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RETHINKING THE HATCH-WAXMAN ACT: BALANCING BOTH SIDES OF THE EQUATION

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I. Introduction

The pharmaceutical industry has come under fire recently in the news because of high prescription drug prices.[2] The high cost of prescription drugs hits consumers without health insurance and who must therefore pay with cash much harder than it does consumers with health insurance.[3] This burden often falls on senior citizens, who must choose between the drugs that prolong and improve the quality of their lives and "the immediate necessities of life: rent, food, heat, electric power, [and] telephone service."[4] Patents play a significant role in the high price of prescription drugs because a company holding patents on a prescription drug can exclude others from manufacturing and selling the drug, thereby stifling any competition in the marketplace during the term of the patent.

The rising prices of pharmaceutical products have caused many consumers to look for lower priced options in Canada and Mexico.[5] Several

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[2] *See generally* Jane Bryant Quinn, *A Remedy for Pricey Drugs*, NEWSWEEK, Sept. 27, 2004, at 31, *available at* http://www.msnbc.msn.com/id/6039139/site/newsweek/.

[3] Lori Chordas, *Crossing Borders: Importing Prescription Drugs, Illegally or Legally, Into the United States Isn't Expected To Have a Significant Short-Term Impact on Health Insurers, But Long-Term Could Be a Different Story*, BEST'S REVIEW, Dec. 1, 2004.

[4] Wyn Snow, *FDA Strangling Consumer Health* (Nov. 6, 2003), http://www.supplementquality.com/news/skyrocketing_drug_costs.html.

[5] Chordas, *supra* note 3.

cities and states allow their employees to purchase Canadian drugs through their employee plans.[6] This is cause for concern because some of these products may not contain the same amount of the active ingredient as their counterparts from the United States.[7] Drugs purchased in Canada may actually come from countries in Asia or Africa.[8] Additionally, the fillers used in the drugs may be different from what is used in the United States, increasing the potential for allergic reactions.[9] Finally, imported drugs may also be counterfeit, expired, or contaminated.[10]

The reasons given by commentators for the high cost of prescription drugs are many. Perhaps the most common reason cited by the pharmaceutical industry is the large cost of the research and development process.[11] The cost of individual drugs on the market must factor in the attempts at creating new drugs that failed at some point in the development process.[12] Additionally, effective patent terms on pharmaceutical products are often significantly shorter than terms for other inventions.[13] Therefore, there is less time to recover the cost of research and development.[14]

One of the most significant pieces of legislation affecting patent law and the pharmaceutical industry is the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act.[15] The Hatch-Waxman Act paved the way for generic manufacturers of medications to enter the marketplace.[16] Global generic drug sales are expected to "rise from $29 billion in 2003 to $49 billion in 2007."[17] However, many commentators are concerned that the ease of obtaining FDA approval for generic manufacturers and shorter patent terms for brand name drugs may

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[6] Quinn, *supra* note 2.

[7] Chordas, *supra* note 3.

[8] *Id.*

[9] *Id.*

[10] Reuters, *FDA Battle Over Canada Drugs Heats Up* (Feb. 4, 2004), *available at* http://www.msnbc.msn.com/id/416105.

[11] Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93, 96-97 (2004).

[12] *Id.*

[13] *Id.*

[14] Jaclyn L. Miller, Note, *Drug Price Competition and Patent Term Restoration Act: The Elimination of Competition Between Drug Manufacturers*, 5 DEPAUL J. HEALTH CARE L. 91, 96 (2002).

[15] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Hatch-Waxman Act was amended as part of the Medicare Prescription Drug and Modernization Act of 2003. Pub. L. No. 108-173, Title XI, 1101, 1102 (codified as amended at 21 U.S.C. §§ (j)(2) and (5) (2004)). *See generally*, Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 IOWA J. CORP. L. 309 (2005).

[16] James Frederick, *Stars Align for Generic Drug Industry*, Drug Store News, Feb. 16, 2004.

[17] *Id.*

result in less incentive for research-based pharmaceutical companies to invest in costly research and development.[18] Smaller investments in research and development would, in theory, result in fewer new lifesaving medications.[19]

Part Two of this paper will discuss the patent system and the procedures for FDA approval of new drugs. Part Three will discuss the differences between research-based pharmaceutical companies and generic manufacturers. The Hatch-Waxman Act and its ramifications will be discussed in Part Four. Part Five will discuss the arguments made by research-based companies and generic manufacturers about the effects of the Hatch-Waxman Act. Finally, Part Six of this paper will analyze the current state of the law and provide suggestions for balancing the interests of society with incentives for the research-based manufacturers to continue to develop new drug products.

II. Basics of Patents and FDA Approval

Pharmaceutical products are unlike many other inventions because, in addition to obtaining a patent, the company must also gain the approval of the Food and Drug Administration (FDA) in order to market the drug.[20]

A. Patent Laws

The patent laws of the United States are derived from Article I, Section 8 of the Constitution, which grants Congress the authority "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."[21] A patent grants the right to prevent others from making, using, offering for sale, or selling the patented product.[22] After obtaining a patent, the inventor is given these exclusive rights to exclude others from making and selling their inventions for a term of 20 years from the date the patent application is filed.[23] This period is 17 years from the issue date for patents filed before June 8, 1995, when the Uruguay Round Agreements Act went into effect.[24]

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[18] Miller, *supra* note 14, at 106.
[19] *Id.*
[20] Kuhlik, *supra* note 11, at 94.
[21] U.S. CONST. art. I § 8, cl. 8.
[22] 35 U.S.C. § 271(a) (2004).
[23] 35 U.S.C. § 154(a)(2) (2004).
[24] 35 U.S.C. § 154(c)(1) (2004).

One rationale behind granting a patent is that the inventor can sell her invention before others can, essentially granting the inventor a monopoly.[25] In exchange for this grant, the inventor must disclose how to make and use the invention.[26] Although patents may grant monopolies, which are generally discouraged in America, it is thought that the benefits to society outweigh the cost of the monopoly.[27] The economic theory behind granting patents is that encouraging invention by personal gain will result in greater benefits to society.[28] The system of granting patents attempts to balance "two competing goals: giving adequate economic incentives to pioneering inventors while ensuring that the improvers who followed—and the public as a whole—could make effective use of inventions."[29] Thus, patents encourage new inventions to be disclosed to the public and "provide a financial incentive to invent new technologies."[30]

Patent law recognizes three separate types of discoveries: utility inventions, designs, and asexually reproduced plants.[31] Patentable subject matter includes "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[32] Although the statute indicates a wide range of material that may be patented, some things, such as laws of nature, physical phenomena, and mathematical expressions, are not directly patentable.[33] The reasoning behind not allowing these types of discoveries to be patented is that "patent law should not operate to dispossess society of those things that are 'manifestations of… nature, free to all men and reserved exclusively to none.'"[34]

In addition to the subject matter requirement for patentability, there are several statutory requirements that must be met: novelty,[35] non-obviousness,[36] and utility.[37] Novelty requires that the invention be new and

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[25] David Kelly, Note, *The Federal Circuit Transforms the Written Description Requirement into a Biotech-Specific Hurdle to Obtaining Patent Protection for Biotechnology Patents*, 13 ALB. L.J. SCI. & TECH. 249, 253 (2002).

[26] *Id.*

[27] Charles Allen Black, Note, *The Cure for Deadly Patent Practices: Preventing Technology Suppression and Patent Shelving in the Life Sciences*, 14 ALB. L.J. SCI. & TECH. 397, 401 (2004).

[28] *Id.*

[29] Matthew J. Conigliaro et al., *Foreseeability in Patent Law*, 16 BERKELEY TECH. L.J. 1045, 1046 (2001).

[30] Black, *supra* note 27, at 402.

[31] *See* 1 DONALD S. CHISUM, CHISUM ON PATENTS, § 1.01 (2006).

[32] 35 U.S.C. § 101 (2004).

[33] Kelly, *supra* note 25, at 254.

[34] *Id.* (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

[35] 35 U.S.C. § 102 (2004). *See generally* 1 Chisum, *supra* note 31, § 3.01.

[36] 35 U.S.C. § 103 (2004). *See generally* 2 Chisum, *supra* note 31, § 5.01.

[37] 35 U.S.C. § 101 (2004). *See generally* 1 Chisum, *supra* note 31, § 4.01.

original.[38] The non-obvious requirement denies a patent if a person of ordinary skill in the applicable field finds obvious "the differences between the subject matter sought to be patented and the prior art."[39] Finally, "[u]tility requires that the invention have some specific and substantial practical use."[40]

The final requirement for obtaining a patent is a written description of the invention or "specification" as set forth in 35 U.S.C. § 112. Section 112 states, in part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[41]

Even if all of the requirements for obtaining a patent are met and the patent issues, the pharmaceutical company must also gain FDA approval prior to commercially marketing the drug.[42]

B. FDA Approval

The Food and Drug Administration (FDA) has the regulatory authority to approve new drugs, and no new drug may enter the U.S. market without FDA approval.[43] The Food, Drug and Cosmetic Act[44] defines a "new drug" as any "drug not generally recognized among experts… as safe and effective under the conditions prescribed, recommended or suggested in the labeling thereof."[45] Alternatively, a "new drug" may be one which has been recognized as safe and effective under such conditions based on research but "has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions."[46] The approval process for new drugs consists of four phases: Pre-Clinical, Clinical, New Drug Application Review, and Marketing.[47]

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[38] 35 U.S.C. § 102 (2004).
[39] 35 U.S.C. § 103 (2004).
[40] Kelly, *supra* note 25, at 255. *See also* Brenner v. Manson, 383 U.S. 519, 534-536 (1966).
[41] 35 U.S.C. § 112 (2004).
[42] Patricia I. Carter, *Federal Regulation of Pharmaceuticals in the United States and Canada,* 21 LOY. L.A. INT'L & COMP. L.J. 215, 229 (1999).
[43] *Id.*
[44] 21 U.S.C. §§ 301-399 (2004).
[45] 21 U.S.C. § 321(p) (2004).
[46] *Id.*
[47] Carter, *supra* note 42, at 230.

1. Pre-Clinical Phase

In the pre-clinical phase, the drug manufacturer completes initial laboratory research, including studies on animals, and determines that a drug may be useful in treating a specific disease.[48] If it appears from this initial research that it would be reasonably safe to begin trials using human subjects, the manufacturer will file an Investigational New Drug Application (IND) with the FDA.[49] The IND gives notice to the FDA that clinical trials will be conducted, and it includes information about the drug's class, formula, and active ingredients; the plan for investigation; the person(s) responsible for conducting the investigation and reviewing the data; a summary of any previous animal or human studies; and possible risks and side effects.[50] Clinical studies may start thirty days after the FDA receives the IND notice, unless approval is granted earlier or an objection is issued.[51]

2. Clinical Phase

The Clinical Trials Phase consists of three separate parts.[52] "[A] Phase I Study is first conducted on a relatively small number of healthy human volunteers, to identify the safe dosage range and obtain other basic information."[53] If it appears from the results of the Phase I study that the drug could be safely tested on humans, "a Phase II Study follows to test the drug's effectiveness on a limited number of patients with specific medical conditions."[54] If the Phase II Study does not raise any significant safety concerns, "the drug is tested for safety and efficacy in wider clinical use."[55] It is during the Phase III Study that the manufacturer attempts to determine the optimal dosage level.[56]

3. NDA Phase

The manufacturer may submit a New Drug Application (NDA) to the FDA after the Clinical Trials Phase is complete.[57] The NDA is the "principal regulatory device for controlling pharmaceutical companies in the United States."[58] An NDA is an extremely detailed document, including

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[48] *Id.*

[49] *Id.* at 230-231.

[50] 21 C.F.R. § 312.23 (2006). *See generally* Carter, *supra* note 42, at 231.

[51] Carter, *supra* note 42, at 231. *See also* 21 C.F.R. § 312.40 (2006).

[52] *See* 21 C.F.R. § 312.21 (2006).

[53] Carter, *supra* note 42, at 231-232. Phase I studies typically involve 20 to 80 subjects. 21 C.F.R. § 312.21 (2006).

[54] Carter, *supra* note 42,at 232. Phase II studies generally include "no more than several hundred subjects." 21 C.F.R. § 312.21 (2006).

[55] Carter, *supra* note 42, at 232. Anywhere from "several hundred to several thousand subjects" may be involved in a Phase III study. 21 C.F.R. § 312.21 (2006).

[56] Carter, *supra* note 42, at 232.

[57] *Id.*

[58] *Id.*

information regarding the safety and effectiveness of the drug, the composition of the drug, the manufacturing process, and quality control procedures.[59] "The FDA reviewers thoroughly 'examine the clinical, chemical, statistical and pharmacological data submitted by the sponsor.'"[60] The FDA reviewers often require drug sponsors to supplement the NDA with additional information.[61] In order for the FDA to approve a new drug, the sponsor must demonstrate that the drug is both safe and effective.[62]

NDA approval time has significantly improved in recent years.[63] In 1995, it took the FDA an average of 16.2 months to review an NDA.[64] By 2004, this number had decreased to 11.9 months.[65] NDAs with the fastest review times are for those that are assigned a priority status by the FDA and for sponsors that are experienced.[66]

4. Marketing Phase

The drug can be marketed in the United States after the FDA approves the NDA.[67] However, despite gaining FDA approval, the drug may remain classified as a new drug for several years.[68] Additionally, manufacturers have a continuing duty to disclose any "adverse drug experiences" to the FDA.[69]

III. Differences Between Research-Based Companies and Generic Manufacturers

There are essentially two types of pharmaceutical companies: research-based companies and companies that make generic drugs.[70] Generic drug manufacturers typically profit from the research conducted by other

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[59] 21 U.S.C. § 355(b)(1) (2006). *See also* Carter, *supra* note 42, at 232.

[60] Carter, *supra* note 42, at 232.

[61] *Id.*

[62] *Id. See also* 21 C.F.R. § 314.2 (2006).

[63] Center For Drug Evaluation and Research, CDER Report to the Nation: 2004, August, 22, 2005, at 16, *available at* http://www.fda.gov/cder/reports/rtn/2004/rtn2004.pdf [hereinafter *CDER Report*].

[64] *Id.*

[65] *Id.*

[66] Carter,*supra* note 42, at 234. The FDA grants priority status based on the product "represent[ing] significant improvements compared with marketed products." *CDER Report*, *supra* note 63, at 14. The FDA's goal is to review 90 percent of priority applications within 6 months. *Id.*

[67] *Id.* at 233.

[68] *Id.*

[69] *See* 21 C.F.R. § 314.80 (2006). *See also* Carter, *supra* note 42, at 233.

[70] Gerald J. Mossinghoff, *Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide,* 2 J.L. & TECH. 307, 307 (1987).

companies instead of conducting their own research.[71] Patents provide research-based pharmaceutical companies the ability to exclude generic compositions from the market and are therefore considered the "commercial lifeblood" of research-based pharmaceutical companies and the enemy to the generic manufacturers.[72]

"Pharmaceutical research is extremely costly and time consuming."[73] It is estimated that developing a drug and getting it to market costs anywhere from $250 million to $900 million, with $500 million being the most-cited number.[74] Research-based manufacturers have stated:

> [E]very year scientists screen more than 126,000 chemicals for potential drug development. Of that number, they will actually follow up on about 1,000. Of that number only sixteen will ever make it through the regulatory process and eventually appear in the pharmacy. Only one tenth of one percent of all chemicals entering the process will finally be approved.[75]

Because of the large investment of time and financial resources required to create a drug and get FDA approval, the research-based pharmaceutical companies rely extensively on the ability to patent the drug to recover these costs.[76]

The generic manufacturers, on the other hand, invest a relatively minor amount of time and money in their products.[77] They produce drugs that are no longer under patent protection, usually because the patent has expired or is unenforceable.[78] Since patents must describe how to make and use the drug, the generic manufacturers do not have to invest in significant research. Further, since the drugs have already been approved by the FDA, the generic manufacturers can bring a generic drug to market much faster and without the costs associated with FDA approval of a new drug. The generic manufacturers are generally exposed to lower risks because they only sell drugs that were successfully developed and marketed by a research-based company.[79]

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[71] *Id.*
[72] *Id.*
[73] *Id.* at 308.
[74] Snow, *supra* note 4.
[75] Miller, *supra* note 14, at 103-104.
[76] *See* Mossinghoff, *supra* note 70, at 308.
[77] *Id.*
[78] *Id.*
[79] *Id.*

IV. Hatch-Waxman Act

To adequately examine the current state of the law and the adoption of the Hatch-Waxman Act, it is necessary to explore the evolution of laws affecting pharmaceutical products.

A. Pre-1984

The first legislation in the United States to address the safety of food and drugs was the Pure Food and Drug Act of 1906.[80] This Act required all drugs to meet standards for strength, quality, and purity.[81] However, this Act had considerable flaws because "it did not adequately assure safe and effective products."[82] For example, the Act did not require most labels to state the contents.[83]

The issue of drug regulations was thrust into the public view once again by the sulfanilamide disaster of 1937.[84] A manufacturer of sulfa drugs decided to produce a liquid form using antifreeze, resulting in 107 reported deaths.[85] As a result, Congress enacted the Food, Drug and Cosmetic Act of 1938 (FDCA).[86] The FDCA required the pharmaceutical manufacturer to submit a New Drug Application (NDA) to the Food and Drug Administration (FDA) before the FDA would approve the drug for use in the marketplace.[87] The FDCA required adequate testing of drugs to prove that they were safe.[88]

The next major revision to the drug laws followed in 1962 as a result of the problems associated with the drug thalidomide.[89] Thalidomide was a sleeping pill used in Europe, and it was later discovered that use of the drug in the first trimester of pregnancy could result in severe birth defects.[90] Congress responded to this issue by enacting the 1962 Kefauver-Harris Amendments, which increased the powers of the FDA.[91] These amendments required pharmaceutical manufacturers to prove new drugs were both safe and effective before the drug could enter the marketplace.[92] This also

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[80] Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906).
[81] Carter, *supra* note 42, at 217.
[82] *Id.* at 217-218.
[83] *Id.* at 218.
[84] *Id.*
[85] *Id.*
[86] Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938).
[87] Carter, *supra* note 42, at 218.
[88] *Id.* at 219.
[89] *Id.*
[90] *Id.* at 219-220.
[91] *Id.* at 220.
[92] *Id.*

established the modern procedures for New Drug Applications (NDA) and for Investigational New Drugs (IND).[93]

Prior to 1984, there were two significant issues created by the intersection of the patent statutes and the drug laws.[94] First, patent holders felt that they lost effective patent term time and significant amounts of potential profit because of the delay in gaining FDA approval.[95] It is common practice to file patent applications on chemical products years before they are determined to be safe and effective for human consumption because the patent laws encourage prompt filing on inventions.[96] Additionally, there are risks associated with not filing.[97] In particular, there is a risk of disclosure that could render a potentially patentable composition lacking in novelty from a delay in patent filing.[98] In the United States, an inventor has a one year grace period for filing a patent application after a potentially novelty-destroying disclosure.[99] For the most part, however, patent statutes in the rest of the world do not provide a similar grace period.[100] As a result, an intentional or unintentional disclosure of a potentially patentable composition may bar the ability to obtain a patent abroad.[101] Obtaining a patent early with broad claims also deters others from pursuing similar compounds.[102]

Second, generic manufacturers were faced with the holding of *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,[103] which stated that "making, using, or selling a patented invention has infringing activity even if the only purpose of such activity was to obtain regulatory approval."[104] In *Bolar*, Bolar Pharmaceuticals, a manufacturer of generic drugs, was working to produce a generic equivalent of Roche's successful sleeping pill "Dalmane."[105] Because of the length of time required for FDA approval, Bolar began the requisite testing for FDA approval prior to the expiration of Roche's patent.[106] Roche sued Bolar for patent infringement, arguing "that the *use* of a patented drug for federally mandated premarketing tests is a *use*

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[93] *Id.*

[94] Edward V. Filardi, *Patent Issues That Both Regulatory Affairs Personnel and Patent Attorneys Should Understand*, 54 FOOD & DRUG L.J. 215, 215 (1999).

[95] *Id.*

[96] Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 394 (1999).

[97] *Id.*

[98] 35 U.S.C. § 102(b) (2004).

[99] *Id.*

[100] *See* 2 Chisum, *supra* note 31, § 6.02 (2005).

[101] *See* Engelberg, *supra* note 96, at 394.

[102] *Id.*

[103] Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984).

[104] Filardi, *supra* note 94, at 215.

[105] *Bolar*, 733 F.2d at 860.

[106] *Id.*

in violation of the patent laws."[107] The Federal Circuit held that the experimental use defense cannot be construed to apply in cases where the experiments were for commercial purposes.[108] Thus, generic manufacturers were unable to pursue regulatory review activities until the original patent granted to the research-based company expired.[109] In essence, this amounted to a "*de facto* extension to the patent term."[110]

The Hatch-Waxman Act was enacted at least in part to respond to these issues.

B. Enacting the Hatch-Waxman Act

As stated above, patents for pharmaceutical products are significantly different from other utility patents because of the amount of research and the time necessary to obtain FDA approval so that the drug can enter the marketplace.[111] This means that drugs cannot be placed on the market until several years after their patent terms begin.[112] Therefore, "holders of patents for pharmaceutical products effectively receive less than the full term of their patent."[113]

This effective reduction in patent terms may reduce the incentive for research-based companies to invest in research for new drug products.[114] For example, a drop was seen in the number of new products entering the market following the expansion of the FDA's regulatory powers.[115] Between 1958 and 1979 the number of new products approved by the FDA declined by an estimated 81 percent.[116] One commentator stated:

> The current three year lag time between the submission of a pioneer drug to the FDA and approval for introduction to the marketplace is simply unjustified. The three years, combined with the average seven to ten years of research expended to produce the drug, is far too great an investment of time and resources to be economically feasible—unless the drug is used in huge quantities.[117]

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[107] *Id.*

[108] *Id.* at 863.

[109] Filardi, *supra* note 94, at 215.

[110] *Id.*

[111] Matthew Hinsch, Hoescht-Roussel Pharmaceuticals, Inc. v. Lehman, 13 BERKELEY TECH. L.J. 163, 163 (1998).

[112] *Id.*

[113] *Id.*

[114] *Id.*

[115] *Id.*

[116] *Id.* at 163-164.

[117] *Id.* at 164.

Congress enacted The Drug Competition and Patent Term Restoration Act of 1984,[118] commonly known as the Hatch-Waxman Act, to address this problem.[119] Title II of the Act was codified, in part, as 35 U.S.C. § 156, which allows patent holders to extend the term of their patent due to the time lost in regulatory review.[120] In enacting the Hatch-Waxman Act, Congress "hoped to provide an increased incentive for drug research and innovation."[121]

To apply for a patent term extension, the patent holder must file an application with the Patent and Trademark Office within 60 days of obtaining FDA approval.[122] Under 35 U.S.C. § 156(a), an extension of patent term may be granted if five conditions are met: (1) the patent term has not expired; (2) the patent term has not previously been extended; (3) the required application under section 156(d) was submitted; (4) the product was subject to a regulatory review prior to commercial use; and (5) the commercial use is the first commercial use of the product unless the product is made by a new biotechnological procedure. Section 156(b) sets forth what patent rights are extended after the patent extension is granted.[123] The legislative history indicates that section 156(b) provides that "when a product patent claiming the approved product is extended, the holder's rights are limited to any use of the approved product which was approved before the expiration of the extended term of the patent."[124]

The period of the extension of the patent term is specified in section 156(c).[125] The period of the extension may be reduced by any time that the applicant for patent extension failed to act with due diligence during the regulatory review.[126] The due diligence requirement is further reiterated under section 156(d), which requires that the application include "a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities."[127]

In addition to granting patent term extensions, the Hatch-Waxman Act made significant changes to the law concerning patent infringement and generic drugs.[128] The Act expressly overruled the holding of *Bolar* and created an exception for acts of making, using, or selling a patented

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[118] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[119] Hinsch, *supra* note 111, at 164.

[120] *Id. See* 35 U.S.C. § 156 (2004).

[121] Hinsch, *supra* note 111, at 164.

[122] 35 U.S.C. § 156(d)(1) (2004).

[123] 35 U.S.C. § 156(b) (2004).

[124] H.R. REP. NO. 98-857, pt. 2, at 22 (1984), *available at* 1984 WL 37417.

[125] 35 U.S.C. § 156(c) (2004).

[126] 35 U.S.C. § 156(c)(1) (2004).

[127] 35 U.S.C. § 156(d) (2004).

[128] Engelberg, *supra* note 96, at 390-391.

invention which are reasonably related to seeking FDA approval to market a drug as long as there was no commercial use of the patented invention before the patent expired.[129] Additionally, the Act allowed generic manufacturers to file an abbreviated new drug application (ANDA) and exempted generic manufacturers from performing clinical testing.[130] Following the adoption of the Hatch-Waxman Act, the time period between patent expiration and the entry of a generic drug into the market decreased from three or four years to one or two months.[131]

The Hatch-Waxman Act also created special procedures for challenging the validity or infringement of drug patents, essentially guaranteeing the patent holder a preliminary injunction for a period of thirty months unless the adjudication was completed earlier than thirty months.[132] The Act also created a virtual "bounty" for challenging patent validity, infringement, or enforceability by granting 180 days of market exclusivity to the first generic applicant to file a patent challenge.[133]

V. Aftermath of Hatch-Waxman

One thing that most commentators can agree on is that the Hatch-Waxman Act does not work in its current state. However, there is a large divide between the two sides. Research-based pharmaceutical companies argue that the Act is heavily tipped in favor of the generic manufacturers. Generic companies and consumer advocates argue that the Act weighs heavily in favor of research-based pharmaceutical companies.

A. Research-Based Pharmaceutical Companies

Perhaps the strongest argument research-based pharmaceutical companies make is that effective patent life for pharmaceutical products is only eleven to twelve years, while the effective patent life of inventions in other fields averages 18.5 years.[134] One might argue that if a new mousetrap gets 18.5 years of patent protection, it seems surprising that pharmaceutical products that enhance and prolong lives only receive an average of eleven to twelve years of patent protection.[135] This was one of the reasons for enacting

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[129] 35 U.S.C. § 271(e)(1) (2004).

[130] Miller, *supra* note 14, at 100-101.

[131] 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, 518 (2001).

[132] *See* 21 U.S.C. § 355(c) (2004) and 35 U.S.C. § 271(e)(2)-(4) (2004).

[133] 21 U.S.C. § 355(j)(5)(B)(iv) (2004). *See also* Engelberg, *supra* note 96, at 391.

[134] Kuhlik, *supra* note 11, at 96-97.

[135] Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process,* 54 FOOD & DRUG L.J. 187, 191 (1999).

the Hatch-Waxman Act,[136] yet the average length of life for pharmaceutical patents is still significantly less than that of inventions in other fields.[137]

Unlike generic manufacturers, research-based pharmaceutical companies must recover the large amounts of money invested in research and development within the patent life of the drug.[138] Further, the cost of prescription drugs takes into account the many failed attempts at discovering other new drugs.[139] Of the drugs that finally gain FDA approval, statistics indicate that less than one in three drugs make a profit.[140] That means for every Viagra®, there are at least two other drugs that did not make a profit. Again, these research and development costs are not borne by generic manufacturers but are exclusive to research-based pharmaceutical companies.[141]

Further, there are increased costs in gaining FDA approval.[142] While research-based pharmaceutical companies must spend more time and money completing an NDA, the generic manufacturer must submit only an ANDA.[143] Generic companies do not have to conduct clinical trials for FDA approval but can rely on the trials conducted by the research-based companies.[144] Commentators argue that although this process provides generic drugs an easier entry into the marketplace, it does little to create true competition.[145] Instead, they argue, this creates a distinct advantage in favor of the generic manufacturers because the research-based companies cannot possibly sell a drug cheaper than the generic manufacturers.[146]

Another disadvantage to the Hatch-Waxman Act is the express overruling of *Bolar*.[147] Generic manufacturers are allowed to use the brand name product before the patent has expired to conduct their own research so that their generic drug can gain FDA approval.[148] Providing such an advantage to generic manufacturers is viewed as adverse to the very foundations of patent law: "protection and incentive to invent."[149] This may reduce the incentive to invent new drugs because research-based companies

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[136] *Id.*
[137] Kuhlik, *supra* note 11, at 96-97.
[138] Miller, *supra* note 14, at 103.
[139] *Id.*
[140] Wilson, *supra* note 131, at 499.
[141] Miller, *supra* note 14, at 103-104.
[142] *Id.* at 104.
[143] *Id.*
[144] Wilson, *supra* note 131, at 510.
[145] Miller, *supra* note 14, at 104.
[146] *Id.* at 105.
[147] *See Id.*
[148] *Id.*
[149] *Id.* at 106.

do not gain the full protections to their patents that they would otherwise be entitled to.[150]

Research-based pharmaceutical companies also argue that patent restoration does not give the anticipated benefits.[151] The Act was supposed to extend the time of the patent based on the time lost in regulatory review.[152] However, the Act made four exceptions for which time could be limited: (1) failure to act with due diligence; (2) after any reduction due to failure to act with due diligence, the regulatory review period can only include half of the investigational period; (3) the patent term and patent extension cannot exceed fourteen years; and (4) only one patent may be extended even though the drug product may be covered by multiple patents.[153] For example, forty extensions were granted for human drugs in February 1988, but the average extension granted was 1.8 years despite the fact that the regulatory review period averaged 8.2 years.[154] Thus, the research-based companies argue that the benefits that were supposed to occur under the Hatch-Waxman Act have not materialized.[155]

B. Generic Companies and Consumer Advocates

Consumer advocates argue that legislation enacted over the last twenty years has increased the average effective patent life of drugs by at least 50 percent.[156] For example, the effective patent life of a new drug rose from 8.1 years during 1980-1984 to 13.1-15.4 years in the late 1990s.[157] These commentators argue that the "loopholes" present in the Hatch-Waxman Act are primarily responsible for this trend.[158] There are several reasons given as to why the Act favors research-based companies. Specifically, the two most often cited reasons are using "loopholes" in legislation to apply for patent extensions and suing generic manufacturers for patent infringement.[159]

In an effort to prevent drugs from coming "off-patent," drug companies may apply for "a series of patents over a period of time that cover different aspects of a drug so that new patents become active as old patents expire."[160] One recent example involves the antibiotic Augmentin, which was expected

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[150] *Id.*

[151] *See Id.*

[152] *Id.*

[153] 35 U.S.C. § 156(c) (2004). *See also* Miller, *supra* note 14, at 106.

[154] Miller, *supra* note 14, at 107.

[155] *See Id.*

[156] *See* Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 233 (2001).

[157] *IPP Legislation Delaying Generics, "Costing US Consumers Billions of Dollars,"* PHARMA MARKETLETTER (Aug. 7, 2000), *available at* 2000 WL 7542933.

[158] Glasgow, *supra* note 156, at 233.

[159] *Id.* at 234.

[160] *Id.*

to come off-patent in 2002.[161] The manufacturer, however, managed to secure patents covering other properties of the drug such that Augmentin will remain under patent until 2017.[162]

Another common means for extending the life of a patent is through patent infringement litigation.[163] Under the Hatch-Waxman Act, a generic manufacturer must notify the brand name manufacturer that it intends to market a generic version.[164] Commentators argue that this encourages research-based pharmaceutical companies to file lawsuits that are often frivolous, covering insignificant elements of the drug.[165] Under federal law, the FDA cannot approve a generic drug for thirty months after a patent infringement suit is filed unless a district court determines "the patent is invalid or not infringed."[166] Consumer advocates argue that "[t]he way the laws are currently constructed, there are only incentives for the brand-name manufacturers to file lawsuits and claim patent infringement."[167]

Perhaps one of the most alarming methods of extending patent life in recent years is alleged anticompetitive activities in violation of Federal Trade Commission (FTC) rules.[168] The FTC has recently filed complaints alleging that Hoechst Marion Roussel,[169] Abbott Laboratories,[170] and Schering-Plough[171] collaborated with their generic rivals to keep generics off the market.[172] The FTC alleged that these companies determined that it was cheaper to pay the generic manufacturer to keep their generic off the market for the 180-day exclusivity period prescribed by the Hatch-Waxman Act than to lose their monopoly.[173] By agreeing to postpone the launch of the generic, the generic manufacturer effectively bars all other manufacturers from entering the generic market.[174]

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[161] *Id.*

[162] *Id.*

[163] *Id.*

[164] *Id.* at 235.

[165] *See Id.*

[166] 21 U.S.C. § 355(j)(5)(B)(iii) (2006).

[167] David Ranii, *Generic Drug Companies Complain About Brand-Name Pharmaceutical Firms*, NEWS & OBSERVER (Sept. 29, 2001).

[168] *See Id.*

[169] *See* In re Hoechst Marion Roussel, Inc., No. 9293, 2000 FTC LEXIS 142 (March 16, 2000).

[170] *See* In re Abbott Laboratories., No. 981-0395, 2000 FTC LEXIS 15 (March 16, 2000).

[171] *See* In re Schering-Plough Corp., No. 9297, 2001 FTC LEXIS 39 (April 2, 2001).

[172] Ranii, *supra* note 167.

[173] *Id.*

[174] *Id.*

VI. Analysis

It is obvious from analyzing the arguments of both sides that the premise of balancing interests between research-based pharmaceutical companies and generic manufactures has not been realized under the Hatch-Waxman Act. Some commentators and many of the pharmaceutical companies argue that the current system does not allow the research-based companies to recover their investment of time and research.[175] As a result, the incentive to invent may have decreased under the current system.[176] These factors arguably encourage the research-based companies to resort to litigation, frivolous patents, and questionable arrangements with generic manufacturers that may violate antitrust laws.[177] These tactics work to keep generic drugs off the market.[178] Therefore, it appears that the current law does not effectively balance both sides of the equation, even though this was the goal of the Hatch-Waxman Act.

Of primary concern is the potential for a decreased incentive to innovate. This may force companies to consider whether a potentially life-saving drug would be economical to produce and could prevent some drugs from entering the market.[179] It follows that decreasing the incentive to innovate may cause severe harm to individuals who might benefit from these new drugs.[180] As prescription drug treatment is often more economical than other medical treatments, this may also result in higher overall health care costs.[181]

Perhaps a "fair" remedy would be to allow the research-based companies to recover the full time spent in gaining FDA approval. This would benefit both sides of the equation. The patent holder could recover for the full time lost in regulatory review and clinical trials, and this would encourage innovation by allowing the research-based company to recover its expenses.[182] With a longer patent period, the drug companies ideally would be able to lower prescription drug prices.[183]

Using this logic, it would only be "fair" to allow the generic manufacturer to recover for the time spent in obtaining FDA approval following the filing of the ANDA. Thus, the provision in the Hatch-Waxman Act that overruled *Bolar* would then make sense. This would result in getting generic drugs to the market after the patent for the innovator expires,

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[175] Miller, *supra* note 14, at 107-108.
[176] Wilson, *supra* note 131, at 502.
[177] Glasgow, *supra* note 156, at 227-228.
[178] *Id.*
[179] Wilson, *supra* note 131, at 516-518.
[180] *Id.* at 517.
[181] *Id.* at 518.
[182] *Id.* at 496-498.
[183] Miller, *supra* note 14, at 108.

thus benefiting society. Additionally, it would not result in a *de facto* patent term extension for the innovator.[184]

Congress may also want to rethink some other provisions in the Hatch-Waxman Act that are responsible for many of the behaviors that generic manufacturers and consumer advocates criticize the research-based companies for: litigation, frivolous patents, and questionable arrangements with generic manufacturers that may violate antitrust laws.[185] First, eliminating the provision for a thirty-month injunction would force manufacturers to defend a validity challenge to their patents in court.[186] Forcing the companies to litigate the merits of the patent would eliminate many frivolous patents due to the time and expense of litigation.[187] Second, eliminating the 180-day period of marketing exclusivity would eliminate many of the settlements between research-based companies and their generic "competitors."[188] The 180-day exclusivity period often results in preventing subsequent generic manufacturers from entering the market:

> [B]ecause the 180-day period is not triggered until the generic producer chooses to begin commercial marketing or until a court holds the brand-name patent invalid or not infringed, a settlement with the first generic applicant can delay any generic competition until 180 days after a subsequent generic applicant succeeds in a validity or noninfringement challenge.[189]

Further, eliminating the provision allowing for the 180-day exclusivity would likely end settlement agreements because the brand-name manufacturer would have to enter into settlement agreements with every generic manufacturer.[190] Alternatively, Congress may consider requiring generic manufacturers to forfeit the 180-day exclusivity period if a settlement agreement is reached with a brand-name manufacturer.[191]

In recent years, there have been many high profile mergers and acquisitions in the pharmaceutical industry: American Home Products and Solvay; Johnson & Johnson and Cordis; Zeneca and Astra; Hoechst and Marion Merrell Dow; Glaxo and Burroughs Wellcome; Upjohn and

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[184] Filardi, *supra* note 94, at 215.

[185] Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. ILL. L. REV. 173, 196-197 (2001).

[186] *Id.* at 197.

[187] *Id.*

[188] *Id.* at 196-197.

[189] *Id.* at 184.

[190] *Id.* at 196-197.

[191] *Id.* at 196.

Pharmacia;[192] and GlaxoWellcome and SmithKlineBeecham.[193] Commentators point to several reasons why mergers are becoming more frequent: (1) the managed care revolution; (2) patent expirations; and (3) the need to "broaden a firm's product base and spread marketing costs over a larger number of products."[194] The recent mergers and acquisitions may be due primarily to large research and development costs; in order to "engage in first-level research," these companies must combine resources.[195]

Ideally, these mergers will bring together an increased number of talented scientists and allow for more spending on research and development. In fact, many commentators believe that this will be the result.[196] However, these mergers also have the potential to produce just the opposite result. Instead of combining new methods of thinking to produce a superior result, these mergers have the potential to stifle innovation. Some commentators state that the potential for antitrust violations and decreased incentive for competition increase from these types of mergers.[197] Additionally, with fewer "large" companies to invest in research and development, expenditures may become concentrated in certain areas. Further, mergers may create a common way of viewing problems that inhibits creativity instead of encouraging it. Whereas differing approaches may lead to a superior result, a singular approach may not produce the desired results.

Finally, Congress and the White House may want to examine what is one of the biggest factors in rising drug costs: price controls in other countries.[198] Currently, research-based pharmaceutical companies "obtain their highest margins and funding for research and development in the U.S. market."[199] Price ceilings in Canada and Europe essentially make the United States subsidize the foreign markets.[200] Industry representatives note that "if all drugs were sold at [the] cut-rate prices [of Europe and Canada], the incentives that drive medical innovation would vanish."[201] As one Congressman stated:

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[192] *See generally* David A. Balto and James F. Mongoren, *Antitrust Enforcement in Pharmaceutical Industry Mergers*, 54 Food & Drug L.J. 255 (1999).

[193] Robert Stevens, *Glaxo Wellcome-SmithKline Beecham Merger Creates World's Largest Drug Company* (Jan. 22, 2000), *available at* http://www.wsws.org/articles/2000/jan2000/glax-j22.shtml.

[194] Balto and Mongoren, *supra* note 192, at 256-257.

[195] *Id.* at 257.

[196] *Id.* at 278.

[197] Glasgow, *supra* note 156, at 247.

[198] Chordas, *supra* note 3.

[199] *Id.*

[200] *Id.*

[201] Matthew Herper, *Drug Prices: The Genentech Solution*, FORBES (March 16, 2004), *available at* http://www.forbes.com/sceincesandmedicine/2004/03/16/cx_mh_0316drugcosts.html.

> We are a blessed country with a lot of wealth, so we should help make prescription drugs more affordable for developing countries, especially Africa. But subsidizing the entire world and 'the starving Swiss' does not make sense. Americans deserve to have a more fair system so we're not shouldering the entire burden.[202]

However, a recent survey shows that prescription drug prices may correspond to differences in national incomes.[203]

VII. Conclusion

One major problem unique to the pharmaceutical industry is that the average patent life of a drug is significantly shorter than the life of any other invention.[204] Because of the significant research and development costs, lengthy FDA approval process, and shorter patent terms, the research-based pharmaceutical companies are forced to increase prices to recover their investment.[205] Increasing the patent term for the research-based pharmaceuticals would significantly increase the ability of companies to recover the cost of research and development.[206] Further, a longer patent term likely would lead to lower costs of prescription drugs because the companies would have more time to recover their investment.[207]

Other changes to the Hatch-Waxman Act should also be considered. Removing the provision allowing a 180-day exclusivity period to the first generic manufacturer to file a patent challenge would prevent settlements between research-based companies and generic manufacturers that delay other generic manufacturers from entering the marketplace.[208] Additionally, Congress should consider removing the provision granting the brand-name manufacturer a thirty day preliminary injunction.[209] Currently, the law encourages research-based companies to obtain additional patents and to file infringement suits.[210] Removing this provision would force companies to defend their patents on the merits.[211]

The current prescription drug crisis will hopefully awaken a reevaluation of the Hatch-Waxman Act. With many senior citizens

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[202] Snow, *supra* note 4.

[203] Reuters, *Drug Prices Vary By Country*, *available at* http://www.msnbc.msn.com/id/3341608/ (last updated Nov. 4, 2003).

[204] Kuhlik, *supra* note 11, at 96-97.

[205] Miller, *supra* note 14, at 103.

[206] *Id.* at 108.

[207] Wilson, *supra* note 131, at 517.

[208] Rai, *supra* note 185, at 196-197.

[209] *Id.* at 197.

[210] *Id.*

[211] *Id.*

purchasing necessary drugs from Canada and Mexico despite possible safety concerns, the causes of high prescription drug prices must be examined.[212] A balanced examination of the Act shows that it is not creating the intended benefit. Fewer new drugs are being developed,[213] resulting in more litigation and questionable dealings.[214] Revising the Act to close some of the "loopholes" may increase the benefits to the research-based pharmaceutical companies, generic manufacturers, and society overall.

[212] Chordas, *supra* note 3.

[213] Jill Wechsler, *Pharmaceutical Pricing and Innovation: Key Issues For 2003*, PHARMACEUTICAL TECHNOLOGY, Jan. 1, 2003.

[214] Glasgow, *supra* note 156, at 227-228.