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Patent Fairness Act of 1999: The Implications of Extending Patents for Pipeline Drugs

Shilpa Patel

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PATENT FAIRNESS ACT OF 1999: THE IMPLICATIONS OF EXTENDING PATENTS FOR PIPELINE DRUGS

I. INTRODUCTION

On April 28, 1999, during the 106th session of Congress, House Representative Ed Bryant introduced the Patent Fairness Act of 1999. On May 27, 1999, Senator Robert Torricelli introduced a similar measure, known as the Drug Patent Term Restoration Review Procedure Act of 1999. The proposed legislation is an attempt to extend the patent life up to an additional three years for the following pharmaceutical drugs: Claritin, Relafen, Daypro, Dardiogen-82, Dermatop, Nimtop, Eulexin, Penetrex. These drugs, referred to as "pipeline" drugs, had received a patent but were pending Federal Food and Drug Administration (hereinafter "FDA") approval in 1984 when the Drug Price Competition and Patent Term Restoration Act of 1984 (hereinafter "Patent Term Restoration Act") was enacted.

The Patent Term Restoration Act provides a five-year extension on patent life for pharmaceutical drugs that require FDA approval before hitting the market and whose patent life is reduced in obtaining such approval. The provision only applies if the drug obtains a patent or enters the FDA approval phase after the statute's enactment. Therefore, a special provision allowed the pipeline drugs to receive a maximum of a two-year extension, based partly on the assumption that these drugs would be approved within...
that time.\textsuperscript{8} However, some of these pipeline drugs spent between seven and twenty-two years awaiting FDA approval.\textsuperscript{9}

Supporters of the Patent Fairness Act argue that the legislation is an attempt to compensate the pipeline drug manufacturers for the unforeseen delays in obtaining FDA approval, which diminished the life of their patents. The proponents argue that the legislation establishes a fair and impartial process, and not a guarantee, for pipeline patentees, seeking restoration of lost patent life. Pipeline drugs were given only a two-year extension pursuant to the Patent Term Restoration Act, based on a miscalculation of approval time. At that time, FDA approval time averaged 2.25 years. However, some drugs, including the pipeline drugs, spent at least five years in the approval process.

The proponents attribute the delay to the shortage of resources at the FDA, rather than to the medical safety concerns of the products. Since Congress has extended patent life for similar inequities in the past, the proponents argue for the same treatment. Furthermore, the treatment of brand name drugs is quite disparate in comparison with generic drugs, which do not require nearly the same amount of time and money in drug development, and can often bypass most of the lengthy FDA approval process. Finally, other patented inventions, such as computer components, often receive the maximum patent life and require far less capital on development than pharmaceutical drugs.

The opponents argue that the proposed legislation gives the manufacturers of the pipeline drugs a windfall at the expense of consumers. The provisions of the legislation practically guarantee an extension, since the terms unfairly favor the patentee. Further, this issue, at least in the case of


\textsuperscript{9} See Marvin J. Powell, Independent Process for Fair Patent Review Will Assure Fairness, Advance Intellectual Property Rights, METROPOLITAN CORP. COUNS., June 1999, at 25, available in Westlaw, METCC Database (reporting that 17 of 123 pipeline drugs, 17 spent more than five years in the NDA [new drug approval] process after the completion of clinical trials. Several other pipeline drugs, Penetrex, Dermatop, Nimotop, Relafen, and Claritin were subjected to extraordinarily long FDA reviews of over seven years.
Claritin,\textsuperscript{10} has been debated before Congress and the extension has been denied on more than one occasion.

The purpose of the Patent Term Restoration Act was to encourage future development, and the pipeline drugs had already been developed at the time of the statute's enactment. The pipeline drug manufacturers, however, received more than they anticipated at the time they developed the drugs: a two-year extension pursuant to the Patent Term Restoration Act for all of the drugs, and additional time pursuant to the Uruguay Round Agreement Act for some. Furthermore, the brand name drug business, despite the cost of research and development, is earning significant profits and is one of the most profitable industries.

This note provides a background of the Patent Term Restoration Act of 1984, the proposed Patent Fairness Act, the Drug Patent Term Restoration Review Procedure Act, and then considers both the arguments in favor of and against the proposed legislation.

\section*{II. BACKGROUND}

\section*{A. PATENT TERM RESTORATION ACT OF 1984}

1. \textit{History}. The Drug Price Competition and Patent Term Restoration Act was enacted on September 24, 1984, as a compromise between brand name drug manufacturers and generic drug manufacturers. Since “a patent continues to run while the maker of the product is testing and awaiting \textit{[FDA]} approval to market it,”\textsuperscript{11} the brand name drug manufacturers wanted “restoration of some of the time lost on patent life while the product is awaiting pre-market approval.”\textsuperscript{12} By extending the life of a patent, the Act expected “to create a new incentive for increased expenditures for research and development of certain products which are subject to pre-market government approval.”\textsuperscript{13}

In exchange for a restoration term, generic drug makers received an abbreviated new drug approval (ANDA) procedure, whereby generic

\textsuperscript{10} Schering-Plough, the maker of Claritin is the major promoter of this legislation and has the most invested in its passage. Therefore, some of the arguments have focused primarily on Claritin.


\textsuperscript{13} \textit{Id.}
equivalents would surpass the lengthy FDA required clinical human testing for safety and effectiveness, provided the "generic [copy of any drug] is the same [or similar] as the original [patented and/or previously approved] drug." Furthermore, the Act provides "that it is not an act of patent infringement for a generic drug maker to import or to test a patented drug in preparation for seeking FDA approval if marketing of the drug would occur after expiration of the patent." Without an extensive FDA approval process and without waiting for the expiration of the patent to begin testing, the Act "makes more low cost generic drugs" available sooner.

2. Provisions. The Patent Term Restoration Act provides that 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 . . . from the original expiration date of the patent" if the following conditions are met: (1) an application for an extension is submitted by the owner of a patent or an agent before the expiration of the patent, (2) "the term of the patent has never been extended," (3) "the product has been subject to a regulatory review period before its commercial marketing or use," and (4) the product has been approved for commercial marketing for the first time.

The Patent Term Restoration Act provides that a patent term can be extended "by the time equal to the regulatory review period" with the following limitations. The extension is reduced (1) by the time the applicant failed to act with due diligence during the regulatory review period, and (2) by one-half of the testing phase. For drugs which received a patent or began the regulatory review after the statute’s enactment, the
period of extension cannot exceed five years.\textsuperscript{28} However, if the patent was issued and clinical testing had begun, but FDA approval for commercial marketing or use was pending at the time of enactment, the extension may not exceed two years.\textsuperscript{29} The extension is then reduced so that the remaining term of the patent after the regulatory review period does not exceed fourteen years.\textsuperscript{30} Finally, if a product has more than one patent, only one of the patents will be eligible for an extension.\textsuperscript{31}

Generic drug manufacturers may file an abbreviated new drug application (ANDA).\textsuperscript{32} The application must show that the proposed conditions of use,\textsuperscript{33} the active ingredients,\textsuperscript{34} “the route of administration, the dosage form, and the strength,”\textsuperscript{35} and the labeling\textsuperscript{36} of the new drug are the same\textsuperscript{37} as a previously approved drug (referred in the statute as a “listed drug.”\textsuperscript{38}) The application must also show that the new drug is a bioequivalent\textsuperscript{39} of a listed drug.

The applicant must certify one of the following: (1) the patent information of the listed drug has not been filed,\textsuperscript{41} (2) the patent has

\begin{itemize}
  \item \textsuperscript{28} 35 U.S.C. § 156(g)(6)(A), § 156(c)(6)(B).
  \item \textsuperscript{29} 35 U.S.C. § 156(g)(6)(C).
  \item \textsuperscript{30} Id. § 156(c)(3).
  \item \textsuperscript{31} Id. § 156(c)(4).
  \item \textsuperscript{32} 21 U.S.C. § 355(j) (1994).
  \item \textsuperscript{33} Id. § 355(j)(2)(A)(i).
  \item \textsuperscript{34} Id. § 355(j)(2)(A)(ii).
  \item \textsuperscript{35} Id. § 355(j)(2)(A)(iii).
  \item \textsuperscript{36} Id. § 355(j)(2)(A)(v).
  \item \textsuperscript{37} If the new drug has a different active ingredient or route of administration, dosage form, or strength than that of a listed drug, the applicant may have to conduct clinical investigations to show the safety and effectiveness of the new drug or any of its active ingredients, route of administration, dosage form, or strength which differs from the listed drug to receive approval. 21 U.S.C. § 355(j)(2)(C)(i). Further, the applicant must “show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug . . . the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use previously approved for a listed drug.” Id. § 355(j)(2)(A)(iv). However, the application will be rejected if any drug with a different active ingredient cannot “be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.” Id. § 355(j)(2)(C)(ii).
  \item \textsuperscript{38} Id. § 355(j)(2)(A)(vii)(I).
  \item \textsuperscript{39} A drug shall be considered a bioequivalent of a listed drug if the rate and extent of absorption of the drug do not show a significant difference from that of the listed drug when administered under similar experimental conditions in either a single dose or multiple doses. Id. § 355(j)(8)(B)(i).
  \item \textsuperscript{40} 21 U.S.C. § 355(j)(2)(A)(iv).
  \item \textsuperscript{41} Id. § 355(j)(2)(A)(vii)(I).
\end{itemize}
expired, the date on which such patent will expire, or the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."

The application is given approval or disapproval within 180 days. If the generic drug falls into the first or second category, the approval of such application is immediate, whereas under the third classification, the approval is effective upon the date of the patent expiration. If the generic drug falls under the fourth category, the applicant must give notice to the patent owner. Then, the patent owner has forty-five days to file an action for infringement. If no action is filed, approval is effective immediately. If such action is brought, approval depends upon the court’s decision.

Finally, the Patent Term Restoration Act provides that generic drug manufacturers can begin testing before the patent on the brand name drug has expired. Thereby, the generic drug would hit the market as soon as the patent expired, since

it shall not be an act of infringement to make, use, offer to sell or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of

45 Id. § 355(j)(5)(A).
46 Id. § 355(j)(4)(B)(i).
48 The notice shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid or will not be infringed.

49 Id. § 355(j)(2)(B)(ii).
50 Id. § 355(j)(2)(B)(i).
51 Id. § 355(j)(4)(B)(i).
52 "If ... the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision." 21 U.S.C. § 355(j)(4)(B)(ii)(I). "If ... the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35." Id. § 355(j)(4)(B)(ii)(II).
information under a Federal law which regulates the manufacture, use, or sale of drugs.\textsuperscript{53}

In conclusion, the Patent Term Restoration Act was a win-win situation that benefitted both the brand name drug manufacturers, who received additional time on their patents, and the generic manufacturers, who obtained an abbreviated FDA approval process, and could begin research and development on drugs before the expiration of a patent.

B. PROPOSED LEGISLATION: THE PATENT FAIRNESS ACT OF 1999 BY THE HOUSE OF REPRESENTATIVES

The proposed Patent Fairness Act applies to drugs whose patents were in force on September 24, 1984\textsuperscript{54} and claims a drug product,\textsuperscript{55} a method of using a drug product,\textsuperscript{56} or a method of manufacturing a drug product.\textsuperscript{57} The patent owner or an agent must submit an application to the Commissioner of the Patent and Trademark Office.\textsuperscript{58} Parties who may be aggrieved by the restoration may also submit information.\textsuperscript{59}

The proposed Act provides that the Commissioner shall restore the term of the patent if the regulatory period\textsuperscript{60} exceeded sixty months,\textsuperscript{61} and "there is not substantial evidence overcoming the rebuttable presumption that the applicant for the patent term restoration for the drug product acted with due diligence . . . during the [regulatory] period."\textsuperscript{62} The Commissioner, in making a determination, may request and obtain records from the FDA.\textsuperscript{63}

The restoration term is equal to the regulatory period reduced by any period in which the applicant failed to act with due diligence.\textsuperscript{64} The

\textsuperscript{56} Id. § 2(a)(1)(b)(1)(B).
\textsuperscript{57} Id. § 2(a)(1)(b)(1)(C).
\textsuperscript{58} Id. § 2(a)(1)(b)(2).
\textsuperscript{59} Id.
\textsuperscript{62} Id. § 2(a)(1)(b)(2)(B).
\textsuperscript{63} Id. § 2(a)(1)(b)(3).
\textsuperscript{64} Id. § 2(a)(1)(b)(4)(A).
restoration term plus any previous restoration extensions pursuant to the Patent Term Restoration Act of 1984 cannot exceed five years, and the total patent term after the FDA approval cannot exceed 14 years. Since the pipeline drugs have already been given a two-year extension, they would only be eligible for a maximum extension of three years.

Procedurally, the patent owner would have ninety days from the enactment of the Act to file for an extension. Furthermore, the Act provides that within thirty days, the Commissioner shall publish a notice of the application in the Federal Register. Within thirty days of the published notice, aggrieved parties must submit information or comments concerning the application. Upon the expiration of the thirty days, the Commissioner has seven days to forward the aggrieved party’s comments to the applicant.

The applicant can submit a response to the Commissioner within thirty days of the receipt of the comments. Once the Commissioner receives a response, a determination of whether to grant the extension is made within thirty days. Therefore, the total process would take a maximum of 127 days (approximately four months) from the time of filing to the Commissioner’s decision.

If the patent, which has met the above standards, would expire before a determination would be made, the patent is automatically extended until such determination is made to grant the extension, or sixty days after the determination is made not to extend. During the sixty-day period, the applicant may appeal to the Federal Circuit Court of Appeals for “an order directing the Commissioner to extend the patent pending judicial review.”

If other drug manufacturers have begun the process to obtain FDA approval for equivalents of the pipeline drugs, the Patent Fairness Act provides for some compensation. If an abbreviated new drug application (ANDA), has been filed with the Food and Drug Administration and “such

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65 Id. § (2)(a)(1)(b)(4)(C).
67 Id. § (2)(a)(1)(6)(A).
68 Id. § (2)(a)(1)(b)(6)(B)(i).
69 Id. § (2)(a)(1)(b)(6)(B)(iii).
72 Id. § (2)(a)(1)(b)(6)(C)(i).
73 Id. § (2)(a)(1)(b)(6)(C)(ii).
74 Id. § (2)(a)(1)(b)(6)(C)(iii).
75 Id. § (2)(a)(1)(b)(6)(C).
application has been found by the [FDA] on or before the date of the enactment of this section to be sufficiently complete to permit substantive review, such person shall be entitled to compensation of $1,000,000 by the patent owner. The patent owner’s liability, however, cannot exceed $5,000,000. Otherwise, the filing of an ANDA does not affect the grant of the restoration term.

Finally, within one year after the enactment, the Commissioner of the Patent and Trademark office shall submit a report to Congress evaluating the patent term restoration review procedure and shall make a recommendation of “whether Congress should consider establishing such a patent term review procedure for patents not covered by such section.”

C. PROPOSED LEGISLATION: THE DRUG PATENT TERM RESTORATION REVIEW PROCEDURE ACT OF 1999 BY THE SENATE

In contrast to the Patent Fairness Act, the proposed Drug Patent Term Restoration Review Procedure Act in the Senate places the burden on the patentee to establish by “clear and convincing evidence that [he or she] acted with due diligence.” The patentee must also show that “granting the patent restoration would not be detrimental to the public interest and the interest of fairness.” The Commissioner, in making a determination, may and should consider factors such as the commercial availability of alternative treatments for the condition treated by the patented drug, the impact of the tension on society’s interest in encouraging and rewarding pharmaceutical research and innovation, and the unfairness to the patentee in denying the application. Lastly, compensation is $2 million to the drug manufacturers,

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76 Patent Fairness Act, § (2)(d).
77 Id. § (2)(d)(2)(A).
78 Id. § (2)(e).
80 Drug Patent Term Restoration Review Procedure Act, § 1(b)(1)(b)(2)(A)(iii); see also Legislation: Senate Bill Would Extend Patent Term for Drugs Stalled in Regulatory "Pipeline," BNA PAT., TRADEMARK & COPYRIGHT L. DAILY NEWS, June 16, 1999, available in Westlaw, BNA-PTD Database ("S. 1172 makes term extension further contingent on a showing that it would not be ‘detrimental to the public interest and the interest of fairness.’").
who have begun to seek FDA approval for equivalents of the patented drug, with the liability cap set at $10 million. Other than the above mentioned differences, the two proposals are similar.

D. DRUGS AFFECTED

The pipeline drugs whose patents are still running that would be affected by the pending legislation are: Claritin, an antihistamine; Relafen, an arthritis drug; Cardigen-82, a diagnostic imaging agent; Nimotop, a drug used in the treatment of head trauma; Dermatop, a skin rash drug; Penetrex, an urinary tract infection medication; and Eulexin, a prostate cancer treatment.

The table below shows more information about the drugs.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Maker</th>
<th>Patent No.</th>
<th>Expiration Date of Patent</th>
<th>Date of FDA Approval</th>
<th>Total Patent Life After Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claritin*</td>
<td>Schering-Plough</td>
<td>4,282,233</td>
<td>06-19-02</td>
<td>04-12-93</td>
<td>9.2 years</td>
</tr>
<tr>
<td>Relafen</td>
<td>SmithKline Beecham Corp.</td>
<td>4,420,639</td>
<td>12-13-02</td>
<td>12-24-91</td>
<td>11.0 years</td>
</tr>
<tr>
<td>Daypro*</td>
<td>G.D. Searle</td>
<td>4,190,584</td>
<td>08-08-99</td>
<td>10-29-92</td>
<td>6.8 years</td>
</tr>
<tr>
<td>Cardiogen-82</td>
<td>Bracco Diag.</td>
<td>4,400,358</td>
<td>08-23-02</td>
<td>12-29-89</td>
<td>12.7 years</td>
</tr>
<tr>
<td>Eulexin</td>
<td>Schering-Plough</td>
<td>4,329,364</td>
<td>05-11-01</td>
<td>01-27-89</td>
<td>12.3 years</td>
</tr>
<tr>
<td>Nimotop</td>
<td>Bayer</td>
<td>4,406,906</td>
<td>09-27-02</td>
<td>12-28-88</td>
<td>13.8 years</td>
</tr>
<tr>
<td>Dermatop*</td>
<td>Hoechst Marion Roussel</td>
<td>4,242,334</td>
<td>08-02-00</td>
<td>10-05-93</td>
<td>6.8 years</td>
</tr>
<tr>
<td>Penetrex</td>
<td>Rhone-Poulenc Rorer</td>
<td>4,359,578</td>
<td>11-16-01</td>
<td>12-31-91</td>
<td>9.9 years</td>
</tr>
</tbody>
</table>

*These drugs received an additional extension pursuant to the Uruguay Round Agreement Act, of 22.5 months, 5.3 months, and 7.1 months, respectively.

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83 Id. § 1(e).
84 Bills Seek Patent Extensions for Claritin, Other Prescription Drugs, ANDREWS INTELL. PROP. LITIG. REP., October 14, 1999, available in Westlaw, ANIPLR Database.
III. ANALYSIS

A. THE PROVISIONS OF THE ACT

1. Proponents.

a. A Process, Not A Predetermined Outcome. Proponents of the Patent Fairness Act insist that this legislation establishes a fair and consistent process, and not a predetermined outcome, to decide whether to restore lost patent life due to delays in FDA approval. The proponents argue that individual cases of inequities are often overlooked by statutes, such as the Patent Term Restoration Act, and therefore warrant special legislation. An example of such inequity would be a longer than necessary or expected FDA regulatory review period, which significantly reduces the life of the patent. Therefore, the legislation intends to send the message that diligence in seeking FDA approval will be rewarded.

Thus far, Congress has tackled each patent extension situation on an ad hoc, case-by-case basis, which is time-consuming and inefficient for both Congress and the drug company that is seeking an extension. Often "[p]atent extensions—regardless of their merits— are snuck into a bill in the middle of the night, by some [c]ongressman or [s]enator, regardless of the consequences." The restoration of patent life is a general problem, and each company lobbying for its own patent extension may result in even more inequities. For example, some companies may not have the resources or money to successfully lobby for relief. Therefore, establishing a process...
whereby the companies may seek redress would be a more effective and practical method.\textsuperscript{92}

A company that believes its product was unintentionally deprived of patent protection should and must have the opportunity to present its case.\textsuperscript{93} The process, akin to a court hearing, will be conducted in a public forum, by the Patent & Trademark Office (PTO), an independent, non-political review board subject to judicial review. The proponents believe that “[t]he Patent and Trademark Office [rather than Congress or even the Food and Drug Administration] is the right place to hold a hearing about these issues, because these issues involve questions not of medical research, but go to the core of the definition of patent life.”\textsuperscript{94} This process will “ensure that all who seek private relief are treated with uniform fairness.”\textsuperscript{95} “The review board would be bound by objective criteria,”\textsuperscript{96} and “there is no preferential treatment for any affected pipeline drug.”\textsuperscript{97} Thus the legislation protects patent integrity\textsuperscript{98} and takes politics out of the equation.\textsuperscript{99}

2. Opponents.

a. A Virtual Guarantee of an Extension. Opponents argue that the legislation “virtually guarantee[s] a patent extension [for the pipeline drugs].”\textsuperscript{100} The legislation grants an extension where “there is no substantial evidence overcoming the rebuttable presumption that the applicant for patent term restoration for the drug product acted with due diligence . . . during the [regulatory period].”\textsuperscript{101} The brand name drug manufacturers can easily satisfy the due diligence requirement, since “[d]ue diligence in this case means little more than the applicant was actively seeking to have the patent

\textsuperscript{92} \textit{Hearings, supra} note 8 (statement of Peter Barton Hutt).


\textsuperscript{95} \textit{Hearings, supra} note 94 (statement of Lehman, J.).

\textsuperscript{96} 145 CONG. REC. E796-01.

\textsuperscript{97} \textit{Id.}

\textsuperscript{98} \textit{Hearings, supra} note 87 (statement of Rep. Bryant).

\textsuperscript{99} 145 CONG. REC. E796-01.


approved." In fact, no case law exists dealing with the issue of due diligence with regard to the patent extensions.

More importantly, because the patentee gets a presumption of due diligence, the burden to overcome the presumption is on the wrong party. Only an aggrieved party, such as a generic drug manufacturer would challenge the extension, but that "party may not have access to the FDA records or to the company records to overcome the presumption."

Another objection to the legislation is the role of the Patent and Trademark Office (PTO). The opponents argue that there is "[no] credible [evidence] that the [PTO] has sufficient knowledge [and understanding] of the FDA and its processes or pharmaceutical policy [to justify] this delegation of authority." Also, the PTO may "potentially undercut [the] scientific judgments made by the FDA and its advisory committees." The FDA's participation is not required, but rather the FDA is given a significant consultative role. However, questions may arise about the impartiality of the FDA, given that the agency itself might have been at fault for the delays.

Finally, the applicant may get an extension just by initiating the process. Should an extension be denied by the PTO, the applicant can appeal to the Federal Circuit Court of Appeals. Such appeals may prevent the hearing of the patent claims before the expiration of the patent due to the backlog in courts. Therefore, while the court is reviewing the case, the patent is automatically extended. The patents of the pipeline drugs are due to expire

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102 Hearings, supra note 100 (statement of Hon. Berry).
104 Id.
105 Id.
106 PTO Not Qualified to Judge FDA Review of "Pipeline" Products - Barr, THE PINK SHEET, August 9, 1999, available in 1999 WL 8676595 (quoting Sen. Leahy (D-Vt.)).
107 Id.
108 Id.
109 PTO Not Qualified to Judge FDA Review of "Pipeline" Products - Barr, supra note 106.
soon, and thus there is a high likelihood that the patents will need to be extended pending this process. Thereby, the patentee may obtain an extension, even if later it is shown that the patentee initially caused the FDA delays.

b. Other Alternatives Should Be Pursued. Some opponents believe that rather than spending time and resources on this legislation, the pharmaceutical industry would be better served by pursuing other alternatives. One recommendation is placing "a [legislative cap] on prices which may be charged for drugs, perhaps tied to the actual expense put into the research (divided by the number of potential consumers)." Another example is a measure "reducing Federal Food and Drug Administration approval times, if it is done without sacrificing safety." Thereby, both the drug industry and consumers would benefit, rather than only the brand name drug manufacturers, as in this case. The Coalition for Affordable Pharmaceuticals has suggested: "closing loopholes, speeding [FDA] approvals, and expanding coverage to new classes of drugs such as generic biotechnology derived-drug products." Finally, another solution may be to give all patented drugs the same post-market exclusivity period, rather than extending patents on a case-by-case basis.

c. Issue Has Already Been Debated. Opponents point out that Schering-Plough, the maker of Claritin, has already had the opportunity on more than one occasion to present its case. Soon after Congress extended the effective patent life of Daypro by roughly five years in 1996, Schering-Plough began lobbying for extension of the Claritin patent. Schering-Plough has reportedly spent over $11 million on lobbying over the past three years.

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114 Id.

115 Hearings, supra note 103 (statement of Bruce Downey).

116 Drugs: Generic Drug Makers, Consumer Advocates Oppose Extending Patents for Pipeline Drugs, BNA PAT., TRADEMARK & COPYRIGHT L. DAILY NEWS, August 6, 1999, available in Westlaw, BNA-PTD Database.


118 Babcock, supra note 117.

Schering-Plough lobbied tenaciously to add this monopoly extension to the following bills: Omnibus Patent Act of 1997, 120 1998 Omnibus Appropriations Bill, and Omnibus Appropriations Act for fiscal year 1999. 121 One opponent characterized the last attempt as “an effort that continued until the bitter end despite news reports exposing the provision as another infamous ‘special interest’ rider.” 122 The extensions were debated and always denied.123

B. THE PURPOSE OF THE PATENT TERM RESTORATION ACT

1. Proponents. Short Approval Time for Pipeline Drugs Assumption. The proponents cite two fundamental reasons as to why the two-year limitation was included for pipeline drugs: (1) an incentive to continue the FDA approval process and (2) an assumption that the pipeline drugs would be approved shortly after the enactment of the 1984 legislation. 124 Manufacturers who had begun to seek FDA approval by submitting an Investigative New Drug application “had already made the decision to invest resources in the drug and therefore less of an economic incentive was needed to assure continued pursuit of the drug to final FDA approval—particularly when it was anticipated that approval would come not long after enactment of the legislation.” 125 Accordingly, an extension of two years was given as an incentive to complete the FDA approval process and market the drugs. 126

The drafters of the Patent Term Restoration Act gave the pipeline drugs only a two-year extension based on the assumption that since the average time for FDA approval was 2.25 years at that time, 127 approval time would be approximately the same for the pipeline drugs. Therefore, a five-year restoration period seemed excessive and unjustified, but a two-year period

available in 1999 WL 26196449.

120 Besides seeking an extension, “at the end of the 1997 session, there was an effort to award additional market exclusivity for specific products in exchange for a 3% royalty payment to the National Institutes of Health, with no prohibition against the companies passing on this royalty payment to consumers.”

Hearings, supra note 111 (statement of Andrew M. Berdon).

121 Id.

122 Id.

123 Hearings, supra note 103 (statement of Bruce Downey).

124 Hearings, supra note 8 (statement of Peter Barton Hutt).

125 Id.

126 Id.

127 Id.
seemed appropriate given the anticipated short period of time between the
date of enactment and the date of FDA approval for the pipeline drugs. 128
For the most part, the assumption proved to be true. 129

However, for all of the pipeline drugs, that are the subject of the
legislation, the approval time was well beyond two years, a result not
contemplated by the drafters. 130 Total regulatory time was over seven years
for Penetrex, Dermatop, Nimotop, Relafen, and Cardiogen-82, and over 21.3
years for Daypro. 131 Therefore, the proponents argue that some measures
need to be taken to compensate for the inequities that resulted from the
miscalculation of approval time, 132 and to fulfill the intent of the Patent
Term Restoration Act.

2. Opponents.

argue that the policy of the Patent Term Restoration Act was to encourage
future investment in research and development and not to reward past
investment. 133 Pipeline drugs obviously did not need this incentive, 134 since
they were not new and innovative drug products, but drugs that were
already under review by the FDA at the time of negotiations of the Patent
Term Restoration Act. 135 Further, during the negotiations, no dissident
pharmaceutical manufacturer challenged the two-year limit on patent
extensions for pipeline drugs. 136

Therefore, according to Andrew M. Berdon:

The decision to grant a two-year extension to the pipeline
drugs was a carefully considered policy decision to create a
process which has proven successful in assuring high-quality
research and development in conjunction with providing

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128 Id.
129 Id.
130 Id.
131 Powell, supra note 9.
132 Hearings, supra note 8 (statement of Peter Barton Hutt).
133 Frederick, supra note 3. The article reports that the co-author of the Patent Term Restoration Act,
Representative Henry Waxman, has recently stated that pipeline drugs did not receive five years because
the point of the patent extensions was to encourage the research and development of future products.
134 Hearings, supra note 100 (statement of Judge Marion Berry).
135 Hearings, supra note 111 (statement of Andrew M. Berdon).
136 Alfred B. Engelberg, Special Patent Provisions for Pharmaceuticals: Have They Outlived Their
access to affordable pharmaceuticals in a competitive marketplace.

With H.R. 1598 [the Patent Fairness Act], certain brand name companies, led by Schering-Plough Corporation, are selectively attempting to undo the policy decision struck in 1984—the policy that all sides agreed to—in order to extend their monopoly periods at the expense of competition, consumer savings, and healthcare costs without a corresponding benefit to the consumer.137

The pipeline drugs received the appropriate patent life extensions and "[t]hus, the recent claims by pipeline patent owners that they were inadvertently shortchanged by the 1984 Act and deserve additional extensions as a matter of equity is contradicted by the legislative history of the Act."138

In *Merck & Co. v. Kessler*, the court stated that "[t]his restoration period does not recover the full time lost from the patent term due to FDA's premarket approval process but merely 'ameliorates the loss incurred when patent terms tick away while the patented product is awaiting [FDA's] regulatory approval for marketing.'"139

*b. Awareness of the Approval Process.* Finally, drug manufacturers were already aware of the interplay between the patent system and FDA approval for pharmaceuticals before the development of their drugs.140 Therefore, the drug manufacturers made an informed decision to develop the pipeline drugs.141 Furthermore, after FDA approval, the manufacturers were aware of how much time they had remaining on their patents.142 Before marketing the pipeline drugs, the companies most likely established a price that would at a minimum recover their original investment and make a reasonable return.143 Therefore, granting up to three additional years of monopoly

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137 *Id.*
140 *Hearings, supra* note 100 (statement of Hon. Berry).
141 *Id.*
142 *Id.*
143 *Id.*
pricing rights for these products will result in a windfall of billions of dollars.144

c. Two Extensions Already In Existence.145 Schering-Plough has already received two extensions. Both were "unanticipated" when it first began development of Claritin. All of the pipeline drugs received a two-year extension pursuant to the Patent Term Restoration Act of 1984. With the enactment of the Uruguay Round Agreement Act (URAA) of 1994146 and the holding of Merck & Co. v. Kessler, some of the pipeline patents, including Claritin, received additional patent time.

Pursuant to the URAA, which was enacted on December 8, 1994, the United States changed the term of patents from the seventeen years from issuance to twenty years from filing of the patent application.147 As a result of this statute, patents issued from all applications (whether original application, or continuation, divisional or continuation-in-part of pending applications) filed on and after June 8, 1995, will have a term of twenty years from the date of the original filing.148 However, patents in force and patents based on an application pending in the Patent and Trademark Office before June 8, 1995 are entitled to the greater of (1) the seventeen year term from issuance or (2) the twenty year term from filing.149

In Merck & Co. v. Kessler, each of the drug patents received a two-year extension pursuant to the Patent Term Restoration Act.150 The URAA did not address whether the patents issued before June 8, 1995 and which had received a restoration extension under the Patent Term Restoration Act would be entitled to have the additional time added to the twenty years from

144 hearings, supra note 100 (statement of Judge Marion Berry).
145 hearings, supra note 103 (statement of Bruce L. Downey).
147 id.
148 id. § 154(a)(2). the section states
[3]subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the united states or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.
149 id. § 154(c)(1). the section reads
[1]the term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the uruguay round agreements act shall be the greater of the 20-year term as provided in subsection (a) or 17 years from grant, subject to any terminal disclaimers.
150 merck & co. v. kessler, 80 f.3d 1543, 1546, 38 u.s.p.q.2d (bna) 1347 (fed. cir. 1996).
filing. The PTO and FDA took the position that such patents would have to choose between seventeen years from issuance plus the restoration extension or twenty years from filing without the restoration add-on.\textsuperscript{151} The PTO, relying on the language of 35 U.S.C. § 156(a), which states that the term of a patent “shall be extended from the original expiration date of the patent,”\textsuperscript{152} interpreted “original expiration date” to mean the date seventeen years from issuance.\textsuperscript{153} Further, the PTO had concerns that “adding the restoration extension to the twenty-year term violates the fourteen-year cap of § 156(c)(3), absent recalculation.”\textsuperscript{154} Disagreeing with the PTO and FDA, the holders of such patents filed suit.\textsuperscript{155} Of the twelve patents at issue in the case, only five were in force due to the restoration extension.\textsuperscript{156} The rest of the patents would have been in force on June 8, 1995, even without the restoration extension.\textsuperscript{157}

The United States Court of Appeals, Federal Circuit noted that

The purpose of the URRA was not to extend patent terms, although it has that effect in some cases, but to harmonize the term provision of United States patent law with that of our leading trading partners which grant a patent term of 20 years from the date of filing of the patent application.\textsuperscript{158}

Thereby, the court held that “pre-June 8, 1995 patents are entitled to add on the restoration extension to a 20-year from filing term regardless of when such extension is granted except for those patents kept in force on June 8, 1995, only because of a restoration extension.”\textsuperscript{159} The court rejected the PTO’s interpretation, concluding that the “legislative history indicates that the phrase ‘original expiration date’” was inserted to mean “‘the term of the patent had never been extended by a prior restoration extension.’” And, the date was not limited to just one date.\textsuperscript{160} Furthermore, the court held that

\textsuperscript{151} Id. at 1548.
\textsuperscript{152} Id. (quoting 35 U.S.C. § 156(a) (1994)).
\textsuperscript{153} Id.
\textsuperscript{154} Id.
\textsuperscript{155} Id.
\textsuperscript{156} Merck, 80 F.3d at 1548.
\textsuperscript{157} Id.
\textsuperscript{158} Id. at 1547.
\textsuperscript{159} Id. at 1550.
\textsuperscript{160} Merck, 80 F.3d at 1550.
"the 14-year period is a mandatory limit on the extended term and must be given effect. Thus, some pre-June 8, 1995 extensions may need adjustment."^{161}

C. THE SOURCE OF DELAY OF FDA APPROVAL

1. Proponent.
   a. Delay Due to FDA. The proponents of the legislation argue that the patentees were not at fault for the delays at the FDA level. They cite the shortage of personnel and resources at the FDA as the source of the delays,\(^{162}\) rather than issues concerning the patented product's medical safety.\(^{163}\) Problems at the FDA in the 1980's ultimately led Congress to pass the Prescription Drug User Fee Act of 1992.\(^{164}\) Further, since Congress has previously extended patents for delays caused by the FDA, it seems only just that Schering-Plough and the makers of the other pipeline drugs receive the same treatment.

   b. Comparable to Other Statutes. Proponents of the Patent Fairness Act point out that the Patent Term Restoration Act made "no attempt to address unusual or unique situations of lengthy regulatory review for which accepted principles of fairness and equity would justify exceptions."\(^{165}\) The proponents point to seven specific occasions when Congress "has enacted legislation to address particular FDA-regulated products where application of the general rules in the 1984 Act would have been unfair and inequitable."\(^{166}\) They cite the following products: Aspartame (food additive), Forane (new drug), Impro (new animal drug), the oral hypoglycemia drugs, Glyburide (new drug), Lopid (new drug), Olestra (food additive), 2nd Daypro (new drug). The history behind the extension of the patents for the above products warrants some discussion.

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\(^{161}\) *Id.* at 1551.
\(^{162}\) *Hearings, supra* note 8 (statement of Peter Barton Hutt).
\(^{163}\) *Hearings, supra* note 86 (statement of Rep. McDermott).
\(^{164}\) *Hearings, supra* note 8 (statement of Peter Barton Hutt).
\(^{165}\) *Id.*
Of the seven products, four products, Aspartame, Forane, Impro and the oral hypoglycemic drugs were not subject to the Patent Term Restoration Act. However, Congress did enact special patent extensions based on extenuating circumstances. In the Aspartame, Forane, and oral hypoglycemia drugs cases, the extensions covered delays above and beyond the normal regulatory review period, which were caused by the FDA and not the patentee. In the Impro case, the delay was caused by the United States Department of Agriculture (USDA), resulting in an almost zero patent life after approval. In all of these cases, the patentee had submitted the necessary information, but due to FDA errors, the marketing of their products were delayed more than necessary.

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167 The Aspartame patent was not subject to the Patent Term Restoration Act, since the FDA approved it before 1984. Nevertheless, Aspartame received almost a six-year extension. The developers of Aspartame, G.D. Searle & Co., received a patent in 1970 and received FDA approval in 1974. However, when two private parties objected to the approval, raising questions about the authenticity of the laboratory reports, the FDA imposed a stay of approval on December 5, 1975. After almost six years, the FDA formally declared that the laboratory results submitted by Searle were in fact authentic, and that Searle was not at fault for the delay. Aspartame was granted final approval for commercial marketing effective October 5, 1981. The patent extension covered the period from imposition of the stay to the final approval. Cooper, supra note 166, at 65.

168 The story of Forane is similar to aspartame. Forane was patented in 1970. During the FDA approval process, the FDA notified the patentee, by letter dated February 20, 1976, that the product’s new drug application was not approved due to a report raised by a doctor that the Forane’s inhalation agents may have carcinogenic potential. Later, the doctor’s report was found to be deficient, and on May 26, 1981, Forane received final FDA approval after more than ten years after the issuance of its patent. Here again, the makers of Forane, Ohio Medical Anesthetics, Inc., were not at fault, and Forane’s patent was extended for five years and three months, covering the period from the delay due to the doctor’s study to the final approval. Cooper, supra note 166, at 66.

169 Impro is a veterinary biological product subject to approval by the United States Department of Agriculture (USDA). The USDA denied approval, concluding the product was ineffective based on its own study on Impro. Ultimately, a federal court found the USDA report was false and misleading. However, the delay in approval and the litigation resulted in a lost patent life of 16 years. Therefore, Congress granted a fifteen-year patent extension. Cooper, supra note 166, at 67-68.

170 Five oral hypoglycemic drug patents were extended to an uniform expiration date, resulting in extensions from three years to nearly six years. Although the FDA concluded the drugs were safe and effective in 1974, they were not approved for marketing due to an issue of class labeling. The patentees offered to market with temporary labeling, but the FDA denied the request. Even after the FDA gave assurances that the issue would be resolved quickly, ten years would pass before the issue would be resolved. Cooper, supra note 166, at 68-69.

171 Hearings, supra note 8 (statement of Peter Barton Hutt).

172 Id.

173 See supra text accompanying note 169.

174 See supra text accompanying notes 167-70.
The patent on Lopid, a cardiovascular drug, was specially extended by Congress following the enactment of the Patent Term Restoration Act. The patent was issued in 1972. In 1981, Lopid received approval on a limited basis, provided that the makers, Warner-Lambert, continued financing a heart attack prevention study by the Helsinki, Finland Heart Council. Upon completion of the five-year study, Warner-Lambert expected FDA approval on expanded uses of Lopid and marketing exclusivity for five years. With the enactment of the PTR Act, Lopid would only be entitled to a patent extension of two years (since the patent was approved before 1984 and FDA approval was pending), and generic equivalents would be able to compete immediately upon expiration of the patent. In light of the potential harm to Warner-Lambert, Congress granted an extension of three years and six months. In April 1996, Congress passed a bill to extend the five-year marketing exclusivity of Daypro, a nonsteroid, antiinflammatory drug (NSAID), known as Oxaprozin, for an additional two years. The makers of Daypro

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PATENT TERM EXTENSION. (a) GENERAL RULE.—Except as provided in subsection (b), the term of United States Patent number 3,674,836 issued for the drug Lopid shall be extended in accordance with section 9202 for 3 years and 6 months from the date of its expiration.

(b) CONDITIONS.—(1) No extension of the term of the patent described in subsection (a) may be made unless there has been submitted for the drug Lopid a supplemental new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act for the approval of an expansion of the permitted indications and usage in the labeling of the drug.

176 Cooper, supra note 166, at 69-72.

177 Id. at 70.

178 Id. at 69-72.

179 Id. at 70.


(a) IN GENERAL.—Any owner on the date of enactment of this Act of the right to market a nonsteroidal antiinflammatory drug that—(1) contains a previously patented active agent; (2) has been reviewed by the Federal Food and Drug Administration for a period of more than 120 months as a new drug application; and (3) was approved as safe and effective by the Federal Food and Drug Administration on October 29, 1992, shall be entitled, for the 2-year period beginning on October 29, 1997, to exclude others from making, using, offering for sale, selling, or importing into the United States such active agent, in accordance with section 154(a)(1) of title 35, United States Code.

received a patent in 1971, filed an Investigational New Drug Application (INDA) in 1972, and then filed the New Drug Application (NDA) in August of 1982. On October 29, 1992, more than twenty years after obtaining a patent, the Food and Drug Administration finally approved Daypro for marketing. At this point, Daypro had no remaining patent life since patents lasted only seventeen years from issuance at that time. Under the Patent Term Restoration Act, Daypro was not eligible for any patent extensions since the patent had expired. However, Daypro was entitled to five years of marketing exclusivity.

Furthermore, congressional testimony suggests that Daypro was not at fault for the long delay. Rather, “the FDA effectively imposed a moratorium on the approval of all NSAIDs” after serious problems were encountered with previously approved NSAIDs. The record further reflects that the FDA did not impose this moratorium to collect further data or due to safety and health concerns related to Daypro. In fact, the FDA later based its approval on the original data submitted by the makers of Daypro. The approval time for Daypro was the longest of all the pending NSAIDs. An expired patent and an extremely long FDA approval process probably were the major factors leading Congress to pass this bill.

The proponents of the Patent Fairness Act argue that the situation of the pipeline drugs is similar to that of these drugs. The approval was delayed due to the FDA and not the patentee. Just as the Patent Term Restoration Act did not contemplate extenuating circumstances for Lopid and Daypro, it also did not contemplate excessive approval times for the pipeline drugs. Therefore, since Congress enacted special legislation for Lopid and Daypro drugs, in all fairness it should similarly enact legislation for the pipeline drugs.

2. Opponents
   a. Delay Due to Patentee. The opponents of the Patent Fairness Act argue that unanticipated delays in the FDA’s review of Claritin does not

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182 Id. at S19,118.
183 Id.
184 Id.
185 Id.
186 141 CONG. REC. S19,118.
188 Id.
189 Id.
make this legislation fair. The opponents argue that it would be fair to "reduce any new extension by the length of the unanticipated extensions it has already secured." Further, the opponents attribute the delays to the patentee, Schering-Plough. During the approval process, Schering-Plough changed the product from a capsule to a tablet form. As a result, the FDA had to address bioequivalence issues. Additional studies needed to be performed due to concerns of Claritin as a carcinogen.

D. TREATMENT OF BRAND NAME DRUGS V. GENERIC DRUGS

1. Proponents.

a. Cost of Drug Development. The proponents argue that the treatment between brand name drugs and generic drugs is quite disparate. Brand name drug companies spend $20 billion on new drug research, and generic companies spend less than $500 million. Generic drug manufacturers also file an abbreviated new drug application, ANDA that does not require duplicate testing for safety and effectiveness for generic drugs equivalent to those drugs already approved. Although generic drug companies charge approximately sixty percent less than brand name drug companies, Schering-Plough argues that they do not contribute to research and development of new drugs.

Brand name drug manufacturers need a continued incentive to create new drugs. "[D]rug products have helped to contain the total cost of health care by shortening hospital confinement, eliminating the need for surgery, curtailing visits to physicians and reducing the number of employee sick days." Therefore, drug development is critical. "The money to fund these research and development projects comes from sales of existing drugs."

190. *Hearings, supra* note 111, at 46 (statement of Andrew M. Berdon).
191. *Id.*
192. *Id.*
193. *Id.*
194. *Id.*
195. *Hearings, supra* note 8 (statement of Peter Barton Hutt).
196. *Id.*
199. *Id.* at 127.
Furthermore, "drug research and development is a risky business." Mandatory product testing and the low rate of success in bringing products to the market are major drawbacks in drug development. Time and money are wasted when manufacturers must abandon potential new products. "Moreover, drug research and development expenditures are 'up-front' costs that offset marketing gains." Other problems facing pioneer drug companies are "limits on their ability to protect intellectual property from competition, which in turn decreases revenue, and the litigation risks of companies producing potentially dangerous products, which increase expenditures." "Market revenues are greatly diminished by even small delays in the FDA approval process."

b. Comparison with Other Patented Products. Another significant disparagement in the treatment of brand name drugs is illustrated when comparing these drugs with other patented inventions. For example, patents in the computer components and software industries are receiving much more "life," approximately eighteen years after an estimated two-year patent prosecution period. These products often require "far less capital and involve far less risk than is the case in pharmaceutical innovation." Even though the Patent Term Restoration Act attempts to compensate drug manufacturers by extending the life of the patent, there is still a fourteen-year cap on the remaining effective patent life after approval.

2. Opponents.

a. Profitable Drug Companies. Despite the alleged "hardships" on brand name drug companies, these companies are making incredible profits. The pharmaceutical industry has the highest level of net profit as a percentage of revenue than any industry group in the United States. "Pharmaceutical firms have been the most profitable industry for nearly two

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201 Id.

202 Id.

203 Id.


205 Keyack, supra note 200, at 170.

206 *Hearings, supra note 94 (statement of Hon. Bruce Lehman).*

207 Id.

208 Id.

209 Schondelmeyer, *supra note 85.*
decades, and for two decades prior to that time, pharmaceuticals were the second most profitable industry.”

It has further been reported that “overall U.S. inflation between 1980-1992 was 21.7 percent, but pharmaceutical inflation during that same period was 128.4 percent, six times the rate of general inflation.”

Claritin provides thirty-four percent of Schering-Plough’s total revenue worldwide, which was reported to be $7.3 billion in 1998. “Relafen and Daypro are also major drugs with 1998 sales of $450 million and $300 million, respectively.” The other five pipeline drugs, Cardiogen-82, Eulexin, Nimotop, Dermatop, and Penetrex, collectively, are estimated to have 1998 U.S. sales of about $170 million.

b. Drug Pricing and Expenditures. Currently, there is no cap on the prices of prescription drugs. High prices have been attributed to factors such as “direct manufacturing costs, research and development costs, overhead, clinical factors, marketing and distribution costs, and profit potential.” The price charged for a single drug is much more than the actual cost of developing that drug.

Specifically, the industry averages for administrative expenditures such as marketing, advertising, and selling are about thirty percent of revenues. However, Schering-Plough’s expenditures are about 38.9%. Further, the industry average for research and development is twenty percent, whereas Schering-Plough spends only 12.5%, which is considerably below the industry average. Furthermore, prescription drug prices are expected to increase to compensate for the increased rate of expenditures facing the brand name drug manufacturers.

Id.

Robin Elizabeth Margolis, Prescription Drug Manufacturers Get Warning on Prices, 10 No. 3 HEALTHSPAN 19, 19 (March 1993), available in Westlaw, HTHSP Database.

Schoendelmeyer, supra note 85.

Id.

Id.


Id.

Schoendelmeyer, supra note 85.

Id.

Id.

Health Insurance Association of America, Prescription Drugs: Cost and Coverage Trends (September 1999) <http://www.hiaa.org/news/news-state/prescriptiondrugs.htm> (reporting that the rate of growth for expenditures is due to several critical factors including: “[1] direct-to-consumer advertising is
Drug pricing also depends on the therapeutic advantage of the product and the cost of alternative therapies. A current example would be “a major breakthrough in a new therapeutic category where no substitutes exist, as in the case of AIDS drugs, carries a high profit potential and will be priced according to such potential.” Similarly, when Claritin was introduced, it had a high profit potential, since allergy medication was limited. Therefore, the makers of Claritin have reaped the rewards on their investment.

c. The Cost for Delay of Generic Drugs. The availability of generics is critical, especially since drug prices are not monitored. First, prescription drugs are not always covered by Medicare or private health insurance plans, requiring consumers to pay full price out of their own pockets. Second, the elderly, often living on fixed incomes, require a greater amount of prescription drugs. Furthermore, some consumers do not respond to the drugs available. Therefore, by passing this legislation, the concern of these consumers would be neglected.

d. Life After the Expiration of a Patent. Brand name drugs will continue to be profitable even without the patent term extension and even with the introduction of generic drugs. One reason is while the Patent Term Restoration Act gives only one patent extension, there is potentially no limit on the number of patents a pharmaceutical manufacturer can obtain. For example, some critics charge that “pharmaceutical manufacturers develop ‘me-too’ products, that is, drugs differing only slightly from previously developed drugs with arguably little or no added therapeutic value, in order to obtain [additional] patents and higher prices for the new products.”

The second reason is prices are not automatically lowered upon the introduction of generics in the market, since the brand name manufacturers...
will successfully advertise and promote their products to ensure continuing support.\textsuperscript{27} With new guidelines adopted by the FDA,\textsuperscript{28} brand name drug companies have more flexibility to directly advertise to consumers. Practices such as sending representatives and free samples to physicians often result in brand name loyalty.\textsuperscript{29} Thereby, "[d]espite the revival of generics and pressure to contain costs, physicians typically do not consider price differentials when prescribing."\textsuperscript{30}

\section*{IV. Conclusion}

Both supporters and opponents of the Patent Fairness Act have made compelling arguments. The proponents of the Patent Fairness Act believe this legislation will address inequities in the treatment of pipeline drugs, drugs that had obtained a patent but were pending FDA approval when the Patent Term Restoration Act was enacted. The proponents have passionately argued that the legislation does not include any guarantees other than a process, whereby the manufacturers of the pipeline drugs can present their case. No patent of a pipeline drug will be extended without the necessary showing that the extension is justified. By foregoing this process, Congress will have to continue to evaluate each patent extension exception, and thereby incorporating politics, rather than fairness, into the equation.

The opponents argue the legislation is a guarantee, since the provisions unfairly favor the patentee. The opposing party has the initial burden of showing that the patentee did not act with due diligence and, should the burden shift to the patentee, the patentee will easily satisfy the requirement of due diligence since it is a low threshold. The opponents argue the opposing party will be a generic drug manufacturer, who may not have access to company records to make a case. Further, the FDA will be put in

\begin{itemize}
\item \textsuperscript{27} Id. at 369.
\item \textsuperscript{28} The FDA issued final guidance concerning consumer-directed broadcast advertisements for prescription drugs on August 6, 1999. Consumer-directed broadcast ads for prescription drugs must contain: a. A toll-free number for consumers to call; b. A referral to a print advertisement in a concurrently running print publication or the provision of product brochures in various convenient outlets; c. A healthcare provider referral (to a physician, pharmacist, veterinarian, or other healthcare provider); and d. An Internet Web page address. Ads broadcast over radio, television, and through telephone communications systems must also include a thorough "major statement" prominently disclosing all of the major risks associated with the drug.
\item \textsuperscript{29} Griffin, supra note 215, at 369.
\item \textsuperscript{30} Id.
\end{itemize}
a compromising position. The legislation gives it a consultative role, while at the same time the FDA may have been responsible for the delays, and therefore, may be defending against the patentee, which is like being a judge and defendant at the same time. The opponents argue that other measures, such as increasing FDA approval, which serve both the drug industry and consumers, should be pursued instead of wasting time and resources on this legislation. This is particularly true given that the issue, at least in the Claritin case, has been debated and denied on three occasions.

Both proponents and opponents agree that the purpose of the Patent Restoration Act was to encourage future investments in drug development and the two-year limitation was based on the fact that approval time was 2.25 years when the Act was debated. Proponents emphasize that the gross miscalculation of time resulted in substantial inequities, which now must be redressed, while the opponents argue the pipeline drugs did receive appropriate extensions.

The opponents argue that the drug makers had already made the decision before the Act to develop such drugs and some pipeline drugs have received two unanticipated extensions. For example, Claritin received two years pursuant to the Patent Term Restoration Act and 22.5 months with the enactment of the Uruguay Round Agreement of 1994.

The proponents blame the shortage of personnel and resources at the FDA level for the delays, whereas the opponents blame the patentees, at least in the case of Claritin. Claritin had changed from a capsule to a tablet form during the middle of the approval process, which may have caused additional delays. The proponents further argue that in the past, where the FDA was at fault, Congress has enacted special legislation extending the time of the patents. Therefore, assuming the delay was caused by the FDA, these pipeline drugs should have the same treatment.

Finally, the proponents argue that drug development is not only critical, but also very costly and time consuming. Often, there are many trial products which never reach the marketplace, and for the products that do reach the marketplace, there are associated safety and health-related testing costs. Generic equivalents often bypass much of the research and development.

The opponents argue that the pharmaceutical companies are some of the most profitable. In fact, the rise of prescription drugs has superceded the general inflation increase. Furthermore, prescription drug prices are not monitored; therefore consumers without insurance or with limited insurance
are paying a hefty price for health care. Even without a patent or an extension, brand name drugs most likely will continue to be profitable, especially since some drugs have more than one patent.

As Congress prepares to debate the Patent Fairness Act and the Drug Patent Term Restoration Review Act during the upcoming term, it will have to decide whether to look backward, or forward. The proponents want some compensation for delays that occurred in the past, while the opponents argue that new drugs should be encouraged, rather than giving more money to drugs that already exist.

SHILPA PATEL