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The emerging effects of the drug price competition and patent term restoration act of 1984

The Drug Price Competition and Patent Term Restoration Act of 1984 (the Act) was enacted to serve two competing objectives: 1) to make more low cost generic drugs available to the public; and 2) to create new incentives for research and development of certain products subject to premarket approval by the government. To accomplish the first objective, the Act established an abbreviated new drug application procedure for generic drugs undergoing marketing approval before the Food and Drug Administration (FDA). Congress addressed the second objective by creating a procedure to restore the patent life of products awaiting premarketing approval by the FDA.

In Part I, this Comment will focus briefly on the history and provisions of the Act. Part II will address the effects of the legislation, Part III will examine whether the objectives of the Act are being met, and finally, Part IV will suggest changes through which the Act could be amended or interpreted to more effectively accomplish its stated objectives.

I. HISTORY AND PROVISIONS

The Drug Price Competition and Patent Term Restoration Act of 1984 was the result of a compromise between the generic and pioneer drug industries. The generic drug industry, supported by a number of consumer interest groups, lobbied Congress to enact legislation that would simplify the approval procedure for generic drugs whose brand name equivalents were


361
already approved by the FDA. Legislation introduced by Congressman Henry A. Waxman (D-Cal.) provided for an abbreviated new drug application (ANDA) procedure whereby generic drugs could be approved by the FDA if they were shown to be the "bioequivalent" of an approved drug. The ANDA provision would eliminate the expense and delay of proving the safety and effectiveness of a generic drug in clinical tests on humans when a pioneer drug manufacturer had already proven such requirements.

The pioneer drug industry, on the other hand, had complained since the late 1970s that the seventeen year patent term for pioneer drugs patented prior to receiving FDA approval was effectively reduced by the time that it took the FDA to approve the product for the consumer market. The industry argued that this loss in the effective life of the patent was damaging because it reduced the incentive to invest the large sums of money necessary for research and development of new and innovative drug products.

6. Prior to passage of the Act, the FDA required manufacturers of both pioneer and generic drugs to conduct clinical tests on humans to show that their drugs were both safe and effective. In order to gain marketing approval, the results were then submitted for approval to the FDA in a new drug application (NDA). An exception to this requirement, however, allowed for an abbreviated new drug application (ANDA) procedure whereby the generic drug manufacturer needed only to show that the generic drug was the same as a pioneer drug approved prior to 1962 and that it would be properly manufactured and labeled. Id. at pt. 1, at 16, reprinted in 1984 U.S.C.C.A.N. at 2649.


A drug shall be considered bioequivalent to [an approved] drug if the rate and extent of absorption of the generic drug do not show a significant difference from the rate and extent of absorption of the [approved] drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses.


9. The pioneer drug industry was primarily represented by the Pharmaceutical Manufacturers Association (PMA). Id. at pt. 2, at 4, reprinted in 1984 U.S.C.C.A.N. at 2664. The "pioneer drug industry" generally includes those drug manufacturers that are the first to develop, manufacture, and market new drugs. This industry is often referred to as the "brand name drug industry." However, by 1989 brand name drug producers were also producing generic equivalents which accounted for approximately 25% of the generic drug market. Skyrocketing Prescription Drug Prices: Hearings Before the Special Comm. on Aging, 101st Cong., 1st Sess. 156 (1989) [hereinafter Skyrocketing Prescription Drug Prices Hearings 1989] (statement of Gerald J. Mossinghoff, Pharmaceutical Manufacturers Association President).


11. See id. at pt. 2, at 6, reprinted in 1984 U.S.C.C.A.N. at 2690 ("[P]roponents of [patent term restoration] have argued that without some form of legislative relief in this area there would be a diminished stimulus to innovation and research. Thus, it is argued patent term extensions will create incentives for increased expenditures.").

In 1989, pioneer drug manufacturers spent $7.3 billion in private funds for research and development (R&D); in 1988, the industry invested 16.3% of its sales in R&D, compared with
address this problem, both houses of Congress introduced patent term restoration bills.\textsuperscript{12}

When it became clear that neither the ANDA nor the patent term restoration proposals could singlehandedly gain enough support for passage, legislators agreed to combine the two.\textsuperscript{13} The result of this compromise was the Drug Price Competition and Patent Term Restoration Act of 1984, signed into law by President Reagan on September 24, 1984.\textsuperscript{14}

The Act consists of three parts: Title I which provides for the ANDA procedure, Title II which implements the patent term restoration provision, and Title III, which is an unrelated provision dealing with textile labeling. Title I, the ANDA provision,\textsuperscript{15} establishes a generic drug approval procedure for pioneer drugs approved after 1962, by amending the Federal Food, Drug, and Cosmetic Act.\textsuperscript{16} Under the provisions of Title I, the FDA must approve the ANDA within 180 days\textsuperscript{17} from the time of filing if the applicant shows that: 1) the conditions for prescribed, recommended, or suggested use for the new generic drug have been previously approved for a prior drug;\textsuperscript{18} 2) the generic drug has the same active ingredient(s) as the prior approved drug;\textsuperscript{19} 3) the generic drug uses the same route of administration, dosage form, and strength as the approved drug;\textsuperscript{20} 4) the generic drug is the "bioequivalent" of an approved drug;\textsuperscript{21} and 5) the labeling proposed for the ge-


17. 21 U.S.C. § 355(j)(4)(A) (1988). The applicant and FDA may agree to extend the 180 day limit. \textit{Id.}


\textit{A} drug shall be considered to be a bioequivalent to a listed drug if —

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or
necic drug is the same as the labeling approved for the prior drug.\textsuperscript{22} Additionally, applicants must certify that, in their opinion and to the best of their knowledge, neither the generic drug nor its use is patented, or, if patented, then the applicant must certify: 1) that the patent has expired, 2) the date the patent will expire, or 3) that the patent is invalid or will not be infringed.\textsuperscript{23} If the generic drug or its use is not patented or if the patent has expired, then the approval is effective immediately.\textsuperscript{24} If the generic drug or its use is patented, then the approval is effective on the patent's expiration date.\textsuperscript{25} When the applicant certifies that the patent is invalid or will not be infringed, the effective date of approval may be delayed 180 days if the patent owner files an action for patent infringement.\textsuperscript{26} Finally, Title I provides that pioneer drugs approved for the first time after the enactment of the legislation receive four to five years of exclusive market life,\textsuperscript{27} and if approved for the first time between 1982 and the legislation's date of enactment, the pioneer drugs receive an exclusive market life of ten years.\textsuperscript{28}

Title II of the Act added a new section\textsuperscript{29} to the U.S. Patent Code providing for the extension of the seventeen year patent term on certain products subject to premarket approval, their method of use, or their method of manufacture. Under the Code, an inventor of "any new and useful process, machine, manufacture, or composition of matter, or any new and useful im-

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

§ 355(j)(7)(B).


27. § 355(j)(4)(D)(ii). This provision, which prohibits the approval of a generic equivalent for four years, is of particular importance for those pioneer drugs that are unpatentable or whose patents are invalid. For example, if an inventor publishes a paper disclosing her new drug more than one year prior to the filing of a patent application her drug would be unpatentable under 35 U.S.C § 102(b) (1988) ("A person shall be entitled to a patent unless . . . (b) the invention was patented or described in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . "). However, the new drug could be approved for sale in the United States by the FDA in a new drug application (NDA) pursuant to 21 U.S.C. § 355(b) (1988).

28. § 355(j)(4)(d)(i). This provision is of particular importance for those pioneer drugs that are unpatentable or whose patents are invalid.

provement thereof, may obtain a patent ...,” provided that the invention is novel and not obvious. A patent gives its owner “the right to exclude others from making, using, or selling the invention throughout the United States ...” for a term of seventeen years. The products that qualify for patent term extension include drug products, “medical devices, food additive[s], [and] color additive[s] subject to regulation under the Federal Food, Drug, and Cosmetic Act.” Additionally, Title II amends the patent code by providing that “[i]t 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 ... .”

Title II places four limitations on the period of patent extension. First, the extension is limited to two years for those products being tested or awaiting approval at the time of the enactment of the legislation. Second, the extension period for all other products is limited to five years. Third, any period of time in which the manufacturer failed to act with due diligence in gaining approval will be subtracted from the extension. Finally, the patent term remaining at the time of regulatory approval cannot be extended beyond fourteen years under the term extension provisions.

II. THE EFFECTS OF THE ACT

A. The ANDA Provision

One of the most dramatic changes in the prescription drug industry since the passage of the Act has been the increase in the generic drug industry’s prescription drug market share from eight percent in 1984 to thirty-three

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34. A “drug product” is defined as the active ingredient of “a new drug, antibiotic drug, ... human biological product [or a] ... new animal drug or veterinary biological product ... which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques ... .” 35 U.S.C. § 156(f)(2)(A)-(B) (1988).
38. § 156(g)(6)(A)-(B).
40. § 156(c)(3).
percent in 1989.\textsuperscript{41} The ANDA provision has highlighted a number of factors that create this progeneric environment. These factors include: the recent expiration of a significant number of patents on widely prescribed drugs;\textsuperscript{42} the demand by patients, hospitals, and health insurance companies for less expensive drugs;\textsuperscript{43} the recent dramatic price increase for prescription drugs;\textsuperscript{44} and the enactment of state laws which permit and often encourage the doctor or pharmacist to authorize the use of a generic, rather than a brand name drug.\textsuperscript{45} The change from brand name to generic drugs generally provides savings between thirty and fifty percent,\textsuperscript{46} and in some cases the savings may be as high as ninety percent.\textsuperscript{47}

At the time of the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, it was estimated that the ANDA provision would save consumers $920 million over the first 12 years, as well as provide substantial savings to federal and state governments by increasing the availability of lower priced generic drugs for government supported health programs.\textsuperscript{48} In 1985, generic drug manufacturers flooded the FDA with 1069

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\bibitem{} \textquotedblleft [E]ight of the ten highest dollar-volume pharmaceuticals in the U.S. lost patent protection between 1984 and 1986.	extquotedblright \ Goldbaum, supra note 1, at 7. \textit{See also} Horwitz, supra note 41, at B2 ("By the end of the decade [1990], nearly all of the current 50 top-selling drugs will be free from patent restrictions and possibly available in generic form . . . .")

\bibitem{} Eklund, supra note 41, at 64; \textit{see also} Horwitz, supra note 41, at B2.

\bibitem{} The American Association of Retired Persons (AARP) reports that "[b]etween 1980 and 1989, prescription drug prices rose by 128\%, compared with an increase in the overall Consumer Price Index (CPI) of just over 50\%" and that "[i]n 1989 alone, when the overall rate of inflation was 4.8\%, average prescription drug prices rose by 8.7\%." \textit{Rx for Generic Drug Safety: Accurate Information for Older Americans: Hearing Before the Subcomm. on Housing and Consumer Interests of the Select Comm. on Aging House of Representatives, 101st Cong., 2d Sess. 23 (1990) [hereinafter Rx for Generic Drug Safety Hearing]}


\bibitem{} Eklund, supra note 41, at 64 ("Connecticut . . . offers a $.50 bonus to druggists for every generic-drug prescription they are able to substitute when filling prescriptions for medicaid patients."); \textit{see also} Horwitz, supra note 41, at B2. For a detailed discussion of the barriers to the use of generic drugs, see James J. Wheaton, \textit{Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984}, 35 \textit{CATH. U. L. REV.} 433 (1985).


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ANDAs compared with 470 generic drug applications the previous year.\textsuperscript{49} Small companies specializing in generic drugs became overnight successes. For example, Mylan Laboratories, Inc., of Pittsburgh, saw its earnings grow 166\% to $12.5 million and its stock jump 800\% in eighteen months.\textsuperscript{50} In 1987, Medicaid bolstered the industry's growth with the institution of the Pharmacists' Incentive Program which encourages pharmacists to substitute generic drugs for more costly brand name drugs.\textsuperscript{51} The incentive program has saved the federal and state governments over $100 million annually.\textsuperscript{52} 

The tremendous growth of the generic drug industry has come at the expense of the brand name industry and has fostered stiff competition between the two. The Pharmaceutical Manufacturers Association estimates that within one year after a patent on a pioneer drug expires, thirty-five percent of the market is lost to generic substitutes and by the second year, fifty percent of the market is controlled by the generic industry.\textsuperscript{53} In one instance, Hoffman-LaRouche Inc., a brand name drug manufacturer, was faced with the expiration of its patent on Valium (a popular tranquilizer) and the filings of ANDAs by at least two generic drug makers for generic equivalents.\textsuperscript{54} The company streamlined its operation by dismissing 1000 of its 8000 employees,\textsuperscript{55} attempted to capitalize on consumer loyalty by punching a distinctive "V" in the middle of its Valium tablets,\textsuperscript{56} and filed a petition with the FDA challenging the manner in which the generic ANDAs are shown to be equivalent.\textsuperscript{57} Critics, however, claimed that the petition as well as other similar actions by the brand name industry merely amount to delaying tactics.\textsuperscript{58}  

\textsuperscript{50} Eklund, supra note 41, at 64; see also Horwitz, supra note 41, at B2.
\textsuperscript{51} FDA Investigation Hearings: (Part 2), supra note 49, at 69 (statement of Frank E. Young, M.D., Ph.D., FDA Commissioner).
\textsuperscript{52} Id.
\textsuperscript{54} Reginald Rhein, A Soaring Market in Generics Draws the Drug Majors, CHEMICAL Wk., Mar. 20, 1985, at 8.
\textsuperscript{55} Eklund, supra note 41, at 68.
\textsuperscript{56} Rhein, supra note 54, at 8. In a similar effort, Ayerst Laboratories of American Home Products gave its brand name drug, Inderal, a distinctive hexagonal shape. Id.
\textsuperscript{57} Horwitz, supra note 41, at B2.
\textsuperscript{58} Id.
In another effort to protect market share, the brand name drug industry pointed to several limited examples in which individuals experienced problems when switching from one version of a drug to another, warning against "indiscriminate switching of drug products, whether from brand-name to generic, generic to brand-name, or from one generic to another . . . ." The industry contended that "[p]atients on maintenance regimens whose daily dosage must be individualized are especially at risk when drug products are changed." In a hearing on drug industry competition, Senator Howard Metzenbaum (D-Ohio) charged that brand name pharmaceutical companies have attempted to discourage the use of generic drugs. The companies' efforts included letters to pharmacists implying that they would be liable for prescribing generic drugs, claiming the drugs to be inferior; letters to physicians warning that their patients' health and welfare will suffer if doctors insist on prescribing generics; paying so-called "experts" to tour the country and make speeches about the dangers of generic drugs; funding institutions to report the alleged problems associated with generic drugs; advertising in medical journals stressing the need to insist that prescriptions be filled only with brand name drugs; presenting scientifically flawed studies to state authorities that suggest the superiority of brand name drugs; and undertaking studies that falsely suggest that brand name drugs are less expensive than generics. Congressman Waxman has alleged that the brand name drug industry is waging an "aggressive anti-generic campaign" and is "spending millions of dollars on false and misleading advertising to raise doubts in the minds of physicians, pharmacists, and consumers about the safety and effectiveness of generic drugs." Dee Fensterer, President of the Generic Pharmaceutical Industry Association (GPIA), contends that "[e]very day the increasing use of generic products can be retarded by even a few percentage points translates into millions of dollars in sales for these firms" and that "[c]reating even the slightest doubt about the comparative


61. Id. at 2 (statement of Senator Metzenbaum).

62. Id. Another interesting tactic used by the brand name drug firm Ayerst allowed physicians to receive free airline tickets for prescribing Ayerst's product, Inderal L.A., to fifty patients and filling out a marketing survey. Id. at 16 (statement of Dr. Jere E. Goyan, Dean, School of Pharmacy, Univ. of Calif., San Francisco, Ca.).

63. Horwitz, supra note 41, at B1.
safety and efficacy or therapeutic equivalence of generic drugs . . . helps brand-name marketers to persuade physicians to preclude the substitution of equivalent generic drugs . . .

Although the competition between generic and brand name drug manufacturers has been fierce, the competition among generic drug manufacturers themselves has been even more intense. The drug company that first markets a generic substitute for a widely used brand name drug that lost patent protection stands to gain substantially in short term profits by establishing a foothold in the market before other generics are approved. The high stakes of being the first to market a generic substitute, coupled with the rapidly expanding generic drug market, has created an environment in which a troubling number of instances of fraud and corruption have surfaced.

In June, 1988, the generic firm Mylan Laboratories exposed the first instances of illegal activity. Frustrated by what Mylan executives perceived as inequities in the ANDA approval process and the failure of FDA management to respond to complaints, the company hired a private detective to investigate its suspicions that competing generic drug manufacturers were bribing FDA employees in order to obtain quicker approval of their generic drug applications. The investigator discovered evidence that payoffs had been made to a supervisory FDA chemist. Mylan turned the evidence over to the House Energy and Commerce Subcommittee on Oversight and Investigations, which began its own investigation.

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64. Dee Fensterer, Generics vs. Brand-Names: Therapeutic Debate Hides Real Issue, BUS. INS., Sept. 12, 1988, at 48.
65. Generic Drugs, supra note 41, at 311 ("The first firm [to market a generic version of a popular drug] could charge relatively high prices . . . and clinch the lion’s share of generic sales for several months or more. By contrast, latecomers gained but a sliver of the market and charged much less . . ."); see also Henig, supra note 47, at 6.
67. Id. Dingell characterized Mylan’s action as “very courageous.” Id. James Benson, Acting FDA Commissioner, testified before Congress that the FDA management possibly failed to take action on Mylan’s complaints because “they didn’t feel the tips were well grounded,” there were “concerns” in the Agency about taking action against its employees, fears of “getting in the way of evolution of the industry,” and the allegations were in part discounted because of their source. Penalties for Illegal Activities in the Approval of Drugs: Hearings Before the Subcomm. on Health and the Environment of the Comm. on Energy and Commerce House of Representatives, 101st Cong., 2d Sess. 49-50 (1990) [hereinafter Penalties Hearing 1990].
68. FDA Investigation Hearings (Part I), supra note 66, at 120. Mylan’s “gamble paid off when they were able to obtain photographs and other documentary evidence that strongly suggested Mr. [Charles] Chang [the supervisory chemist] was receiving gifts of considerable value from generic drug firms.” Id. at 121.
sulted in a number of charges against, and convictions of, FDA officials, drug firms, and consultants.⁶⁹ In July 1989, the scandal unfolded further with the discovery that at least one generic drug firm had substituted a previously approved brand name drug for its generic sample to support its ANDA.⁷⁰ Further probes indicated that some generic drug companies had falsified the test results required for ANDA approval.⁷¹ In regard to the substitution of brand name drugs for the required generic samples, Representative John D. Dingell (D-Mich.), Chairman of the House Energy and Commerce Subcommittee on Oversight and Investigations, stated, “[N]o one at the FDA knows the composition, much less the bioavailability, of the medicine that is actually prescribed and sold to the unsuspecting public.”⁷² Dingell continued, “If a firm is willing to risk bribing or attempting to bribe an FDA employee to achieve a competitive advantage, why not commit the less risky fraud of switching testing materials?”⁷³ U.S. Attorney Breckinridge L. Wilcox, commenting on American Therapeutics’ guilty plea for paying more than $60,000 in illegal gratuities to FDA chemists, falsifying test records, obstructing FDA inspections, and ignoring manufacturing standards, characterized the company’s behavior as “benign when compared to some of its competitors” and predicted that the “picture will get even darker as the probe of the industry continues.”⁷⁴

By November 1989 the FDA had collected and analyzed over 2,500 samples representing the 30 most prescribed generic drugs in an effort to determine the extent of the fraud and to ensure that the nation’s drug supply was safe and effective.⁷⁵ Approximately 1% of the 2,500 samples failed to com-

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69. Among those charged were David Brancato, a chemist who reviewed generic drug applications and pleaded guilty to accepting bribes of approximately $9,600, and his boss, Charles Chang, who pleaded guilty to racketeering charges for accepting almost $20,000 worth of “unlawful benefits.” Henig, supra note 47, at 6. As of January 1991, “five FDA employees, seven executives of generic drug firms, one consultant, and three manufacturing companies have been convicted on charges ranging from racketeering to giving and receiving thousands of dollars in cash, furniture, free trips, and other gratuities.” Paul W. Valentine, Former FDA Official Is Sentenced in Generic Drug Inquiry, WASH. POST, Jan. 24, 1991, at A9.

70. Vitarine Pharmaceuticals of Queens, N.Y. admitted to submitting as their generic version of Dyazide, the original Dyazide packaged in a Vitarine capsule, as well as making similar switches in four other generic drug applications. Henig, supra note 47, at 6.

71. Paul W. Valentine, $1 Million Fine Levied in Generic Drug Fraud, WASH. POST, Oct. 19, 1990, at A3. In a proceeding against the generic firm American Therapeutics, Inc., prosecutors filed a statement alleging that “company employees fabricated stability test results and back dated data on potency, content uniformity and hardness for various drugs. In other cases, they exaggerated the size of research batches to meet FDA standards . . . .” Id.


73. Id.

74. Valentine, supra note 71, at A3.

75. FDA’s Generic Drug Approval Process (Part 3): Hearings Before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce House of Representatives,
ply with the standards established by the United States Pharmacopoeia or the FDA—a ratio consistent with historical rates for brand name and generic drug products. Additionally, specialized inspections by the FDA identified seven firms having applications based “at least in part, on fraudulent or questionable data.” In each case, the FDA “requested a recall, changed that product’s bioequivalence rating, and/or proceeded to withdraw marketing approval.” By early 1990, approximately 63 products involving the seven firms had been affected out of a generic drug industry comprised of approximately 350 firms and 8,000 to 9,000 products. The series of specialized inspections also uncovered twelve other firms that deviated from FDA regulations on Good Manufacturing Practice; the Agency took regulatory action against these firms. Further, to insure that product safety was not in question, the FDA reviewed applications handled by three former FDA employees found guilty of accepting illegal gratuities as well as applications submitted by the four firms who offered the bribes.

As a result of what has been termed “the worst scandal in the history of the Food and Drug Administration,” the agency instituted new procedures to control and limit access of drug company officials to FDA reviewers. In addition, the Agency implemented procedures regarding the assignment of applications to ensure that certain firms are not arbitrarily treated in a preferential or discriminatory manner and mandated “ethics awareness training” for all FDA employees. Furthermore, in August 1989 the Agency announced plans to intensify its surveillance of the generic drug industry, reorganize the drug review program into a newly created office of generic drugs, establish an independent ombudsman to report directly to the FDA Commissioner, coordinate more closely with the Inspector General of the Department of Health and Human Services, lobby for legislation to

101st Cong., 1st Sess. 198-99 (1989) [hereinafter FDA Investigation Hearing (Part 3)] (reprinting the FDA “Interim Report on Generic Drugs” dated Nov. 17, 1989 and submitted by FDA Commissioner Frank E. Young)).

76. Id. at 199-200.
77. Id.
78. Rx for Generic Drug Safety Hearing, supra note 44, at 60 (statement of Dr. Carl C. Peck, Director, Center for Drug Evaluation and Research).
79. Id.
80. Id.
81. Id. at 61.
82. Id. at 60.
84. FDA Investigation Hearings (Part 2), supra note 49, at 74-75 (statement by FDA Commissioner Frank E. Young).
85. Id.
strengthen the Secretary of Health and Human Services' power to act against improprieties in connection with drug approval applications, and secure additional funding from Congress to implement these actions.\textsuperscript{86}

Despite the steps taken by the FDA to ensure that the generic drug supply is safe and effective, the public's confidence in the drugs remains shaken. A study comparing consumer perceptions of generic drugs before and after the scandal revealed that after the scandal, "consumers were more skeptical of the safety, effectiveness, and quality of generics; were less willing to use or recommend generics; and were even less likely to ask pharmacists about generics."\textsuperscript{87}

B. The Patent Term Restoration Provision

The effects of the Act's patent term restoration provision are less obvious than those of the ANDA provision. From the time of enactment through February 1988, at least sixty-five patents were granted patent term extension periods of no more than two years.\textsuperscript{88} When compared to the 201 ANDAs filed with the FDA on the first day that the Act took effect,\textsuperscript{89} this number appears relatively small. However, in making this comparison it is important to recognize that for each brand name drug whose patent term has expired, several different ANDAs may be filed.\textsuperscript{90} Furthermore, the initial rush of ANDA filings included many drugs whose patent terms had expired prior to the effective date of the Act.\textsuperscript{91}

Perhaps the best gauge for determining the effectiveness of the patent term extension provision is to examine the strength of research and development in the pharmaceutical industry. Proponents of the provision argued that "it would create a significant, new incentive which would result in increased expenditures for research and development, and ultimately in more innova-

\textsuperscript{86} FDA Investigation Hearing (Part 3), supra note 75, at 204-206 (FDA Interim Report).

\textsuperscript{87} Penalties Hearing 1990, supra note 67, at 86 (report by Mathew Perri, III, Ph.D. and Alan P. Wolfgang, Ph.D., College of Pharmacy, University of Georgia). In 1988, 16.1\% of those surveyed strongly agreed, 68.8\% agreed, 5.6\% disagreed, and 1.1\% strongly disagreed with the statement that "[g]eneric prescription medications are just as safe as brand name medications," compared with 10.2\% who strongly agreed, 48.8\% who agreed, 30.7\% who disagreed, and 4.7\% who strongly disagreed with the same statement in October of 1989. \textit{Id.} at 89 (Table 1).

\textsuperscript{88} Alan D. Lourie, A Review of Recent Patent Term Extension Data, 71 J. PAT. OFF. SOC'Y 171 (1989).

\textsuperscript{89} Hogan, supra note 13, at 850.

\textsuperscript{90} Generic Drugs: supra note 41, at 310 (explaining that "[t]here are more than 8000 generic clones of about 170 brand-name drugs.").

\textsuperscript{91} FDA Investigation Hearings (Part 2), supra note 49, at 70.
tive drugs." In 1987, the Pharmaceutical Manufacturing Association (PMA) estimated expenditures of $5 billion for discovering new life-saving medicines. By 1989, the PMA estimated that research and development expenditures had risen to $7.3 billion, or 16.3% of its sales compared to an average 3.4% of sales for other high-technology industries. Although the increase in expenditures reflects many factors including inflation, increased complexity of technology, and tax incentives, it indicates that research expenditures have increased significantly since passage of the Act.

The increased competition from generic drugs created by the ANDA provision is possibly a more significant factor in promoting research and development for pioneer drugs than the patent term extension provision. As recognized by Jacob Schein, Chief Executive Officer of the generic drug firm Henry Schein, "the 'speed with which the large drug companies accelerate their R&D programs and come up with new and exciting products' could blunt generics growth." Schein reasoned "that new drugs with increased effectiveness could undercut the older generics."

Although the market effects of the Act's patent term restoration provision are far from clear, the noninfringement clause of the provision has caused most of the legal debate. The noninfringement clause provides that "[i]t 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 . . . ." The noninfringement clause has "the net effect of reversing the holding of the Federal Circuit Court of Appeals in Roche Prod-

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94. Skyrocketing Prescription Drug Prices Hearings 1989, supra note 9, at 122-23.
95. Id. at 171.
96. Cristine Gorman, The Price Isn't Right, TIME, Jan. 8, 1990, at 57 ("[D]rug companies must contend with the increasing complex nature of medicine. Many of the 'simpler' bacterial and viral illnesses . . . have passed from the scene . . . . Finding treatments for [heart disease, diabetes, and Alzheimer's disease] and other chronic ailments requires more sophisticated research, lengthier study and, of course, larger research budgets.").
97. Skyrocketing Prescription Drug Prices Hearing 1989, supra note 9, at 4. Committee Chairman Senator David Pryor (D-Ark) argues that "[t]he American public is footing much of the bill for these companies' research and development costs . . . . For example, in 1985, . . . drug companies received R&D-related tax breaks of almost $1 billion, representing more than 24% of their tax expenditures." Senator Pryor continued stating that, "[t]he 1986 tax law provided even more liberal incentives for the drug companies in research and development and other tax breaks and subsidies."
98. Rhein, supra note 54, at 8.
99. Id.
ucts, Inc. v. Bolar Pharmaceutical Co., Inc.101 In Roche, the defendant, Bolar Pharmaceutical, a generic drug manufacturer, admitted to possessing Roche’s patented product, but argued that the use of the product was solely for purposes of performing tests necessary to obtain data for a new drug application before the FDA.102 The court found that such use constituted an act of infringement under 35 U.S.C. § 271(a) and refused to make an exception for testing necessary to gain regulatory approval.103 While the legislative reversal of Roche has been criticized as an unconstitutional taking under the Fifth Amendment of the U.S. Constitution,104 recent litigation has focused on the statutory scope of the provision.

In Eli Lilly and Co. v. Medtronic Inc.,105 the Supreme Court affirmed a Federal Circuit Court of Appeal’s decision that interpreted the noninfringement clause to include medical devices even though the particular provision refers only to “the manufacture, use, or sale of drugs.”106 Justice Scalia, writing for the majority, reasoned that “the phrase ‘a Federal law which regulates the manufacture, use or sale of drugs’ more naturally summons up the image of an entire statutory scheme of regulation”107 and that, “[i]f only

102. 733 F.2d at 860.
103. Id. at 863. 35 U.S.C. § 271(a) states, “Except as otherwise provided in this title, whoever without authority makes, uses, or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent.”

For an interesting constitutional challenge under Art. I, sec. 8, cl. 8 of the Constitution, (“Congress shall have the Power To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”), see Robert M. Patti, Section 202 of the Drug Price Competition and Patent Term Restoration Act — Has Congress Acted Constitutionally?, 69 J. PAT. OFF. SOC’Y 567 (1987) (arguing that the Constitution gives Congress the power to grant an exclusive right and that while Congress has the power to regulate the standards for awarding that exclusive right and the lifetime of that exclusive right, Congress has no power to make that right nonexclusive).
107. 110 S. Ct. at 2686-87.
[drug] patents were meant to be included, there were . . . infinitely more clear and simple ways of expressing that intent." 108 The Court rejected Eli Lilly's argument that the legislative history of the noninfringement provision mentions only drugs, 109 and instead focused on the "1984 Act taken as a whole." In viewing the Act as a whole, the Court deemed it "implausible" that Congress would have intended to give the owners of medical device patents the benefit of an extended patent life while awaiting FDA approval, 111 without also addressing the distortion in which generic manufacturers would be prevented from obtaining data to gain FDA approval so that the generic product could be marketed immediately upon the expiration of the patent. 112 Justice Kennedy, joined by Justice White, dissented from what he considered "the Court's decision contrary to the most plausible reading of the statutory language." 113

III. ARE THE OBJECTIVES OF THE ACT BEING MET?

The first objective of the Act was to make more low cost generic drugs available to the public. In regard to this objective, the Act has increased the availability of low cost generic drugs. 114 However, this increase has not come without a price. Once the patent term of a brand name medication expires, the availability of generic equivalents results in an immediate drop in the market share of the patented medication by as much as thirty-five percent during the first year. 115 PMA President Gerald J. Mossinghoff contends that the "market for brand name drugs virtually collapses, after the expiration of the patent, because of the Drug Price Competition and Patent Term Restoration Act of 1984." 116 The brand name industry, which relies on the sale of existing drugs to fund its research and development, 117 is forced to make up for lost revenues by raising the prices on brand name

108. Id.
109. Id. at 2688 n.2.
110. Id. at 2688.
111. 35 U.S.C. § 156(f)(1) specifically includes medical devices stating that "[f]or purposes of this section: (1) The term 'product' means: . . . (B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act".
112. 110 S. Ct. at 2690.
113. Id. at 2693 (Kennedy, J., dissenting).
114. See Generic Drugs, supra note 41, at 310. "The bioequivalence test [provided by the ANDA provision] allowed generic firms to market products relatively quickly and inexpensively. Soon after the 1984 law was passed, the FDA was being inundated with drug approval applications. Generic drugs now account for about one-third of all new prescriptions filled by pharmacists." Id.
117. Gorman, supra note 96, at 57.
drugs after a patent expires. Other companies continue to price brand name drugs as if the drugs were still under patent protection, even after a number of generic products have come on the market at prices considerably below that of the brand name drug. Thus, while the Act has helped provide for more low cost generic drugs, it has also increased the price of brand name drugs. This increase, along with the public’s shaken confidence in generic drugs in light of the generic drug scandal, tends to offset the Act’s desired effect of increasing the availability of low cost generic drugs.

The second objective of the Act was to create incentives for increased expenditures for research and development of products subject to premarket approval by the government. While research expenditures have risen significantly from $5 billion in 1987 to $7.3 billion in 1989, it is unclear how much of this increase is directly attributable to the Act’s patent term restoration provision and how much is attributable to other factors such as inflation, the “increasing complex nature of medicine” which “requires ... larger research budgets,” and tax incentives. Unlike the ANDA provision, the effects of the patent term restoration provision are “only now beginning to be felt,” with only a handful of products in their extended patent terms. Though “[s]ome experts believe [the patent term] extensions may ultimately be converted into profits worth billions to the pioneer companies,” it is likely that it will take years for producers of brand name drugs to stabilize their pricing strategies given the opposing effects of increased generic competition and extended patent terms.

IV. SUGGESTED CHANGES TO THE ACT

A number of proposals have been made for dealing with the consequences

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118. Id. at 58. “When generic versions of the potent heart medication Dyazide were introduced in the mid-1980s, the drug’s inventor, SmithKline Beckman, raised the compound’s price 23% ...” Id.

119. Skyrocketing Prescription Drug Prices Hearings 1989, supra note 9, at 195. In a comparison of average wholesale price increases for brand name drugs under patent protection (single source drugs) and brand name drugs whose patent term had expired (originator brand of multiple source drugs), Laughrey testified that those under patent protection averaged price increases of 7.9% in 1987 and 9% in 1988, whereas for those drugs whose patents had expired, the price increases were 6.9% in 1988 and 6.4% in 1988. Id. at 194.

120. Competitive Problems Hearing 1987, supra note 59, at 58.

121. Skyrocketing Prescription Drug Prices Hearings 1989, supra note 9, at 122-23.

122. Gorman, supra note 96, at 57.

123. Skyrocketing Prescription Drug Prices Hearings 1989, supra note 9, at 4. Committee Chairman Senator David Pryor argues that “[t]he 1986 tax law provided even more liberal incentives for the drug companies in research and development and other tax breaks and subsidies.” Id.

124. Id. at 155 (statement of Gerald Mossinghoff, PMA president).

125. Hogan, supra note 13, at 850.
of the increased availability of low cost generic drugs. These proposals have come primarily in response to the generic drug scandal. The most notable is the introduction of legislation by Congressman Dingell, whose subcommittee investigated the scandal.\footnote{H.R. 4810, 101st Cong., 2d Sess. (1990).} The legislation authorizes the Secretary of Health and Human Services to bar individuals and companies from submitting drug applications if previously convicted of illegal activities related to the development or approval process of a generic drug.\footnote{H.R. 4810 § 2.} Additionally, the Secretary is authorized to impose civil penalties on those convicted and to suspend or withdraw the approval of ANDAs obtained through fraudulent activity.\footnote{H.R. 4810 §§ 4-6.} The legislation also would give the inspector general of the Department of Health and Human Services the authority to conduct investigations regarding allegations of impropriety by the FDA in a wide range of areas.\footnote{H.R. 4810 § 8.} Finally, the bill includes a “sunshine provision” requiring public disclosure of the applicant, drug, and FDA reviewers for each ANDA submitted.\footnote{H.R. 4810 § 9.}

The debarment, withdrawal, suspension, and civil penalty provisions of the proposed legislation were criticized as being directed exclusively at the generic drug industry. James Benson, Acting Commissioner of the FDA, took the position that the sanctions should be “in place across the board for the products that the FDA regulates . . . .”\footnote{Penalties Hearing 1990, supra note 67, at 41.} On the other hand, the generic drug industry argued that the “selective focus” of a generics-only bill “sends the public a clear but negative message that generics are second-class medicine.”\footnote{Id. at 60 (statement of Dee Fensterer, President GPIA).} Congressman Bliley (R-Va.), a co-sponsor of the legislation, countered that “one of the principal reasons” for the abuses was the unique abbreviated nature of the generic drug approval process which “justifies the generic focus of our legislation.”\footnote{Id. at 95 (statement of Congressman Bliley).} The proposed legislation was not enacted prior to the expiration of the 101st Congress. However, a similar bill has been introduced recently and is pending.\footnote{See H.R. 2454, 102nd Cong., 1st Sess (1991).}

CONCLUSION

Seven years after the Drug Price Competition and Patent Term Restoration Act of 1984 became law, the twin objectives of Congress in passing the legislation are arguably being accomplished. The abbreviated new drug ap-
Application procedures provided for in the Act have resulted in dramatic growth in the lower priced generic prescription market. The effectiveness of the Act's objective in promoting research and development of new drugs is uncertain and should be continually monitored so that changes may be implemented if the industry weakens. Achievement of Congressional objectives under the Act has not come without disruption to the prescription drug market and legislation to strengthen the enforcement powers of the FDA to prevent abuse in the generic drug industry has been introduced. Perhaps only after passage of additional time may a more definitive assessment of whether the goals of the Act have been accomplished be appropriate.

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