&D at a level below the norms in their industries.<sup>105</sup>

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100. See Testimony of the Biotechnology Industry Organization Before the Federal Trade Commission and the Department of Justice, at 2 (Feb. 26, 2002), available at <http://www.bio.org/ip/pdf/ftc022002.pdf> (last visited Aug. 8, 2003).

101. See Susan DeSanti, The Intersection of Antitrust and Intellectual Property Issues: A Report from the FTC Hearings, Remarks for the Business Development Association Conference on Antitrust for High-Tech Companies (Feb. 2, 1996), available at <http://www.ftc.gov/speeches/other/desanti1.htm>.

102. See SCHERER, *supra* note 32, at 67-68, 74.

103. *Id.* at 75 ("To sum up, the analysis of 1975 research and development spending patterns provides no significant indication that 44 companies subjected to compulsory patent licensing under antitrust decrees sustained less intense R&D efforts than other firms of comparable size and industry origin. If anything the opposite tendency is revealed.").

104. In an earlier survey of thirty-eight companies affected by compulsory licenses, Scherer observed a statistically significant decline in patenting by companies. Based on interviews, he concluded that this was due to a statistical fluke or shift toward trade secrecy. *Id.* at 66-67.

105. *Id.* (observing a statistically significant simple average decline of 15% in absolute patenting).

Scherer's study focused on antitrust licensing decrees. These decrees mandated compulsory licensing as part of case settlements.<sup>106</sup> The majority of these licenses did not require future licensing of patents issuing from the year studied, but covered past inventions.<sup>107</sup> Although Scherer hypothesized that specific past experience with compulsory licenses or the general threat of licenses might produce an adverse impact on R&D behavior, he found no statistical results to support these hypotheses.<sup>108</sup> In the short-term, the largely unpredictable licenses studied did not appear to impact behavior in the year studied. The view that firms focused on the long-term was expressed in an earlier study conducted by Scherer that focused on companies that either had been or were on the verge of being forced to license patents in the antitrust context.<sup>109</sup> The most common explanation provided by the firms for not changing R&D was their long-term interest in the impacted business, and the view that they needed to continue R&D in order to stay competitive.<sup>110</sup>

#### **D. Compulsory Licensing of Drugs in Canada**

While the short-term, unpredictable nature of the antitrust licenses studied by Scherer may explain in part why he observed no negative impact on innovation, Canada's experience with compulsory licensing provides a useful example of the opposite extreme—completely predictable licenses.<sup>111</sup> From 1923 to 1993, Canadian legislation authorized compulsory licensing over medicines under sections 4(1) and 39(4) of the Canadian Patent Act. Canada's policy of issuing compulsory licenses for drugs became so routine that it led to the development of a domestic generic drug industry.<sup>112</sup>

In 1985, the Eastman Commission reported the effects of Canada's broad compulsory licensing system on innovation, focusing especially on the pharmaceutical industry.<sup>113</sup> From 1969 to 1983, the period studied by the Commission, almost 80% of the applications for licenses were granted,

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106. *Id.* at 63 (describing compulsory licensing in antitrust decrees generally).

107. *Id.* at 69.

108. *Id.* at 69, 74.

109. *Id.* at 62-63.

110. *Id.* at 62.

111. *See* REICHMAN & HASENZ AHL, *supra* note 7, at 18-20.

112. *See* SCHERER, *supra* note 32, at 83. The Canadian Parliament abolished the program in 1993 after intense lobbying by the U.S. government during NAFTA negotiations. Objecting vigorously to Canada's broad embrace of compulsory licensing, the U.S. government feared that other countries might follow suit. *See* REICHMAN & HASENZ AHL, *supra* note 7, at 21-22.

113. *See* McFetridge, *supra* note 95, at 83.

resulting in an average of approximately twenty compulsory licenses per year.<sup>114</sup> Comparing R&D intensities in Canada to intensities in other small, developed countries, the Commission concluded that compulsory licensing did not significantly affect innovation in Canada.<sup>115</sup>

One reason for this result may be the relative insignificance of the Canadian market to the worldwide market for pharmaceuticals. Researchers noted that for the most part, “Canadian R&D . . . expenditures constitute[d] a very small fraction of [corporate parent] R&D and . . . remain[ed] below the minimum efficient scale for in-house R&D in this industry.”<sup>116</sup> As a result, the lack of patent protection in Canada had little influence on R&D decisionmaking.

Thus the Scherer and Eastman Commission studies both concluded that compulsory licensing had little adverse impact on licensor innovation, but probably for different reasons. In the case of U.S. antitrust licenses, the unpredictability and short-term nature of the licenses may explain why they did not greatly affect innovation. In the case of Canadian drug licenses, the relative insignificance of the Canadian market may have accounted for the lack of a noticeable adverse impact.

#### **E. Licensing of U.S. Government Inventions**

In contrast to the Eastman and Scherer studies, a study conducted by Harbridge House reported that in some cases, a loss of patent rights might result in negative effects on innovation and commercialization. In the 1960s, the Federal Council for Science and Technology commissioned Harbridge House to investigate whether or not contractors based their decision to commercialize inventions they made for the government on exclusivity grounds.<sup>117</sup> Under the contracts studied, when a contractor created a patented invention for the U.S. government, the government could either take a license to the invention or take title to the invention itself. When the government merely took a license, the contractor had exclusivity over the civilian utilization of the invention. However, if the government took title to the invention, the contractor had no assurance of exclusivity. The contractor would then effectively be subject to the threat of a

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114. *Id.* at 82 tbl.1.

115. *Id.* at 88.

116. McFetridge reports that with the exception of Merck, 1994 Canadian R&D expenditures as a percentage of worldwide expenditures were less than 2%; e.g. 1.3% for Glaxo, 1.0% for Hoffman LaRoche, 0.7% for Pfizer, 1.2% for Sandoz, 1.4% for Ciba, 1.7% for Eli Lilly, and 6.1% for Merck. *Id.* at 84 n.24.

117. *See* SCHERER, *supra* note 32, at 78-84.

compulsory license in which the government or its potential licensees would have a complete, royalty-free right to use the patent.<sup>118</sup>

From its study of 1,720 contractor inventions, Harbridge House found a substantial difference in contractor utilization of patents depending on whether or not contractors had exclusive rights in civilian markets, although prior commercial experience proved to be the most significant factor.<sup>119</sup> Among contractors with commercial experience, 23.8% who had exclusive rights chose to commercialize their inventions. The figure was only 13.3% among contractors who did not have exclusive rights.<sup>120</sup> Among those without prior experience, there was also a demonstrable difference, although the shares are small—while 6.6% of those with exclusive rights chose to develop the technology, only 2.2% of those without exclusive rights did.<sup>121</sup> In-depth interviews revealed that small firms, new entrants, or firms facing substantial development and technological risks were the most sensitive to the presence or lack of exclusivity. These firms were generally unwilling to invest in commercialization without an assurance of exclusivity.<sup>122</sup> On the other hand, where contractors perceived that they had an advantage in the relevant market or that marginal costs were small relative to potential revenues, development was likely even despite a lack of exclusivity.<sup>123</sup>

The Harbridge study suggests that the relative importance of the markets implicated by a compulsory license matters with respect to innovation. In the case of the “licenses” analyzed, the contractors faced the loss of exclusivity in the civilian sector, which was their primary, most important market. In contrast, the licenses studied by the Eastman Commission implicated the Canadian market, which was viewed as less important by pharmaceutical patent holders. The implication of these two data points is that where the impacted market is important (as in the Harbridge study), an adverse impact on development may be more likely than where the impacted market is unimportant (as in the Eastman study).

In terms of predictability, commercialization was expected, as reported in the Harbridge study, because the government’s election to take title to a patent signaled its intent to commercialize that patent in the future. The threat posed by government utilization was thus more similar to the regular licensing regime of Canada in the Eastman Commission study

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118. *Id.* at 78-79.

119. *Id.* at 79-81.

120. *Id.* at 80.

121. *Id.*

122. *Id.* at 82.

123. *Id.*

than the sporadic licensing of the U.S. antitrust decrees in the Scherer study.

Thus, the Harbridge licenses were both predictable *and* covered a market significant to the patentee. Although appearing to discourage commercialization, the Harbridge licenses can be distinguished from the compulsory licensing schemes studied by Scherer and the Eastman Commission, where no negative impact on innovation was observed. The Scherer licenses were generally not predictable, issuing as part of investigative probes by the government. Although the Eastman licenses were predictable, they did not cover an important market for the patentees. The implication of these results appears to be that where licenses are unpredictable (Scherer) or implicate insignificant markets (Eastman), there will not necessarily be an adverse impact. However, licenses that are both predictable and affect significant markets, such as the Harbridge licenses, potentially are more risky, and appear to have a greater chance of being accompanied by a negative impact on innovation.

#### **F. Hypothetical Licensing of All Pharmaceutical Inventions**

Research conducted by Taylor and Silberston in the form of opinion surveys is consistent with this conclusion. The researchers asked officials from British industries, including the pharmaceutical industry, to predict the impact of a hypothetical system in which all patents, both domestic and foreign, were made available for licensing at reasonable royalties.<sup>124</sup> This extreme form of licensing would be predictable in its reach on future patents and would cover all, and therefore significant, markets. Executives from all industries were asked to evaluate this hypothetical system. The pharmaceutical industry respondents were the most concerned. On average, they predicted that 64% of R&D would be displaced without effective patent protection, as compared to a weighted average of 8% among all industries.<sup>125</sup>

#### **G. Summary of Results**

In summary, research to date indicates that, at a minimum, the presence of two factors may be required in order for compulsory licenses to impact innovation. These factors are the predictability of the license being granted and the significance of the market affected by the license. Where either factor is absent, little measurable effect on R&D expenditures has been observed, as shown in the studies performed by Scherer and the Eastman Commission. However when predictable licenses actually

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124. *Id.* at 61.

125. *Id.* at 62.

(Harbridge) or hypothetically (Taylor and Silberston) issue over important markets, the risk of a negative impact is greater. It should be emphasized that although these factors emerged from comparing these studies, other factors such as level of compensation may be just as important. Even if licenses are predictable and affect significant markets, if the price of the license is set at market rates, the license probably will not harm innovation. The factors of predictability and significant market impact may thus be necessary but not sufficient for producing a negative impact on innovation.

## **V. CASE STUDIES OF INVESTMENT IN INNOVATION AFTER SIX ANTITRUST CONSENT DECREES**

To test the hypothesis that only licenses that are both predictable *and* threaten a significant market adversely impact investment in innovation, I studied six cases from the 1980s and 1990s where the FTC issued pharmaceutical compulsory licenses. These cases were the only ones I could find in which licensing, rather than divestiture or other remedies, was prescribed and which were recent enough that data concerning the R&D behavior of the affected firms was available. However, these incidents of licensing are imperfect proxies for compulsory licensing in the international public health sphere for several reasons. The primary objective of these antitrust licenses was to preserve competition, not to increase consumer access to drugs per se. In addition, the licensing events were limited in scope in that they affected specific products produced by specific firms, rather than affecting broad therapeutic areas in entire industries. Such a broad license could be implicated if, for instance, compulsory licenses were made available to all African countries over AIDS vaccines drugs. Nonetheless, the licenses are relevant to the question of whether past compulsory licenses have been accompanied by a decline in innovation.

The licenses I studied were ordered under antitrust consent decrees issued by the FTC. Of the six licenses, four were sporadic and two were predictable, and three covered nascent and therefore relatively less important markets, whereas three jeopardized already developed, and therefore important, markets. Within this modest data set, I considered the relevance of the predictability and market significance of licenses to the R&D outputs of the affected companies. While general trends are reported below, case studies of each FTC order that analyze the license, overall business environment, and subsequent record of innovation by the licensor in the relevant market can be found in the Appendix.

While building on past work, this study introduces several new considerations. First, rather than analyze company-level activity, as did Scherer, I concentrate solely on company activity within an affected therapeutic area. This focus seems appropriate given the size and diversification of pharmaceutical companies—a substantial change to one therapeutic area may not be reflected in the activity of a company as a whole. However, this focus could overstate any impact on net innovation to the extent that a shift in activity away from the affected therapeutic area to another within a company that does not reduce overall R&D would appear as a decline in activity. Second, this study contemplates drug patents from the 1980s and 1990s. Selecting data from this period allowed me to test the robustness of previous findings in light of the trend toward strengthened patent protection, generally and over biological inventions.<sup>126</sup>

### A. The Antitrust Drug Licenses

With the exception of the *Eli Lilly* license (see Table 1), all of the licenses I studied arose in the acquisition or merger context.<sup>127</sup> Although each order resulted from negotiations with the FTC, four were “sporadic” in that they occurred only once to remedy a specific concern, and left little discernable expectation of future licenses in the near-term. In contrast, the licenses ordered in the *Eli Lilly* and *Merieux* cases both covered future innovation.<sup>128</sup> In the *Eli Lilly* case, the order called for all patents issued or applied for in the five-year period following the order to be subject to a royalty-free license. In the *Merieux* case, the order required that the acquirer, Institut Merieux S.A. (“Merieux”), lease Bioscience Connaught’s (“Connaught”) rabies vaccine business long-term, and that it retain no future interest in the business.<sup>129</sup>

**Table 1: Drug License Orders under Antitrust Decrees**

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126. See also *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (expanding patent protection to human made microorganism); see generally Jon F. Merz & Nicholas M. Pace, *Trends in Patent Litigation: The Apparent Influence of Strengthened Patents Attributable to the Court of Appeals for the Federal Circuit*, 76 J. PAT. & TRADEMARK OFF. SOC’Y 579 (1994) (noting the increase in judgments finding patents either valid or infringed, as opposed to invalid).

127. See *In re Ciba-Geigy Ltd.*, 123 F.T.C. 842 (1997); *In re Baxter Int’l Inc.*, 123 F.T.C. 904 (1994); *In re Dow Chem. Co.*, 118 F.T.C. 730 (1994); *In re Roche Holding Ltd.*, 113 F.T.C. 1086 (1990); *In re Institut Merieux S.A.*, 113 F.T.C. 742 (1990); *In re Eli Lilly & Co.*, 95 F.T.C. 538 (1980).

128. See *infra* Part VIII.C-D.

129. See *infra* Part VIII.D.

Licensor, Invention (Year of order)	Triggering Event	S(poradic) v. G(eneral) license	E(arly) v. M(id) v. L(ate) Stage of Drug Dev't	Nature of Market Affected	Subject of License	Compensation
Baxter, Fibrin Sealant <sup>130</sup> (1997)	Merger	S	M	Mature/ Significant	Patents +, manufacturing	0
Marion Merrell Dow, Dicyclomine <sup>131</sup> (1994)	Merger	S	L	Mature/ Significant	Patents +, manufacturing	0
Ciba-Geigy/Chiron, HSV-tk <sup>132</sup> (1997)	Merger	S	E	Nascent/ Less significant	Patents +	"no minimum"
Roche, CD4 <sup>133</sup> (1990)	Merger	S	E	Nascent/ Less significant	Patents +	1-3% of net sale
Eli Lilly, Insulin <sup>134</sup> (1980)	Illegal Conspiracy	G	E	Nascent/ Less significant	Future Patents+	Reasonable share of R&D expenses
Connaught, Rabies Vaccine <sup>135</sup> (1990)	Merger	G	L	Mature/ Significant	Entire Business	Reasonable sum

The stage of development of the affected technology varied among the cases. The *Chiron* and *Roche* cases involved concerns about patents

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130. *In re Baxter Int'l Inc.*, 123 F.T.C. 904 (1997).

131. *In re Dow Chem. Co.*, 118 F.T.C. 730 (1994).

132. *In re Ciba-Geigy Ltd.*, 123 F.T.C. 842 (1997).

133. *In re Roche Holding Ltd.*, 113 F.T.C. 1086 (1990).

134. *In re Eli Lilly & Co.*, 95 F.T.C. 538 (1980).

135. *In re Institut Merieux S.A.*, 113 F.T.C. 742 (1990).

over broad basic technologies and therefore covered some early-stage, pre-clinical technologies.<sup>136</sup> Similarly, the *Eli Lilly* license covered patents over insulin produced by novel recombinant DNA methods that had not yet undergone clinical trials at the time the order was issued.<sup>137</sup> The *Baxter* case was prompted by concerns about the merger of two companies that each had products in early development.<sup>138</sup> On the other end of the spectrum, the *Merieux* case involved older patents, and the *Dow* case covered a product market in which generic competition had already been introduced.<sup>139</sup>

The stage of technology is relevant to this analysis because, as described earlier, the drug development process is inherently uncertain. Candidate compounds are eliminated at each step. Taking away patent protection over an early stage technology arguably does not affect a patentee's competitive position as much as a license over a technology that has already surpassed many major milestones. Thus, as reported in Table 1, I characterized licenses over mid-to-late stage technologies as impacting developed and significant markets, and compulsory licenses covering early stage technologies as covering relatively less significant markets.

Importantly, each license from each of the six cases involved more than just patents, and most provided for access to know-how and other intangible assets. As stated earlier, this licensing practice reflected the FTC's recognition of substantial market barriers in the drug industry not associated with patents in general, as well as its view that a more robust form of licensing was crucial to the success of licensees.<sup>140</sup> Although individual license orders varied, most contained a provision of either reasonable or no compensation for the rights to use the patented invention. However, the *Baxter* and *Dow* licenses required the manufacturing and delivery of the patented product, so these orders provided for additional compensation to cover the costs of supply.<sup>141</sup>

## B. Measurement of the Impact of Drug Licenses

To determine whether licenses brought about a decline in innovation, I looked at patent applications filed by each licensor as reported in the Lexis-Nexis "Utility Patents" database, and where available, considered clinical trial, product launch, and other data specific to the affected

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136. See *infra* Part VIII.E-F.

137. See *infra* Part VIII.C.

138. See *infra* Part VIII.A.

139. See *infra* Part VIII.B, D.

140. See *supra* note 72 and accompanying text.

141. See *infra* Part VIII.A-B.

company in the affected product area during the years before and after the ordering of a consent decree. Although several weaknesses were inherent in this approach, as discussed below, patent applications appeared to provide the best means for measuring licensor impact in a specific technology area, which might otherwise be masked by either industry-level or aggregate company data. Although budget information regarding R&D in specific therapeutic areas or interviews with the companies themselves would also have been useful, I was unable to secure either source of information

To identify patent applications, I used keyword searching in the specifications and claims of patent applications that eventually matured into patents. Because queries are sensitive to the search terms used, I selected my terms by reading about the technology area and then formulating searches based on the original patents or patent applications licensed by the FTC order. I also asked a medical doctor to review the terms I used for the more ambiguous technological areas.<sup>142</sup>

To make my analysis less sensitive to the absolute number of patents filed for by the impacted companies during the affected timeframe, I replicated my searches in the entire Utility Patents database. I compared shares of patents filed by an affected company to patents filed for by the general population before, during, and after the affected period so as to eliminate any general bias due to changes in patenting. Based on the normalizations, I saw no difference in the patterns. Because of the time lag between R&D investment and the issuance of a patent based on the investment, I tried wherever possible to capture activity over long pre- and post-licensing event windows. Through this method, and by focusing on patent applications rather than patent grants, I tried to eliminate some of the time lag between innovative activity and patenting. For the older cases, I was able to capture up to fifteen years before and after the license; however, for the most recent cases, I was only able to capture four years of activity after the license.

Although I took the precautions described to filter biases from my data, other factors may affect the accuracy of my results. For example, companies may choose not to patent or to delay patenting inventions for strategic or other reasons. This fact tends to discredit the use of patenting activity as a measure of company investment in innovation. However, the patents at issue in the six cases at hand were most likely important to the relevant companies because the FTC considered the patents important enough to require that they be licensed. Another limitation is the possibility that the companies shifted their intellectual protection strategies to-

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142. The chosen search terms are described in the case studies in the Appendix.

wards trade secrecy, thereby maintaining their pre-licensing level of R&D while reducing patent output. If this is the case, post-licensing investment in innovation will have been understated by the patent counts.

To address the problems presented by using patents as a measure of investment in innovation, I used other measures of company commitment to each therapeutic area. I searched BioSpace Inc.'s Clinical Competitive Intelligence System for clinical trials that had been in progress sometime in the 2000 to April 2002 period.<sup>143</sup> The BioSpace database covers about 50% to 60% of all private and public clinical trials, and is reportedly the most comprehensive of all clinical trials database, including the development database offered on the Pharmaceutical Research and Manufacturers of America website. I also looked at each company's annual reports and websites for new drug announcements, infrastructure commitments, and other clues about each firm's commitment to innovation in the affected area.

The main limitation of this study is that it comprises only six data points and therefore cannot support any statistical conclusions. At most, the case studies analyzed in this Article provide anecdotal illustrations of how compulsory licensing might impact investment in innovation.

### C. Impact of Compulsory Licensing

#### 1. Sporadic Licensing

Based on patent application activity (see Figure 1) and both qualitative and clinical trial evidence (see Appendix), it appears that none of the four "sporadic" licenses were accompanied by a reduction in innovation. This is in line with both the existing literature and common-sense expectations; the element of surprise and the unpredictable nature of the licenses presumably made it impossible for any of the licensors to change their behavior in anticipation of the license.

For each licensing event, Figure 1 shows the absolute number of patents in the therapeutic area affected by the license filed by a licensor in the years preceding and following the FTC order. For the most part, I counted applications filed in twelve-month increments beginning with the month following the order, rather than based on the calendar year.<sup>144</sup> In the

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143. See generally BioSpace: Competitive Clinical Intelligence System, (Biospace 2003) at <http://www.biospace.com/ccis/index.cfm> (providing a searchable database of, *inter alia*, clinical trials).

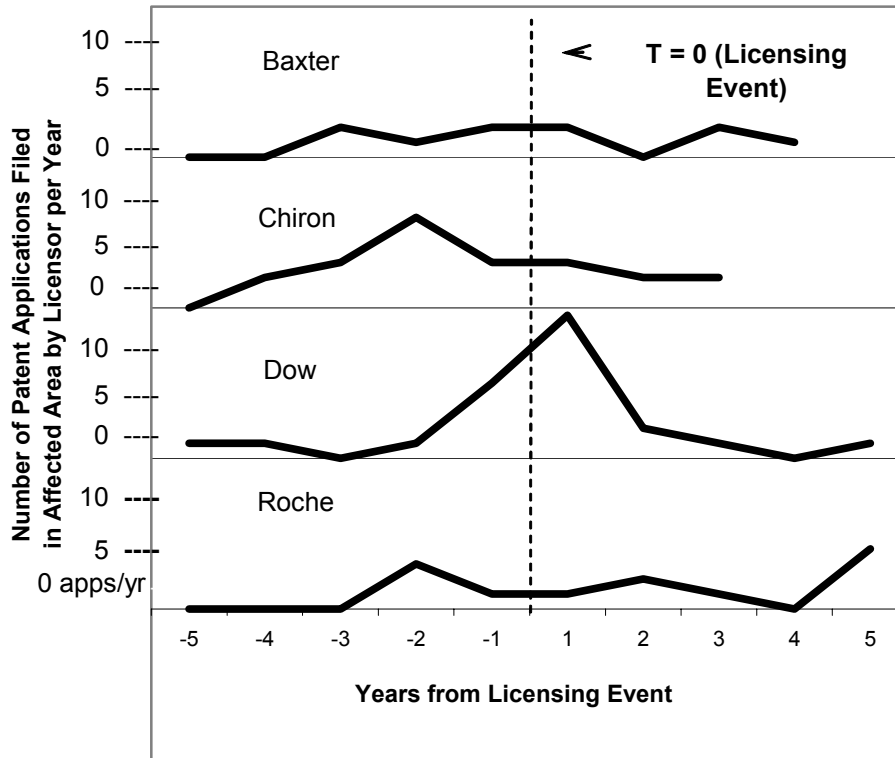
144. For the last two years of the Baxter data, I used international patent filing data, which captures all applications that have been on file for at least eighteen months, to supplement U.S. filing data given the long lags between filing and issue of fibrin sealant pat-

instances of Baxter International (“Baxter”) and Roche Holding Ltd. (“Roche”), there appeared to be no interruption of the general trend of patent applications. With Chiron Corporation (“Chiron”), the absolute number of patent applications peaked before the licensing order, but the company continued to steadily file applications in successive years. The opposite is true for Merion Merrell Dow (“Dow”), where the twelve-month period following the order was the most productive in terms of the number of applications filed. Based on the few data points provided, no systematic negative impact on patent applications was observed. This result is in line with earlier research.

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ents. As a result I relied on calendar twelve-month increments in order to capture as much application activity as possible.

Figure 1: Sporadic Licenses - Absolute Patenting



Although the graphs do not reveal clear trends, compulsory licensing did not cause dramatic reductions in R&D according to measures besides patent counts. In the instance of Baxter, marketing considerations seemed to encourage the firm to continue investing in its fibrin sealant product line. After several years of competition with Haemacure Corporation (“Haemacure”), its licensee, Baxter still retained a market share of 75% and enjoyed a high revenue growth rate, particularly with respect to its other blood products.<sup>145</sup> With Chiron and Roche, each company currently captures a considerable share of clinical trials, signaling long-term commitments to the affected product lines. As for Dow, the dwindling importance of dicylomine as a treatment for irritable bowel syndrome (“IBS”) makes it probable that factors other than the license influenced the

145. See *infra* Part VIII.A.

company's decisionmaking. Each of these examples is explored more fully in the Appendix.

## 2. *Predictable Licensing*

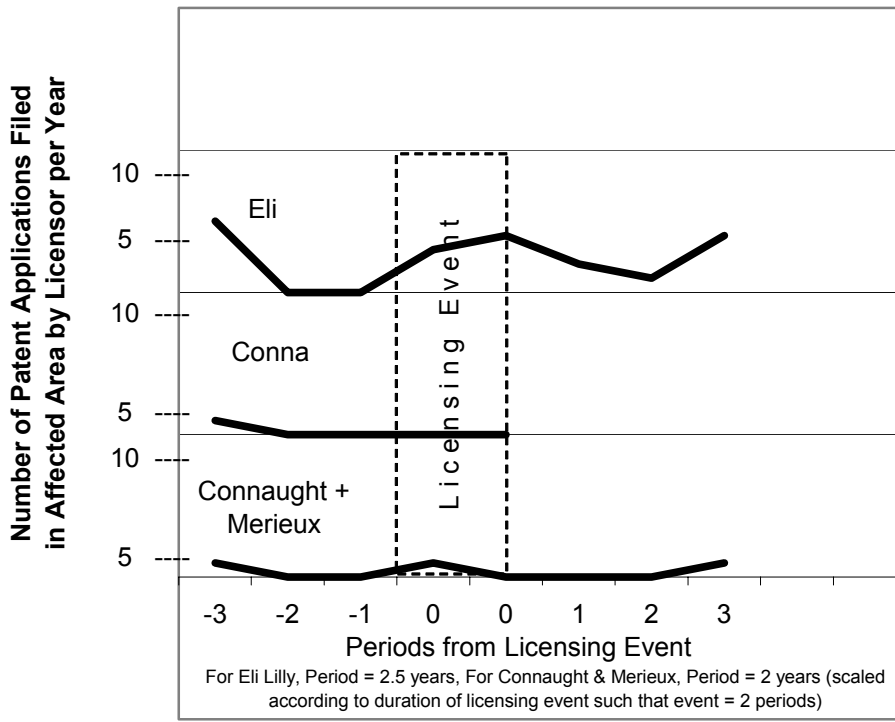
The two instances of predictable licensing present a more complex problem. While both Eli Lilly & Co. ("Eli Lilly" or "Lilly") and Connaught/Merieux were subject to licenses covering future innovation, Eli Lilly flourished during the time of its compulsory license while Merieux claimed to be adversely impacted. This difference is reflected in Figure 2, which shows the absolute patent filings of Eli Lilly and Connaught before, during, and after the compulsory licensing period.

In the situation of Eli Lilly, the data indicate that the licensing event was not coupled with a negative change in the company's patenting activity. Innovative outputs actually rose rather than declined. In the Connaught example, patent application counts are of limited value because there was very little patenting activity in the relevant therapeutic area. Although Connaught did not file any patents during the four years it was affected by a licensing agreement, it also did not file any patents prior to the licensing. However, evidence other than patenting suggests that Connaught's inventive activities declined after licensing. For example, Connaught reported to the FTC that the license prevented it from upgrading its facilities.<sup>146</sup> Also, Merieux's continued patenting activity before, during and after the licensing (see Figure 2), suggest that Merieux, which was not subject to the license continued to innovate even while Connaught did not. A more detailed discussion of these two case studies follows.

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146. *In re Institut Merieux S.A.*, 113 F.T.C. 742 (1990).

Figure 2: Predictable Licenses - Absolute Patenting



The consent decree in *Eli Lilly* was very broad. It provided access to Eli Lilly's intangible assets for all who, within five years of the decree, stated a bona fide intention to produce and sell insulin products in the United States. Included in the intangible assets made available by the decree were all patents issued to and applied for by Eli Lilly during the five-year period.<sup>147</sup> One limitation on the broad decree was a provision requiring that a licensee contribute to Lilly's R&D expenses if asked to do so.<sup>148</sup> Because the order was so broad, providing for an unlimited amount of licensing covering both extant and future patents on any insulin technology, it effectively prevented Lilly from obtaining patent protection over its insulin technology during the affected period. Faced with this severe version of compulsory licensing, one might expect Lilly to have been discouraged from further developing its insulin product for the five-year period set

147. *In re Eli Lilly & Co.*, 95 F.T.C. 538, 1980 FTC LEXIS 85, \*17 (1980).

148. *Id.*

forth in the order, or perhaps to have delayed patent applications until after the period had expired, relying on trade secrets or other forms of protection in the interim.

However, Eli Lilly continued to dominate the emerging human insulin market in performing R&D, surpassing major milestones during the period from 1980 to 1985 covered by the consent decree. Following the initial production of human insulin through recombinant DNA techniques in 1978, Lilly initiated clinical trials of its human insulin product, “Humalin,” in the United States in 1980, and invested in additional research facilities.<sup>149</sup> In 1982, Lilly was rewarded for its efforts, receiving the first FDA approval for human insulin in the United States.<sup>150</sup> Eli Lilly was actually more active in filing for patents during the five-year period of the decree than it was during the previous and subsequent five years combined.

Several factors seem to have motivated Eli Lilly’s continued innovation during this period. First, and perhaps most importantly, Lilly was extremely well-positioned to explore and benefit over the long-term from the genetics revolution emerging at the time. The company maintained its early lead into the testing and commercialization phases of insulin, and over the decade following expiration of the order was usually first or second to introduce products of increasing purity on the market.<sup>151</sup> In addition, Lilly historically enjoyed a position of market leadership. As it stated in the 1984 Annual Report: “With our historical position in diabetes, and the patients we serve, it is clear we have to aggressively go out and look at proinsulin. If it is potentially better, then we have an obligation to bring it forward. We owe this to society and humanity.”<sup>152</sup>

Furthermore, insulin has long been one of Eli Lilly’s most important products. Shortly after Lilly took the first license to insulin in 1923, insulin accounted for half of the company’s profits, and it was the company’s second largest revenue producer in 1994.<sup>153</sup> Finally, Lilly has faced

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149. See ELI LILLY, 1981 ANNUAL REPORT 5-6 (1982) [hereinafter ELI LILLY 1981 ANNUAL REPORT].

150. See, e.g., *A Market Face-off for Two Insulin Pioneers*, BUS. WK., Nov. 1, 1982.

151. See, e.g., CLAYTON M. CHRISTENSEN, ELI LILLY AND COMPANY: INNOVATION IN DIABETES CARE 4-5 (Harv. Bus. Sch., Case Study no. 9-696-077, 1996).

152. See ELI LILLY, 1984 ANNUAL REPORT 17 (1985) [hereinafter ELI LILLY 1985 ANNUAL REPORT]. Eli Lilly’s position of market leadership began in 1923, with its exclusive license over the manufacture of insulin with the University of Toronto, where Nobel Prize Winner Frederick Banting did his ground-breaking work. See Irving S. Johnson, *Human Insulin from Recombinant DNA Technology*, 219 SCIENCE 632 (1983).

153. See CHRISTENSEN, *supra* note 151, at 1, 3. Insulin has continued to be a high revenue generator, despite being viewed as a commodity product because of significant

continuous pressure from its main competitor, Novo Nordisk. In 1980 the two companies together controlled 77% of the insulin market—53% by Eli Lilly and 24% by Novo Nordisk. By 1995, the figure rose to over 90%, with Eli Lilly capturing 46% and Novo Nordisk capturing 45% of the market.<sup>154</sup> The pressures generated by market leadership, a desire for market dominance, and competition provided Lilly significant motivations to keep innovating, notwithstanding the temporary suspension of patent rewards.

The case study of Connaught's business also involves predictable licensing. At the time it received the FTC order, Merieux was the sole supplier of rabies vaccines in the United States. Prior to the order, Merieux had acquired the company Connaught, one of two potential entrants into the market.<sup>155</sup> Worried that Merieux's monopoly would remain unchallenged, the Commission called upon Merieux to lease Connaught's entire rabies vaccine manufacturing business, including both tangibles and intangibles, to an approved lessee for a minimum of twenty-five years.<sup>156</sup> However, Merieux was unable to find a suitable buyer for Connaught's manufacturing business.<sup>157</sup> Nearly four years after the decree had issued, the FTC withdrew the leasing requirement from the order.<sup>158</sup>

The requirement that Merieux lease Connaught presumably reduced Merieux's incentive to invest in Connaught's facilities. Merieux stated as much in its request to the FTC that the leasing requirement be dropped. The company claimed that "the continuing lease requirement may be harmful to competition . . . because it adversely affects Connaught's ability to respond to the increased demand for vaccine with capital investments to upgrade and expand the business's productive capacity."<sup>159</sup> Although evidence of this decline was not provided in the consent order, Connaught did not file any patents for rabies vaccine inventions during the contested period. In contrast, Merieux (which ultimately became Aventis) filed five such patents in the subsequent years.

One possible reason that Connaught temporarily discontinued patenting is its potential entrance in the U.S. market, over which Merieux had

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barriers to entry including the high cost of clinical trials for new biotechnology products and the cost of efficient manufacturing facilities. *See id.* at 4.

154. *Id.* at 17 exh.9.

155. *In re Institut Merieux S.A.*, 113 F.T.C. 742, 1990 FTC LEXIS 291, 3-4 (1990).

156. *Id.* at 7-9.

157. *In re Institut Merieux S.A.*, 117 F.T.C. 473, 474-75 (1994) (modifying 1990 order).

158. *Id.* at 482.

159. *Id.* at 477.

a stronghold. In this light Merieux may have viewed any enrichment of Connaught's business as tantamount to enriching a potential competitor in the same market. Even though the consent decree was flexible enough to enable Merieux to recoup any improvements it made to the Connaught business, given that the decree called for a reasonable lump sum payment by the licensee, Merieux's competitive interests arguably created an incentive to neglect Connaught's rabies vaccine business while enriching its own. Indeed, during the same period in which Connaught did not file for any patents, Merieux sustained its lead in the rabies vaccine business, filing for a patent in late 1991, and launching a new product, Raboral, in 1992.<sup>160</sup>

#### **D. Results**

These results, although limited, lend support to the theory that only those drug licenses that issued predictably in significant markets are likely to harm innovation. Of the six companies subjected to compulsory licensing, Merieux was the only one that exhibited a decline in patenting. Merieux's licensing event was the only one that was both anticipated and affected a market that was significant to the company. Although the data used in this study cannot prove that the licensing event caused Merieux's decline in patenting, it does indicate how pharmaceutical companies might react to these types of compulsory licenses.

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160. See *Merieux Doubles Profits, Sees Growth in Rabies Vaccine*, AGENCE-FRANCE-PRESSE, Mar. 16, 1992 [hereinafter *Merieux Doubles Profits*], available at 1992 WL 8462395.

**Table 2: Summary of Antitrust Case Results**

Antitrust Licenses	Sporadic v. General license	Nature of Market Affected	Perceived or Actual Negative Impact?
Baxter	Sporadic	Developed/Significant	No
Dow, Roche	Sporadic	Developed/Significant	No
Chiron/Ciba-Geigy	Sporadic	Nascent/Less Significant	No
Roche	Sporadic	Nascent/Less Significant	No
Eli Lilly	General	Nascent/Less Significant	No
Merieux/Connaught	General	Developed/Significant	Yes

The results of this study are contrary to the prevalent assumption that compulsory licensing categorically harms innovation. Were the assumption true, all six cases would reveal a drop in investment in innovation subsequent to licensing, yet no such uniform downward trend was observed. In fact, the opposite seems to be true—in all cases but one, activities of innovation continued at the same or even higher pace than before the advent of a license. These results cast doubt on concerns that compulsory licensing is uniformly deleterious.

The study also suggests that, notwithstanding the absence of a uniform downward trend, the circumstances surrounding a compulsory licensing event can impact innovation. Where a license is predictable and the market it affects is significant, a negative impact on innovation may be possible. More caution may be in order when such licenses are contemplated over patents held by companies or individuals who depend on patent profits.

## **VI. IMPLICATIONS FOR DRUG LICENSING IN DEVELOPING COUNTRIES**

As discussed in the preceding section, at least two factors may influence whether compulsory licenses impact pharmaceutical innovation. These factors, namely the predictability of the license and the significance

of the affected market, have implications for the compulsory licensing of drugs by developing countries.

An important consideration in determining whether compulsory licenses taken by developing countries will impact innovation is the type of drug licensed. Developing countries care about two categories of drugs, each with its own set of incentives.<sup>161</sup> First, there are “global” drugs that are created for rich markets, but are also useful in developing countries. Examples of these are cancer drugs and AIDS therapeutics.<sup>162</sup> Second, there are drugs specific to developing countries. Examples of these include drugs to treat malaria or tuberculosis, or an AIDS vaccine specific to strains of the virus found primarily in Africa.<sup>163</sup> Historically, such drugs have not been the priority of pharmaceutical companies. For example, a 2001 Harvard School of Public Health survey of twenty large pharmaceutical firms found that “[o]f 11 responders, eight had done no research over the past year in tuberculosis, malaria, African sleeping sickness, leishmaniasis, or Chagas disease; seven spent less than 1% of their research and development budget on any of these disorders.”<sup>164</sup>

Funds for researching diseases specific to developing countries often come from public or philanthropic resources such as the Centers for Disease Control or public-private partnerships like those created by the International AIDS Vaccine Initiative. The Medicines for Malaria Venture, for instance, matches academic researchers with private firms to generate collaborations in malaria medicines, an area that has largely been overlooked by industry.<sup>165</sup> The Global Alliance for Tuberculosis Drug Development, partly sponsored by the Rockefeller Foundation, similarly tries to shift product development risk away from drug companies by conducting costly clinical trials for promising drug candidates.<sup>166</sup> Efforts to develop an AIDS vaccine for countries in Africa have likewise been collaborative.<sup>167</sup>

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161. See LANJOUW, *supra* note 91.

162. See *id.*

163. See *id.*

164. Ricki Lewis, *Fighting the 10/90 Gap*, SCIENTIST, May 13, 2002, [http://www.the-scientist.com/yr2002/may/lewis\\_p22\\_020513.html](http://www.the-scientist.com/yr2002/may/lewis_p22_020513.html) (last visited July 22, 2003).

165. Martin Enserink *Malaria Researchers Wait for Industry to Join the Fight*, 287 SCI. 1956, 1958 (2000).

166. *Exotic Pursuits*, ECONOMIST, Jan. 30, 2003, available at 2003 WL 6244875.

167. See, e.g., Alexandra Bojak et al., *The Past, Present, and Future of HIV-Vaccine Development: A Critical View*, 7 DRUG DISCOVERY TODAY 36, 41-43 (2002) (describing the funding of basic research by the European Union and other governments and the continued need for collaboration between rich and poor countries and for money from donor organizations such as the European Vaccine Efforts); Paul J. Weidle, et al., *HIV/AIDS Treatment and HIV Vaccines for Africa*, 359 LANCET 2265 (2002) (describing

Research to date suggests that if compulsory licenses are taken in less significant markets, their impact on innovation should be marginal. For global drugs such as AIDS therapy, this would imply that compulsory licenses that are limited to developing countries (i.e. ancillary markets) and do not impact the target markets for the drugs (i.e., rich countries) might not be detrimental to research efforts in the rich developed countries. This is in accord with common sense. For global drugs, companies are responsive to the incentives provided by wealthy markets and consumers. As long as these incentives stay intact, selective compulsory licensing for developing nations should have little impact on overall R&D investment. The major caveat to this conclusion is that it assumes that the affected market is limited to developing countries and not enlarged to include rich nations as well, for instance through parallel trade.

The implication is somewhat different for drugs developed to treat diseases endemic to developing countries, such as malaria. As discussed above, much of the research on these diseases is carried out or facilitated by public or philanthropic institutions, for whom patent protection and the promise of a patent monopoly are less, if at all, important. In addition, the potential for monopoly abuse which compulsory licenses are designed to counter could also be less likely. If pharmaceutical companies, on the other hand, begin investing significantly in such disease areas due to the introduction of patent protection, as is hoped, a compulsory license covering all developing country markets might well usurp the primary target markets. Threatening or implementing licenses on a regular, predictable fashion may deter pharmaceuticals from initiating and carrying out R&D investments.

Based on these observations, and focusing exclusively on innovation concerns, one can make a preliminary case for employing different approaches to compulsory licensing depending on whether global or developing country-specific drugs are licensed. Because the relative importance of developing country markets is small when it comes to global drugs, the incentive to develop these drugs, which comes from the developed world, is not substantially impacted. This means that allowing developing countries to take compulsory licenses to AIDS therapy drugs should not produce a negative impact on AIDS therapy research and development. It should be underscored that this policy implication springs from purely innovation concerns, and does not resolve the political considera-

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*Treatment and HIV Vaccines for Africa*, 359 LANCET 2265 (2002) (describing HIV vaccine trials in Africa as sponsored by the NIH, CDC, IAVI, and other public and philanthropic organizations).

tions surrounding the potential re-importation of these drugs into rich markets.

The picture is different when it comes to drugs being developed specifically to treat developing country diseases, such as AIDS strains endemic to Africa. Compulsory licenses for developing countries could cover the entire target market of local and international pharmaceuticals. The threat of systematic compulsory licensing of these drugs is likely to make a difference and could cause some companies to avoid these markets altogether. To date, the patent incentive has arguably not successfully prompted R&D in these medicines. Therefore, the importance of preserving the current patent incentive should not be overstated. This is particularly true because of the strong role played in this area by public and philanthropic institutions, which presumably are not motivated by monopoly profits.

Compulsory licensing is far from an easy solution; exploiting it fully requires political will. Based on the past record of licensing, countries that elect to take licenses must demonstrate a willingness to endure lawsuits, pressure, and threats of trade sanctions from the United States.<sup>168</sup> In addition, producing drugs pursuant to a license requires a level of technical and manufacturing capability possessed by few countries.<sup>169</sup> Overreliance on compulsory licensing may also produce unintended negative downstream impacts on social measures other than innovation.<sup>170</sup> In addition, without the ability to import drugs made cheaper by compulsory licensing, many countries will not benefit from compulsory licenses.<sup>171</sup> Still, the credible threat of compulsory licensing may reduce drug prices

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168. The U.S. and western pharmaceutical companies have routinely used the Special 301 mechanism for authorizing trade sanctions and lawsuits at the WTO and in domestic courts to oppose policies implemented by other countries that are unfavorable to pharmaceutical company interests. *See, e.g.,* Sarah Boseley, *How the U.S. Wields a Big Stick for Big Pharm*, *GUARDIAN*, Feb. 18, 2003 (describing actions against Thailand); Carin Håkansta, *The Battle on Patents and AIDS Treatment*, 16 *BIOTECH. AND DEV. MONITOR* 34 (1998) (describing early battles against India in the TRIPS court), available at <http://www.biotech-monitor.nl/3406.htm> (last visited Aug. 27 2003).

169. *See* Attaran & Gillespie-White, *supra* note 5 (describing non-patent barriers to drugs, such as insufficient finances, lack of political will, poor medical care and infrastructure, inefficient drug regulatory procedures, and high tariffs and sales taxes).

170. REICHMAN & HASENZAHN, *supra* note 7, at 26-27 (describing the potential risks associated with the aggressive use of compulsory licensing, such as discouraging domestic inventors, hindering foreign investment and technology transfer, and overshadowing regulatory or cooperative measures that might otherwise increase investment in local production facilities).

171. *See* ABBOTT, *supra* note 19, at 38-39.

faster and more efficiently than other voluntary options that have been explored.<sup>172</sup>

While high drug prices comprise only one aspect of the AIDS problem,<sup>173</sup> there has been a growing realization that increasing access to drugs must be a part of any solution—whether through compulsory licensing resulting from improved public relations,<sup>174</sup> or the genuine initiative of drug-makers.<sup>175</sup> This is partly due to a number of factors that have shifted attention towards affordable treatment and vaccination rather than prevention alone.<sup>176</sup> The initial push for prevention was based on the conventional wisdom that prevention (through education, the empowerment of women, and distribution of condoms) is the best cure for the AIDS problem, and that AIDS therapy regimes were too expensive and complicated to be suitable for developing countries. However, in the past two years, experience has shown that people in developing countries can and will comply with drug regimes at levels equal to or greater than their Western counterparts. At the same time, there has been a realization that attitudes and culture are hard to change and that solutions other than behavioral

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172. See ALAIN GUILLOUX & SUERIE MOON, HIDDEN PRICE TAGS: DISEASE-SPECIFIC DRUG DONATIONS: COSTS AND ALTERNATIVES 5-7 (2000), available at <http://www.accessmed-msf.org/upload/ReportsandPublications/492001217138/Hidden%20price%20tags.pdf> (last visited July 20, 2003) (describing the limitations of drug donation programs in terms of their reach and reliability); REICHMAN & HASENZAHN, *supra* note 7, at 12-13 (describing voluntary price reductions by pharmaceutical companies due to the threat of compulsory licensing).

173. Some scholars have suggested that cheap drugs might actually aggravate the problem by diverting attention away from prevention. See, e.g., Michael Specter, *India's Plague*, NEW YORKER, Dec. 17, 2001, at 74.

174. See, e.g., Geoff Dyer, *Investors Warn Drugs Industry of Backlash over Health Crises*, FIN. TIMES, Mar. 24, 2003, at 25.

175. Recently, pharmaceutical companies have voluntarily reduced prices on a number of drugs. See, e.g., Geoff Dyer, *How Do You Price AIDS Treatment?*, FIN. TIMES, Mar. 26, 2003, at 13 (describing Roche's statement that it will not enforce intellectual property rights on its AIDS drug Fuzeon, priced at \$20,000 a year per user, in sub-Saharan Africa); Michael Grunwald, *All-Out Effort Fails to Halt AIDS Spread; Botswana's Program Makes Progress, But Old Attitudes Persist*, WASH. POST, Dec. 2, 2002, at A1 (describing Merck's offer of an unlimited supply of antiretroviral drugs to Botswana); Paul Jacobs, *Gilead Unveils AIDS Drug Plan*, SAN JOSE MERCURY NEWS, Apr. 4, 2003 (describing how Gilead Sciences plans to offer its successful AIDS drug Viread to 68 developing countries at substantially reduced prices), available at 2003 WL 14985084.

176. See, e.g., *Hope for the Best. Prepare for the Worst—the Future of Aids.*, ECONOMIST, July 11, 2002 (describing the growing intensity in AIDS vaccine research in light of the limitations of prevention and treatment), available at 2002 WL 7246756; Michael Specter, *The Vaccine*, NEW YORKER, Feb. 3, 2003, at 54.

transformation must be explored.<sup>177</sup> In addition, the availability of drugs is crucial not only for treating sick patients but also for diagnosing and stopping the spread of AIDS because “people who are infected and cannot be treated have little incentive to get tested; that, in turn, means they do not know they are infected, and so do not take precautions against infecting others.”<sup>178</sup> All of these factors have made access to AIDS drugs a more pressing and realistic objective.

Still, the focus on cheap drugs for therapy today should not draw attention away from the hope of an AIDS vaccine tomorrow. How compulsory licensing programs are designed and implemented matter in this regard, and the possibility of widespread yet careful implementation of licensing deserves serious consideration and study.

## VII. CONCLUSION

Although modest, the data analyzed in this study yield potentially surprising implications for the current debate over compulsory licensing. At a minimum, they challenge the wholesale rejection of licensing schemes for AIDS drugs based on their perceived negative impact on AIDS innovation. They also invite consideration of how compulsory licenses are designed and implemented. They suggest that, based on innovation concerns, the use of different kinds of licenses over global and developing country diseases may be appropriate given the different incentives driving innovation in these areas.

## VIII. APPENDIX: ANTITRUST LICENSE CASE STUDIES

### A. Baxter/Fibrin Sealant

#### 1. *The Order*

In early 1997, the FTC ordered Baxter to license its rights to fibrin sealant, a topical agent used to control surgical bleeding, in connection with Baxter’s acquisition of Immuno International AG (“Immuno”).<sup>179</sup> Although the product had been available in Europe for several years before the order, Baxter and Immuno were two of just a handful of companies seeking FDA approval for the first product launch in the U.S. market,<sup>180</sup> estimated to be worth up to \$200 million annually.<sup>181</sup>

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177. See Grunwald, *supra* note 175; Rosenberg, *supra* note 7.

178. *Hope for the Best. Prepare for the Worst—the Future of Aids*, *supra* note 176.

179. *In re Baxter Int’l Inc.*, 123 F.T.C. 904 (1997).

180. *Id.* at 906.

The part of the order pertaining to fibrin sealant required Baxter to provide a license to all of Immuno's intangible assets and rights (including patents, trade secrets, technology, know-how, specifications, customer lists, and FDA approval data) related to the R&D, manufacture, and sale of fibrin sealant.<sup>182</sup> The order mandated one commission-approved licensee.<sup>183</sup> Once Baxter obtained FDA approval, the order required the company to supply the licensee with Immuno's fibrin sealant product until the licensee received approval for its own product.<sup>184</sup> In exchange, the order required the licensee to reimburse Baxter for the costs of manufacturing the fibrin sealant product while demonstrating a continuing commitment to obtain approval from the FDA for its own fibrin sealant product.<sup>185</sup> Other portions of the order called for the divestiture of Immuno's Factor VIII assets.<sup>186</sup>

Within six months of the order, the FTC approved Haemacure as the fibrin sealant licensee.<sup>187</sup> A little over a year after the order was issued, in May 1998, Immuno's fibrin sealant received FDA approval, and both Baxter and Haemacure introduced the product into the U.S. market.<sup>188</sup> Over the next few years, Baxter and Haemacure were the only sellers of fibrin sealant in the U.S. market, with Baxter capturing 75% of the market in 1999.<sup>189</sup> The FTC approved several requests by licensee Haemacure to extend the license, and in 2002, Haemacure estimated that the license could expire in 2004.<sup>190</sup>

## 2. *Impact on Innovation*

Baxter's interest in pursuing follow-on innovation and products could have hypothetically declined with their loss of exclusive control over the market because the license required them to share late-stage tech-

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181. See Gary Shepherd, *To Haemacure, 'Scab' is Not a Four-Letter Word*, TAMPA BAY BUS. J., Sept. 11, 1998, available at 1998 WL 33483931.

182. *Baxter*, 123 F.T.C. at 910, 921.

183. *Id.* at 921.

184. *Id.*

185. *Id.*

186. *Id.* at 910-916.

187. See *For Your Information*, Fed. Trade Comm'n Office of Public Affairs, Aug. 1, 1997, at <http://www3.ftc.gov/opa/1997/08/petapp40.htm> (last visited Aug. 11, 2003).

188. See Christiane Truelove, *Baxter's Bloodline*, MED. AD NEWS, Sept. 1, 1999, available at 1999 WL 12977876; *Haemacure Announces Fiscal Year 2001 Financial Results*, CAN. NEWSWIRE, Jan. 11, 2002, at [http://www.newswire.ca/releases/January 2002/11/c1986.html](http://www.newswire.ca/releases/January%2002/11/c1986.html) (last visited Aug. 11, 2003).

189. See HAEMACURE CORP., 1999 ANNUAL INFORMATION FORM 8 (2000), <http://www.haemacure.com/pdf/infoform/Ai280400a.pdf> (last visited Aug. 11, 2003).

190. See *Haemacure Announces Fiscal Year 2001 Financial Results*, *supra* note 188.

nology and profits with Haemacure. On the other hand, the late stage of the technology possibly reduced other uncertainties associated with the technology, and also potentially provided the chance to capture additional revenue with little investment.

Since the order, Baxter continues to invest in fibrin sealant and related therapeutic areas. This is shown by their patenting activity, new product development, and clinical trials. The company filed about as many patent applications for this technology in the five years following the order as in all years prior to it.<sup>191</sup> Additionally, Baxter introduced a follow-on application device,<sup>192</sup> and worked on a patch, rather than liquid, version of the product.<sup>193</sup> Also, the company conducted clinical trials on a hemostatic sealant, which it subsequently introduced on the market.<sup>194</sup> In 2000, the company announced a \$400 million commitment to upgrade facilities used for fibrin sealant and other plasma and recombinant DNA products.<sup>195</sup> Overall, Baxter did not appear to reduce its investment in R&D in fibrin sealant and related products.

Product economics may explain Baxter's interest and aggressive marketing concerning fibrin sealant. According to a Lehman Brothers report issued in late 1999, the projected revenue compounded annual growth rate for fibrin sealants was over 35%, which was the highest rate in Baxter's blood product division.<sup>196</sup> Additionally, Baxter was projected to capture nearly 60% of the international fibrin sealant market by 2001, of which approximately half was estimated to come from the United States.<sup>197</sup> Other companies, including Aventis, Omrix, the American Red Cross, Vitex, and a Bristol-Meyers Squibb subsidiary also developed fibrin sealants.<sup>198</sup> Thus, Baxter was plausibly motivated to capture the first-mover advantage in the years just after the license was ordered.

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191. This finding is based on a date and assignee search of the LEXIS patent application database using the keyword "fibrin sealant." The company successfully obtained six patents prior to the order, and obtained five patents after it.

192. See News Release, Baxter, Baxter's New Fibrin Sealant Application System Cleared by FDA (July 10, 2000), available at <http://www.baxter.com/utilities/news/releases/2000/07-10tissomat.html> (last visited Aug. 11, 2003).

193. See Glenn M. Reicin & Jason H. Wittes, *A Feel-Good Analyst Meeting*, Morgan Stanley Dean Witter, Mar. 23, 2001, at 8 (on file with author).

194. According to Biospace's CCIS database (based on date search and keyword "sealant").

195. See *supra* note 194.

196. See David A. Gruber et al., *A Potential Source of Stability*, Lehman Brothers, Oct. 6, 1999 (on file with author); Reicin & Wittes, *supra* note 193, at 14.

197. See Reicin & Wittes, *supra* note 193, at 14.

198. See HAEMACURE CORP., *supra* note 189, at 8.

## B. Marion Merrell Dow/Dicyclomine

### 1. *The Order*

In late 1994, the FTC ordered Dow to license its rights to dicyclomine, a product used for the treatment of IBS.<sup>199</sup> At the time of the order, Dow's product was already on the market with only 60% of the \$7 to \$8 million market, due to generic competition.<sup>200</sup> Dow's acquisition of Rugby Darby, the only generic company approved to manufacture the drug at the time, raised antitrust concerns.<sup>201</sup>

Given that Rugby Darby already made dicyclomine, some key patents were presumably expired, but other barriers, described by the FTC order as "difficult and time consuming," prevented other generic companies from entry.<sup>202</sup> Accordingly, the order required Dow to provide a perpetual license to a commission-approved licensee, including all formulations, patents, trade secrets, technology, know-how, and specifications.<sup>203</sup> The order did not specify a price, but stated that there was "no minimum price" for the license, implying that no potential deal could be rejected on the basis of price. The order also required Dow to provide manufactured dicyclomine to the licensee until it received FDA approval. In exchange, the order mandated that the licensee pay up to 48% of the wholesale price of the dicyclomine, while attempting to obtain FDA approval for its own manufacturing facilities.

### 2. *Subsequent Developments*

Within one year of the order, Hoechst Marion Roussel, Inc. ("HMRI"), Dow's successor through merger, requested and obtained FTC approval to award a license to Endo Laboratories, a subsidiary of Dupont Merck Pharmaceutical Company.<sup>204</sup> During this time, other generic companies entered the dicyclomine market,<sup>205</sup> causing the IBS market to mature by the last half of the 1990s, with few new product introductions until 2000.<sup>206</sup> Although dicyclomine was one of just three main products in the

199. *In re Dow Chem. Co.*, 118 F.T.C. 730, 736-38 (1994).

200. *See Lannett Expects Increased Sales and Profit with the Launch of its Third and Most Significant Generic Drug Product*, BUS. WIRE, July 21, 1994.

201. *Dow*, 118 F.T.C. at 732-33.

202. *Id.* at 732.

203. *Id.* at 736.

204. *See For Your Information*, Fed. Trade Comm'n Office of Public Affairs, July 19, 1996, <http://www3.ftc.gov/opa/1996/07/petapp41.htm> (last visited Aug. 11, 2003).

205. *Id.*

206. *See Stewart Adkins et al., Irritable Bowel Syndrome, Poetry in Motion*, Lehman Brothers, Sept. 2, 1999, at 19 (on file with author).

anti-cholinergic and anti-spasmodic segment of IBS medications, other medication segments such as anti-diarrhea and constipation were more important.<sup>207</sup> Dicyclomine's share of the overall IBS medication market eventually dwindled to less than 2% in 2000.<sup>208</sup>

### 3. *Impact on Innovation*

Even though generic manufacturers were producing Dicyclomine at the time of the order, the license conferred advantages principally associated with the head start that Dow achieved over the generic manufacturers. It is unclear whether much opportunity existed for innovation in this particular therapeutic area, because the product was already mature. Still, assuming that Dow and its successor HMRI had to make a decision about the IBS market, its weak market position and the relatively small size of the dicyclomine market could potentially deter any future investment.

A year after the license issued, HMRI stopped filing for patents.<sup>209</sup> However, it is difficult to attribute this absence in activity only to the license, because the year following the license was the most productive year in terms of number of patent applications, with six patent applications filed. Although it is possible that these were merely the result of pre-license innovation activities, the presence of other factors such as dwindling market share and the earlier loss of patent protection could each plausibly explain the rise and then discontinuation of patenting. Even though little can be definitively concluded about this case, it does not appear that licensing alone entirely explains HMRI's exit from the R&D IBS market.

## C. **Eli Lilly/Insulin**

### 1. *The Order*

In 1980, the FTC charged Eli Lilly with involvement in a wide-ranging conspiracy, dating back to 1952, with other manufacturers of pancreatic insulin.<sup>210</sup> The FTC ordered the firm to license the know-how and rights relating to both its existing and future insulin-related patents.<sup>211</sup> Any

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207. *See id.* at 6.

208. *See* Jeffrey Chaffkin et al., *Company & Therapeutic Prescription Statistical Update*, Paine Webber, Oct. 23, 2000, at 96 (on file with author).

209. While other companies have continued to develop IBS medications, with sixteen products in clinical trials during the 2000-2002 period according to Biospace, Dow/HMRI has not participated in any reported drug development activities. Search conducted by the author of the Biospace database using keywords "irritable bowel syndrome" or "dicyclomine."

210. *In re* Eli Lilly & Co., 95 F.T.C. 538, 1980 FTC LEXIS 85, \*5 (1980).

211. *Id.* at \*17, \*23.

potential entrant who, within five years of the decree, stated a bona fide intention to produce and sell insulin products in the United States would obtain access to Lilly's intangible assets, including all patents issued and applied for during the five-year period.<sup>212</sup> Significantly, Lilly could impose a charge on the licensee equal to a "[r]easonable pro rata share of the amounts actually spent by Lilly in acquiring, or financing the research and development . . . [of] such licensed patents and know-how," in addition to a requirement to give grantbacks.<sup>213</sup> The order also required licensees to keep all production in the United States.<sup>214</sup>

## 2. *Subsequent Developments*

No information is available on whether any companies came forward and took advantage of the compulsory license made available by the consent decree.<sup>215</sup> However, Lilly continued to dominate the emerging human insulin market in both research and development, surpassing major milestones during the five-year period covered by the consent decree. In 1980, following the initial production of human insulin through recombinant DNA techniques in 1978, Lilly initiated clinical trials in the United States of its human insulin product "Humalin" and invested in research facilities to carry out additional work.<sup>216</sup> In 1982, the FDA rewarded Lilly for its efforts with the first approval for human insulin in the United States.<sup>217</sup>

## 3. *Impact on Innovation*

The broad order, covering future patents issued on any insulin technology and allowing a potentially large number of licensees, effectively prevented Lilly from obtaining patent protection over its insulin technology during the affected period. Faced with this severe version of compulsory licensing, the company was potentially discouraged from any innovation in insulin technology during the five-year period. Additionally, Lilly probably at least delayed patent applications until after the licensing period, relying instead on trade secret or other forms of protection. The

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212. *Id.* at \*17.

213. *Id.* at \*24.

214. *Id.* at \*23.

215. Because the license was made available to any domestic company with a bona fide intention to enter the insulin market, and the licensee did not require FTC approval, the FTC did not publicly track whether any licenses were implemented. The FTC would only have intervened had there been a complaint of non-compliance. Telephone Interview with Kenneth Davidson, Fed. Trade Comm'n Bureau of Competition (Apr. 26, 1995).

216. See ELI LILLY 1981 ANNUAL REPORT, *supra* note 149, at 5-6.

217. See *A Market Face-off for Two Insulin Pioneers*, *supra* note 150.

one significant mitigating factor, however, was the license's provision that the licensee could be asked to contribute to the R&D expenses.<sup>218</sup>

Based on a few indicators, Lilly continued to aggressively pursue insulin R&D during the period covered by the license. For example, patenting behavior did not appear to be affected. The company filed for seven patents over the five-year licensing period, whereas fewer than seven patents were filed during the periods five years prior and subsequent to the licensing event combined.<sup>219</sup>

Several factors seemed to motivate Lilly's continued innovation during the licensing period. One is historical market leadership. The company's 1984 Annual Report states that "[w]ith our historical position in diabetes and the patients we serve, it is clear we have to aggressively go out and look at proinsulin. If it is potentially better, then we have an obligation to bring it forward. We owe this to society and humanity."<sup>220</sup> Another factor is that Lilly was an early leader in the research leading to the production of human insulin through recombinant DNA methods in 1978. Through subsequent testing and commercialization, the company was often first or second to introduce products of increasing purity to market.<sup>221</sup> Likewise, insulin was always one of Lilly's most important products. Shortly after the company took its first license in 1923, insulin accounted for half of all Lilly's profits, and in 1994, it was still the company's second largest revenue producer.<sup>222</sup>

Insulin continues to be a high revenue generator, despite being viewed as a commodity product due to significant barriers to entry such as the high cost of clinical trials for new biotechnology products and the cost of an efficient manufacturing facility.<sup>223</sup> Finally, Lilly continues to face continuous pressure from competitor Novo Nordisk; in 1980 the two companies together held nearly 80% of the insulin market (53% by Eli Lilly and 24% by Novo Nordisk), and by 1995, the two virtually split 91% of the market (Eli Lilly capturing 46% and Novo 45% of the market).<sup>224</sup> The pressures generated by market leadership, a desire for market dominance, and competition provided significant motivations for Lilly to continue to innovate, even during the compulsory licensing period.

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218. See *In re Eli Lilly & Co.*, 95 F.T.C. 538, 1980 FTC LEXIS 85, \*24 (1980).

219. Search using keyword "insulin."

220. See ELI LILLY 1983 ANNUAL REPORT, *supra* note 152, at 17.

221. See CHRISTENSEN, *supra* note 151, at 1.

222. See *id.* at 1, 4.

223. See *id.* at 4.

224. See *id.* at 17, exh.9.

## D. Connaught/Rabies Vaccine

### 1. *The Order*

In 1992, citing concerns about increased domination of the U.S. rabies vaccine market, the FTC ordered Merieux to lease the rabies manufacturing business of the company it acquired, Connaught Bioscience.<sup>225</sup> Merieux was the sole supplier of rabies vaccine in the United States, and Connaught was one of two potential entrants into the market. Worried that Merieux's monopoly would remain unchallenged, the Commission called upon Merieux to lease Connaught's entire rabies vaccine manufacturing business, including both the production facility and technology, to an approved lessee for a minimum of twenty-five years.<sup>226</sup> In exchange, the order provided for the lessee to give a lump sum payment, under customary and reasonable terms, to Merieux/Connaught.<sup>227</sup>

### 2. *Subsequent Developments*

Despite contacting twenty-eight prospective licensees over the next several years, including serious negotiations with a few parties, Merieux could not find a suitable buyer for Connaught's rabies manufacturing business.<sup>228</sup> The most serious offer, from North American Vaccine, Inc., was rejected because of a lack of relevant experience.<sup>229</sup> In April 1994, the FTC modified the original order and removed the leasing requirement, citing the entry of SmithKline Beecham into the market and Merieux's bona fide attempts to satisfy the consent decree.<sup>230</sup>

### 3. *Impact on Innovation*

During the period between the original and modified order, Merieux had little incentive to invest in Connaught's facilities, given that the order required it to lease the business away at uncertain prices. In fact, in the consent modifying order, Merieux suggested that "the continuing lease requirement may be harmful to competition . . . because it adversely affects Connaught's ability to respond to the increased demand for vaccine with capital investments to upgrade and expand the business's productive capacity."<sup>231</sup> Although evidence of this decline is not in the consent order,

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225. *In re* Institut Merieux S.A., 113 F.T.C. 742, 1990 FTC LEXIS 291,\*8-9 (1990).

226. *Id.*

227. *Id.*

228. *In re* Institut Merieux S.A., 117 F.T.C. 473, 474-75 (1994) (modifying the 1990 order).

229. *Id.* at 476.

230. *Id.*

231. *Id.* at 477.

no patents were filed by the would-be leased Connaught for rabies vaccine inventions during the contested period, while 5 patent applications were filed by Connaught-Merieux, which ultimately became Aventis, in the subsequent years.<sup>232</sup>

Based on the evidence, it appears likely that Connaught's rabies vaccine practice suffered under this most extreme version of compulsory licensing. Given Connaught's position as a potential entrant in the U.S. market, the potential of enriching a competitor in the same market probably served as a major deterrent. Despite the continued interest of Merieux in the rabies business, little motivation may have existed for them to invest in Connaught. During the same interim period in which Connaught did not file for any patents, Merieux remained interested in the rabies vaccine business, launching a new product in 1992<sup>233</sup> and filing for a patent in late 1981. All of this is consistent with Merieux's statement to the Commission that the order adversely affected its incentives to maintain and improve the Connaught manufacturing capabilities.

## **E. Chiron/HSV-tk Related Therapeutics**

### *1. The Order*

In early 1997, the merger of Ciba Geigy, which owned the largest share of Chiron, and Sandoz concerned the FTC. Believing that the combination would create a "killer" patent portfolio<sup>234</sup> concerning the herpes simplex virus-thymidine kinase (HSV-tk) gene, the FTC ordered the companies to license their patent portfolios to an approved licensee.<sup>235</sup> The FTC was concerned that combining the patent portfolios would heighten already existing barriers to entry in the market for HSV-tk gene therapy, in which Chiron and Sandoz were leaders.<sup>236</sup> Anticipating that the combined portfolio would reduce the parties' incentives to license their patents, the order called for the licensing of other key gene therapy patents and divestitures in unrelated areas.<sup>237</sup> Unlike the other situations discussed here, this decision seemed to be openly motivated by protecting public health in addition to protecting competition. FTC Bureau of Competition Director William Baer even stated, "[t]his case is about saving lives. Today there

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232. Search using keywords "rabies" and "vaccine" with incidental mentions screened out.

233. *See Merieux Doubles Profits*, *supra* note 160.

234. James B. Kobak Jr. & Richard P. McGuire, *FTC Looks at Merger's Antitrust Effects on R&D*, NAT'L L.J., Mar. 31, 1997, at C3.

235. *In re Ciba-Geigy Ltd.*, 123 F.T.C. 842, 873-77 (1997).

236. *Id.* at 864-73, 877-86.

237. *Id.* at 846-47.

are two firms racing to develop new gene therapies to combat deadly diseases. The deal threatened to eliminate that competition. Our order ensures that this sprint to the finish line will continue.”<sup>238</sup>

The order required the merging parties to offer perpetual rights to their HSV-tk patent portfolios and provide related know-how to Rhone-Poulenc Rorer (“RPR”) or another approved licensee. In order to ensure that a license would be issued, the FTC specified that compensation could be in the form of an equivalent cross-license or a royalty.<sup>239</sup> Within six months of the decree, the Commission approved the licensing of Chiron’s HSV-tk portfolio to multiple companies in fulfillment of the order.<sup>240</sup> In exchange, one licensee, Novartis, paid Chiron \$60 million in addition to cross-licenses to some of its technologies.<sup>241</sup>

## 2. *Impact on Innovation*

Chiron’s loss of exclusivity and “killer” patents over HSV-tk technologies potentially dampened its enthusiasm and willingness to invest in additional research. However, the opportunities presented by the cross-licenses given by Novartis, in addition to Chiron’s market leadership position, probably mitigated any such effect. Chiron was likely not interested in scaling back research merely based on the speculative downstream impact of a licensee.

In the years following the order, Chiron continued to patent HSV-tk technologies at a rate comparable to its filings before the order.<sup>242</sup> Additionally, in 1998, the company reported that it had two products in development, one for graft-versus-host disease and another for hemophilia A.<sup>243</sup> Over the 2000 to 2002 period, Chiron and Novartis were involved in two of the fifteen trials reported in the Biospace CCIS database.<sup>244</sup> Meanwhile, licensee RPR, which became part of the larger pharmaceutical entity Aventis, appeared to make strides in the gene therapy market. The com-

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238. See Press Release, Fed. Trade Comm’n Office of Public Affairs, FTC Accord in Ciba Geigy/Sandoz Merger to Prevent Slowdown in Gene Therapy Development & Preserve Competition in Corn Herbicides, Flea-Control Markets (Dec. 17, 1996), available at <http://www.ftc.gov/opa/1996/12/ciba.htm> (last visited Aug. 27, 2003).

239. *In re Ciba-Geigy Ltd.*, 123 F.T.C. at 873-77.

240. See *For Your Information*, Fed. Trade Comm’n Office of Public Affairs, Sept. 12, 1997, <http://www.ftc.gov/opa/1997/09/petapp50.htm> (last visited Aug. 11, 2003).

241. See *Chiron to License RPR for HSV-tk Gene and Cross-License Technologies with Ciba-Novartis*, BUS. WIRE, Dec. 17, 1996.

242. Search using keywords “gene therapy”, “retroviral vector”, and “HSV.”

243. CHIRON CORP., 1998 ANNUAL REPORT 9 (1999).

244. Search using keyword “HSV.”

pany launched RPR Gencell to develop gene therapies for cancer and other diseases in collaboration with other companies.<sup>245</sup> According to these measures, the license does not appear to have significantly harmed Chiron's innovation.

## F. Roche/CD-4

### 1. *The Order*

In late 1990, the FTC ordered Roche, in connection with its acquisition of Genentech, to license its future rights to pending patents covering CD4-based technologies.<sup>246</sup> Although both companies were early in their development of HIV treatments using CD-4 based therapeutics, the order circumscribed the relevant market.<sup>247</sup> At the time, Genentech led the market with a product in clinical trials, with Roche following along with several patent applications. However, given the early stage of the technology, the merging parties were at most only potential competitors in the marketplace.<sup>248</sup>

The order provided perpetual access to Roche's patents in exchange for 1% of net sales for process patents and 3% of net sales for product patents. The license could be requested by any competitor or potential entrant over the ten years following the order, subject to its continuing commitment to CD4 research.<sup>249</sup>

### 2. *Subsequent Developments*

In the years following the order, Roche's patenting activity<sup>250</sup> far outperformed its pre-order levels. This is not surprising given that Roche only began to file for patents shortly before the order. In addition, the company remained committed to the investigation of CD4-based therapeutics in the treatment of AIDS. During the two-year period from 2000 to 2002, the company was a partner in four of the twelve clinical trials of drugs, three with Genentech and another with Baxter International.<sup>251</sup> Accordingly, the order did not significantly affect Roche's CD4 HIV research.

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245. Jim Papanikolaw, *Waiting for the Fruits of Gene Therapy*, CHEM. MKTG. REP., Mar. 20, 2000.

246. *In re Roche Holding Ltd.*, 113 F.T.C. 1086, 1990 FTC LEXIS 543, \*25 (1990).

247. *Id.* at \*3.

248. *Id.* at \*4.

249. *Id.* at \*25-26.

250. Search using keywords "CD4" and "viral."

251. According to Biospace's CCIS database.

3. *Impact on Innovation*

To the extent that Roche relied on its patents to secure its competitive position in the CD4-based therapeutic market, the patent weakening license potentially discouraged Roche from investing as heavily as without the license. Even without the license, Roche presumably could have decided to abandon its own efforts relying instead on the innovation of leader Genentech. However, given the early stage of CD4 therapeutic development, Roche most likely decided that the compulsory license posed little threat in the ultimate therapeutic market.