

# STRETCHING THE LIMITS OF INTELLECTUAL PROPERTY RIGHTS: HAS THE PHARMACEUTICAL INDUSTRY GONE TOO FAR?

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## INTRODUCTION

It is well established that there is a tension between intellectual property (“IP”) and antitrust law.<sup>1</sup> Perhaps nowhere is this tension more obvious than in the pharmaceutical industry, where intellectual property rights are pushed to their limits in an attempt to maximize profits on popular brand name drugs. Of particular interest right now are concerns, voiced by the Federal Trade Commission (“FTC”), Congress, and the public, that large drug companies are abusing the formidable monopoly power afforded by their drug patents at the expense of consumer public welfare and competition.

This article examines what role antitrust law ought to play in assessing and enforcing potentially undesirable behavior by drug companies. Specifically, this article will examine the several ways by which pharmaceutical companies attempt to lengthen the patent life of their brand name drugs which include: (1) using legislative provisions and loopholes to apply for a patent extension; (2) suing generic manufacturers for patent infringement; (3) merging with direct competitors as patent rights expire in

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<sup>1</sup> See Robert Merges *et al.*, *Intellectual Property in the New Technological Age* 1037-41 (Aspen Law & Business 1997); See also Mark Lemley, *Intellectual Property and Antitrust Law* 1-21 (in press).

an effort to continue the monopoly; (4) recombining drugs in slightly different ways to secure new patents and layering several patents on different aspects of the drug to secure perennial monopoly rights; and (5) using advertising and brand name development to increase the barrier to entry for generic drug manufacturers.

An evaluation of the various practices employed by the large companies specializing in brand name drugs indicates that intellectual property protection is not being used to promote an incentive to create and innovate. Rather, intellectual property rights are being used to gain and maintain an exclusive market share for the most profitable, not necessarily the most beneficial, drugs. Antitrust law, in addition to avenues such as legislative reform, should properly step in to curtail those abuses of intellectual property rights that have clearly moved beyond their proper scope.

## I. THE THEORETICAL BASES OF INTELLECTUAL PROPERTY AND ANTITRUST LAW

### A. *Intellectual Property Law*

Several theories have been offered to validate the notion of giving individuals exclusive rights in their own ideas. Though some theorists have rooted their philosophies in natural rights or in personhood, the primary basis for intellectual property protection in the United States is the utilitarian or economic incentive framework.<sup>2</sup> This philosophy is supported by the United States Constitution, in which it expressly provides the grant of power in the patent and copyright clause in order "to Promote the Progress of Science and [the] Useful Arts."<sup>3</sup> It is additionally cited as the main reason behind intellectual property law in judicial decisions:

The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that the best way to advance public welfare through the talents of authors and inventors in the 'Science and useful Arts.' Sacrificial days devoted to such creative activities deserves rewards commensurate with the services rendered.<sup>4</sup>

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<sup>2</sup> See Lemley, *supra* n. 1, at 2.

<sup>3</sup> U.S. Const., art. I, § 8, cl. 8.

<sup>4</sup> *Mazer v. Stein*, 347 U.S. 201, 219, 100 U.S.P.Q. 325, 333 (1954).

The economic incentive framework recognizes the financial investment required for invention and creation. Substantial resources must often be expended for research, development and marketing purposes. Absent any intellectual property protection, a person's ideas could be easily copied and distributed by competitors at a much lower cost, eliminating the ability for the original inventor to recoup the investment costs and make a profit. Since the potential outcome of this situation is likely the discouragement of original inventors to exert the mental and financial capital necessary to develop their ideas for public distribution, Congress has instituted an intricate body of laws providing control, sometimes exclusively, over the use and distribution of their ideas.

### **B. Antitrust Law**

The antitrust laws seek to control the exercise of private economic power by preventing behavior that threatens competition. The laws prevent a wide array of anticompetitive conduct including the development of monopolies, establishment of cartels, and the implementation of price discrimination schemes.

The fundamental assumption underlying antitrust law is that competition is a desirable goal because it promotes economic efficiency and consumer welfare, though this philosophical foundation of antitrust law is somewhat difficult to pin down. Judge Robert Bork, for instance, concluded that the legislative record of the Sherman Antitrust Act<sup>5</sup> suggests that antitrust law "displays the clear and exclusive policy intention of promoting consumer welfare."<sup>6</sup> Other scholars, however, have disputed this theory in favor of other policy goals. These include preserving opportunities for smaller firms and individuals to compete,<sup>7</sup> preventing unfair redistributions of wealth from consumers to producers,<sup>8</sup> and shifting wealth from large manufacturers to small merchants and farmers.<sup>9</sup>

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<sup>5</sup> 15 U.S.C. §§ 1, 2 (1994 & Supp. IV 1998).

<sup>6</sup> See Robert H. Bork, *The Antitrust Paradox: A Policy at War with Itself* 61 (Basic Books, Inc. 1978).

<sup>7</sup> See Eleanor M. Fox, *The Modernization of Antitrust: A New Equilibrium*, 66 Cornell L. Rev. 1140, 1142-43 (1981).

<sup>8</sup> See Robert H. Lande, *Wealth Transfers as the Original and Primary Concern of Antitrust: The Efficiency Interpretation Challenged*, 34 Hastings L.J. 65, 114 (1982).

<sup>9</sup> See Thomas J. DiLorenzo, *The Origins of Antitrust: An Interest Group Perspective*, 5 Intl. Rev. L. & Econ. 73, 75-76 (1985).

Despite the debate in the literature, it appears that the economic efficiency/consumer welfare framework has attracted the most support from judicial decisions. In *Brown Shoe Co. v. United States*,<sup>10</sup> for instance, Chief Justice Earl Warren observed, "taken as a whole, the legislative history [of the antitrust provision at issue] illuminates congressional concern with the protection of competition, not competitors."<sup>11</sup> Legislative debates "suggest that Congress designed the Sherman [Antitrust] Act as a 'consumer welfare prescription.'"<sup>12</sup>

### C. *The Interaction Between Intellectual Property and Antitrust Law*

A tension between intellectual property and antitrust law arises out of seemingly contradictory theoretical foundations. On one hand, antitrust law seeks to promote competition by ensuring that no single company or individual secures exclusive market power for a particular good or product.<sup>13</sup> On the other hand, intellectual property law seeks to promote innovation and creation by providing what the antitrust laws specifically prohibit, namely, a lawful monopoly over a particular good.<sup>14</sup> Indeed, in many cases the intellectual property laws translate to a situation where fewer people buy a particular good than if it were sold competitively, and these people each pay more for the good.

Because intellectual property rights result in actual costs to the consuming public, they can only be justified as valid incentives to create and innovate only to the extent they actually encourage enough creation and innovation of new works to offset these costs.<sup>15</sup> In fact, intellectual property rights are limited in their breadth and duration in order to balance the cost directed to the consuming public with the benefit of encouraging the production of creative new works.<sup>16</sup>

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<sup>10</sup> 370 U.S. 294, 320 (1962).

<sup>11</sup> *Id.*

<sup>12</sup> *Reiter v. Sonotone Corp.*, 442 U.S. 330, 343 (1979) (citing Robert H. Bork, *supra* n. 6, at 66).

<sup>13</sup> See Bork, *supra* n. 6, at 51.

<sup>14</sup> See *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 886-87, 228 U.S.P.Q. 90, 100-01 (Fed. Cir. 1985) (The purpose of the patent system is to "encourage innovation and its fruits"; the purpose of the antitrust laws is "to promote competition").

<sup>15</sup> See Lemley, *supra* n. 1, at 12.

<sup>16</sup> See *id.*

It is when intellectual property rights are utilized beyond their rightful scope that intellectual property law is no longer in balance with antitrust law, but rather in direct conflict. In situations where intellectual property rights are used to obtain unwarranted market power, or to interfere with competition beyond what is enabled by the law, antitrust law must step in to curtail the potential excessive cost to the consuming public. Thus, it is not the legitimate exercise of one's particular lawful intellectual property right that provides problems for antitrust; it is the illegal abuse of that right. It is this issue that is the focus of the present article.

## II. THE PHARMACEUTICAL INDUSTRY

The American pharmaceutical industry is massive. Drug expenditures account for 8% of all health care spending and will soon surpass spending for physicians' services and hospitalization costs.<sup>17</sup> In 1997, the dollar sales of prescription drugs in the United States amounted to \$71.8 billion.<sup>18</sup> Of this amount, about 90% come from the sales of brand name prescription drugs.<sup>19</sup>

The profit power of brand name prescription drugs relies heavily on a drug company's patent rights. With a valid patent and regulatory approval by the Food and Drug Administration ("FDA"), a drug company can lawfully exercise its monopoly rights and reign as the sole producer of a particular drug until the patent expires and generic manufacturers enter the market. Securing a patent for a brand name prescription drug carries with it enormous costs. For instance, it is estimated that the cost of bringing a single brand name prescription drug to market is somewhere between \$250-500 million.<sup>20</sup> This figure includes the costs of research and development of the drug, extensive testing for FDA approval and production of the drug.<sup>21</sup>

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<sup>17</sup> See Marcia Angell, *The Pharmaceutical Industry: To Whom Is It Accountable?*, 342 *New Eng. J. Med.* 1902 (2000).

<sup>18</sup> See Robert Levy, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change*, Bureau of Economics Staff Report, Fed. Trade Comm. (Mar. 1999).

<sup>19</sup> See The Gale Group, *Intellectual Property Rules: A Delicate Balancing Act for Drug Development*, 23 *Chain Drug Rev.* RX13 (2001).

<sup>20</sup> See Levy, *supra* n. 18, at 7. See also Stephen S. Hall, *Prescription for Profit*, *N.Y. Times Mag.* 42 (Mar. 11, 2001).

<sup>21</sup> While drug companies have to first jump through the PTO hoops to secure a patent on the drug, it must also prove to the FDA that it is safe and effective by documenting expensive and lengthy trials that the pill will not have harmful side effects and will do

Because the FDA approval process generally occurs once the drug has been approved for a patent, the drug's time in waiting at the FDA severely cuts down on the effective patent life, the term used to describe how long a patented drug has left on its patent once it enters the market. The average length of time it takes to secure marketing approval from the FDA for a new brand name drug is nine years.<sup>22</sup>

The financial blow incurred by a manufacturer of an original brand name drug when its patent expires, and generics enter the market, is substantial. Generic drugs, those drugs that are chemical equivalents of an original drug and capable of receiving FDA approval without having to invest in the initial research and development, account for \$5 billion of all drug sales.<sup>23</sup> While this is currently not a substantial share of the overall drug market, it is rising annually, with one estimate speculating that the market potential for generic drugs may eventually reach 75% of all drug sales.<sup>24</sup> To illustrate the financial impact of the loss of a patent on a profitable drug, consider the case of Claritin, an allergy drug that costs \$85 a month to consumers and has annual sales of \$2 billion.<sup>25</sup> When Claritin's patent expires, and a competing generic enters the market, "the cost of generic Claritin will drop to 80 percent of current prices. When everyone else jumps in six months later, the price will fall off a cliff . . . the price will drop to \$10 [per month] very quickly."<sup>26</sup>

The incentive to extend the patent life of brand name drugs is overwhelming. In a desperate effort to maximize the length of time their potential brand name patented drugs can maintain market exclusivity, pharmaceutical companies have employed several clever strategies. While some of this conduct, discussed *infra*, has been investigated by the FTC for possible antitrust violations, many of these strategies have been left unscrutinized by the federal government. The following sections closely examine these strategies and the likely impact on competition and consumers. The strategies are divided into five categories, although many of

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what it is manufactured to do. See Hall, *supra* n. 21, for a detailed explanation of the FDA approval process.

<sup>22</sup> See Levy, *supra* n. 18, at 8.

<sup>23</sup> See Heidi Grygiel, *Now They GATT Worry: The Impact of the GATT on the American Generic Pharmaceutical Industry*, 6 U. Balt. Intell. Prop. L.J. 47, 47 (1997). This figure is likely low given the date of the article.

<sup>24</sup> See Jane Everhart, *Panelists Detail Barriers to Wider Use of Generics*, 216 Am. Druggist 16 (May 1, 1999).

<sup>25</sup> See Hall, *supra* n. 20, at 40.

<sup>26</sup> *Id.* at 59.

the strategies overlap: (1) Attempts to extend patents through legislative loopholes and lobbying; (2) Initiating patent infringement litigation; (3) Merging with direct competitors as patent rights expire to maintain market share; (4) Layering of patents and combining drugs for new patents; and (5) Using brand name development and advertising to increase barriers to entry for generic manufacturers. Section VIII follows with an analysis regarding whether the behavior of the pharmaceutical industry favors continued protection of intellectual property rights or whether its behavior favors a stricter antitrust policy that closely curtails potential and actual abuses of intellectual property rights.

### III. ATTEMPTS TO EXTEND PATENTS THROUGH LEGISLATIVE LOOPHOLES AND LOBBYING

Methods employed by the pharmaceutical industry to extend the patent life of their most profitable drugs through legislative means are perhaps one of its most utilized and underscrutinized strategies. Through a series of legislative amendments and acts passed by Congress to encourage competition in the pharmaceutical industry, and to level the playing field for generic manufacturers, the major drug companies have found statutory loopholes that enable them to extend their patent rights by several months, or even years. By some estimates, these legislative statutes have increased the average patent life of many new drugs by at least 50% over the course of the last two decades.<sup>27</sup>

The most used vehicle for patent extension is the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act.<sup>28</sup> The law was designed to reward innovation at major pharmaceutical companies and protect intellectual property while at the same time lowering costs by making it easier for generic drug manufacturers to reach the American marketplace.<sup>29</sup> As part of the Hatch-Waxman Act, new drugs being developed after the law was enacted in 1984 could receive automatic patent extensions of up to five years.<sup>30</sup> The more than 100 drugs already in development when the law was passed were given an extension of two years.<sup>31</sup> Also as part of the Hatch-Waxman Act, the first generic

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<sup>27</sup> See The Gale Group, *supra* n. 19, at RX13.

<sup>28</sup> 21 U.S.C. § 355 (1994).

<sup>29</sup> See Hall, *supra* n. 20, at 58-59.

<sup>30</sup> See 35 U.S.C. § 156(d)(5)(E)(i) (1994).

<sup>31</sup> See Hall, *supra* n. 20, at 59.

manufacturer to receive FDA approval via an Abbreviated New Drug Application (ANDA) for a generic version of a competing brand name drug is entitled to 180 days of exclusivity as the only generic on the market once the original patent holder's patent expires.<sup>32</sup>

The Hatch-Waxman Act is unfortunately littered with loopholes, most of which center on the provisional use of the words coming "off-patent."<sup>33</sup> While originally meant to simply designate the time a drug patent's expires, it has been interpreted and used by drug companies to devise ways in which they can avoid the technicality of coming "off-patent," and thus indefinitely prevent the introduction of generics on the market.

One of the ways that drug companies can avoid coming "off-patent" includes applying for a series of patents over a period of time that cover different aspects of a drug so that new patents become active as old patents expire. For instance, Augmentin, a powerful and expensive antibiotic produced by SmithKline, was initially expected to come off-patent in 2002 at which time the patent for the original compound amoxicillin was to expire.<sup>34</sup> However, by securing patents covering other properties of the drug Augmentin will now remain covered until 2017, fully 15 years more than expected.<sup>35</sup> This new patent was not granted for innovative research on a new drug, but for work conducted in the early 1970's.<sup>36</sup> Similarly, the makers of the popular anti-anxiety drug BuSpar, whose main patent was set to expire in November of 2000,<sup>37</sup> triumphantly announced that it had secured a new patent covering the absorption of BuSpar just one day before a generic competitor was set to begin distribution of its pill that would have given consumers a 25% discount.<sup>38</sup>

Yet another way the Hatch-Waxman Act has been exploited to extend patent rights is through patent litigation. When generics create a copy of a patented drug, the generic manufacturer files with the FDA an ANDA,

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<sup>32</sup> See *id.*

<sup>33</sup> See *id.*

<sup>34</sup> See U.S. Pat. No. 4,529,720 (issued July 16, 1985).

<sup>35</sup> See David Pilling & Richard Wolfe, *Drug Abuses: As Pharmaceutical Companies Go to Extraordinary Lengths to Expiring Patents, Regulators are Starting to Pay Close Attention*, Financial Times (London) (Apr. 20, 2000).

<sup>36</sup> See *id.*

<sup>37</sup> See Robert Langreth & Victoria Murphy, *Perennial Patents*, Forbes 52 (Apr. 2, 2001).

<sup>38</sup> See *id.* In the case of BuSpar, the new patent covers a metabolite produced when BuSpar is broken down in the liver. Its manufacturer, Bristol-Myers, claims that generics can't produce equivalents without infringing because any generic would violate the new patent when the drug is digested.

which formally seeks the FDA's approval to sell a generic version of a brand name drug once it expires (and once the first generic gets its 180 days of exclusivity).<sup>39</sup> The Hatch-Waxman Act requires that the generic manufacturer notify the original brand name manufacturer of its plans to distribute a generic.<sup>40</sup>

Like clockwork, original brand manufacturers, aware that their drug cannot come "off-patent" when there is ongoing patent litigation, have filed suit against generic manufacturers claiming patent infringement on one or more "layers" of patents subsequently filed on various, and often insignificant, elements of the drug. While some of these suits are no doubt meritorious, initiating litigation has the additional benefit of prolonging the length of time the original brand name drugs can exclusively occupy the market, and therefore maximize the original manufacturer's profit.<sup>41</sup> To date, there are ongoing patent infringement suits between the original brand name manufacturers and generic competitors for the following drugs: Claritin,<sup>42</sup> BuSpar,<sup>43</sup> Cardizem,<sup>44</sup> and Prozac.<sup>45</sup>

In addition to the many patent extension benefits afforded by the Hatch-Waxman Act, drug companies have also turned to other less dramatic forms of legislative assistance: the Uruguay Round Agreement Act ("URAA")<sup>46</sup> and extensions for pediatric testing.<sup>47</sup>

In 1994, the federal government signed the URAA, which implemented the trade agreements reached during the latest negotiating of General Agreement of Tariffs and Trade (GATT).<sup>48</sup> The URAA amended

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<sup>39</sup> See Gygiel, *supra* n. 23, at 51.

<sup>40</sup> See Hall, *supra* n. 20, at 59.

<sup>41</sup> See *id.*

<sup>42</sup> See *id.*

<sup>43</sup> See Langreth, *supra* n. 38, at 52.

<sup>44</sup> See Umi Company, *Up Against the Law: Hoechst Faces Antitrust Suits*, 33 Med. Mktg. & Media 22 (Oct. 1, 1998).

<sup>45</sup> See Information Access Company, *Barr Says Generic Prozac Could Launch by August 2001*, 22 Drug Store News 14 (Aug. 28, 2000).

<sup>46</sup> 19 U.S.C. § 3501 (Supp. II 1996).

<sup>47</sup> See 21 U.S.C. § 355a(a)(2)(A)(ii) (1994).

<sup>48</sup> See Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost and Access in the Post-Genomics Era*, 2001 U. Ill. L. Rev. 173, 182 & n. 31 (2001). In 1994, Congress passed the Uruguay Round Agreements Act (URAA) which amended U.S. patent law to prescribe a twenty-year term that begins to run at the time of patent application.

two sections of the patent code. In order to harmonize the United States patent term with other GATT nations, URAA amended the patent code providing that patents issuing after 1995 receive patent terms of 20 years from the date of application filing.<sup>49</sup> In addition, the URAA provided a term of longer than seventeen years from the date of grant or twenty years from the date of filing for patents in force in 1995 or patent applications filed prior to this date.<sup>50</sup> The transition provisions in effect lengthened protection for any drug patent that received FDA approval in three years or less, because the URAA extended patents of drugs without giving any additional protections for generic drug makers. For instance, Glaxo's ulcer medication, Zantac, gained nineteen months of protection.<sup>51</sup> The drug Claritin received an extra twenty-two months of exclusivity.<sup>52</sup> Once again, these extensions were not for any additional innovation or creation, but rather were the result of simple legislative maneuvering.

Any drug company that conducts pediatric testing for its patented drugs receives an additional six months of patent exclusivity.<sup>53</sup> While six months might seem negligible when discussing patent terms of seventeen or twenty years, these extensions nevertheless amount to significant additional profits. For an estimated \$3 million pediatric trial, Claritin was able to extend its patent life by six months which translated into earnings of close to \$1 billion.<sup>54</sup>

The legal and political maneuvering by brand name drug companies to extend their patent life on profitable drugs is staggering in its costs to consumers and competition. For example, the extensions secured on Claritin by utilizing loopholes in the Hatch-Waxman Act, the URAA, and pediatric trials amounted to an extra four and a half years or \$13 billion in revenues for its manufacturer, Schering-Plough.<sup>55</sup> The cost to consumers and insurance companies is also staggering, when one considers the potential savings had generic competitors been able to slash the price of generic Claritin to \$10 per a one-month supply.

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<sup>49</sup> *See id.*

<sup>50</sup> *See id.*

<sup>51</sup> *See Grygiel, supra* n. 23, at 54.

<sup>52</sup> *See Hall, supra* n. 20, at 59.

<sup>53</sup> *See id.*

<sup>54</sup> *See id.*

<sup>55</sup> *See id.* This estimate excludes additional extensions due to ongoing litigation or layering of new patents.

Eager for more legislative assistance in maintaining its market power over Claritin, Schering-Plough has mounted a tireless and expensive lobbying effort to pass favorable language that would enable Claritin to continue its dominance in the market.<sup>56</sup> So far, efforts by Congress to place discretion in the hands of the FDA to determine whether patent extensions should be granted have failed, despite a \$20 million lobbying effort by Schering-Plough.<sup>57</sup> The proposed legislation is perceived by many as nothing more than an attempt to unfairly extend the monopoly power of Schering-Plough and has even been mockingly referred to as the "Claritin Monopoly Relief Act."<sup>58</sup>

So far, the FTC has not pursued any action against pharmaceutical companies stemming exclusively from their attempts to take advantage of loopholes in legislative provisions or by lobbying for favorable language that would extend their patent term. This is despite the fact that these legislative measures have provided the drug companies with billions of dollars in revenues at the expense of consumers who could be purchasing less expensive generics. The unwillingness on behalf of the FTC to investigate this type of conduct likely reflects an institutional policy of not investigating behavior that has been officially sanctioned through legislative provisions. Indeed, any action by the FTC is likely precluded by the *Noerr-Pennington* doctrine.<sup>59</sup> While the FTC may be more willing to scrutinize transactions that indirectly arise from legislative loopholes or lobbying efforts, *e.g.*, litigation settlements incorporating anticompetitive clauses, it might prefer to defer to Congress on potentially faulty legislative provisions that are better mitigated through legislative reform.

Indeed, legislative reform is already underway to close the loopholes that have enabled drug companies to employ so many questionable practices and consequently maintain their patent monopolies. Ironically, the biggest supporters of legislative amendment to the Hatch-Waxman Act are the authors themselves, who appear both frustrated and surprised that their procompetitive legislation has been used for motives that are in direct opposition to the policies underlying the Act. Congressman Henry Waxman has stated, "The Hatch-Waxman Act has been turned on its head. We were

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<sup>56</sup> See Hall, *supra* n. 20, at 59. See also Michael F. Conlan, *Claritin Patent Showdown Postponed Until 2000*, 143 Drug Topics 29 (Dec. 6, 1999).

<sup>57</sup> See Hall, *supra* n. 20, at 59.

<sup>58</sup> *Id.*

<sup>59</sup> The *Noerr-Pennington* doctrine was first established in *Eastern R. R. Pres. Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and embellished in *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965).

trying to encourage more generics and through different business arrangements, the reverse has happened."<sup>60</sup> He has also stated that while the bill sought to create greater competition between generic and brand name drugs, it "has been used to delay competition, rather than foster it."<sup>61</sup> Co-author Senator Orrin Hatch has echoed Waxman's sentiments indicating that he would be willing to reopen the Act if generic and brand name drug manufacturers could agree to develop a "balanced bill," which he says could deal with the "unintended consequences" of the Act.<sup>62</sup> Alfred Engelberg, a principal advocate of the original legislation who has since altered his position in light of problematic loopholes that call for the legislature to revisit the Act, declared that the 180-day exclusivity provision is "being used by both sides and produce[s] no public benefit that would not otherwise occur."<sup>63</sup>

A new bill has additionally been proposed by Senators John McCain and Charles Schumer that would ease the entry of generic drugs into the marketplace.<sup>64</sup> Specifically, the bill would ban brand name companies from filing frivolous patents, such as those that include non-therapeutic drug claims.<sup>65</sup> The bill would also discourage paid arrangements between brand name and generic drug companies that delay a generic drug's market entry.<sup>66</sup>

#### IV. INITIATING PATENT INFRINGEMENT LITIGATION

Another strategy zealously employed by brand name drug companies is to initiate patent infringement litigation against generic competitors. While there is the possibility that infringement suits are undertaken in pursuit

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<sup>60</sup> David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 Food & Drug L.J. 321 & n. 1 (2000) (citing Sheryl Stolberg & Jeff Gerth, *Keeping Down the Competition: How Companies Stall Generics and Keep Themselves Healthy*, N.Y. Times A-1 (July 23, 2000)).

<sup>61</sup> American Health Line, *Rx Drugs II: FTC Probes Brand Name-Generic Drug Deals*, 6 Am. Health Line 4 (Oct. 12, 2000).

<sup>62</sup> American Health Line, *Drug Patents: Hatch to Revisit Generic Drug Issue*, 6 Am. Health Line 9 (Mar. 8, 2001).

<sup>63</sup> See Information Access Company, *Another Look at the Waxman-Hatch Act Urged*, 21 Chain Drug Rev. RX21 (July 19, 1999).

<sup>64</sup> See The Gale Group, *Senators McCain and Schumer Introduce New Generic Legislation Bill to Help Level Playing Field for Generic Drugs*, 22 Drug Store News 16 (Oct. 16, 2000).

<sup>65</sup> See *id.*

<sup>66</sup> See *id.*

of legitimate ends such as resolving genuine intellectual property disputes, it may well be the case that the brand name manufacturers are using the infringement suits to pursue illegitimate ends by keeping generics out of the market.

The goal of keeping generics out of the market through patent litigation may be accomplished in two ways. The first has already been discussed and relies on the Hatch-Waxman provision that disallows a generic manufacturer from entering the market while there is ongoing litigation in order to settle intellectual property disputes. As a result, the brand name manufacturer can then extend its patent for thirty months or until the litigation is ended.<sup>67</sup>

The second way that drug companies may extend their market power for profitable brand name drugs is by using negotiation settlements during patent infringement litigation as a pretext for creating agreements that pay off generic manufacturers to delay or refrain from putting a competing drug on the market.

These agreements not to compete, in contrast to the efforts by drug companies to exploit legislative loopholes, are increasingly under attack by the FTC as violations of antitrust law. The following discussion represents a sampling of the cases currently pending or recently resolved regarding anticompetition clauses.

**A. *FTC v. Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products Corporation***

In a complaint issued March 30, 2001, the FTC alleges that brand name manufacturer Schering-Plough conspired with two generic manufacturers to keep a generic version of a Schering high blood pressure drug off the market, costing consumers an estimated \$100 million.<sup>68</sup> The drug at issue is protected under a patent that does not expire until 2006.<sup>69</sup> The generic manufacturer, Upsher-Smith, sought FDA approval to manufacture and distribute a generic version.<sup>70</sup> Under authority of the Hatch-Waxman Act, a generic firm may bring a product to market before a patent expires if it can prove that the patent is invalid or the generic does not

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<sup>67</sup> See discussion of the Hatch-Waxman Act, *supra*, for a more lengthy discussion.

<sup>68</sup> See *In re Schering-Plough Corp.*, 2001 FTC LEXIS 39 at \*1 (Mar. 30, 2001).

<sup>69</sup> See *id.* at \*7.

<sup>70</sup> See *id.* at \*9.

infringe the patent.<sup>71</sup> The patent at issue concerned an extended-release formulation of the drug rather than the active ingredient, which Upsher-Smith felt it could more easily challenge.<sup>72</sup> When Schering-Plough sued Upsher-Smith for patent infringement, the two companies settled in 1997 with Upsher agreeing not to sell any generic version of Schering's drug until September 2001, and Schering-Plough agreeing to license five drugs from Schering for \$60 million.<sup>73</sup> When a similar patent infringement suit was filed against generic manufacturer American Home Products, the two parties settled their suit with American Home Products agreeing not to market any generic version of Schering-Plough's drug until January 2004 with Schering agreeing to license two of American Home Products' drugs for \$15 million.<sup>74</sup>

**B. *FTC v. Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corporation***

This complaint, filed in March of 2000 and now scheduled for an administrative trial, alleged that Hoechst and Andrx entered into an agreement in which Andrx was paid millions of dollars to delay bringing to market a competitive alternative to Cardizem, a hypertension and angina drug.<sup>75</sup> Andrx was the first to file its generic version for FDA approval, but was sued by Hoechst for patent infringement.<sup>76</sup> Because the Hatch-Waxman provides for 180 days of exclusivity to the first generic market entrant, the effect of the lawsuit was to prevent Andrx, as well as other generic competitors, from seeking FDA approval. According to the FTC, Andrx agreed to neither market its product when it received FDA approval, give up or relinquish its 180-day exclusivity period, nor market a non-infringing generic version of Cardizem.<sup>77</sup>

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<sup>71</sup> See 21 U.S.C. § 355(c)(3)(C)(i) (1994).

<sup>72</sup> See *In re Schering-Plough Corp.*, 2001 FTC LEXIS 39 at \*7.

<sup>73</sup> See *id.* at \*9.

<sup>74</sup> See *id.* at \*\*13-14.

<sup>75</sup> See *In re Hoechst Marion Roussel, Inc.*, 2000 FTC LEXIS 142 at \*\*10-11 (Mar. 16, 2000).

<sup>76</sup> See *id.* at \*\*7-9.

<sup>77</sup> See Federal Trade Commission, *FTC Antitrust Actions in Pharmaceutical Services and Products* <<http://www.ftc.gov/bc/rxupdate.htm>> (accessed Sept. 8, 2001).

C. *Abbott Laboratories and Geneva Pharmaceuticals*

In this action, which was settled without any terms disclosed, the complaint alleged that Abbott paid Geneva \$4.5 million per month to delay bringing to market a generic alternative to Abbott's brand-name hypertension and prostate drug, Hytrin.<sup>78</sup> Hytrin provided Abbott with sales of \$542 million in 1998.<sup>79</sup> Geneva, a generic drug manufacturer, sought and received FDA approval to market a generic version of Hytrin.<sup>80</sup> After Geneva received approval, it entered into an agreement with Abbott in which Geneva would refrain from bringing a generic version of Hytrin to market during the ongoing patent litigation in exchange for a \$4.5 million monthly payment.<sup>81</sup> This agreed amount exceeded the amount Abbott estimated that Geneva would have received had it actually marketed the drug.<sup>82</sup> In addition, Geneva also agreed not to waive its right to the 180-day exclusivity period under the Hatch-Waxman Act.<sup>83</sup>

These three cases represent a recent willingness on the part of the FTC to act when pharmaceutical companies are making efforts to extend the life of their market exclusivity for profitable brand name drugs. This is in contrast to situations in which drug companies are seeking extension relief through legislative provisions, lobbying, or private lawsuits despite the fact that both types of conduct carry with it anticompetitive effects that harm consumers.

Agreements not to compete, secured by drug companies in the course of patent litigation, are particularly problematic for a host of antitrust reasons. First, such agreements prevent not only the generic manufacturers, as a party to the agreement, from entering the market, but also non-party manufacturers. This is because the generic party agrees to retain, but not exercise its 180-day exclusivity because, pursuant to the Hatch-Waxman Act, no generic parties are permitted to gain FDA approval during ongoing patent litigation.<sup>84</sup> Antitrust law might have been viewed as a source of potential recourse had there been some ability for other market entrants to provide ameliorative effects even in the presence of this agreement. However, the

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<sup>78</sup> See *In re Abbott Labs.*, 2000 FTC LEXIS 15 at \*\*10-11 (Mar. 16, 2000).

<sup>79</sup> See *id.* at \*6.

<sup>80</sup> See *id.* at \*7.

<sup>81</sup> See *id.* at \*\*11-12.

<sup>82</sup> See Balto, *supra* n. 60, at 333.

<sup>83</sup> See *In re Abbott Labs.* at \*\*10-11.

<sup>84</sup> *Id.*

inability of a manufacturer to penetrate the drug market during the 180-day exclusivity period, as authorized by Congress, has a tendency to trigger antitrust concerns.

Secondly, another major reason antitrust law is being enforced so vigorously against these agreements not to compete is because the generic drugs at issue in the lawsuits are not only unable to enter the market, but potentially noninfringing drugs are prevented as well.<sup>85</sup> On its face, this appears to be an abuse of a company's patent right, and is not likely to be tolerated by the government when investigating these types of transactions.

Third, the nature of the large monetary payments to the generic drug manufacturer do not fit the pattern of a normal patent infringement suit. Typically, the flow of money during a settlement is from the alleged infringer to the claimant. In these cases, it is the alleged infringer, infringing the brand name manufacturer that is benefiting. The abnormal flow of money in these cases raises red flags for the FTC and gives powerful evidence of intent.<sup>86</sup>

## V. MERGERS AND ACQUISITIONS

Mergers and acquisitions of assets are a cornerstone of the American economy. In 1998, the total value of acquired assets in deals announced was \$1.73 trillion dollars.<sup>87</sup> Today's mergers are largely strategic affairs in which companies may use them to gain a competitive advantage or to respond to an economic force.<sup>88</sup> This can entail acquiring market share, expanding product lines, combining research and development capabilities, or achieving greater efficiency.<sup>89</sup>

The number of mergers and acquisitions in the pharmaceutical industry has also dramatically increased whereby the number of transactions increased by almost fifty percent from 1996 to 1997.<sup>90</sup> While mergers are not normally a significant antitrust concern since no one drug company comprises more than five percent of the entire market, there are many

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<sup>85</sup> *Id.* at 333.

<sup>86</sup> *See id.* at 334 for a more detailed discussion of the antitrust implications of patent dispute settlements in the pharmaceutical industry.

<sup>87</sup> *See* David A. Balto & James F. Mongoven, *Antitrust Enforcement in Pharmaceutical Industry Mergers*, 54 *Food & Drug L.J.* 255, 255 (1999).

<sup>88</sup> *See id.* at 256.

<sup>89</sup> *See id.*

<sup>90</sup> *See id.*

situations in which direct or potentially direct competitors of specific therapeutic compounds are coming together to raise some antitrust anxiety.<sup>91</sup>

Of particular concern are the underlying reasons behind the current rash of mergers and acquisitions. The industry faces a record number of patent expirations in the next five years representing several billion dollars in sales for the original drug manufacturers.<sup>92</sup> For instance, the seven drugs that are at issue in Schering-Plough's push for legislation that would extend their patent terms represent \$11 billion in sales for the original manufacturers.<sup>93</sup> Because of the financial blow that original manufacturers suffer when other brand name competitors enter the market, there is an incentive to look towards mergers and acquisitions of direct competitors as a way to maintain the market power over a particular drug or class of drugs.<sup>94</sup>

As is the case with agreements not to compete that stem from patent litigation, the FTC has devoted some attention to scrutinizing the terms of pharmaceutical mergers as they affect intellectual property rights. In making its orders, the FTC has issued several declarations that require merging companies to divest or abandon intellectual property rights in order for a merger to pass antitrust specifications. The following is a summary of several mergers and acquisitions that have taken place in recent years that involve the negotiation of important patent rights between the merging parties. This summary reveals that the FTC is particularly concerned with the anticompetitive effects that may occur with a merger between manufacturers of directly competing goods and its potential harm to innovation.

#### **A. Roche Holding Ltd./Corange Ltd. Merger**

In 1998, the FTC charged that Roche Holding's proposed \$11 billion acquisition of Corange Limited would harm U.S. markets for cardiac thrombolytic agents and drug abuse testing reagents ("DAT"), which are used to treat heart attack victims and to test urine samples for the presence of

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<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> See Information Access Company, *Rx Makers Would Gain \$11 Billion from Extensions*, 143 Drug Topics 8 (Aug. 16, 1999).

<sup>94</sup> While the financial blow that occurs when a generic enters the market is significant, the real problem occurs when there is a competing name brand product for a particular disease or illness. Even when generics are in the marketplace, there are a number of consumers that still opt for the brand name drugs. Mergers eliminate the competition by another brand name drug.

illegal substances, respectively.<sup>95</sup> Should the merger have occurred, there would no longer be a competitive market for thrombolytic agents and only a minimally competitive market for DATs.<sup>96</sup> The FTC argued that, if consummated, the acquisition would eliminate actual competition between the two parties in the markets for the research, development, manufacture, and sale of thrombolytic agents and encourage collusion in the DAT market.<sup>97</sup> Roche was forced to divest or license all of the assets relating to the two parties' cardiac thrombolytic agents business to a buyer approved by the FTC, as well as its assets to its DAT products.<sup>98</sup> Roche was also required to grant to the divestee of the DAT assets an exclusive, world-wide royalty-free license for DAT reagents.<sup>99</sup>

### ***B. American Home Products/Solvay Merger***

In 1997, the FTC filed suit alleging that the acquisition of Solvay's animal health business by American Home Products would harm competition in the U.S. market for three animal vaccines: canine lyme vaccines, canine corona virus vaccines, and feline leukemia vaccines.<sup>100</sup> The two combined companies accounted for virtually all of the market for these vaccines.<sup>101</sup> Entry into each vaccine market was difficult and time consuming because of the required expenditure of financial and research resources over a period of many years with no assurance that a profitable commercial product would result.<sup>102</sup> There existed great concern that the acquisition would result in few to no competitors in the relevant markets.<sup>103</sup> The FTC required American Home Products to divest the three Solvay vaccine assets to Schering-Plough no later than ten days after the date on which the order became final.<sup>104</sup> American Home Products additionally had to assist Schering-Plough in

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<sup>95</sup> *See In re Roche Holding Ltd.*, 1998 FTC LEXIS 60 at \*\* 1-3 (May 22, 1998).

<sup>96</sup> *See id.* at \*\* 5-6.

<sup>97</sup> *See id.*

<sup>98</sup> *See id.* at \*\* 17, 43-44.

<sup>99</sup> *See id.* at \*\* 43-44.

<sup>100</sup> *See In re American Home Prods. Corp.*, 1997 FTC LEXIS 119, \*\*4-6 (May 16, 1997).

<sup>101</sup> *See id.* at \*\*4-5.

<sup>102</sup> *See id.* at \*\*5-6.

<sup>103</sup> *See id.* at \*6.

<sup>104</sup> *See id.* at \*\*16-17.

obtaining the necessary United States Department of Agriculture (“USDA”) certifications.<sup>105</sup>

**C. *Hoechst AG and Rhone-Poulenc S.A.***

The FTC charged that Hoechst's acquisition of Rhone-Poulenc would harm competition in the market for direct thrombin inhibitors.<sup>106</sup> Hoechst's direct thrombin inhibitor, Repludan, obtained FDA approval for treatment of the blood clotting disease heparin-induced thrombocytopenia.<sup>107</sup> Rhone-Poulenc, though not a direct competitor at the time of merger, was in the final stages of developing its own version of a direct thrombin inhibitor, Revasc.<sup>108</sup> The two companies were the closest competitors in the market for distributing drugs to treat blood clotting diseases.<sup>109</sup> By merging, the FTC alleged, all direct competition would be eliminated and incentives to innovate new blood clotting drugs would be diminished.<sup>110</sup> The FTC ordered that Hoechst transfer all of Rhone-Poulenc's rights for Revasc to a third party and to enter into a short term service agreement with the third party in order to ensure the continued performance of development work on the drug.<sup>111</sup>

**D. *Zeneca Group PLC and Astra AB***

Zeneca's proposed acquisition of Astra raised antitrust concerns for the FTC.<sup>112</sup> At issue was the development of new long-acting local anesthetics. Zeneca had entered into an agreement related to the development of new long acting local anesthetics with Chiroscience Group PLC to market and assist in the development of this type of anesthetic.<sup>113</sup> Astra is only one of two companies that is already approved to manufacture and sell the anesthetic.<sup>114</sup> Concerned that the merger would result in an

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<sup>105</sup> See *id.* at \*\*20-21.

<sup>106</sup> See *In re Hoechst AG*, 2000 FTC LEXIS 3 at \*8 (Jan 18, 2000).

<sup>107</sup> *Id.*

<sup>108</sup> See *id.*

<sup>109</sup> See *id.*

<sup>110</sup> See *id.*

<sup>111</sup> See *id.*

<sup>112</sup> See *In re Zeneca Group PLC*, 1999 FTC LEXIS 115 at \*\*5-6 (Jun. 7, 1999).

<sup>113</sup> See *id.* at \*2.

<sup>114</sup> See *id.* at \*4.

elimination of a significant source of new competition, the FTC's consent order required Zeneca to transfer and surrender all of its rights and assets relating to levobupivacaine to Chiroscience since Zeneca had agreed to co-develop the product with Chiroscience prior to the acquisition of Astra.<sup>115</sup>

**E. Glaxo and Wellcome**

When Glaxo attempted to merge with Burroughs-Wellcome in 1995, the FTC alleged competitive harm to innovative markets where the merging parties were the two companies furthest along in the development of an oral therapeutic to treat migraine attacks.<sup>116</sup> The FTC alleged that the acquisition would reduce the number of research and development tracks for these migraine remedies and increase Glaxo's unilateral ability to reduce research and development of these orally-administered drugs.<sup>117</sup> The FTC required Glaxo to divest Wellcome's assets related to its therapeutic indication for the treatment of migraine, i.e. the "311C90" assets.<sup>118</sup> The assets also included patents, trade secrets, and inventory needed to complete all trials and studies to obtain FDA approval.<sup>119</sup>

**F. The Upjohn Co. and Pharmacia Aktiebolag**

When Upjohn sought to acquire Pharmacia Aktiebolag, the FTC alleged that the acquisition would harm competition in the market for topoisomerase I inhibitors, drugs used with surgery to treat colorectal cancer.<sup>120</sup> There were no drugs currently able to treat the disease, but the drugs being developed independently by the two merging companies were the closest to getting to market.<sup>121</sup> The FTC argued that a merger would harm research and development efforts. In addition, the FTC alleged that the few other companies completing research in this area were too small and too far off from product development to constrain the merged firm from terminating

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<sup>115</sup> See *id.* at \*12.

<sup>116</sup> See *In re Glaxo PLC*, 1995 FTC LEXIS 166 at \*3 (Jun. 14, 1995).

<sup>117</sup> See *id.*

<sup>118</sup> See *id.* at \*\*9-10.

<sup>119</sup> See *id.* at \*\*7-8.

<sup>120</sup> See *In re The Upjohn Co.*, 1996 FTC LEXIS 17 at \*\*4-5 (Feb. 8, 1996).

<sup>121</sup> See *id.* at \*\*2-3.

development of the drug or from raising prices.<sup>122</sup> This case was resolved with divestiture of Pharmacia's assets in topoisomerase I inhibitors to the IDEC Pharmaceuticals Company.<sup>123</sup>

As is clear from these summaries, the FTC is extremely weary of pharmaceutical mergers that may compromise an important drug by limiting the competition for research and development, innovation, or sale of the drug in the marketplace. The FTC is additionally quite concerned when the patent rights of one of the merging parties is near expiration and the other merging party has received, or is in the process of obtaining, a patent on a new, yet similar drug. This is consistent with the theoretical foundations of both intellectual property law and antitrust law. While the legal system allows for the grant of a "limited" monopoly when a company has fulfilled the necessary requirements to secure a patent, it steps in when the company goes beyond the patent right to maintain market exclusivity to the detriment of consumers. In the case of pharmaceutical mergers and acquisitions, the relevant market is generally limited to the exact therapeutic compound.<sup>124</sup> This is logical given the inability of most drugs to be substituted. Because the defined market is generally quite narrow, the antitrust concern for anticompetitive conduct is greater. Due to several factors, including the inherent high costs of entry into the research, development, or distribution of a drug, there are typically very few parties competing within a market for a particular brand name drug.<sup>125</sup> It is true that merger enforcement by the FTC sometimes results in the divestiture of legally acquired intellectual property rights, which seems counter to our intellectual property system. Yet when these few parties threaten to merge together and potentially lessen the incentives for competition, antitrust law must step in to ensure that the consolidation of intellectual property rights does not interfere with the public benefits that justify intellectual property rights in the first place.

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<sup>122</sup> See *id.* at \*\*3-5.

<sup>123</sup> See Balto and Mongoven, *supra* n. 89, at 269.

<sup>124</sup> See e.g., *In re Hoechst AG*, 2000 FTC LEXIS 3 at \*8; *In re Zeneca Group PLC*, 1999 FTC LEXIS 115 at \*\*4-5; *In re Roche Holding Ltd.*, 1998 FTC LEXIS 60 at \*\*3-4; *In re American Home Prods. Corp.*, 1997 FTC LEXIS 119 at \*\*4-5; *In re The Upjohn Co.*, 1996 FTC LEXIS 17 at \*\*2-3; *In re Glaxo PLC*, 1995 FTC LEXIS 166 at \*2.

<sup>125</sup> Generics are competing, but generally after the research and development has occurred for a particular drug; generic companies devote relatively few resources to developing drugs that don't have brand name drug counterparts already in the marketplace.

## VI. LAYERING OF PATENTS AND COMBINING DRUGS FOR NEW PATENTS

Another effective and relatively unscrutinized strategy employed by brand name drug companies is the layering of patents and combining of drugs leading to the grant of new patents. By securing patents on different aspects of the same drug, the manufacturers can ensure that the drug will not go “off-patent” for purposes of the Hatch-Waxman Act.<sup>126</sup> Brand name pharmaceutical companies now patent the process of manufacturing the raw material, the medical indications to which the drug can be applied, the formulation of the medicine, and the metabolites resulting from the enzymatic degradation of the parent drug by the body.<sup>127</sup> These patents are applied for over a staggered period of time so that there is a new patent being issued as an old one nears expiration, a practice known as “layering.”<sup>128</sup> This sets the original drug manufacturer in a position to initiate patent litigation should a generic drug manufacturer attempt to apply for marketing approval from the FDA.<sup>129</sup>

Drug companies can additionally use the grant of new patents on what are essentially old drugs as a marketing tool to disguise the likely motivation behind the new patent. Consider the example of Prozac, the “medication whose name has become almost shorthand for antidepressant.”<sup>130</sup> The FDA recently approved a new once-a-week version of the drug after Eli Lilly & Company, the drug's manufacturer, submitted data from clinical trials indicating that the new version demonstrated comparable efficacy for people who had been taking the old version of the drug, in addition to similar side effect profiles.<sup>131</sup> While it is true that the new version of Prozac has some beneficial qualities over the old version, namely convenience for the consumer, some experts have voiced their opinion concerning Eli Lilly's true motivation. Dr. Richard A. Friedman, Director of the Psychopharmacology

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<sup>126</sup> See Hall, *supra* n. 20, at 59.

<sup>127</sup> See *id.*

<sup>128</sup> See *id.*

<sup>129</sup> In the case of Claritin, when Geneva Pharmaceuticals filed its Abbreviated New Drug Application (ANDA), Schering-Plough sued claiming infringement of two Claritin patents. Since the initial lawsuit, Schering-Plough has filed suit against seven other drug manufacturers – Zenith Goldline, Teva Pharmaceuticals, Mylan, Andrx, Impax, American Home Products, and Apotex-Novex – when they have gone to the FDA seeking approval for generic versions of Claritin. See *id.*

<sup>130</sup> John O'Neil, *Cut Back on Prozac With New Prozac*, N.Y. Times, at F6 (Mar. 6, 2001).

<sup>131</sup> See *id.*

Clinic at Cornell Medical Center, said the force behind Prozac Weekly's development "had less to do with treatment than with patent rights."<sup>132</sup> Eli Lilly's exclusive right to the chemical compound synonymous with Prozac, fluoxetine, expires in August of 2001 and the company has been searching for variations that would extend some degree of patent protection.<sup>133</sup> Obtaining a new patent on Prozac Weekly, in conjunction with a new marketing effort directed toward once-a-week ingestion, virtually guarantees that Eli Lilly can look forward to many more years of market dominance in the fluoxetine sector.<sup>134</sup>

This practice of getting new patents on additional aspects of old drugs has been echoed by the manufacturers of Augmentin and BuSpar.<sup>135</sup> Pfizer, for instance, "bought a new lease on life with an additional patent for its popular Neurontin epilepsy drug, whose basic use patent expired in 2000."<sup>136</sup> Like Augmentin and BuSpar, the new patent provides minimal impact with respect to the drug's therapeutic indication or mechanism of action. In essence, the patent covers a new formulation of the drug that prevents enzymatic degradation; a key fact which generic companies hope they can prove was already known.<sup>137</sup> While the generic makers will be taking up the battle in court, the ensuing litigation is expected to cause delay in the expiration of Pfizer's patent for at least a year. It is estimated that this delay will result in \$1.5 billion in sales to Pfizer this year alone.<sup>138</sup>

While generic manufacturers may eventually secure marketing rights on brand name drugs whose protection is extended by new patent rights, this result is not without significant costs to both generic manufacturers and consumers. Bristol-Myers had secured a new patent that was closely related to its original patent on the anti-cancer drug Taxol months before its original exclusivity period expired in 1997.<sup>139</sup> The new patents covered how Taxol

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<sup>132</sup> *See id.*

<sup>133</sup> *See id.*

<sup>134</sup> While there would be a generic version, it does not present the same level of competition against brand name drug Prozac that had significant brand recognition and a large advertising budget.

<sup>135</sup> *See* section on Hatch-Waxman Act, *supra* pt. III, for discussion of the patent layering of Augmentin and BuSpar.

<sup>136</sup> Langreth & Murphy, *supra* n. 37, at 52.

<sup>137</sup> *See id.*

<sup>138</sup> *See id.*

<sup>139</sup> *See id.*

was administered.<sup>140</sup> Generic manufacturer Ivax eventually convinced a court to grant market approval on its version of the drug three years after Bristol-Myers obtained its new patent.<sup>141</sup> This delay in market entry for Ivax and other generics resulted in an additional \$1 billion of Taxol revenue for Bristol-Myers.<sup>142</sup> As a consequence, this \$1 billion windfall translates into millions of lost dollars to consumers whose alternatives were either to pay for the brand name version of the drug, or forego treatment altogether.

Another method employed by pharmaceutical companies to extend patent rights is to obtain new patents on the individual isomers of racemic drugs.<sup>143</sup> Most drug molecules exist in two mirror-image forms, only one of which is active.<sup>144</sup> New chromatographic separation techniques have been developed by drug companies to isolate and discard the non-active component, enabling companies to manufacture essentially the same drug with greater potency and/or fewer side-effects.<sup>145</sup> By obtaining a new patent on a "new molecule" that is a slight variation of the original, and launching an extensive marketing campaign, has enabled drug companies to achieve the benefit of two patent lives with minimal further investment in research and development. This strategy has generated a large number of single-isomer versions of medicines that might have otherwise been subject to generic competition, including Prozac, Losec, and Claritin.<sup>146</sup>

Another ingenious method employed by drug companies with expiring patents is to negotiate complicated business deals that allow for the combination of two companies' drugs whereby the combination product is subsequently amenable to patent protection. Recently, the drug powerhouses of Merck and Schering-Plough negotiated a deal "for the marketing of two new drug combinations, one to lower serum lipid levels and the other to relieve allergies."<sup>147</sup> "Each combination product will pair one company's blockbuster [sic] drug, whose patent as a single product will soon expire," with another drug, owned by a different company, that supplements the pharmaceutical action of the first drug.<sup>148</sup> As a consequence, "[t]he

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<sup>140</sup> *See id.*

<sup>141</sup> *See id.*

<sup>142</sup> *See id.*

<sup>143</sup> *See Pilling & Wolffe, supra n. 35, at 20.*

<sup>144</sup> *See id.*

<sup>145</sup> *See id.*

<sup>146</sup> *See id.*

<sup>147</sup> Angell, *supra n. 17.*

<sup>148</sup> *Id.*

combination drugs will have new patents, and their profits will be shared by both companies.”<sup>149</sup> While no doubt generating millions of dollars in revenue for the companies, the medical benefits of the recombinations are specious.<sup>150</sup>

While this conduct has obvious anticompetitive effects, notably the elimination of generic entrants from the market for up to two patent terms, the FTC has nevertheless declined any form of action regarding combination drug product strategies. Recently, the FTC appeared to clear single isomers of any anticompetitive suspicions when it closed a review of Eli Lilly's exclusive license to market its new version of Prozac.<sup>151</sup>

There may be two explanations for the FTC and other government agencies' hesitancy towards any action pertaining to the issuance of new patents on minor variations of old drugs. Yet neither explanation is very convincing when the ideological foundations of either intellectual property or antitrust law are considered. One explanation may be that there are arguable benefits to some of the new patents. While perhaps not an overwhelming endorsement for single-isomer drugs, experts agree that the new versions do often eliminate or mitigate side effects that were present in the old drug.<sup>152</sup> These benefits may provide enough justification for antitrust law to defer to the policy of granting monopoly rights to innovators of desirable products. Yet, it is questionable whether these therapeutic benefits, achieved by granting brand name companies a new monopoly on slight variations of their old drugs, justify the extraordinary costs to consumers. Furthermore, it is equally questionable whether newly granted patents on expired drug products actually translates into increased investment by drug companies in research and development of riskier, but perhaps more innovative drugs.

A second explanation for why the government has seemingly been unwilling to investigate the potentially anticompetitive effects of granting new patents on popular brand name drugs may be that distinguishing between new patents that are actually beneficial and those that seek to extend a patent monopoly is too difficult. This too, however, seems suspect. With the aid of scientific experts examining the relative medical benefits of "new" drugs, it seems that the FTC or other governmental agencies will be able to conduct evidentiary investigations to accurately determine whether a company is using the patent law legitimately, or as a means to secure a stream of profits at the expense of consumers.

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<sup>149</sup> *Id.*

<sup>150</sup> *See id.*

<sup>151</sup> *See Pilling & Wolffe, supra* n. 35, at 20.

<sup>152</sup> *See id.*

## VII. USING ADVERTISING AND BRAND DEVELOPMENT TO INCREASE BARRIERS TO ENTRY FOR GENERIC MANUFACTURERS

One strategy that has been completely ignored by the federal government as a potential antitrust concern is the increasing reliance by drug companies on marketing and brand name development to sustain their market power after the expiration of their patent rights. The potential effect of creating a recognizable trademark or spending hundreds of millions of dollars on advertising for a popular drug is that consumers will be less likely to switch to generics once they enter the market. This makes it more expensive for generics to enter the market and may in fact discourage them from entering the market at all.

Direct-to-consumer marketing is a relatively new concept in the pharmaceutical industry that surged with the success of the pioneering advertising campaign of Claritin.<sup>153</sup> In 1997, the FDA relaxed its rules governing television advertising.<sup>154</sup> Instead of having to run the tedious fine print required in magazine ads, television commercials were able to satisfy FDA regulations by providing a toll-free number, mentioning a fine print magazine advertisement, or instructing viewers to "ask your doctor" for more information.<sup>155</sup> Claritin decided to capitalize on these new flexible rules and launched a \$322 million advertising campaign in 1998.<sup>156</sup> It was immediately copied with great success for other high-profile drugs such as Viagra and Prilosec. "The campaign was a landmark. The Claritin campaign . . . was very influential. Claritin was clearly the most visible, the most expensive and skillfully executed, and the bottom-line results were immediately apparent."<sup>157</sup>

It is estimated that drug companies spent an estimated \$2.5 billion dollars on consumer advertising last year.<sup>158</sup> And these ads may have brought in as much as \$5 to \$6 returns for each dollar spent. The antitrust concern for pharmaceutical industry's increased expenditure of funds to create a protectable and strong brand for their popular drugs may be found in the complicated interplay between the theories of trademark, patent, and antitrust

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<sup>153</sup> See Hall, *supra* n. 20, at 45.

<sup>154</sup> See *id.*

<sup>155</sup> See *id.*

<sup>156</sup> See *id.*

<sup>157</sup> *Id.* (quoting Seven D. Findlay, National Institute for Health Care Management Foundation).

<sup>158</sup> See *Id.*

laws. As already discussed, patent laws seek to reward inventors for innovation and provide economic incentives to create beneficial products for the public good. The guiding principle of trademark law is to protect consumers so that they may control their purchasing choices by meeting the expectations created by associating a trademark with a particular product. Antitrust laws seek to encourage competition by prohibiting unlawful monopolies.

The potential for concern might be best illustrated by example. Consider the case of Claritin, which first gained patent approval in August of 1981 for the chemical compound.<sup>159</sup> The patent application stated that the compound and claimed chemical analogs were "useful as antihistamines with little or no sedative effects."<sup>160</sup> However, when Claritin underwent the extensive testing necessary to gain FDA approval, it was shown that the drug was only slightly more effective than placebo sugar pills.<sup>161</sup> Thus, while the drug Claritin was approved by the FDA and found to meet the statutory requirements necessary for the grant of a patent, it appears that it is only mildly effective in accomplishing what its patent purports to do.<sup>162</sup>

Perhaps because Claritin was so minimally effective or innovative, the manufacturers mounted an expensive ad campaign in an effort to increase consumer demand for the product, and create a brand name association that would establish Claritin as the dominant market holder for non-sedating antihistamines. Critics have described this as an embarrassing paradox of the marketing and brand name development of drugs; marketing may be most indispensable in categories where new drugs may actually be less innovative, yet the millions spent on marketing puts them in the greatest demand by consumers.<sup>163</sup> "Marketing is meant to sell drugs, and the less important the drug, the more marketing it takes to sell it. Important new drugs do not need much promotion. Me-too drugs do."<sup>164</sup>

Thus, manufacturers of drugs like Claritin are able to take advantage of patent rights despite their relative inability to meaningfully add to the body of drugs currently in existence. As a result, drug manufacturers expend millions of dollars in advertising and brand name development to ensure that

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<sup>159</sup> *See id.* at 42.

<sup>160</sup> *Id.*

<sup>161</sup> *See id.* at 43. Patients taking Claritin demonstrated a 43% improvement in symptoms, while patients taking placebo sugar pills reported a 37 - 47% improvement. *Id.*

<sup>162</sup> *See id.*

<sup>163</sup> *See id.* at 45.

<sup>164</sup> *See id.*

their drugs are perceived by the public to be the dominant, and perhaps best, drug on the market. Though drug companies do not readily disclose marketing figures, the amount spent on marketing is estimated to be much larger than that afforded to research and development efforts.<sup>165</sup> The result is a powerful stranglehold on the market for a drug that makes it difficult, if not impossible, for consumers to reap the benefits of generic entrants. In essence, the financial rewards of developing a blockbuster drug, and exploiting its monopoly potential through every means of intellectual property protection available, far outweighs the costs associated with the research and development of drugs that may or may not result in a profitable drug.

The federal government has expended minimal effort investigating the potentially deleterious effects of marketing and brand name development on competition within the pharmaceutical industry. Surprisingly, only one media report even broaches the subject by calling upon policymakers to examine “whether direct to consumer advertising of prescription drugs has increased the demand for ‘unnecessary medicine,’ and conveys the ‘appropriate information’ for consumers.”<sup>166</sup>

It may be the case that antitrust law has no role to play in monitoring the advertising and brand name development of popular, but only minimally innovative drugs. Indeed, it may be difficult to formulate a way in which the federal antitrust laws could effectively establish a weaker form of IP when a drug is only mildly beneficial as opposed to strong IP protection for drugs that are legitimately innovative. Instead, it appears that the legislature is the most appropriate vehicle by which to pursue any type of reform. Statutory enactments that police the advertising practices of drug companies would serve to level the playing field for generic competitors.

#### VIII. THE PHARMACEUTICAL INDUSTRY: IS THE PROPER BALANCE BEING STRUCK BETWEEN INTELLECTUAL PROPERTY AND ANTITRUST LAW?

Intellectual property and antitrust laws must strike a delicate balance in order to satisfy the competing goals of creating economic incentives to innovate and create (intellectual property), while concomitantly preserving

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<sup>165</sup> See Angell, *supra* n. 17. Pfizer and Pharmacia & Upjohn spent 39.2 % of its revenues on marketing and administration in 1999. *Id.*

<sup>166</sup> April Fulton, *Rx Drug Costs: BCBS Study Chides Drug Ads, Patent Laws*, American Health Line, Politics & Policy (Sept. 26, 2000).

and encouraging competition (antitrust). An examination of the profit-maximizing practices employed by the pharmaceutical industry brings into question whether this balance has tipped unfavorably toward consumers. This section attempts to explain why the theoretical foundations justifying intellectual property rights are not being met by the conduct of the pharmaceutical industry, and why stronger antitrust enforcement policies must be implemented in order to restore the balance between these two areas of the law.

One of the primary justifications advanced by intellectual property law proponents for asset protection is the incentive such protection provides inventors to invest in risky or otherwise costly endeavors necessary to create innovative works that may contribute to the public good. An examination of the findings presented in this article, however, suggests that this justification is not being met when dealing with the pharmaceutical industry.

The risk inherent in bringing brand name drugs to market cannot be used to validate the strong intellectual property protection that has been described in the present article. “The top 10 drug companies are reported to spend on average about 20 percent of their revenues on research and development.”<sup>167</sup> These companies have “so many drugs in the pipeline at any given time that they can count on being able to bring a certain number of drugs to market regularly.”<sup>168</sup> To illustrate just how financially sound the drug business actually is, consider the research and development costs of the large drug companies relative to their profits. The top ten drug companies report profits averaging 30% of their revenues—a substantial margin.<sup>169</sup> “[I]n 1999, the pharmaceutical industry realized on average an 18.6 percent return on revenues,” which exceeds that of commercial banking (15.8%).<sup>170</sup> These profits are over and above the considerable governmental assistance available from the National Institutes of Health (NIH) that subsidize much of the early pre-clinical research, as well as favorable tax treatment that enables a rate of 16.2%.<sup>171</sup> It is difficult, therefore, to characterize an industry that is consistently the most profitable industry in the United States as risky.

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<sup>167</sup> Angell, *supra* n. 17. This figure has been criticized as an overstatement that includes marketing and promotional costs. *Id.*

<sup>168</sup> *Id.*

<sup>169</sup> *See id.*

<sup>170</sup> *Id.*

<sup>171</sup> *See id.* The comparable tax rate for other major U.S. Industries from 1993 to 1996 was 27.3% of revenues. *Id.*

Despite low risks, the American drug industry fails to achieve true innovation. While the benefits enjoyed by consumers for the hundreds of recently launched drugs cannot be underestimated, it is difficult to reconcile the observation that many other new drugs add little to the therapeutic arsenal except expense and confusion for consumers. Recall the layering of patents that are secured on several elements of a blockbuster drug so as to preserve its monopoly power and profit potential; or the cleaning up of old drugs in order to secure a new patent on what is essentially a minimal variation on the old version.

The surplus of "me-too" drugs additionally exemplifies the dearth of innovation in the drug industry. For instance, there are currently several effective drugs to treat high cholesterol, yet each one varies modestly in terms of therapeutic benefit. To make a profitable cholesterol drug, a company need only synthesize a chemical derivative of a preexisting blockbuster drug that is sufficiently capable of meeting the requirements of patentability. With some extensive marketing, the new drug can then return revenues to the maker with minimal research and development costs. Thus, instead of expending funds on research and development for drugs that treat ailments not yet treatable, many drug companies attempt to focus on developing patentably distinct derivatives of preexisting drugs.

The American drug industry cannot be cited as the world leader in pharmaceutical innovation. "The United States accounts for 36 percent of global pharmaceutical research and development."<sup>172</sup> "Europe accounts for 37 percent and Japan for 19 percent."<sup>173</sup> Many other countries contribute significantly to the research and development of new drugs, many operating under government regulations that provide far less protection for individual intellectual property rights.

The evidence suggests that the extension of patent rights over the past decade, due to exploitation of various legislative loopholes and clever patent applications, does little to stimulate the research and development of new therapies. This further places into question the justification of the strong intellectual property protection that is afforded to drug companies. The University of Minnesota College of Pharmacy's Prime Institute examined the impact of extending to patents on eight brand name drugs. It concluded that while the cost of patent extensions to the "American public would be more than \$1 billion a year for 10 years, the extensions would do little to stimulate

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<sup>172</sup> Angell, *supra* note 17.

<sup>173</sup> *Id.*

research and development of [innovative] new therapies."<sup>174</sup> "The Congressional Budget Office says lengthening patent periods is not the most cost effective means of encouraging [research and development]. Reduction of FDA review times is a more effective means of stimulating research and development."<sup>175</sup>

The current state of the pharmaceutical industry indicates that intellectual property rights are being unjustifiably strengthened and abused at the expense of competition and consumer welfare. The lack of riskiness and innovation on the part of the drug industry underscores the inequity that is occurring at the expense of public good. It is an unfairness that cannot be cured by legislative reform alone. While congressional efforts to close loopholes in current statutes, along with new legislation to curtail additionally unfavorable business practices of the pharmaceutical industry, may provide some mitigation, antitrust law must appropriately step in. "Congress has passed a lot of laws, all well intentioned, but they have been a great windfall for the pharmaceutical industry. The current system appears to be out of balance, and it is costing Americans billions of dollars."<sup>176</sup>

While antitrust laws have appropriately scrutinized certain business practices employed by the pharmaceutical industry, such as mergers and acquisitions and agreements not to compete, there are several other practices that need to be addressed. The grant of patents on minor elements of an old drug, reformulations of old drugs to secure new patents, and the use of advertising and brand name development to increase the barriers for generic market entrants are all areas in which antitrust law can help stabilize the balance between rewarding innovation and preserving competition.

Specifically, the FTC and the judicial system may revisit the underlying policies of Section 2 of the Sherman Act to find a mechanism with which to mitigate the ills caused by the pharmaceutical industry. While it is true that courts, since the mid-1970's, have generally upheld efforts by dominant firms to develop new products and market their innovations,<sup>177</sup> it may be possible to limit drug companies' business practices, especially with

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<sup>174</sup> Information Access Company, *Debate on Patent Extensions Intensifies*, 21 Chain Drug Rev. Rx 82 (Aug. 30, 1999).

<sup>175</sup> *Id.* (quoting Stephen Schondelmeyer, Director of Minnesota's Prime Institute).

<sup>176</sup> Scott Gottlieb, *Drug Firms Use Legal Loopholes to Safeguard Brand Names*, 321 Br. Med. J. 320 (Aug. 5, 2000).

<sup>177</sup> See generally *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 209 U.S.P.Q. 889 (2d Cir. 1981) (rejecting attack on Xerox's creation of a patent wall around its dry paper copying process); see also *Memorex Corp. v. International Bus. Corp.*, 636 F.2d 1188 (9th Cir. 1980).

regard to their intellectual property strategies, when their conduct is shown to be motivated by a desire to maximize profit rather than innovation. Intellectual property rights should be awarded to firms that are creating new drugs that offer innovative health benefits. When patent rights are repeatedly granted for one drug at the expense of research and development of other potentially beneficial drugs, courts are likely to infer that a firm's aims constitute the exclusion of competitors through their patent rights with no actual improvement in their existing product offerings. While this inquiry would require at least some investigation of the merits of the patents in question, it might serve as a disincentive by pharmaceutical companies to engage in business practices that are geared towards manipulating the overworked intellectual property system for personal financial gain.

## CONCLUSION

Robert Pitofsky, the current Chairman of the FTC, noted in a speech regarding intellectual property rights and antitrust law, that “[t]he age-old balance between antitrust enforcement and intellectual property protection has begun to tip in favor of the latter” which the pharmaceutical industry exploits in attempting to lengthen the patent life of their brand name drugs.<sup>178</sup> Pitofsky cited the sheer volume of approved patents, which are at an all-time high, as a characteristic of an intellectual property system that “drives companies to seek, and the government to grant, more flimsy [intellectual property] than is justified.”<sup>179</sup> The inability of the Patent and Trademark Office (“PTO”) to sufficiently handle the overwhelming number of patent applications lends further credence to the notion that antitrust laws must take a more active role in matters pertaining to the intellectual property rights of the pharmaceutical industry. Since there exists the increased possibility that some intellectual property rights are invalid, antitrust law, therefore, needs to step in to ensure that invalid rights are not being unlawfully asserted to establish and maintain illegitimate, albeit limited, monopolies within the prescription drug industry.

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<sup>178</sup> Brian Krebs, *IP Issues Cloud Antitrust Role in New Economy – Pitofsky*, Newsbytes (Mar. 5, 2001).

<sup>179</sup> *Id.*