Pharmaceutical Patent Protection: More Generic Favored Legislation May Cause Pioneer Drug Companies to Pull the Plug on Innovation

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Pharmaceutical Patent Protection: More Generic Favored Legislation May Cause Pioneer Drug Companies to Pull the Plug on Innovation

BY MANDY WILSON

INTRODUCTION

In today's fast-paced world where Americans crave a quick fix to their medical woes, it takes more than advice on a healthy lifestyle to satisfy consumers. But along with cutting-edge drugs emerging into the marketplace come their price tags. Americans reportedly spent $125 billion on drugs in 1999, and with baby-boomers headed toward retirement the spending will most likely grow.\(^1\)

The consumers, frustrated with high prices, are being heard by politicians, making prescription drug cost a major legislative issue today.\(^2\) Recently, several bills were introduced in Congress having a potential effect on the speed with which generic drugs will enter the market.\(^3\) The Pharmaceutical Reform Act of 2000 was introduced by Representatives Alan Mollohan (D-West Virginia) and Ken Calvert (R-California).\(^4\) Senators John McCain (R-Arizona), Charles Schumer (D-New York), and Tim Johnson (D-South Dakota)\(^5\) and Representatives John Baldacci (D-Maine) and Tom Coburn (R-Oklahoma)\(^6\) introduced the Greater Access to Affordable Pharmaceuticals Act in the Senate and House, respectively.\(^7\)

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\(^1\) J.D. expected 2002, University of Kentucky.


\(^4\) See, e.g., H.R. 5231; H.R. 5247; S. 3051.

\(^5\) H.R. 5231.

\(^6\) S. 3051.

\(^7\) H.R. 5247.

S. 3051; H.R. 5247.
American consumers will initially receive the benefit of lower-priced drugs if generic entry into the marketplace is further accelerated by the enactment of these bills, but lower-priced drugs today may actually mean higher overall health care costs and fewer new drug options in the future. Investment in pharmaceuticals is already risky; expediting generic entry into the marketplace diminishes the effective patent term of pioneer drugs, thereby increasing the risk of investment in drugs. A secure patent term provides an incentive for pioneer drug manufacturers to spend money on new and better medications because it increases the probability that a profit can be made after the large research and development costs are recovered. Diminishing the effective patent term will reduce the incentive to develop pioneer drugs and may result in fewer new and improved medications. Pharmaceuticals are a cost-effective alternative to other health care options. Overall health care costs may rise under a scheme where fewer new drugs enter the market, forcing use of potentially more expensive treatment alternatives.

This Note begins by discussing factors that contribute to the expense of pharmaceuticals. Part II includes a brief overview of patent protection in the United States and its importance to pioneer drug companies. Part III examines the correlation between intellectual property protection and an incentive to invest in new drug development. Part IV discusses conditions favoring generic drug companies at the expense of pioneer drug companies and recently proposed legislation. Finally, Part V will explore the societal costs associated with truncated pharmaceutical patent terms.

I. RISK FACTORS ASSOCIATED WITH INVESTMENT IN PHARMACEUTICALS CONTRIBUTING TO THE HIGH COST OF DRUGS

The following factors contribute to the risk associated with the future income generated by a new drug.

A. Research and Development

Research and development results in a negative cash flow for drug companies prior to introduction of a drug. Current research and develop-
ment of novel drugs is becoming increasingly complex. Therefore, it costs approximately $200 - $500 million\(^3\) for pioneer companies to develop a new drug.\(^4\) As a result of decreased patent terms, risk of liability, and increased research and development costs, some drugs are no longer profitable for companies to develop.\(^5\)

**B. Food and Drug Administration Approval**

One factor distinguishing drugs from other products are the Food and Drug Administration’s ("FDA") pre-market approval and post-market surveillance requirements established by the Federal Food, Drug, and Cosmetics Act ("FFDCA").\(^6\) Perhaps the biggest safeguard against drugs entering the market with the unknown potential to harm is the prerequisite of approval by the FDA. To obtain FDA approval, a pharmaceutical manufacturer must run extensive investigations on its new drug.\(^7\) An applicant must generate data about the drug, including chemical structure, safety, efficacy, and toxicology analyses *in vitro* and in animals.\(^8\)

The FDA may request further studies, after which human clinical trials may begin.\(^9\) Clinical trials involve three phases.\(^10\) Phase I trials are designed to generate data regarding the metabolic and pharmacologic effects of the drug in humans.\(^11\) This phase of the trials involves a small test population of adults and also produces information about potential side


\(^{14}\) Because a generic drug company can copy the formulation of a pioneer drug and even use the pioneer drug company's data to supplement its FDA approval application, the cost of getting a generic drug approved is only about $1 million for bioequivalence testing. See PhRMA Industry Profile 2000, supra note 13, at 101.

\(^{15}\) CONG. BUDGET OFFICE STUDY, supra note 13, at 47.


\(^{18}\) 21 C.F.R. § 312.23 (2001).

\(^{19}\) Viscusi, supra note 17, at 1443.

\(^{20}\) *Id.*

\(^{21}\) 21 C.F.R. § 312.21(a).
effects. Phase II trials are conducted on a larger population of adults; this time the subjects have the specific condition of interest. This second phase is designed to determine the effectiveness of the drug on the condition. The final phase of clinical trials involves a much larger test population of adults afflicted with the condition of interest. Upon culmination of Phase III trials, a New Drug Application ("NDA") is filed. An NDA "include[s] detailed reports of all animal studies and clinical testing done with the drug, reports of any adverse reactions, and any other pertinent information from worldwide scientific literature." In addition, the manufacturer must submit "specimens of the labeling proposed to be used for [the] drug."

The FDA extensively scrutinizes the data contained in the NDA. The entire NDA process takes approximately five to seven years. During this time, the FDA makes a risk-benefit assessment to determine whether the product will benefit the overall health of the public and must ensure that both safety and efficacy are established by scientific data. The FDA is relied upon for its extensive knowledge of pre-market drug testing and its ability to analyze the data generated therefrom. Even after market approval, the FDA continues exercising its authority by conducting extensive post-market surveillance. The FFDCA requires drug manufacturers to monitor drug effects that are seen by physicians and patients. Ongoing research is also required.

C. Marketability Risk

Not all drugs are successful; thus, companies need to develop highly profitable drugs not only to recover the investment in the profitable drug,

22 Id.; Viscusi, supra note 17, at 1443;
23 Viscusi, supra note 17, at 1443.
24 21 C.F.R. § 312.21(b).
25 See id. § 312.21(c).
26 21 U.S.C. § 355(a), (b) (1994); 21 C.F.R. § 314.50.
29 See Viscusi, supra note 17, at 1444.
30 Id.
32 See Viscusi, supra note 17, at 1442-44.
33 Id. at 1447.
35 Id.
but also to recoup for drugs that failed either before or after they made it to
the market. A recent Congressional Budget Office Study did calculations
on sixty-seven proprietary drugs. Of these products, the top six collec-
tively earned $1 billion, but only the top twenty earned enough to exceed
the average cost of research and development of a single new drug. Such
statistics show that less than one in three pioneer drugs can make a profit
in the current market.

D. Risk of Drug Design Defect Suits

Drugs constitute a unique class of products. They have the ability to
save and greatly improve lives; however, if used by the wrong person, they
also have the ability to do great damage. Slight variations in personal
biological pathways ensure that all drugs will not affect all people the same
way. “There are some products which, in the present state of human
knowledge, are quite incapable of being made safe [for all people] for their
intended and ordinary use. These are especially common in the field of
drugs.”

Even after the FDA has completed its analysis of the safety and
efficacy of a new drug, a pharmaceutical company must consider the risks
of a product liability suit being brought based on a design defect in a newly
marketed drug. Regardless of a potential plaintiff’s ability to establish that
the drug caused an injury, defending such a suit is costly. Even the potential
that a drug design defect suit would have to be defended creates a risk for
new drug investment.

E. Competition from Pioneer Manufacturers

In addition, the possession of a patent does not provide the monopoly
that one might expect. Frequently, drugs target a single reaction in a

36 See CONG. BUDGET OFFICE STUDY, supra note 13, at 48.
37 Id.
38 Id.
39 See id. at 45 (stating that passage of new pro-generic legislation may further
decrease the number of pioneer drugs that can make a profit).
40 RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).
under the patent act does not necessarily provide a drug inventor with a monopoly
on a given treatment. Pharmaceuticals work by targeting the complex mechanisms
of the human. These complex biochemical pathways can be affected in more than
one way, making patented drugs targets of efforts to design around their patents.
specific biochemical pathway to produce an altered biological outcome. Because these pathways involve multiple and complex processes, more than one novel compound may produce the same desired results. By targeting a different step in a multi-reaction biochemical pathway, a competitor can design around a pioneer pharmaceutical company’s patent, limiting its market protection.42

F. Competition from Generic Manufacturers

This Note focuses on the drug investment risk associated with competition from generic drug manufacturers. Patent protection is important to predicting profitability of a developing drug. The moment that a drug is released on the market, its chemical composition is available for analysis and can be subsequently copied by generic competitors. Patent protection is the only defense that a pioneer pharmaceutical company has to prevent forfeiting much of its research and development investment to generic companies who are able to cheaply copy the pioneer.43 Diminishing the effective patent term for pioneer drugs expedites generic entry into the marketplace, resulting in diminished market security for the pioneer drug and the creation of a risk that the drug investment will not be profitable.44 Regardless of the adverse incentive created by truncated patent terms, the current congressional approach to targeting high drug cost is to expedite generic competition.45 The societal cost generated from this type of adverse incentive will be further discussed in Part V of this Note.46

II. PATENT PROTECTION IN THE UNITED STATES: SIGNIFICANCE TO THE PHARMACEUTICAL INDUSTRY

Congress takes its power to legislate patent protection from the patent clause of the United States Constitution.47 The drafters of the Constitution believed that inventors should be rewarded for their discoveries with a...
limited monopoly "to promote the Progress of Science and useful Arts." Congress began recognizing patents as early as 1790 and established the United States Patent Office in 1836. In 1952, with continued use of this constitutional power, Congress assembled a Patent Act based on review of potential inventions by the United States Patent and Trademark Office ("USPTO"). The USPTO now has the power to grant inventors limited monopolies in exchange for disclosure of their inventions. An inventor is required to submit a specification, which is "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." In addition to this detailed description, the inventor is required to give his or her own subjective opinion of the preferred embodiment, or best mode, of the invention. Ultimately, the inventor's submission will be scrutinized to determine whether it meets the statutory requirements of usefulness, novelty, and non-obviousness. This incentive-based program endures today, with only a few exceptions. Many of the recent exceptions, described below, are directed towards the pharmaceutical industry.

The moment that a drug is released on the market, competitors can copy its composition. Trade secret protection for composition is therefore impossible. Thus, patent protection has significant importance in the

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48 Id.
52 See id.
53 Id.
56 Id. §§ 101-103.
57 See id. §§ 1-293.
59 In the case of a drug invention, the drug itself (the subject of patent protection) is placed on the market, and anyone is free to purchase that drug. This differs from other inventions, such as a method of making a drug. The method can be kept secret by limiting use of the method to laboratories within the inventor company's facility—thus, a patented method has the ability to become a trade secret.

A drug, on the other hand, cannot be kept secret if it is to be marketed. Once on the market, a competitor can purchase the drug and easily determine its composition. Thus, it cannot be kept secret while being marketed. This is just the nature
pharmaceutical industry. Pioneer companies, the inventors, expend large amounts of money on research and development, while generic companies are able to copy the pioneer drug composition at relatively little cost.  

The average effective patent life for products other than pharmaceuticals is 18.5 years. Amendments to the FFDCA and the Patent Act have whittled the average effective patent life for pharmaceuticals down to between eleven and twelve years in the 1990s. An adequate patent protection term is required for pioneer companies to recover their expenses and produce a profit. With the risk of even shorter terms, the incentive to pay the price associated with innovation is likely to decrease.

III. CORRELATION BETWEEN INTELLECTUAL PROPERTY PROTECTION-BASED LEGISLATION AND INVESTMENT IN NEW PHARMACEUTICAL DEVELOPMENT

The correlation between legislation protecting pioneer drug manufacturers and introduction of novel treatments on the market is very real. Modifications to the FFDCA and the Patent Act in the past twenty years have greatly affected patent terms. Not surprisingly, the extent of intellectual property protection strongly influences the investment decisions of pharmaceutical companies. These companies have indicated that sixty-five percent of their drugs would not have been developed or commercially introduced if patent protection had not been available.

The Orphan Drug Act was enacted temporarily in 1983, reenacted periodically, and permanently reenacted in 1994. The Act creates incentives of this particular invention. If patent protection was not available, there would be nothing stopping immediate copying and marketing by competitors.

See PhRMA Industry Profile 2000, supra note 13, at 102.

Id.


PhRMA Industry Profile 2000, supra note 13, at 103.

See id. at 100-04; see generally Cong. Budget Office Study, supra note 13.

PhRMA Industry Profile 2000, supra note 13, at 101. The cost of research and development for a drug introduced in 1990 has been estimated to be as much as $500 million. Id.

Id. at 100.

Id. at 104 fig. 8-5 (citing Edwin Mansfield, Intellectual Property Protection, Direct Investment, and Technology Transfer (1995)).

Id. at 100 fig. 8-1.

for inventors of "orphan drugs." These rewards include federal funding for research and clinical trials, beneficial tax credits, and the exclusive right to market a qualified drug for a limited period. To qualify as an orphan drug, the product must treat a rare disease or condition. The FFDCA defines a "rare disease" as one affecting less than 200,000 people in the United States. Congress enacted the Orphan Drug legislation to encourage research and development of treatment for rare diseases, as the market for treatments of rare diseases, by nature, is not highly profitable.

A total of ten orphan drugs were approved from 1972 to 1982, the ten years before the Orphan Drug Act was passed. Since its enactment, there have been 193 orphan drugs approved. The response to the Orphan Drug Act is an example of how favorably the industry responds to increased intellectual property protection that lowers the risk of investing in research, development, and marketing of a new drug.

The Pediatric Exclusivity Section of the Food and Drug Administration Modernization Act of 1997 is similar incentive-based legislation. The Pediatric Section offers an exclusivity period of six months following a patent term to pioneer companies conducting clinical investigations to determine safe and effective doses for children.

As the Pediatric Exclusivity Section is relatively recent legislation, its effect on the entry of pediatric drugs into the market is not clear. Unfortunately, the exclusivity provision expired on January 1, 2002. Some argue that without reenactment of this provision, the "number of prescription drugs indicated for pediatric patients will likely remain unchanged." A permanent reenactment, similar to that of the Orphan Drug Act, could allow the true effect of this targeted legislation to be seen.

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71 Id. § 1(a)(2).
74 Id.
75 Rohde, supra note 72, at 127.
76 PhRMA Industry Profile 2000, supra note 13, at 42.
77 Id.
80 Id. at 742-43.
82 Karst, supra note 79, at 772.
IV. CONDITIONS LIMITING PATENT TERMS AND OTHERWISE FAVORING GENERIC DRUGS AT THE EXPENSE OF PIONEER DRUGS

A. Substitution Laws

Although control over pharmaceuticals and pharmaceutical patents is usually thought to lie with Congress and such federal agencies as the FDA and the USPTO, state legislatures have passed laws that affect the pharmaceutical market. Anti-substitution laws, which forbid substituting any drug brand that is not specifically prescribed, is an example of such a law. A pharmacist practicing in a state where an anti-substitution law has been enacted cannot sell a generic drug to a patient if the physician prescribed a brand name drug. Prior to 1970, almost every state had enacted anti-substitution laws. The purpose of these laws was to ensure that the patient received the exact drug prescribed and that the physicians would have the right to control the drug selection of his or her patients. Consumer advocates saw these laws, not as safety measures, but as tools for drug price exploitation. These advocates argued that if there were bio-equivalent drugs capable of being dispensed at a lower cost to patients, the pharmacist should not be limited to dispensing the brand name prescribed. In response to growing public adversity to the laws, every state repealed its anti-substitution law.

Many states followed the Model Drug Product Selection Act ("Model Act"), published by the Federal Trade Commission, when repealing their anti-substitution laws and enacting substitution laws. The Model Act allows, but does not require, pharmacists to substitute a generic drug for a prescribed brand name drug when such a substitution would cost the patient less. The result of adopting the Model Act is that a pharmacist may rely on his or her professional opinion as to whether a generic drug is bio-equivalent to the prescribed drug, precluding the need to defer to the exact language of the physician’s prescription.

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84 PHARM. LAW DIGEST 249 (Joseph L. Fink III et al. eds., 35th ed. 2000).
85 Id.
86 Id.
87 Id.
88 Id.
89 Id. at 250.
90 MODEL DRUG PRODUCT SELECTION ACT, reprinted in BUREAU OF CONSUMER PROTECTION, FED. TRADE COMM’N, DRUG PRODUCT SELECTION 15-17 (1979).
91 PHARM. LAW DIGEST, supra note 84, at 250.
92 Id.
Some states go much further and actually encourage, even require, the pharmacist to substitute drugs in certain situations. These substitution laws are one example of a condition favoring the generic drug industry. In addition to state legislation, federal administrative regulations and legislative enactments result in increasing the generic drug market share at the expense of the pioneer drug manufacturers.

B. Administrative Delays

While the statutory patent term for utility patents is a generous twenty years, barriers exist that can substantially limit their effective lifetime. For example, a patent term begins to run the day that a patent application is filed, and patent registration can take several years of prosecution in the USPTO. The average prosecution time for a U.S. patent is 3.4

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93 The Kentucky substitution statute, K.R.S. § 217.822 (Michie 1995), states:
(1) When a pharmacist receives a prescription for a brand name drug which is not listed by generic name in the nonequivalent drug product formulary prepared by the board, he shall select a lower priced therapeutically equivalent drug which he has in stock, unless otherwise instructed by the purchaser or his physician, provided however that if such selection is made, the label on the container of the drug shall show the name of the drug dispensed.

(2) When an equivalent drug product is dispensed in lieu of a brand name drug prescribed, the price of the equivalent drug product dispensed shall be lower in price to the purchaser than the drug product prescribed.

(3) If, in the opinion of a practitioner, it is to the best interest of his patient that an equivalent drug should not be dispensed, he may indicate in the manner of his choice on the prescription “Do Not Substitute,” except that the indication shall not be preprinted on a prescription.

(4) The selection of any drug by a pharmacist under the provisions of this section shall not constitute the practice of medicine.

(5) A pharmacist who selects an equivalent drug product pursuant to KRS 217.815 to 217.826 assumes no greater liability for selecting the dispensed drug product than would be incurred in dispensing a prescription for a drug product prescribed by its generic name.

(6) When a pharmacist receives a generically written prescription for a multiple source drug product, he shall dispense an equivalent drug product in accordance with the provisions of KRS 217.815 to 217.826.

94 See infra notes 95-172 and accompanying text.
96 Id.
years. For a biotechnology patent, the average prosecution time is increased to 4.4 years. A pioneer pharmaceutical is not protected until successful prosecution has been completed and a patent registers. By this time, it has lost several years of its twenty-year term.

In addition, before the drug can enter the marketplace, it must meet the guidelines set out in the FFDCA, which include review by the FDA. The actual FDA approval times have decreased in recent years from thirty to fifteen months. The administrative delays of both the USPTO and the FDA result in an abbreviated patent life, or effective patent term, which is much smaller than the twenty-year statutory term found in the Patent Act.

C. The Drug Price Competition and Patent Term Restoration Act of 1984

Although its name implies that it favors longer patent terms for pioneer drugs, the Drug Price Competition and Patent Term Restoration Act of 1984 actually results in shorter effective patent terms. Although it was purported to be an attempt to strike a balance between generic and pioneer drug marketing, the Act was much more beneficial to generic drug companies than it was to pioneer drug companies.

In the early 1980s, the pharmaceutical industry was feeling the effect of increased FDA regulations. These regulations resulted in more rigorous testing requirements for approval, increased review periods, and

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99 Id. at 406.
102 Deborah G. Parver, Expediting the Drug Approval Process: An Analysis of the FDA Modernization Act of 1997, 51 ADMIN. L. REV. 1249, 1255 (1999); Viscusi, supra note 17, at 1444 (the entire new drug application process, including clinical trials, takes approximately five to seven years).
105 See PhRMA Industry Profile 2000, supra note 13, at 103.
107 Keyack, supra note 106, at 153-54.
truncated patent terms for pioneer drug companies. The generic drug companies were also affected by FDA approval requirements, causing delay in getting their product to market. Both pioneer and generic drug companies, eager to increase their market share, began congressional lobbying efforts. In addition, the two industries battled each other in court.

Roche Products, Inc. v. Bolar Pharmaceutical Co., was one such battle. In Bolar, a pioneer company sought an injunction to keep a generic drug company from using its product during the patent term. The generic drug company argued that its possession of the plaintiff’s product was for the purpose of performing tests required for FDA approval of its generic drug equivalent and that such use was an exception to infringement under the experimental use doctrine. The court of appeals held that the generic drug company’s use was not experimental, but instead was “a violation of the patent laws in the guise of ‘scientific inquiry’ . . . [for] commercial purposes.” Generic companies claimed that this definition of infringement gave pioneer companies market exclusivity that extended beyond the term of their patent. Generic companies would have to wait until the pioneer patent expired before starting the lengthy FDA approval process on their generic drug equivalent. At the same time, pioneer companies were demanding extended terms to make up for lost time resulting from lengthy FDA approval for the pioneer drugs themselves. Congress stepped in to provide relief in the form of the Drug Price Competition and Patent Term Restoration act of 1984 (“1984 Act”), also known as the “Hatch-Waxman Act.”

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108 Id.
109 Id. at 154 n.53.
111 Id. at 860.
113 Bolar, 733 F.2d at 862 (citing Peppenhausen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279)).
114 Id. at 863.
115 See Keyack, supra note 106, at 154-55.
116 See id.
117 See id.
119 The Drug Price Competition and Patent Term Restoration Act of 1984 was drafted by Senator Orrin Hatch and Representative Henry Waxman.
The 1984 Act was a combination of two bills pending in Congress. One bill would shorten the FDA application and approval process for generic drugs, while the other would restore pioneer drug patent time lost during FDA approval. The resulting Act was eventually adopted, significantly altering sections of both the FFDCA and the Patent Act.

Title I of the 1984 Act was designed to benefit the generic drug companies for the purpose of increasing access to generic drugs at a lower cost to consumers. This end was achieved by establishing an Abbreviated New Drug Approval application ("ANDA"), which substantially shortened approval time in the FDA for generic drugs. A generic drug company meeting the statutory requirements can file an ANDA and receive a response from the FDA within 180 days. These statutory requirements include: (1) a showing that the proposed generic drug is the same as, or bio-equivalent to, an FDA approved drug; (2) submission of a certification disclosing whether that approved drug is protected by a patent; and (3) submission of a statement that the applicant does not use a method of producing the proposed generic drug that is protected by a method of production patent. Once an ANDA applicant is approved, the generic drug may enter the market absent a patent infringement claim. To increase the incentive for a generic drug company to quickly file an ANDA, the first approved ANDA applicant will enjoy a 180-day exclusivity period against competing ANDA versions of the drug.

Title II of the 1984 Act was designed to benefit pioneer drug companies for the purpose of providing incentives for increased research and development of new drugs by offering an extension of the patent term.

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124 Id. § 355(j)(1).
125 Id. § 355(j)(4)(A).
126 Id. § 355(j)(2)(A)(i)-(vi).
127 Id. § 355(j)(2)(A)(vii).
128 Id. § 355(j)(2)(A)(viii).
129 Id. § 355(j)(5)(B)(iii).
130 Id. § 355(j)(5)(B)(iv).
where certain statutory conditions are met. The extension is based on the

time lost during the FDA approval process.

In addition to providing this benefit to pioneer drug companies, Title
II also created a new exception to patent infringement. This alteration to
the Patent Act is known as the "Bolar Amendment" because it overruled Roche Products, Inc. v. Bolar Pharmaceutical Co., wherein the court
held that the generic drug company's use of a patented product for
performing tests required for FDA approval of its bioequivalent drug was
infringement. Title II, while purportedly designed to benefit pioneer drug
companies, actually gave generic drug companies a windfall. The Patent
Act awards a patent owner the exclusive right to make, use, or sell the
patented invention, but the Bolar Amendment takes the exclusive right to

132 35 U.S.C. § 156(a) states:
The term of a patent which claims a product, a method of using a product,
or a method of manufacturing a product shall be extended in accordance
with this section from the original expiration date of the patent if—
(1) the term of the patent has not expired before an application is
submitted under subsection (d)(1) for its extension;
(2) the term of the patent has never been extended under subsection
(e)(1) of this section;
(3) an application for extension is submitted by the owner of record of
the patent or its agent and in accordance with the requirements of
paragraphs (1) through (4) of subsection (d);
(4) the product has been subject to a regulatory review period before its
commercial marketing or use.

133 Id. § 156(d)(1).

134 35 U.S.C. § 271(e)(1) states: "It shall not be an act of infringement to make,
use, or sell a patented invention . . . solely for uses reasonably related to the
development and submission of information under a Federal law which regulates
the manufacture, use, or sale of drugs. . . ."

135 Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984). The
Court of Appeals for the Federal Circuit decided two very similar cases in 1984, Roche Products, Inc. v. Bolar Pharmaceutical Co. and Paper Converting Machine
Co. v. Magna-Graphics Corp., 745 F.2d 11 (Fed. Cir. 1984). In both Bolar and
Magna-Graphics, the court found that the defendant's commercial development of
a product patented by the plaintiff during the term of the patent constituted
infringement. In Bolar, the product was a pharmaceutical; in Magna-Graphics, the
product was an automatic paper-rewinding machine. The 1984 Act carefully carved
out an exception to patent infringement for pharmaceuticals by overruling Bolar
but not Magna-Graphics, which continues to be good law.

136 Bolar, 733 F.2d at 863.

137 Keyack, supra note 106, at 160-61.
use their patented invention away from pioneer drug companies. This exception to infringement only occurs in the field of pharmaceutical patents; all other patent holders continue to have the exclusive right to use their patented invention during the term of the patent.

Another benefit of the 1984 Act to pioneer drug companies is patent term extensions for time lost during FDA approval; however, these extensions are very limited and do not make up for the exclusivity period taken away by the other provisions of the 1984 Act. Patent restoration under the 1984 Act limits extension such that the maximum patent term may not exceed fourteen years. Thus, it is virtually impossible, even under patent term restoration, for a pharmaceutical patent term to be as lengthy as the average eighteen and a half-year patent term for any other invention.

In addition, generic companies are no longer required to conduct the expensive clinical trials required for FDA approval; instead, they can rely on the trials conducted by pioneer companies and merely conduct relatively inexpensive bioequivalence studies. This new legislation not only saves generic companies substantial amounts of money in research costs, but also allows for a much shorter FDA approval period for generic drugs, resulting in increased speed to market.

With the benefits of shortened FDA approval and the Bolar Amendment's new exception to patent infringement, a generic drug has the ability to be on the market almost immediately after a pioneer patent expires. Before 1984, generic drug companies could not begin drug development, clinical trials, or the FDA approval process until the pioneer patent had expired. Clinical trials and FDA approval take approximately eight and a half years to complete; thus, the 1984 Act resulted in cutting pioneer drug effective patent terms by several years. Although the 1984 Act was considered a compromise at the time it was passed, generic companies

138 Id. at 160.
140 Id. (the extension is limited to a fourteen-year effective term).
141 Keyack, supra note 106, at 158, 160-61.
143 PhRMA Industry Profile 2000, supra note 13, at 102-03.
145 See Reid, supra note 120, at 317-18.
146 Keyack, supra note 106, at 160.
148 Price, supra note 97, at 656.
appear to have gained more than they have lost—at the expense of pioneer companies.¹⁴⁹

D. The 1996 Senate Judiciary Committee Hearings on the 1984 Act

Despite the lack of balance in the 1984 Act, little has been done to counteract the disadvantage it has placed on pioneer drug companies. In 1996, a Senate Judiciary Committee held hearings to answer the question: “If we placed our ‘legislator’s level’ on the Hatch-Waxman Act today, would it still be in balance?”¹⁵⁰ The co-drafters of the 1984 Act continued to be pleased with their piece of legislation, as was apparent through their comments at the 1996 Senate Judiciary Committee Hearings on the 1984 Act.¹⁵¹ Ultimately the co-drafters found the “legislator’s level” to be in balance as they affirmatively answered the posed question.¹⁵²

Senator Hatch stated his belief that the 1984 Act is still the most important consumer bill of the decade, while Representative Waxman called it one of his “proudest achievements.”¹⁵³ Not surprisingly, witnesses from the generic drug industry praised the Act’s success.¹⁵⁴

Representatives of the pioneer drug companies did not share the same enthusiasm as the generic representatives. Gerald Mossinghoff, President of the Pharmaceutical Research and Manufacturers of America (“PhRMA”), agreed that generic drugs are less expensive but pointed out that these low prices result from the fact that “pharmaceuticals are extremely expensive and difficult to develop, [but] they can be copied cheaply and easily.”¹⁵⁵ Mr. Mossinghoff further noted that research and development costs had increased and commented on how “expensive and risky” the pioneer drug industry had become.¹⁵⁶ He concluded that while innovation had a history of improving health through new drug technology, innovation and technology goals can only be met if strong patent protection is afforded to manufacturers.¹⁵⁷

¹⁵¹ Id.
¹⁵² Id.
¹⁵³ Id.
¹⁵⁴ Id.
¹⁵⁵ Id. at 328.
¹⁵⁶ Id.
¹⁵⁷ Id.
Research and development costs for pioneer drugs are approximately $200-500 million.\textsuperscript{158} Since generic companies can copy the formulation of a pioneer drug and even use the data of a pioneer drug company to supplement its FDA approval application, the cost of getting a generic drug approved is only about $1 million for bioequivalence testing.\textsuperscript{159}

The committee was not swayed by the witnesses representing the pioneer industry and closed the Hearings without significantly changing the 1984 Act.\textsuperscript{160}

\section*{E. Recent Legislation Favors Inventors But Does Not Target Pharmaceutical Inventors}

The American Inventors Protection Act of 1999 ("AIPA"),\textsuperscript{161} attempts to give across-the-board intellectual property protection rather than focus on a discrete area such as "orphan drugs" or "pediatric drugs."\textsuperscript{162} AIPA, which was passed by Congress on November 29, 1999,\textsuperscript{163} positively affects patent terms, among other things, and can therefore be thought of as incentive-based legislation. Subtitle D of Appendix I of the Act, entitled the Patent Term Guarantee Act of 1999 ("PTGA"), applies to any patent application\textsuperscript{164} filed on or after May 29, 2000.\textsuperscript{165} The PTGA allows for patent extensions to compensate for delays in USPTO examinations and in prosecution that exceed more than three years.\textsuperscript{166} Because the statutory patent term is twenty years from the date of filing,\textsuperscript{167} the PTGA extension guarantees most patents a minimum seventeen-year patent term. This extension is available to pharmaceutical patents.\textsuperscript{168} Pharmaceutical patents, however, will seldom experience a patent term of seventeen years because,

\begin{quote}
\textsuperscript{159} \textit{PhRMA Industry Profile 2000}, supra note 13, at 101.
\textsuperscript{160} Reid, supra note 120, at 329.
\textsuperscript{162} See generally id.
\textsuperscript{163} Id.
\textsuperscript{164} See id. Design patents are not eligible for adjustment under this Act. Id.
\textsuperscript{166} See Patent Term Guarantee Act of 1999 § 4402.
\textsuperscript{168} Changes to Application Examination and Provisional Application Practice, 65 Fed. Reg. 14,865 (Mar. 20, 2000) (to be codified at 37 C.F.R. pt. 1).}

before placing a patented drug on the market, it must go through not only prosecution or examination in the USPTO, but also the drug testing and approval process in the FDA.\(^6\)

Because FDA approval causes pharmaceuticals additional delay in getting on the market, pioneer drug companies must continue to rely on "Patent Term Restoration" under the 1984 Act\(^7\) to make up for this delay. "Patent Term Restoration" only allows for a maximum effective life of fourteen years after FDA approval.\(^8\) Because of safety concerns, the standards for FDA-approved drugs should not be decreased in order to increase the rate of FDA approval. Due to the pressures that the application examiners are under, it is unlikely that the approval time in the FDA will decrease for other reasons.\(^9\) Accordingly, it will be impossible for PTGA to actually guarantee all patents a life of seventeen years without allowing pharmaceutical patents a term extension for time lost during FDA approval.

**F. Proposed Legislation with Potential to Further Affect Pharmaceutical Patent Terms**

Although interest in amending the 1984 Act was not present during the Senate Judiciary Committee Hearings in 1996, interest has since grown. In September 2000 alone, several bills suggesting amendments to the 1984 Act were introduced targeting high health care costs.\(^10\) Today, however, the congressmen proposing amendments do not seem concerned with answering the question: "If we placed our 'legislator's level' on the Hatch-Waxman Act today, would it still be in balance?"\(^11\) The recently proposed bills do not attempt to balance the pioneer and generic drug companies' concerns, but rather propose to tip the scale even further in favor of generic drug companies.\(^12\)

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\(^{7}\) PhRMA Industry Profile 2000, supra note 13, at 102.

\(^{8}\) Id.

\(^{9}\) Parver, supra note 102, at 1264-65. Reviewers are under pressure to approve drugs from drug manufacturers, physicians, and Wall Street. Id.


\(^{11}\) Reid, supra note 120, at 327.

\(^{12}\) See H.R. 5231; H.R. 5247; S. 3051.
Amendments to the FFDCA and the Patent Act with respect to abbreviated applications (ANDA) for the approval of new drugs are proposed in the Pharmaceutical Reform Act of 2000,176 introduced by Representatives Alan Mollohan (D-West Virginia) and Ken Calvert (R-California).177

Currently, under the FFDCA, a generic drug company can file an ANDA and receive a response from the FDA within 180 days178 if it meets several statutory requirements. These requirements include submission of a certification disclosing whether a patent protects the approved pioneer drug to which the generic drug claims bioequivalence.179 The Pharmaceutical Reform Act, among other things, would limit the scope of the pioneer patent claims for purposes of this statutory requirement.180 In the proposed amended statute, "a patent [would] not be considered to claim a listed drug unless, with respect to such drug, the patent claims an active ingredient."181 In addition, the proposed Act would prohibit any state or local government from limiting substitution of a prescribed pioneer drug for a generic drug that has been determined to be bioequivalent by the FDA.182 As mentioned above, anti-substitution legislation favors generic drug companies at the expense of pioneer drug companies.183 This bill, if enacted, would further tilt the legislative scale in favor of generic drug companies.

Senators John McCain (R-Arizona), Charles Schumer (D-New York), and Tim Johnson (D-South Dakota),184 and Representatives John Baldacci (D-Maine) and Tome Coburn (R-Oklahoma)185 introduced a bill in the Senate and House, respectively, entitled the "Greater Access to Affordable Pharmaceuticals Act of 2000" ("GAAPA").186 This proposed legislation would amend the FFDCA and the Patent Act for the stated purpose of "mak[ing] generic drugs more available and accessible, and thereby reduc[ing] health care costs."187 It purports to achieve this goal by once again tipping the legislative scale in favor of generic drug companies.

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176 H.R. 5231.
177 Id.
179 Id. § 355(j)(2)(A)(vii).
180 See H.R. 5231.
181 Id.
182 Id.
183 See supra notes 83-89 and accompanying text.
186 H.R. 5247; S. 3051.
GAAPA may allow further infringement of pioneer patents by generic companies. In addition to a patent covering the composition of a drug, a pioneer company may have invented a novel method of producing the drug. The novel production method may be entitled to patent protection separate from the patent protecting the drug composition.\textsuperscript{188} The Bolar Amendment,\textsuperscript{189} found in the 1984 Act, provides certain exceptions to infringement of drug composition patents for generic drug companies seeking FDA approval of a bioequivalent drug by filing an ANDA.\textsuperscript{190} The Amendment did not provide an exception to infringement of pioneer companies' method of production patents. GAAPA may allow such infringement.\textsuperscript{191} Currently the statutory prerequisites for a generic drug company to file an ANDA include submission of a statement that the applicant does not use a method of producing the proposed generic drug, which is protected by a method of production patent.\textsuperscript{192} GAAPA proposes to eliminate this requirement\textsuperscript{193} as one among other proposals favoring generic drug companies at the expense of pioneer drug companies.

Ultimately, in the attempt to lower health care costs, legislators want to take an intellectual property scheme that already disfavors pioneer drug companies and make it even more disadvantageous. This method of attacking health care costs has the potential to adversely affect society. By increasing the risks inherent in creating new drugs, the proposals essentially decrease a pioneer company's incentive to invest in new drug development.

\textsuperscript{189} \textit{id.} § 271(e)(1) (2000); see generally Reid, \textit{supra} note 120, at 339 n.39.
\textsuperscript{190} See 35 U.S.C. § 271(e)(1).
\textsuperscript{191} S. 3051, 106th Cong. (2000). The GAAPA proposes completely striking 21 U.S.C. § 355(b)(2)(B) and § 355(j)(2)(A)(viii). These subparagraphs state as follows:

If with respect to the drug for which investigations described in paragraph (1)(A) [safety and efficacy reports] were conducted information was filed . . . for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.


If with respect to [the FDA approved drug to which the new generic drug is bioequivalent] information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

\textsuperscript{193} S. 3051; H.R. 5247.
The result is potentially decreased availability of new drugs, as well as increased overall health care costs for Americans.

V. SOCIA L COSTS GENERATED BY TRUNCATED PHARMACEUTICAL PATENT TERMS

Monopolies are not only illegal in the United States, but the idea of limiting the potential for competition is adverse to the idea of a capitalist society. Thus, it would not be a surprise to discover that many Americans could be naturally skeptical of the limited monopolies associated with patent terms. The pharmaceutical industry, however, is one that could not function without these limited monopolies. Because of the nature of this class of products, a competitor can copy a new drug with great ease. Without the protection of a patent, immediate competition from generic companies copying and marketing a new drug make the risk of investing in a new drug far too great to justify proceeding with new research and development. Society has patent terms to thank for the availability of beneficial new drugs.

Clearly, complete elimination of a pharmaceutical patent term would be detrimental to a society that wishes to have access to new drugs; however, the societal costs generated by truncated pharmaceutical patent terms may not be as intuitive. The following hypothetical attempts to illustrate this point.

A. Societal Costs Generated by the Shortened Effective Patent Terms: A Hypothetical

Incentive to invest in drug development is correlated to the risk associated with the future income streams that a new drug will generate. Although the profit generated from a drug is potentially very high, the potential loss associated with investing in a drug that is not profitable or that generates substantial liabilities is also great. This large dispersion in outcomes produces a significant risk.

Consider the following scenario. Company $P$ developed Drug $X$ as a potential cancer suppressing agent for women who have previously battled

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195 This hypothetical is admittedly simplistic and is used only to illustrate the role that pharmaceutical patent terms play in determining whether to invest in the development of a new drug.
breast cancer. Drug X generated optimistic data in both cultured cells and in preliminary animal studies. Company P is considering obtaining a patent for the composition of Drug X and starting the lengthy and expensive FDA approval process.

If patent protection and FDA approval for Drug X are received, valuation experts at the company predict that if Drug X is sold at an “affordable price,” it could make the company $100 million, but it is also possible that the company could lose $25 million (by being unable to recoup research and development costs). These figures may vary depending on the success of marketing and public acceptance, among other things. Ultimately, the investment appears to be financially sound.

Because Company G, a manufacturer of generic drugs in the area of cancer suppressing agents, is likely to pursue FDA approval of a generic version of Drug X, the term that Company P may market Drug X exclusively is likely to be truncated. When the shortened effective patent term is factored in, the most optimistic return on the investment remains at $100 million; however, the most pessimistic return must be recalculated. Experts estimate that the company could lose $100 million.

Although the total utility of the income generated from investment in Drug X will increase with each dollar, the marginal utility does not increase with each dollar. Said another way, the utility generated by gaining $100 million is less than the detriment generated by losing $100 million. The increased dispersion in outcomes associated with a shorter effective patent term has made further investment in Drug X an unwise financial decision.

However, experts from Company P determine that by increasing the price of the drug to a “very expensive price,” enough consumers will still be able to purchase the drug and its maximum return could be increased to as much as $125 million. Increasing the cost of Drug X can salvage the investment. Shorter patent terms can actually cause pharmaceutical cost to increase.

The company must also consider other risk factors such as competition from other pioneer drug companies, products liability suits, and the possibility that legislation will be passed to further shorten the effective patent term of Drug X. If experts from Company P calculate that the price of Drug X cannot be further raised without severely limiting the number of consumers that could afford the drug, thus making it impossible to raise the maximum possible return any further, the investment cannot be salvaged.

Herein lies the ultimate problem. Such deterrence has two detrimental results: (1) harming those people whose lives could be benefitted or saved by the drug, and (2) increasing overall health care costs. By limiting the availability of drugs based on the fear that they may be too expensive for
the American consumer, the potentially beneficial drug never makes it to market and never has the ability to help those it was designed to benefit.

With regard to increasing health care costs, one must consider that the most efficient ways to cut these costs may be through preventative treatment. If drugs can prevent medical problems such as strokes or facilitate the management of diseases such as cancer, then expensive hospital visits, surgeries, and treatments can be eliminated or greatly reduced. Because drugs are a cost-effective alternative to many other health care options, it is imperative that the development of novel and improved pharmaceuticals is not stifled when attempting to reduce Americans' health care expenses.

CONCLUSION

The legislative acts and administrative regulations put in place by the 1984 Act resulted in increasing the risk of investing in drug innovation. Generic companies now enjoy a shortened FDA approval time. The usual period between patent expiration and generic entry has decreased from three or four years prior to 1984, to one or two months. When a generic drug entered the marketplace prior to 1984, it received a 12.7% share of the market. Today, upon entering the market, a generic drug quickly climbs to a 57.6% share of the market.

In the world of intellectual property term protection, no inventor is at more of a disadvantage than the pioneer drug developer. The effective patent term of a pioneer drug is statutorily set below the average effective patent life for products other than pharmaceuticals, allowing a maximum life of only fourteen years after the 1984 Act extension. Furthermore, not all patents are eligible for this extension. The average effective patent term for pioneer drugs is actually only eleven or twelve years, which is approximately forty percent lower than the effective term for other patented products.

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196 See Reid, supra note 120, at 330-36.
197 See supra Part IV.
198 CONG. BUDGET OFFICE STUDY, supra note 13, at 38.
199 Id. at 39.
200 Id.
201 PhRMA Industry Profile 2000, supra note 13, at 102 (compare eighteen and a half years to eleven to twelve years for pharmaceuticals).
202 Id.
204 PhRMA Industry Profile 2000, supra note 13, at 102-03.
Legislators seem to justify this disparity by arguing that drugs have such a high utility that they need to be more available to the consumers. In order to effectuate increased availability, drug prices must be decreased. This may be accomplished by expediting generic market entry, but the result may be detrimental to the pioneer drug market.\textsuperscript{205} However, it seems more logical to argue that because pharmaceuticals have such a high social utility, the incentive for pioneer drug development should be greater than the incentive to create inventions of low social utility. Passing legislation that further decreases pharmaceutical patent terms, in effect, reduces the incentive to invest in the development of these highly useful compounds because of the potential risk of being unable to recover the costs of research and development.

Decreasing the cost of prescription drugs while continuing the incentive to invent new drugs is a difficult balance to achieve. Congress has purported to pass legislation in the past aimed at achieving this balance.\textsuperscript{206} Realistically, the scales continue to be tipped in favor of generic drug companies. Legislation has recently been proposed that will attempt to "reduce health care costs"\textsuperscript{207} by lowering prescription drug costs. Decreasing the effective patent term of pioneer drugs, thus allowing generic drugs accelerated entry into the marketplace, will initially lower prescription drug costs. However, decreased effective patent terms for drugs will adversely affect incentive to invest in development of new drugs, leading to a decreased number of novel drug treatments being introduced in the future.

The cost of drugs is an important consumer concern,\textsuperscript{208} but high-priced, cutting-edge drugs may be more cost-effective than initially apparent. "When one considers the costs deferred by drug treatment, such as: (1) surgical intervention, (2) pain and suffering, (3) loss of time from work, (4) quality of life decline, and (5) pre-mature loss of life, it becomes apparent that society should reward the pharmaceutical industry for inventing the[se] drug[s]."\textsuperscript{209} One of the most efficient ways to cut health care costs is

\textsuperscript{205} See supra notes 104-60, 174-93 and accompanying text.
\textsuperscript{207} S. 3051, 106th Cong. (2000).
\textsuperscript{208} See generally Noonan, supra note 1.
\textsuperscript{209} Milenkovich, supra note 106, at 773.
through preventative treatment—^{210}—including pharmaceuticals geared to preventing medical problems before expensive hospital care is required.^{211}

In addition to being a cost-effective alternative to other medical treatment options, drugs have the ability to save and improve lives. Because of this social benefit, the law must not truncate patent terms to the point that the risk of drug investment becomes too great to justify any innovation in pharmaceuticals.

^{210} Id.

^{211} See supra text accompanying note 196.
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The editors and staff respectfully dedicate this issue to the memory of Paul Oberst