Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation

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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.

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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 limited monopoly, is irreparably skewed in favor of drug companies. Defenders of strong patent rights, on the other hand, insist that any weakening of existing protections would undermine the potential for future innovation.

Compulsory licensing, the practice of authorizing a third party to make, use, or sell a patented invention without the patentee’s consent, has long provided an antidote to the perceived ills of the patent system. 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. Under the Agreement on Trade-
Related Aspects of Intellectual Property Rights ("TRIPS"), compulsory licensing is authorized under certain circumstances, such as public health emergencies. However, until recently, few compulsory licenses had been actually issued under TRIPS. 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." The twin goals of increasing access to existing medicines and promoting research and development of new medicines have been portrayed as competing with each other.

This Article questions this fundamental assumption. It explores whether past compulsory licenses over drugs have 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.


8. See Tren, supra note 2, at A10.
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 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"). 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 need not discourage innovation. They also underscore that the manner in which compulsory licenses are structured and implemented matters, 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 discusses the implications of these results for policymaking.

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 pat-
ent owner’s consent.” Because they limit the power conferred by patents, compulsory licenses have long been controversial. 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, 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. 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.

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. In order to preserve the incentive for innova-

10. 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, e.g., Machlup & Penrose, supra note 4, at 10-11.
14. 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.\textsuperscript{15} With the subsequent adoption of compulsory licensing by the 1883 Paris Convention,\textsuperscript{16} the world’s foremost international patent agreement, compulsory licensing became a fixture in almost all patent systems.\textsuperscript{17}

While specific provisions vary, compulsory licenses are generally authorized in the event of undesirable behavior by the patentee, such as anticompetitive, 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.\textsuperscript{18} 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,\textsuperscript{19} but less than “lost profits,” another basis for calculating infringement damages.\textsuperscript{20} 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.”\textsuperscript{21}

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\textsuperscript{15} Id.
\textsuperscript{16} 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).
\textsuperscript{19} 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”).
\textsuperscript{20} ROBERT P. MERGES, PATENT LAW AND POLICY 1038-84 (2d ed. 1997).
\textsuperscript{21} SCHERER & WATAL, supra note 3, at 28.
B. United States versus Developing Country Perspectives on Compulsory Licensing

Within the general framework of compulsory licensing, however, there has been little consensus on how best to implement it. 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. Commentators have noted that the resulting provisions, discussed below, were left intentionally vague, reflecting the parties' inability to come to an agreement.

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. 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 (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 18.

23. 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 & HASENZAHL, supra note 7, at 12-13 (stating that the resulting language ultimately vindicated the stance of developing countries over that of the United States).

24. 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.\textsuperscript{25} 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 healthcare infrastructure.\textsuperscript{26} 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.\textsuperscript{27} 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.\textsuperscript{28} Compulsory licensing provides an important safeguard to ensure that technology transfer happens in the event of non-working or high prices. In contrast, countries such

\textsuperscript{25} See Attaran & Gillespie-White, supra note 5, at 1890.


\textsuperscript{27} 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/2001/01 performreport.pdf. Most of the remaining patents were granted to inventors from developed countries. \textit{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 24.

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. 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. By 1977, the Federal Trade Commission ("FTC") and DOJ had issued approximately 125 decrees over thousands of patents and a wide range of technology. Recently, such decrees have been ordered in the context of mergers, price-fixing, and the abuse of monopoly or market power. 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.

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


32. 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 twenty-five compulsory licenses issued since the mid-90s, roughly half resulted from mergers and acquisitions, while the remainder resulted from other forms of anticompetitive behavior).

her invention, 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.” 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, the government has used it in a wide range of circumstances. Since 1948, the year of the statute’s enactment in its current form, the Court of Federal Claims and its predecessors have decided almost 300 cases, involving a wide variety of technologies, under § 1498. 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

34. 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).

35. 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).

36. 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. 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,\textsuperscript{39} as compared to a 58% success rate of patentees against accused infringers in general.\textsuperscript{40} Outside the context of section 1498, compulsory licenses have been authorized for public policy reasons, but on a more limited scale.\textsuperscript{41}

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.\textsuperscript{42} Spain, Portugal, Greece, and Norway introduced product patents over drugs as recently as 1992.\textsuperscript{43} At the end of the 1980s, at least forty developing countries, including the most populous, provided no patent protection for pharmaceuticals.\textsuperscript{44} The rationale behind this policy of non-protection

\textsuperscript{39} This figure is based on an analysis of cases from 1982 to 1993. See Lavenue, \textit{supra} note 37, at 502.


\textsuperscript{41} 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 \textit{de facto} authorized compulsory licensing by rewarding 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), \textit{cert. denied}, 293 U.S. 576 (1934).


\textsuperscript{43} \textit{Id.}

\textsuperscript{44} \textit{Id.} at 1. However, all WTO members are obligated to offer pharmaceutical patent protection by 2016. See ABBOTT, \textit{supra} note 18, at 11.
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,\textsuperscript{45} 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.\textsuperscript{46} Accordingly, surveys published in 1986 and 2000 all concluded that the pharmaceutical, biotechnology, and chemical industries rely more heavily on patents than other industries.\textsuperscript{47} 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 Food

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\textsuperscript{45} 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., \textit{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. \textit{Id.} Using data from PhRMA, Public Citizen estimates the cost of development to be between $114 million and $150 million. \textit{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 preclinical 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. \textit{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.}

\textsuperscript{46} \textit{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 45 (estimating the development cost of a new pharmaceutical to be $802 million).}

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. 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. 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. 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. 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.

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 price


51. Tollman *et al.*, *supra* note 45 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 50, at 35 (stating that average extensions are two to three years in length).

52. *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).
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. In 1962, Congress enacted the Kefauver-Harris amendments, which increased the FDA's involvement in the development and advertising of drugs. U.S. lawmakers again addressed price control mechanisms in 1972 with the proposal of the Public Health Price Protection Act, which was ultimately unsuccessful.

During the 1990s, several trends came together to focus attention on drug pricing, the most prominent being the "relentless escalation" of health care costs. By 1992, the United States devoted 14% of its Gross National Product to healthcare costs, more than any other industrialized country. Prices rose much faster on drugs than on other goods, and pharmaceutical profitability levels topped those of all other industries. 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. 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.

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

54. Id.
55. Id. at 404.
57. Id.
58. Id. at 98.
government to produce drugs for public health purposes. In the 1960s and 1970s, the U.S. government made and used tetracycline and meprobamate 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%.

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. One of the most notable early cases involved the licensing of tetracycline, ampicillin, and related products as part of a judgment against Pfizer, American Cyanimid, and other pharmaceutical companies, in response to an antibiotic price-fixing scheme.

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. 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. 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 their objective was 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,

64. Scherer & Watals, supra note 3, at 17.
67. Id.
or set at 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. Royalty-free licenses are issued more rarely—usually in cases of misconduct.

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. 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. 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.” This pro-

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

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.
vision 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.”72 Before licenses are granted, the proposed user must try unsuccessfully for a reasonable amount of time to secure a license on reasonable terms.73 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.”74 Such use must be non-exclusive and non-assignable.75 Additionally, unless the patentee has engaged in anti-competitive behavior, the use must predominately supply the domestic market.76 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.”77 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.”78

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.”79 Article 27 allows member countries to exclude from patentability inventions needed to protect public health.80 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,81 it states in part:

72. TRIPS Agreement art. 31(h).
73. Id. art. 31(b).
74. Id.
75. Id. art. 31(d)-(e).
76. Id. art. 31(f), (k).
77. Id. art. 31(g).
78. Id. art. 30.
79. Id. art. 8(1).
80. Id. art. 27(2).
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.\(^8\)

In addition, the Doha Declaration clarifies that member countries may define for themselves "what constitutes a national emergency or other circumstances of extreme urgency."\(^8\) 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.\(^8\)

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.\(^8\) Although the Declaration required that the TRIPS Council find an "expeditious solu-

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82. WTO, Ministerial Declaration, Fourth Ministerial Conference in Doha, Qatar, ¶ 17 (adopted Nov. 14, 2001).
83. 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].
84. \textit{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.

\textit{Id.}

tion” to these issues by the end of 2002, it was not until late August 2003 that an accord was reached.

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. 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. 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. 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). 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. In light of these

86. Doha Declaration, supra note 83, ¶ 6.
87. See, e.g., Elizabeth Becker, Poor Nations Can Purchase Cheap Drugs Under Accord, § 1, at 14.
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 47.
90. See infra note 80 and accompanying text.
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 is priced 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.93 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,

Cockburn, supra note 42, at 3-4 (establishing for future reference the current baseline of research efforts devoted to those diseases specific to developing countries).

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 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.94 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.95 The most thorough study to date, which 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.96 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.97

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.98 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.99

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 of

94. See Lanjouw & Cockburn, supra note 42.
96. See Scherer, supra note 31, at 67-75.
97. See McFetridge, supra note 95.
98. See Scherer, supra note 31, at 78-82.
the original innovation. Indeed, follow-on innovation by competing licensees or by potential entrants is often the very aim of licensing orders in the antitrust context. The question of whether a potential tradeoff between increased licensee innovation and decreased licensor innovation exists, however, is beyond the scope of this Article.

1. 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. 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. 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. Nevertheless, he concluded that compulsory licensing had not forced firms to invest in R&D at a level below the norms in their industries.


102. See SCHERER, supra note 31, 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. The majority of these licenses did not require future licensing of patents issuing from the year studied, but covered past inventions. 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. 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. 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.

2. 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. 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.

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

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 & Hasenahh, supra note 7, at 18-20.  
112. See Scherer, supra note 31, 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 & Hasenahh, 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. 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.  

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 consti-
tute[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." 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.

3. 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. 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 exclusive civilian use 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 compulsory license in

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 31, at 78-84.
which the government or its potential licensees would have a complete, royalty-free right to use the patent.\textsuperscript{118}

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.\textsuperscript{119} 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.\textsuperscript{120} 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.\textsuperscript{121} 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.\textsuperscript{122} 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.\textsuperscript{123}

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 regu-
lar licensing regime of Canada in the Eastman Commission study 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.

4. 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. 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.

C. 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 (Har-
bridge) 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.\textsuperscript{126}

A. The Antitrust Drug Licenses

With the exception of the \textit{Eli Lilly} license (see Table 1), all of the licenses I studied arose in the acquisition or merger context.\textsuperscript{127} 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 \textit{Eli Lilly} and \textit{Merieux} cases both covered future innovation.\textsuperscript{128} In the \textit{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 \textit{Merieux} case, the order required that the acquire, Institut Merieux S.A. (“Meriuex”), lease Bioscience Connaught’s (“Connaught”) rabies vaccine business long-term, and that it retain no future interest in the business.\textsuperscript{129}


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

\textsuperscript{128} See infra Part VIII.C-D.

\textsuperscript{129} See infra Part VIII.D.
Table 1: Drug License Orders under Antitrust Decrees

<table>
<thead>
<tr>
<th>Licensor, Invention (Year of order)</th>
<th>Triggering Event</th>
<th>S(poradic) v. G(eneral) license</th>
<th>E(ary) v. M(id) v. L(ate) Stage of Drug Dev’t</th>
<th>Nature of Market Affected</th>
<th>Subject of License</th>
<th>Compensation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marion Merrell Dow, Di-cyclomine (1994)</td>
<td>Merger</td>
<td>S</td>
<td>L</td>
<td>Mature</td>
<td>Patents +, manufacturing</td>
<td>0</td>
</tr>
<tr>
<td>Roche, CD4 (1990)</td>
<td>Merger</td>
<td>S</td>
<td>E</td>
<td>Nascent</td>
<td>Patents +</td>
<td>1-3% of net sale</td>
</tr>
<tr>
<td>Eli Lilly, Insulin (1980)</td>
<td>Illegal Conspiracy</td>
<td>G</td>
<td>E</td>
<td>Nascent</td>
<td>Future Patents+</td>
<td>Reasonable share of R&amp;D expenses</td>
</tr>
</tbody>
</table>

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

broad basic technologies and therefore covered some early-stage, pre-clinical technologies. 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. The Baxter case was prompted by concerns about the merger of two companies that each had products in early development. 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.

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 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. 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.

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 com-

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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 71 and accompanying text.
141. See infra Part VIII.A-B.
pany 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.  

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. 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. In the in-


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-
stances 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.

![Figure 1: Sporadic Licenses - Absolute Patenting](image)

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.\textsuperscript{145} 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 dicyclomine as a treatment for irritable bowel syndrome ("IBS") makes it probable that factors other than the license influenced the company's decisionmaking. Each of these examples is explored more fully in the Appendix.

2. \textit{Predictable Licensing}

The two instances of predictable licensing present a more complex problem. While both Eli Lilly and Connaught/Merieux were subject to licenses covering future innovation, Eli Lilly flourished during the time of its compulsory license while Connaught 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 Eli Lilly example, 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.\textsuperscript{146} 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.

\textsuperscript{145} See infra Part VIII.A.

\textsuperscript{146} In re Institut Merieux S.A., 113 F.T.C. 742 (1990).
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. 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. 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 exercising its patent rights over 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 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

148. *Id.*
production of human insulin through recombinant DNA techniques in 1978, Lilly initiated clinical trials of its human insulin product, "Humalog," in the United States in 1980, and invested in additional research facilities.\textsuperscript{149} In 1982, Lilly was rewarded for its efforts, receiving the first FDA approval for human insulin in the United States.\textsuperscript{150} 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 exploit 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.\textsuperscript{151} 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."\textsuperscript{152}

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.\textsuperscript{153} Finally, Lilly has faced 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

\textsuperscript{150} See, e.g., A Market Face-off for Two Insulin Pioneers, Bus. Wk., Nov. 1, 1982.
\textsuperscript{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).
\textsuperscript{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).
\textsuperscript{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 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.
Lilly capturing 46% and Novo Nordisk capturing 45% of the market.\textsuperscript{154}

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.\textsuperscript{155} 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.\textsuperscript{156} However, Merieux was unable to find a suitable buyer for Connaught’s manufacturing business.\textsuperscript{157} Nearly four years after the decree had issued, the FTC withdrew the leasing requirement from the order.\textsuperscript{158}

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.”\textsuperscript{159} 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 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 incen-

\begin{itemize}
  \item \textsuperscript{154} Id. at 17 exh.9.
  \item \textsuperscript{155} In re Institut Merieux S.A., 113 F.T.C. 742, 1990 FTC LEXIS 291, *3-4 (1990).
  \item \textsuperscript{156} Id. at 7-9.
  \item \textsuperscript{157} In re Institut Merieux S.A., 117 F.T.C. 473, 474-75 (1994) (modifying 1990 order).
  \item \textsuperscript{158} Id. at 482.
  \item \textsuperscript{159} Id. at 477.
\end{itemize}
tive 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 1992.160

D. Results

These results, although limited, lend support to the theory that only drug licenses that issue 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.

Table 2: Summary of Antitrust Case Results

<table>
<thead>
<tr>
<th>Antitrust Licenses</th>
<th>Sporadic v. General License</th>
<th>Nature of Market Affected</th>
<th>Perceived or Actual Negative Impact?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baxter</td>
<td>Sporadic</td>
<td>Developed</td>
<td>No</td>
</tr>
<tr>
<td>Dow, Roche</td>
<td>Sporadic</td>
<td>Developed</td>
<td>No</td>
</tr>
<tr>
<td>Chiron/Ciba-Geigy</td>
<td>Sporadic</td>
<td>Nascent</td>
<td>No</td>
</tr>
<tr>
<td>Roche</td>
<td>Sporadic</td>
<td>Nascent</td>
<td>No</td>
</tr>
<tr>
<td>Eli Lilly</td>
<td>General</td>
<td>Nascent</td>
<td>No</td>
</tr>
<tr>
<td>Merieux/Connaught</td>
<td>General</td>
<td>Developed</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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 ob-

served. 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. 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. 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. 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.”

Funds for researching diseases specific to developing countries often come from public or philanthropic resources such as the Centers for Dis-

161. See LANJOUW, supra note 91.
162. See id.
163. See id.
ease 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.¹⁶⁵ 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.¹⁶⁶ Efforts to develop an AIDS vaccine for countries in Africa have likewise been collaborative.¹⁶⁷

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. If these incentives stay intact, selective compulsory licensing for developing nations should have little impact on overall R&D investment as long as the affected market is limited to developing countries.

On August 30, 2003, a historic accord on compulsory licensing was announced addressing this concern. After several days of negotiations, the United States and other WTO countries effectively agreed to allow poor countries to import generic drugs through compulsory licenses as long as measures to prevent re-exportation of the drugs to other, rich markets are taken.¹⁶⁸ For example, such measures include special packaging or coloring to clearly delineate drugs that have been exported under compulsory

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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 HIV vaccine trials in Africa as sponsored by the NIH, CDC, IAVI, and other public and philanthropic organizations).

licenses from drugs sold in rich countries. The United States has demanded that the scope of the accord cover life-threatening diseases. While some details about its coverage are yet to be resolved, the accord is indisputably intended to reach AIDS therapy drugs.

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. The recent WTO accord is entirely appropriate in this regard.

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 may make a difference and could cause some companies to avoid these markets altogether. To the extent that the compulsory licensing framework that devel-

169. WTO Aug. 30 Statement, supra note 168.
ops under the WTO accord also covers such diseases, as it likely will, special care should be taken to ensure that incentives remain intact. 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 and technical capability. In the past, countries that have elected to take licenses have had to endure lawsuits, pressure, and threats of trade sanctions from the United States. In addition, producing drugs pursuant to a license requires a level of technical and manufacturing capability possessed by few countries. The August 2003 WTO accord significantly deals with these issues. Still, meeting the accord’s requirements for licensing could prove challenging, or at least bureaucratic. Over-reliance on compulsory licensing may also produce unintended negative downstream impacts on society.

While high drug prices comprise only one aspect of the AIDS problem, the WTO accord evidences the growing realization that increasing access to drugs must be a part of the solution. This is partly due to a number of factors that have shifted attention towards affordable treatment and vaccination rather than prevention alone. The initial push for prevention

172. See id.
173. 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).
174. 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).
175. Becker, supra note 87, § 1, at 14 (describing the concerns of some groups that “red tape” will discourage use of compulsory licenses).
176. Some 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.
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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 transformation must be explored. 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.” 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 emerging regime of compulsory licensing deserves continued attention in this respect.

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

180. Even before the August 2003 WTO accord, the pharmaceutical industry voluntarily reduced prices on a number of drugs in recognition of the humanitarian crisis. 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); Grunwald, supra note 178, 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; see also Geoff Dyer, Investors Warn Drugs Industry of Backlash over Health Crises, FIN. TIMES, Mar. 24, 2003, at 25 (describing investor pressure for price cuts).
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”).

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, estimated shortly after the order to be worth up to $200 million annually.

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. The order mandated one commission-approved licensee. 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. 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. Other portions of the order called for the divestiture of Immuno’s Factor VIII assets.

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182. Id. at 906.
185. Id. at 921.
186. Id.
187. Id.
188. Id. at 910-916.
Within six months of the order, the FTC approved Haemacure as the fibrin sealant licensee. 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. 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. The FTC approved several requests by licensee Haemacure to extend the license, and in 2002, Haemacure estimated that the license could expire in 2004.

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

After the order, Baxter continued 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. Additionally, Baxter introduced a follow-on application device, and worked on a patch, rather than liquid, version of the product. Also, the company conducted clinical trials on a hemostatic


193. 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.


sealant, which it subsequently introduced on the market. In 2000, the company announced a $400 million commitment to upgrade facilities used for fibrin sealant and other plasma and recombinant DNA products. 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. 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. Other companies, including Aventis, Omrix, the American Red Cross, Vitex, and a Bristol-Meyers Squibb subsidiary also developed fibrin sealants. Thus, Baxter was plausibly motivated to capture the first-mover advantage in the years just after the license was ordered.

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. 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. Dow’s acquisition of Rugby Darby, the only generic company approved to manufacture the drug at the time, raised antitrust concerns.

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. Accordingly, the order required Dow to provide a per-
petual license to a commission-approved licensee, including all formulations, patents, trade secrets, technology, know-how, and specifications.\textsuperscript{205} 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. \textit{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.\textsuperscript{206} During this time, other generic companies entered the dicyclomine market,\textsuperscript{207} causing the IBS market to mature by the last half of the 1990s, with few new product introductions until 2000.\textsuperscript{208} Although dicyclomine was one of just three main products in the anti-cholinergic and anti-spasmodic segment of IBS medications, other medication segments such as anti-diarrhea and constipation were more important.\textsuperscript{209} Dicyclomine’s share of the overall IBS medication market eventually dwindled to less than 2\% in 2000.\textsuperscript{210}

3. \textit{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.

\textsuperscript{205} Id. at 736.
\textsuperscript{207} Id.
\textsuperscript{208} See Stewart Adkins et al., \textit{Irritable Bowel Syndrome, Poetry in Motion}, Lehman Brothers, Sept. 2, 1999, at 19 (on file with author).
\textsuperscript{209} See id. at 6.
\textsuperscript{210} See Jeffrey Chaffkin et al., \textit{Company & Therapeutic Prescription Statistical Update}, Paine Webber, Oct. 23, 2000, at 96 (on file with author).
A year after the license issued, HMRI stopped filing for patents.\textsuperscript{211} 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.\textsuperscript{212} The FTC ordered the firm to license the know-how and rights relating to both its existing and future insulin-related patents.\textsuperscript{213} Any 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.\textsuperscript{214} 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.\textsuperscript{215} The order also required licensees to keep all production in the United States.\textsuperscript{216}

2. Subsequent Developments

No information is available on whether any companies came forward and took advantage of the compulsory license made available by the

\textsuperscript{211} 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.”


\textsuperscript{213} Id. at *17, *23.

\textsuperscript{214} Id. at *17.

\textsuperscript{215} Id. at *24.

\textsuperscript{216} Id. at *23.
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. In 1982, the FDA rewarded Lilly for its efforts with the first approval for human insulin in the United States.

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 one significant mitigating factor, however, was the license’s provision that the licensee could be asked to contribute to the R&D expenses.

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.

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 “[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 obli-

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217. 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).


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


221. Search using keyword “insulin.”
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. 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.

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. 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). 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.

D. Connaught/Rabies Vaccine

1. The Order

In 1992, citing concerns about increased domination of the U.S. rabies vaccine market, the FTC ordered Mérieux to lease the rabies manufacturing business of the company it acquired, Connaught Bioscience. Mérieux was the sole supplier of rabies vaccine in the United States, and Connaught was one of two potential entrants into the market. Worried that Mérieux’s monopoly would remain unchallenged, the Commission called upon Mérieux 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. In exchange, the or-

222. See ELI LILLY 1983 ANNUAL REPORT, supra note 152, at 17.
223. See CHRISTENSEN, supra note 151, at 1.
224. See id. at 1, 4.
225. See id. at 4.
226. See id. at 17, exh.9.
228. Id.
der provided for the lessee to give a lump sum payment, under customary and reasonable terms, to Merieux/Connaught.229

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.230 The most serious offer, from North American Vaccine, Inc., was rejected because of a lack of relevant experience.231 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.232

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."233 Although evidence of this decline is not in the consent order, no patents were filed by the would-be leased Connaught for rabies vaccine inventions during the contested period, while five patent applications were filed by Connaught-Merieux, which ultimately became Aventis, in the subsequent years.234

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 active in the rabies vaccine busi-

229. *Id.*
231. *Id.* at 476.
232. *Id.*
233. *Id.* at 477.
234. Search using keywords "rabies" and "vaccine" with incidental mentions screened out.
ness, launching a new product in 1992235 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 portfolio236 concerning the herpes simplex virus-thymidine kinase (HSV-tk) gene, the FTC ordered the companies to license their patent portfolios to an approved licensee.237 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.238 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.239 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 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."240

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.241 Within six months of the decree, the Commission approved the licensing of Chiron's

235. See Merieux Doubles Profits, supra note 160.
238. Id. at 864-73, 877-86.
239. Id. at 846-47.
HSV-tk portfolio to multiple companies in fulfillment of the order. In exchange, one licensee, Novartis, paid Chiron $60 million in addition to cross-licenses to some of its technologies.

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. Additionally, in 1998, the company reported that it had two products in development, one for graft-versus-host disease and another for hemophilia A. Over the 2000 to 2002 period, Chiron and Novartis were involved in two of the fifteen trials reported in the Biospace CCIS database. Meanwhile, licensee RPR, which became part of the larger pharmaceutical entity Aventis, appeared to make strides in the gene therapy market. The company launched RPR Gencell to develop gene therapies for cancer and other diseases in collaboration with other companies. 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. The order narrowly defined the relevant mar-

244. Search using keywords "gene therapy", "retroviral vector", and "HSV."
246. Search using keyword "HSV."
ket as “CD-4 based therapeutics for the treatment of AIDS and HIV infection.” 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.

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.

2. Subsequent Developments

In the years following the order, Roche’s patenting activity 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. Accordingly, the order did not significantly affect Roche’s CD4 HIV research.

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.

249. Id. at *3.
250. Id. at *4.
251. Id. at *25-26.
252. Search using keywords “CD4” and “viral.”
253. According to Biospace’s CCIS database.