

Abstract

Melody Wirz is a third year law student at The University of Oklahoma College of Law. She is a registered patent agent and has received a B.S. from Oklahoma State University as well as an M.B.A. from Oklahoma City University. Ms. Wirz addresses current legislative loopholes concerning patents on pharmaceutical drugs as well as the effect legal monopolies have on generic drug entry into the marketplace. She would also like to extend her gratitude and thankfulness to her husband, Trey Wirz. Without his support, her success, both at law school and in life, would not be possible.

**ARE PATENTS REALLY LIMITED TO 20 YEARS?—A CLOSER LOOK AT
PHARMACEUTICALS**

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I. Introduction

As discussed in Part I, a patent is usually granted for twenty years. However, a special circumstance exists in the case of pharmaceutical companies. Such companies are granted special patent protections because of the cost of research, development, and clinical trials, and because FDA approval takes considerable time to process. This issue is further addressed in Part II. The current law which governs the ability to extend drug patent protection is embodied in the Hatch-Waxman Act, as discussed in Part III. Unfortunately, the Act has a number of loopholes that drug companies can manipulate to their advantage. Part IV explores the number of tactics used in the manipulation of patent terms, which includes extending patents through legislative loopholes and lobbying, initiating litigation alleging patent infringement, layering of patents and the combination of drugs to create new patents, as well as advertising and developing brand names to increase barriers for generic entry into the pharmaceutical market. Part V of this article addresses the recent legislation on this issue.

II. Patent Terms

In today's patent system, patents grant a legal monopoly on an invention for twenty years, which begins on the date the patent application is filed with The United States Patent and

Trademark Office. A three-year extension changed the law prior to 1995; the law prior to 1995 initially granted a period of exclusivity for only seventeen years from the time a patent had been granted.¹ This change in the law was promulgated through The Uruguay Round Agreement Act as a piece on The General Agreement on Tariffs and Trade. Essentially, it synchronized U.S. patent terms with other nations.² The different durations for patent protection are still notable as patents that are currently due to expire were extended under the old rule. While the date of the patent dictates the length of patent protection, the patent term is the same for most inventions, including new drugs.³

III. FDA Approval

Any new drug must go through an extensive governmental approval process before it can be marketed to the public. The Food and Drug Administration (“FDA”) may take many years to approve a new pharmaceutical. Accordingly, drug companies are granted the right to apply for a patent extension for up to five years so that they can have a maximum effective patent life of fourteen years.⁴ However, since clinical trials and FDA approval takes about eight and a half years to complete, the viable patent term may be even shorter than the fourteen years specified.⁵ Therefore, pharmaceutical companies have a fairly short monopoly time to recover the extensive research and development costs associated with developing a new drug. The Hatch-Waxman Act of 1984⁶ further limits developers of new drugs, as discussed below in Part III.

¹ Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 235-36 (2001).

² *Id.* at 236.

³ The term of a design or plant patent differs from that of a utility patent.

⁴ Mandy Wilson, Note, *Pharmaceutical Patent Protection: More Generic Favored Legislation May Cause Pioneer Drug Companies to Pull the Plug on Innovation*, 90 KY. L.J. 495, 513 (2001-2002).

⁵ *Id.*

⁶ Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C.A. §§ 355 and 271(E) (1994)).

IV. Hatch-Waxman Act

The current law in the area of patents is The Hatch-Waxman Act, which proposes to balance the competing interests of brand name companies, generic companies, insurance companies, and the public by promoting competition and decreasing drug costs.⁷ The Act has two provisions of great interest in the dispute between brand name companies and other interested parties. The first is the automatic 30-month stay granted to the patent holder when the patent holder brings an infringement suit against a new generic manufacturer. This stay prevents the approval of a generic version of the name brand drug regardless of whether the original patent has expired. The second provision of interest allows a 180-day period of exclusivity granted to the first generic company to enter the market after the patent expires.⁸ In both instances, brand name manufacturers are able to manipulate the Act in order to extend the life of their patent. The methods for doing so are discussed below.

V. Patent Extension Tactics

There are at least four ways brand name drug companies effectively extend the life of their patents.⁹ These include the following: (1) extending patents through legislative loopholes and lobbying; (2) initiating litigation alleging patent infringement; (3) layering of patents and the combination of drugs to create new patents; and (4) advertising and developing brand names to increase barriers for generic entry.¹⁰

⁷ Kristin E. Behrendt, *The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?*, 57 FOOD & DRUG L.J. 247, 254 (2002).

⁸ *Id.*

⁹ Glasgow, *supra* note 1, at 232.

¹⁰ *Id.* at 233.

A. Extending Patents Through Legislative Loopholes and Lobbying

One of the most utilized ways to extend the patent life for profitable drugs is through the use of The Hatch-Waxman Act.¹¹ The Act was passed to give generic drugs a greater opportunity to benefit consumers and insurance companies. However, The Hatch-Waxman Act has many loopholes.¹² One of the ways companies continue patent protection is by applying for new patents for the existing drug during the protection period.¹³ An example of this would be tying the drug to another use than what was originally applied for, or by filing for patent protection for some of the unique properties of the drug, such as a purified form.¹⁴ Patents may also be extended through litigation.¹⁵ Hatch-Waxman allows for an automatic 30-month stay when infringement is alleged.¹⁶ This is discussed further in Section B.

Another tool used by drug companies stems from The Uruguay Round Agreement.¹⁷ If companies begin testing for pediatric use, they get an automatic 6-month extension on their patent.¹⁸ Thus, by combining the pediatric extension with the 30-month stay and the possibility of a new patent granted on the same drug for one of the “new” properties of the drug or for a change in the drug’s use, drug companies may extend their exclusivity by at least three years. Patent protection is meant to reward innovation and research. Skillful lawyering or lobbying should not be rewarded as much as true innovation. However, the loopholes further a policy that does little to spur new innovation, which ultimately is the fundamental basis for patent protection.

¹¹ *Id.*

¹² *Id.* at 234.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.* at 238.

B. Initiating Litigation Alleging Patent Infringement

Brand name drug companies continue to abuse the two major provisions of The Hatch-Waxman Act.¹⁹ By initiating litigation, whether legitimate or not, pharmaceutical companies are able to keep generics out of the market for at least thirty months after the original patent expires.²⁰ Generic manufacturers are not allowed to enter the market while a dispute is ongoing, which results in larger profits for the brand name manufacturer.²¹ Sometimes, the brand name drug manufacturer is able to get multiple stays resulting in even more years of an extended monopoly term.²² For example, GlaxcoSmith-Kline was able to get five patent extensions totaling sixty-five months for Paxil.²³ In the meantime, the company netted more than \$1 billion on the drug in just one year of the stay.²⁴

Additionally, major pharmaceutical companies manipulate The Hatch-Waxman Act by colluding with the first generic to market.²⁵ Often, the generic drug company enters an agreement not to compete with the brand name drug.²⁶ While this appears to be a legitimate result of litigation surrounding a patent, the scenario is somewhat backward. The generic party will retain the 180-day exclusivity period and opt out of using it in exchange for a settlement sum.²⁷ Typically, settlement funds flow from the alleged infringer to the patent holder, not the

¹⁷ *Id.* at 236.

¹⁸ *Id.*

¹⁹ *Id.* at 238-39.

²⁰ *Id.* at 239.

²¹ *Id.* at 238.

²² *Id.* at 239.

²³ Editorial, *Time For a Vote*, TIMES-PICAYUNE, Oct. 7, 2002, available at <http://www.timespicayune.com> (last visited Aug. 1, 2003).

²⁴ *Id.*

²⁵ Glasgow, *supra* note 1, at 239.

²⁶ *Id.* at 241.

²⁷ *Id.*

other way around.²⁸ Basically, this practice amounts to the brand name manufacturer paying the generic manufacturer not to compete for the 180-day period of exclusivity. The policy indicated by this loophole is problematic and certainly needs updating.

C. Layering of Patents and the Combination of Drugs to Create New Patents

Often, drug companies facing the expiration of a patent will develop a new use or different version of their old drug.²⁹ This practice is referred to as layering. Eli Lilly's Prozac demonstrates one example of a drug company obtaining a new patent on an additional aspect of an old drug.³⁰ When faced with the patent expiration of the popular antidepressant drug, Eli Lilly developed a weekly version of the drug.³¹ By advertising this new feature to the public, the drug company basically killed the demand for the old product along with any likely generic imitation.

Drug companies also avoid losing monopoly rights due to patent expiration by combining two different drugs and patenting the combination.³² The combination often consists of one drug to treat a medical condition and a secondary drug to alleviate a side effect of the primary drug.³³ While this does improve the drug, it is not new innovation. However, patent protection is frequently granted for these pharmaceutical combinations. Again, the drug company can use advertising to essentially eliminate demand for the old product, as well as any comparable generic substitute. Of course, public awareness of the improved drug is necessary if the generic is to be disregarded as a viable option.

²⁸ *Id.*

²⁹ *Id.* at 248.

³⁰ *Id.*

³¹ *Id.* at 249.

³² *Id.* at 250.

³³ *Id.* at 251.

In the past, a manufacturer would claim a new patent for the drug based on an unapproved use to treat a medical condition.³⁴ However, the U.S. Court of Appeals for the Federal Circuit made a ruling in January, 2003, that may change this practice.³⁵ For further details on this ruling, see *Warner-Lambert Co. v. APOTEX Corp.*³⁶

D. Advertising and Developing Brand Names to Increase Barriers For Generic Entry

There is no question that advertising is an effective vehicle for increasing sales. Since the 1997 relaxation of direct consumer advertising by the FDA, drug companies have increasingly utilized this strategy to gain and retain customers.³⁷ One source estimates that drug companies spent \$2.5 billion on consumer advertising in 2000.³⁸ The same source also estimated that these ads might have brought in as much as \$5 to \$6 in return for each dollar spent on advertisements.³⁹ While drug companies do not openly disclose marketing expenditures, the amount is estimated to be much more than what is allocated to research and development.⁴⁰ While drug companies argue that patent term extensions are necessary to justify large research and development costs, this reasoning falls short when the major cost in new drugs is advertising, rather than research and development.

V. New Legislation

In the middle part of 2002, a new bill was proposed. The Greater Access to Pharmaceuticals Bill, also known as The McCain-Schumer Bill, sought to reform the earlier

³⁴ Steve Seidenberg, *Federal Circuit Throws Out Warner-Lambert Claim Over Gabapentin*, 2/10/03 Nat'L L.J. A20, (Col. 2).

³⁵ *Id.*

³⁶ *Warner-Lambert Co. v. APOTEX Corp.*, 316 F.3d 1348 (6th Cir. 2003).

³⁷ Glasgow, *supra* note 1, at 252.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.* at 254.

Hatch-Waxman Act of 1984.⁴¹ The bill proposed two relevant changes to the Hatch-Waxman rule. First, McCain-Schumer sought to change the structure of the 30-month stay.⁴² Rather than being automatic, the new bill proposed to require judicial review for the stay to occur.⁴³ Second, the bill attempted to establish a “use it or lose it” standard for the 180-day period of exclusivity given to the first generic manufacturer.⁴⁴ Under this rule, if a generic challenger fails to launch its product within a specified time, the second generic manufacturer would inherit the exclusive right.⁴⁵ This would eliminate any incentive for the pioneer drug manufacturer to keep the first generic manufacturer out of the market by settling an infringement suit.⁴⁶

The Senate approved The McCain-Schumer Bill on July 31, 2002⁴⁷ by a margin of 78-21.⁴⁸ However, industry blocked passage in the House.⁴⁹ Thus, the legislation is not likely to be re-considered this year⁵⁰ or in the current Congress.⁵¹

VI. Conclusion

Pharmaceutical companies use a number of tactics to extend the effective life of patents. While these companies argue that a longer life is necessary to justify the substantial research and development costs involved in producing a new drug, the practices are nonetheless suspect. The legislation that would have eliminated these practices passed the Senate by a large

⁴¹ Deborah Josefson, *US Senate Considers Proposal to Tighten Drug Patent Law*, 5/18/02 BRIT. MED. J. 1176.

⁴² Julia Rosenthal, *Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers*, 17 BERKELEY TECH. L.J. 317, 328-29 (2002).

⁴³ *Id.*

⁴⁴ *Id.* at 329.

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ Steven Lee, *Third Party Without Remedy in Orange Book Case: 4th Circuit Holds That FDA's Refusal to List a Patent Was Not Arbitrary or Capricious*, 11/11/02 NAT'L L.J. C6, (Col. 1).

⁴⁸ Billy House, *Reform of Drug Patents Gets Nod from Senate Expediting of Generics Is Bill's Aim*, ARIZ. REPUBLIC, Aug. 1, 2002, at A8.

⁴⁹ Jill Wechsler, *Health Policies Threaten Industry Innovation*, 1/1/03 PHARMEXEC 28.

⁵⁰ Jill Wechsler, *GOP to Highlight Pharmacy Coverage*, 12/1/02 PHARMEXEC 32.

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(formerly 2003 OKJOLT REV. 5)
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margin and demonstrates that this is an issue of concern to the public. However, the industry was able to block the legislation from coming to a vote in the House. Additionally, the new makeup of the House indicates that it is unlikely that this issue will be addressed any time soon. This is unfortunate. If legislation comparable to The McCain-Schumer Bill were to pass, it would certainly benefit consumers through greater generic availability, rather than permitting large pharmaceuticals to continuously prey on generic drug companies by using questionable legal tactics.

The Bush administration plans to take considerable steps to shorten the time it will take a generic drug to enter the pharmaceutical market. This plan, announced on January 24, 2003, includes increased FDA funding so that the amount of time it takes the FDA to approve a generic drug will be reduced by approximately two months. This will shave considerable time off the average 21.5 months it took the FDA to process an application for generic drug entry in the year 2002. This plan will be incorporated into the Bush administration budget proposal for the Fiscal Year of 2004 and calls for a thirteen million dollar increase in funding to the FDA.⁵¹ Thus, Bush plans to press for the reduction of time that the generic review process will take. However, this push will take the form of FDA backing instead of legislative reform.

⁵¹ Henry Dummett, *United States – President Bush to Reduce Generic Review Times*, 1/27/03 WMRC Daily Analysis (Pg. Unavail. Online).