

REINING IN PATENT TERM EXTENSIONS FOR
RELATED PHARMACEUTICAL PRODUCTS
POST-*PHOTOCURE* AND *ORTHO-MCNEIL*

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ABSTRACT—The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch–Waxman Act, was enacted with the dual goals of fostering economic incentives for pioneer pharmaceutical research and development as well as making available more low-cost generic alternatives. While generally regarded as having successfully balanced both branded and generic interests, the Act’s provisions have also been circumvented and manipulated by pharmaceutical companies’ anticompetitive efforts, as illustrated by two recent decisions regarding its Patent Term Extension provision. In *Ortho–McNeil Pharmaceutical, Inc. v. Lupin Pharmaceuticals, Inc.* and *PhotoCure ASA v. Kappos*, both decided in May 2010, the Federal Circuit affirmed term extensions on new compounds highly related to drugs already approved and in commercial use in order to compensate for time lost during lengthy Food and Drug Administration regulatory review. Such decisions signal a shift in the historically inconsistent Federal Circuit treatment of the statutory term “product” for purposes of patent-term-extension analysis by easing extension grants for new drug products highly related to those previously approved and marketed. This Comment argues that a reversal from the Federal Circuit’s recent treatment of highly related compounds is necessary to establish a more beneficial balance between innovation and consumer protection in the patent regime, and to prevent further manipulation of Hatch–Waxman provisions.

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INTRODUCTION

The stated purpose of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch–Waxman Act, is “to make available more low cost generic drugs” and “to create a new incentive for increased expenditures for research and development,”¹ better motivating drug companies to supply the American public with “the best medicine that pharmaceutical science can provide.”² In furtherance of these goals, the Hatch–Waxman Act seeks to balance the competing interests of branded pioneer pharmaceutical companies and their generic counterparts in order to protect the financial interests of the consumer while still fostering economic incentives to innovate.³

While the Act has generated greater competition in the pharmaceutical market and provided increased access to low-cost generic alternatives, its provisions have also been circumvented and manipulated by companies whose anticompetitive efforts aim to “turn the [A]ct on its head.”⁴ Brand-name pharmaceutical companies employ a number of strategies to extend their patent lifetimes that abide by the letter of the Hatch–Waxman Act but not by its spirit, including the initiation of patent infringement suits, reverse settlement agreements, and the strategic temporal layering of patents over

¹ H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48.

² *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) (quoting Remarks on Signing S. 1538 into Law, 20 WKLY. COMP. PRES. DOC. 1359, 1360 (Sept. 24, 1984) (statement of President Reagan)) (internal quotation mark omitted).

³ See Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L.J. 51, 53 (2003).

⁴ Henry A. Waxman, Op-Ed., *False Alarms on Clean Air*, WASH. POST, Mar. 5, 1997, at A21; see also Kristin E. Behrendt, *The Hatch–Waxman Act: Balancing Competing Interests or Survival of the Fittest?*, 57 FOOD & DRUG L.J. 247, 248 (2002).

different aspects of one drug product.⁵ A prime example of a new opportunity for major pharmaceutical companies to “game” the system in such a manner is the recent treatment of related drug compounds under the Act’s Patent Term Extension provision.

The Patent Term Extension provision provides up to five additional years on a patent to compensate for the patent term length and potential profits lost to the increasingly lengthy period of mandatory Food and Drug Administration (FDA) regulatory testing.⁶ By restoring that portion of patent life for a pharmaceutical product, the statute aims to boost the economic incentive for new drug development, a motivation already diminished to some degree by the immense research-and-development costs inherent to the pharmaceutical industry.⁷ Despite its straightforward underlying purpose, the Patent Term Extension provision has given rise to inconsistent and controversial rulings as courts have wrestled with the definition of “product” and its application to highly related drug compounds.⁸ Because the extension statute stipulates that the commercial marketing of the drug after the regulatory review at issue must be the “first permitted commercial marketing or use of the product,”⁹ the definition of “product” is a key determination dictating the validity of an extension. The word’s definition is particularly problematic in the context of new pharmaceuticals that are highly structurally related to previously approved products, such as an approved product’s derivative forms, polymorphs, and stereoisomeric combinations.¹⁰ A broad interpretation of “product” that includes any derivative form of the active pharmaceutical ingredient such as salts, esters, or stereoisomeric combinations would foreclose extensions on

⁵ Melody Wirz, Comment, *Are Patents Really Limited to 20 Years?—A Closer Look at Pharmaceuticals*, 1 OKLA. J.L. & TECH. 5, at 4 (2003), <http://www.okjolt.org/images/pdf/2003okjoltrev5.pdf> (“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 . . .”).

⁶ 35 U.S.C. § 156 (2006); Behrendt, *supra* note 4, at 252.

⁷ Soehnge, *supra* note 3, at 75 (estimating the cost of a pioneer drug company in bringing a new drug from research stages to FDA approval to be \$500–\$600 million in 2001); Mandy Wilson, *Pharmaceutical Patent Protection: More Generic Favored Legislation May Cause Pioneer Drug Companies to Pull the Plug on Innovation*, 90 KY. L.J. 495, 497 (2001) (citing decreased patent terms, risk of liability, and increased research costs as factors decreasing the profitability of drug development).

⁸ See, e.g., *Ortho-McNeil Pharm., Inc. v. Lupin Pharm., Inc.*, 603 F.3d 1377, 1380–81 (Fed. Cir. 2010); *PhotoCure ASA v. Kappos*, 603 F.3d 1372, 1374–76 (Fed. Cir. 2010).

⁹ § 156(a)(5)(A).

¹⁰ A chemical derivative is a structural analogue that theoretically can be formed from the precursor compound. See OXFORD DICTIONARY OF BIOCHEMISTRY AND MOLECULAR BIOLOGY 173 (Richard Cammack et al. eds., 2d ed. 2006) (defining “derivative” as “any compound that may, at least theoretically, be formed from another compound to which it is structurally related”). A stereoisomer is a molecule that has the same molecular formula and sequence of bonded atoms as another molecule, but differs only in the three-dimensional orientation of its atoms in space. See INT’L UNION OF PURE & APPLIED CHEMISTRY, COMPENDIUM OF CHEMICAL TERMINOLOGY: GOLD BOOK 1450 (2012), available at <http://goldbook.iupac.org/PDF/goldbook.pdf>.

any related drug compounds whose parent active ingredient has already been marketed. If an ester of the drug for which an extension is sought has already been marketed, the argument goes, its forthcoming commercial marketing would not be the first marketing of the “product,” and therefore no extension could be granted.

Conversely, defining “product” narrowly to mean only the exact chemical structure found in a marketed drug compound would allow a subsequent derivative to enjoy its own patent extension since that specific “product” would not have been previously brought to market. With little statutory guidance, the Federal Circuit has treated the term inconsistently, endorsing each definition at different times and thus creating an undesirable element of unpredictability in the Act’s application.¹¹

Specifically, two recent Federal Circuit decisions applying the narrow interpretation of “product” suggest a break away from the circuit’s previous approach of limiting the prevalence of term extensions.¹² In *Ortho–McNeil Pharmaceutical, Inc. v. Lupin Pharmaceuticals, Inc.* and *PhotoCure ASA v. Kappos*, both decided in May 2010, the Federal Circuit shifted to a more consistent application of the narrower “product” definition.¹³ The Federal Circuit allowed patent term extensions in both cases by reasoning that an enantiomer and methyl ester, respectively, of two previously approved and marketed drug products were in fact different “products” than their predecessors already in commercial use.¹⁴ These decisions contradict previous rulings limiting extensions by defining “product” more broadly,¹⁵ and instead make it easier for branded pioneer companies to obtain term extensions over drug compounds highly related to already marketed drugs. They therefore threaten to tilt the delicate balance in the current patent regime between branded and generic companies further away from the consumer interest in low-cost, high-quality pharmaceuticals.¹⁶

¹¹ Compare *Pfizer Inc. v. Dr. Reddy’s Labs., Ltd.*, 359 F.3d 1361, 1367 (Fed. Cir. 2004) (finding that the statutory definition of “product” included an active ingredient and its derivatives, such as salts), and *Fisons plc v. Quigg*, 876 F.2d 99, 101 (Fed. Cir. 1989) (rejecting plaintiff’s argument that “product” should be restricted to the particular structure rather than its underlying active ingredient), with *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 399–400 (Fed. Cir. 1990) (construing the term “product” to mean only the specific structure physically found in the compound, not including any salt, ester, or other noncovalent derivative of the active ingredient).

¹² See William L. Warren et al., *Unique Active Ingredient in Drug Product Can Mean Patent Term Extension*, EMERGING ISSUES, May 2010, at 1, 1.

¹³ *Ortho–McNeil*, 603 F.3d at 1380–81; *PhotoCure*, 603 F.3d at 1374–76.

¹⁴ *Ortho–McNeil*, 603 F.3d at 1381; *PhotoCure*, 603 F.3d at 1376.

¹⁵ See, e.g., *Fisons*, 876 F.2d at 101; *Pfizer*, 359 F.3d at 1366–67.

¹⁶ See James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 481 (1986) (“[P]atent extension and market exclusivity may be costly to consumers, but real increases in future drug innovation may not follow.”).

Although a consistent, predictable approach to patent term extensions is desirable, the Federal Circuit's current trend towards relaxing term-extension grants signals dangerous consequences for a patent system currently struggling to balance the competing interests of consumers, branded pharmaceutical companies, and generic manufacturers.¹⁷ Indeed, with anticompetitive incentives already being fostered, albeit inadvertently, by other provisions of the Hatch–Waxman Act, major pharmaceutical companies are hardly in need of another legislative loophole to exploit in order to extend patent lifetimes.¹⁸ The Federal Circuit should therefore abandon its current endorsement of a narrow definition of “product” in favor of its prior line of reasoning where it interpreted the term more broadly. A broad interpretation of “product” limits the granting of extensions and better upholds the harmonizing aims of the Hatch–Waxman Act. This interpretation not only reflects the desired purpose of the term-extension provision, but also fosters the desired balance between the incentive to innovate and the concern for consumer protection in the patent regime.¹⁹

Part I of this Comment introduces the history of the Hatch–Waxman Act and its patent-term-extension provision. Part II discusses the difficulties that the ambiguous “product” language within the statute creates for the courts, and Part III covers the courts' past disparate treatment of related drug compounds in the context of term extensions and examines the rationales behind these inconsistent rulings. Part IV explains the Federal Circuit's recent rulings in *Ortho–McNeil* and *PhotoCure ASA* and the implications for future related drug compound cases. Finally, Part V argues that the shift toward a more liberal granting of extensions represents yet another opportunity for branded pharmaceutical companies to “game” the

¹⁷ Soehnge, *supra* note 3, at 51 (noting that although the Hatch–Waxman Act was passed to better balance the intellectual property interests of pioneer drug developers with the need of the American public for lower cost generic alternatives, the legislation has been circumvented by manufacturers in ways that “decrease competition in the drug market and, in turn, decrease availability of generic drugs to the public”).

¹⁸ See Behrendt, *supra* note 4, at 248 (noting that the Act has “prompted . . . rival competitors to join hands” in anticompetitive agreements); Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, in 4 INNOVATION POLICY AND THE ECONOMY 145, 147 (Adam B. Jaffe et al. eds., 2004) (“[T]he major drug companies have learned to game the system to delay competition, creating a need for a fresh look at the special Hatch–Waxman provisions that govern pharmaceutical patent infringement litigation.”); Daniel I. Gorlin, *Staving Off Death: A Case Study of the Pharmaceutical Industry's Strategies to Protect Blockbuster Franchises*, 63 FOOD & DRUG L.J. 823, 824–25 (2008) (describing the anticompetitive strategies employed by AstraZeneca and Schering–Plough in extending the patent terms over Prilosec and Claritin, respectively); *infra* Part IV.

¹⁹ Natasha N. Aljalian, *The Role of Patent Scope in Biopharmaceutical Patents*, 11 B.U. J. SCI. & TECH. L. 1, 2 (2005) (“The federal patent system . . . embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful and nonobvious advances in technology . . . in return for the exclusive right to practice the invention for a period of years.” (omissions in original) (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989)) (internal quotation marks omitted)).

patent system, with harmful consequences for consumer interests. This Comment argues that a reversal from the recent shift in the Federal Circuit's treatment of highly related compounds is necessary to establish a more beneficial balance between innovation and consumer protection in the patent regime, and to prevent further manipulation of Hatch–Waxman provisions.

I. THE HISTORY AND PURPOSE OF THE HATCH–WAXMAN ACT

A. *The Pharmaceutical Industry Prior to the Hatch–Waxman Reforms*

The Hatch–Waxman Act, the first major piece of federal pharmaceutical drug legislation enacted since the passage of the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA),²⁰ was designed to better promote generic drug alternatives while still facilitating pioneer drug research and development.²¹ The collective discontent felt by both generic and branded pioneer pharmaceutical companies under the FDCA's original statutory framework motivated the passage of the Hatch–Waxman reforms.²² Pioneer pharmaceutical companies complained that the regulatory approval process under the FDCA significantly shortened patent terms and dulled financial incentives to innovate.²³ Companies that manufactured generics, in turn, characterized the Act as unfairly delaying drug competition to the detriment of the consumer.²⁴ The Hatch–Waxman Act therefore reflects Congress's efforts to “balance two conflicting policy objectives: to induce brand name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.”²⁵

The FDA played a pivotal role in the regulation of the pharmaceutical industry under the FDCA framework and continues to do so.²⁶ Empowered with the authority to review the safety of any new pharmaceutical product before it could be introduced into commerce, the FDA requires the manufacturer of a new drug to submit a new drug application (NDA)

²⁰ Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399 (2006)).

²¹ David J. Bloch, *If It's Regulated Like a Duck . . . Uncertainties in Implementing the Patent Exceptions of the Drug Price Competition and Patent Term Restoration Act*, 54 FOOD & DRUG L.J. 111, 112 (1999) (“A central congressional goal in passing [the Act] was to remedy these distortions.”); Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch–Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 585 (2003).

²² Weiswasser, *supra* note 21, at 590.

²³ See Wheaton, *supra* note 16, at 434–35 (describing the lobbying efforts on the part of generics and branded pharmaceutical companies in the years leading up to the Hatch–Waxman Act of 1984).

²⁴ *Id.*

²⁵ Mylan Pharm., Inc. v. Thompson, 268 F.3d 1323, 1326 (Fed. Cir. 2001) (quoting Abbott Labs. v. Young, 920 F.2d 984, 991 (D.D.C. 1990) (Edwards, J., dissenting)) (internal quotation mark omitted).

²⁶ Weiswasser, *supra* note 21, at 587.

containing studies demonstrating that the product was safe for human use.²⁷ Any unpublished data used in support of an NDA was to be kept confidential and could not be disclosed or used by another company to support its own NDA on a similar or identical drug. Through this protection, the FDA acknowledged the high cost of such testing for branded companies and the opportunity for generics to benefit at pioneer companies' expense.²⁸ Therefore, even from its inception in 1938, the FDA was keenly aware of the tension existing between branded and generic drug companies stemming from the huge research costs inherent in bringing a pharmaceutical product into commerce.²⁹

In fact, the Patent Act itself developed from the assumption that a period of exclusivity is necessary to stimulate the optimal level of innovation for society.³⁰ The Patent Act establishes within the United States Patent and Trademark Office (USPTO) the "power to grant inventors limited monopolies in exchange for the disclosure of their inventions."³¹ After satisfying certain statutory requirements including novelty, utility, and nonobviousness,³² patent holders are granted the right to prevent others from using, manufacturing, selling, offering to sell, or importing the patented product or process.³³ For the majority of patents filed on or after January 1, 1995, the term of protection is twenty years from the date the application is filed.³⁴ A pioneer drug firm would thus first seek to satisfy the elements of patentability under the Patent Act during a drug's development process, and then meet the safety requirements of the FDCA in order to bring the product to market.

However, in 1962, Congress passed the Kefauver–Harris Amendments to the FDCA, requiring not only proof of safety on the part of newly patented drug products, but also proof of efficacy.³⁵ Prior to these amendments, a pharmaceutical company was not required to corroborate any purported health benefits of its products before putting them on the market, so long as they had been proven safe for human consumption.³⁶ The

²⁷ Pub. L. No. 75-717, § 505, 52 Stat. 1040, 1052 (1938) (codified as amended at 21 U.S.C. § 355 (2006)) (detailing the application and approval process for new drugs); *see also* Pub. L. No. 75-717, § 2(p), 52 Stat. 1040, 1041 (codified as amended at 21 U.S.C. § 321(p)) (defining "new drug").

²⁸ Weiswasser, *supra* note 21, at 587.

²⁹ *Id.*

³⁰ ROCHELLE COOPER DREYFUSS & ROBERTA ROSENTHAL KWALL, *INTELLECTUAL PROPERTY: CASES AND MATERIALS ON TRADEMARK, COPYRIGHT AND PATENT LAW* 565 (2d ed. 2004).

³¹ Wilson, *supra* note 7, at 501.

³² 35 U.S.C. §§ 102–103 (2006).

³³ *Id.* § 271.

³⁴ *Id.* § 154.

³⁵ Drug Amendments of 1962, Pub. L. No. 87-871, 76 Stat. 780 (1962); *see* Sam Peltzman, *An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments*, 81 J. POL. ECON. 1049, 1051 (1973); Wheaton, *supra* note 16, at 439.

³⁶ Peltzman, *supra* note 35, at 1051; Wheaton, *supra* note 16, at 439.

1962 Amendments, however, added the requirement of “substantial evidence” of the efficacy of a product’s intended purpose; this requirement has customarily come to mean that a company must conduct at least two “adequate and well-controlled clinical investigations” demonstrating a statistically significant benefit for consumers.³⁷ This efficacy requirement proved quite costly to pioneer pharmaceutical companies as products stalled in lengthy regulatory testing. Such delays became a significant financial drain as years of market exclusivity rights, which companies rely upon to recoup research-and-development costs, consequently went unexploited.³⁸

This problem developed because in general, innovators secure patent protection over drug products as early as possible in the development process so as to prevent competitors from entering the market with the same drug. However, a patent term begins to toll as soon as the patent is secured over the product, often before the requisite regulatory testing for market entry has been completed or even begun. Thus, with the heightened efficacy requirements instituted in 1962, an increasing number of years of market exclusivity were wasted in testing.³⁹ One study concluded that the average 13.6 years of patent-protected market exclusivity enjoyed by drug manufacturers prior to 1962 shrank to an average of only 9.5 years by 1979.⁴⁰ With the addition of the efficacy requirement, therefore, doubly burdened pharmaceutical companies saw research-and-development costs increase while the effective length of the patent terms they enjoyed in the marketplace simultaneously decreased.⁴¹ Indeed, the negative ramifications of this reduction in patent exclusivity on the overall level of pharmaceutical innovation resulted in much congressional lobbying throughout the 1970s.⁴² During this decade the Executive Branch also began to advocate restoring a longer period of patent exclusivity.⁴³

Pioneer companies were not the only players in the pharmaceutical market burdened by the pre-Hatch–Waxman regulatory framework. The effective term-length reduction occasioned by the passage of the 1962

³⁷ Hearing Regulations and Regulations Describing Scientific Content of Adequate and Well-Controlled Clinical Investigations, 35 Fed. Reg. 7250, 7250 (May 8, 1970); Weiswasser, *supra* note 21, at 588 & n.15 (quoting 35 Fed. Reg. 7250).

³⁸ See Weiswasser, *supra* note 21, at 588. Marketing exclusivity is a primary benefit of a patent, as it allows a patent holder to exclude any other manufacturers from intruding on the market for its product, and thus represents the opportunity to be the sole beneficiary of any financial gain from the product. Wheaton, *supra* note 16, at 434–35 (discussing pioneer companies’ reliance on their period of market exclusivity to recoup innovation costs).

³⁹ See Weiswasser, *supra* note 21, at 588.

⁴⁰ Gorlin, *supra* note 18, at 826.

⁴¹ See *id.* (describing the FDCA amendments as “significantly shorten[ing] the window of exclusivity within which manufacturers could recoup their investment”).

⁴² See Wheaton, *supra* note 16, at 435.

⁴³ See Gorlin, *supra* note 18, at 826. Both the Carter and Reagan Administrations formally supported restoring a term of marketing exclusivity to pharmaceutical patents. *Id.*

Amendments was also onerous to generic manufacturers, who were now responsible for proving the efficacy—in addition to the safety—of their products.⁴⁴ The generic industry furthermore could not recycle either the efficacy or safety studies already conducted by their pioneer counterparts on the originally patented drug they were now seeking to replicate.⁴⁵ As a result, the costs of independently proving safety and efficacy in order to gain FDA approval for an equivalent drug were often prohibitively large for generic manufacturers, dramatically lessening the economic incentive to bring a low-cost alternative to market.⁴⁶

Further stifling generics was the fact that whatever independent studies a generic manufacturer did opt to perform could only take place after the pioneer drug went off patent.⁴⁷ This requirement effectively lengthened the patent term life of a given drug since generic entry was delayed until both the patent expired and after independent testing could be completed.⁴⁸ Consequently, the generic presence in the pharmaceutical marketplace dwindled drastically.⁴⁹

By 1984, as a result of the general unwillingness of generic drug manufacturers to shoulder the cost necessary to achieve FDA approval, only 35% of off-patent products had generic equivalents.⁵⁰ With generic competition stifled and the economic incentives for pioneer companies to develop new medicines dulled by the FDCA's regulatory scheme, congressional fears of rising drug costs and decreasing availability of pharmaceuticals intensified.⁵¹

B. *The Balancing Provisions of the Hatch–Waxman Act*

In order to effectively remedy this potential market stagnation, legislation would have to assuage pioneer manufacturers as well as their generic competitors in hopes of best serving their common beneficiary: the American consumer.

Cosponsored by Representative Henry A. Waxman (D-CA) and Senator Orrin Hatch (R-UT), the Drug Price Competition and Patent Term

⁴⁴ See Behrendt, *supra* note 4, at 249 (describing the generic industry between 1962 and 1984 as “not a robust industry” and “not economically profitable”); *supra* note 35 and accompanying text.

⁴⁵ See Behrendt, *supra* note 4, at 249; Gerald J. Mossinghoff, *Overview of the Hatch–Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187–89 (1999).

⁴⁶ Behrendt, *supra* note 4, at 249.

⁴⁷ *Id.*

⁴⁸ *Id.* at 249–50. The Federal Circuit ruled in *Roche Products, Inc. v. Bolar Pharmaceutical Co.* that the manufacture of a patented product by a generic company for purposes of regulatory testing qualified as an act of infringement. 733 F.2d 858 (Fed. Cir. 1984). This ruling was ultimately overruled by the passage of the Hatch–Waxman Act, specifically § 271(e)(1). Behrendt, *supra* note 4, at 250.

⁴⁹ Behrendt, *supra* note 4, at 249–50 (noting that these forces led to a “low number of generic drugs on the market prior to 1984”).

⁵⁰ Gorlin, *supra* note 18, at 827.

⁵¹ See Weiswasser, *supra* note 21, at 590.

Restoration Act of 1984 was drafted with a keen awareness of the legislative priorities of all three players.⁵² To address the imbalance between the patent-exclusivity interests of pioneer drug developers and the market-entry concerns of generics, the Act restored patent protection that was lost to the profit-stalling FDA regulatory process while relaxing the regulatory pathway faced by generic drug makers. The Act also incentivized generics to challenge the validity of current pharmaceutical patents.⁵³ In this way, the Act aimed to eliminate the statutory distortions affecting both the beginning and end of a patent term: the regulatory-testing delay prematurely shortening an awarded patent term before the product even reached the market, and the delayed entry of generic competition artificially lengthening the effective patent term even after the patent's original expiration.⁵⁴

Due to the legislation's competing aims, the identity of the true beneficiary of the Hatch–Waxman provisions is hotly debated—both generic and pioneer companies claim that Congress more satisfactorily addressed their counterpart's interests.⁵⁵ However, both sides benefit distinctly from separate provisions of the Act, and it is generally regarded as successful in achieving its goals of facilitating both generic and pioneer drug research and development.⁵⁶

Branded pharmaceuticals benefit most clearly from the patent-term-extension provision within § 156 of the Act, which allows for the lengthening of a patent term to compensate for time lost to regulatory testing. Specifically, in order to remedy the front-end distortion preventing pioneer companies from benefiting financially from their product during its regulatory scrutiny, the Act provides for the extension of patent terms over

⁵² See Behrendt, *supra* note 4, at 250 (“[T]he Act . . . was intended to strike a balance between the competitive and commercial forces in the drug industry, namely balancing the interests of consumers, the brand-name pharmaceutical industry, and the generic drug industry.”).

⁵³ Soehnge, *supra* note 3, at 51.

⁵⁴ Natalie Pous, *Shifting the Balance Between Branded and Generic Pharmaceutical Companies: Amendments to Hatch–Waxman Past, Present, and Future*, 19 FED. CIR. B.J. 301, 301 (2009).

⁵⁵ Compare Wilson, *supra* note 7, at 510–11 (characterizing the generic industry as favored by the Hatch–Waxman Act to the exclusion of pioneers), with Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 232–33, 237–38 (2001) (describing pioneer companies as truly benefiting from Hatch–Waxman, in no small part because of their manipulation of its provisions).

⁵⁶ Weiswasser, *supra* note 21, at 586. Regarding the Act's success in promoting the generic market, the FTC has reported that the Hatch–Waxman Act promoted growth of the generic drug market from 19% of the total pharmaceutical market in 1984 to more than 47% in 2002. FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY*, at i (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>. The Act has also successfully promoted research and development in the pioneer drug industry; the combined \$1.06 billion spent by branded pharmaceutical companies on research and development of new drug products in 1975 grew to exceed \$49.42 billion in 2010. PHARM. RESEARCH & MFRS. OF AM., *PHARMACEUTICAL INDUSTRY: 2011 PROFILE* 42 tbl.1 (2011), available at http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf.

pharmaceutical products that have been subject to regulatory testing by up to five years.⁵⁷

As previously discussed, statutory restrictions permit extension only for those products subject to regulatory review by a federal authority before their first commercial marketing or use.⁵⁸ An application for a patent extension must be filed within sixty days after the product is approved, and the sum of the patent extension and the amount of the patent remaining after the product finishes the regulatory review cannot exceed fourteen years.⁵⁹ Furthermore, despite pioneer companies' common practice of "layering" a series of patents covering different aspects of a single product over time so that the drug stays perpetually on patent, only one patent per drug may be extended.⁶⁰ Any lack of due diligence by a pioneer company that causes delay in the extension process will also reduce the ultimate term extension granted.⁶¹

Due to the extremely high costs of pharmaceutical research and development, such additional grants of market exclusivity are highly advantageous to pioneer drug companies. One study estimated that in 2000, the cost of bringing a single drug to market was approximately \$500 million and represented twelve to fourteen years of research and development, making any increase in the period of marketing exclusivity desirable in light of such an immense investment.⁶² For example, the extra two years of exclusivity awarded to the manufacturers of Claritin under the Act amounted to an extra \$5 billion of sales for the branded product.⁶³

⁵⁷ 35 U.S.C. § 156(a) (2006). The Patent Term Extension statute states:

The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent . . . if—

(1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2) the term of the patent has never been extended under subsection (e)(1) of this section;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use

Id.

⁵⁸ *Id.*

⁵⁹ *Id.* § 156(c)–(d)(1).

⁶⁰ *Id.* § 156(g)(4); Glasgow, *supra* note 55, at 234 (describing the layering approach used by pioneer companies to avoid coming "off patent").

⁶¹ Thomas Chen, Note, *Authorized Generics: A Prescription for Hatch–Waxman Reform*, 93 VA. L. REV. 459, 464 (2007).

⁶² David Noonan, *Why Drugs Cost So Much*, NEWSWEEK, Sept. 25, 2000, at 22, 26.

⁶³ See Behrendt, *supra* note 4, at 253. By taking advantage of other extension provisions in the Uruguay Round Agreement Act, the Hatch–Waxman Act, and pediatric trials, Schering–Plough ultimately secured over four years of extended patent protection, amounting to \$13 billion in revenue. Glasgow, *supra* note 55, at 236.

Pioneer interests are also furthered by the amendments made to the FDCA in Title I of the Hatch–Waxman Act concerning the Abbreviated New Drug Application (ANDA) process for generic copies of patented drugs.⁶⁴ Under Title I, an ANDA filed by a potential generic competitor must include information demonstrating that the generic is bioequivalent to the pioneer, among other requirements.⁶⁵ The filer of an ANDA must also certify that the generic drug will not infringe any patents held by the maker of the pioneer drug, that any patents on the pioneer drug have expired or the date on which relevant patents will expire, or that the patent on the pioneer drug is invalid.⁶⁶ A generic manufacturer’s certification that the pioneer patent is invalid is known as a “Paragraph IV” challenge. If the generic company asserts in the ANDA that the generic drug will not infringe existing patents or that existing patents are invalid, the generic filer must give notice to the pioneer patentee that the ANDA has been submitted and include a detailed explanation of his basis for the claim of invalidity or noninfringement.⁶⁷

Significantly, if the branded patentee brings an infringement suit within forty-five days of such notice, Title I prohibits the FDA from approving the generic ANDA for thirty months from the date of the notice, unless the trial court decides prior to that time that the patent is invalid or not infringed.⁶⁸ Unless the patent litigation concludes in less than thirty months, unlikely in most federal courts, the patent holder extends his exclusive market power with the filing of an infringement suit.⁶⁹ Thus, the biggest boon the Hatch–Waxman Act provides to branded-pharmaceutical manufacturers is the opportunity to extend patent lifetimes and thus retain market exclusivity.

To balance these pro-pioneer interest provisions, the Hatch–Waxman Act also addresses the back-end distortion artificially lengthening patent

⁶⁴ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, §§ 101–106, 98 Stat. 1585, 1585–97 (1984) (codified as amended at 21 U.S.C. § 355(j) (2006)); *see also* Wheaton, *supra* note 16, at 458–59.

⁶⁵ 21 U.S.C. § 355(j)(2)(A)(iv). According to the FDA’s definition, “[f]or two orally administered drug products to be bioequivalent, the active drug ingredient or active moiety in the test product must exhibit the same rate and extent of absorption as the reference drug product.” CTR. FOR DRUG EVALUATION & RESEARCH, FDA, GUIDANCE FOR INDUSTRY: BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES FOR ORALLY ADMINISTERED DRUG PRODUCTS—GENERAL CONSIDERATIONS 2 (2003), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070124.pdf>; *see also* Donald J. Birkett, *Generics—Equal or Not?*, 26 AUSTRALIAN PRESCRIBER 85, 85 (2003) (“Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bioavailabilities (rate and extent of availability) after administration in the same molar dose are similar to such a degree that their effects, with respect to both efficacy and safety, can be expected to be essentially the same.”).

⁶⁶ § 355(j)(A)(2)(vii); *see also* Wheaton, *supra* note 16, at 459 & n.132.

⁶⁷ § 355(j)(2)(B).

⁶⁸ *Id.* § 355(j)(5)(B)(iii); *see also* Wheaton, *supra* note 16, at 460.

⁶⁹ Wheaton, *supra* note 16, at 460–61.

terms to the detriment of generics. Title II of the Hatch–Waxman Act⁷⁰ makes it clear that the manufacture or use of a patented product “solely for uses reasonably related to the development and submission of information” to the FDA is not an act of infringement.⁷¹ Generics are thereby empowered by the Act to begin testing their replication of a branded product before the expiration of its patent, directly overturning the ruling in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*⁷² The regulatory testing allowance within this provision is unique to the field of pharmaceutical patents; no other patent holder is denied the right to exclusive use of her patented invention during the actual term of the patent without her consent, as through a licensing scheme.⁷³ Furthermore, the Act reduces the generic’s burden of proof in its testing requirements to a standard of bioequivalence with the patented target.⁷⁴ Thus, rather than satisfy separate safety and efficacy tests, a generic manufacturer only needs to prove that its drug contains the same active ingredient and basic pharmacokinetics of the branded product it imitates.⁷⁵ Beyond this showing, the generic manufacturer may freely rely upon the safety and efficacy studies performed by the patent holder, thus eliminating duplicative research costs and ultimately bringing generic alternatives to market more quickly and cheaply.⁷⁶

The simplified ANDA process also encourages generics to challenge patented products with the reward of a 180-day exclusivity advantage over any other generic manufacturers for successful invalidity claims.⁷⁷ The drug application process outlined in the Act provides that the holder of any approved NDA must list pertinent pharmaceutical patents it believes would

⁷⁰ Pub. L. No. 98-417, §§ 201–203, 98 Stat. 1598, 1598–1603 (1984) (codified as amended at 21 U.S.C. § 271).

⁷¹ 35 U.S.C. § 271(e)(1) (2006); see Bloch, *supra* note 21, at 120.

⁷² 733 F.2d 858 (Fed. Cir. 1984), *superseded by statute*, § 271(e)(1); see also Wilson, *supra* note 7, at 509–10 (describing Title II’s reversal of the holding in *Roche* that a generic company’s use of a patented product to perform the FDA required testing to bring a bioequivalent drug to market was infringement).

⁷³ See Wilson, *supra* note 7, at 509–10; Susan Kopp Keyack, *The Drug Price Competition and Patent Term Restoration Act of 1984: Is It a Healthy Long Term Solution?*, 21 RUTGERS L.J. 147, 160–61 (1989) (“[S]ection 271(e)(1) offsets the benefits gained by the pioneer manufacturers from the patent extension provisions.”).

⁷⁴ 21 U.S.C. § 355(j)(2)(A)(iv) (2006).

⁷⁵ Chen, *supra* note 61, at 463. An active ingredient is the chemical compound that produces the drug’s intended therapeutic effect, in contrast to inactive ingredients used for color or flavor. See Huba Kalász & István Antal, *Drug Excipients*, 13 CURRENT MEDICINAL CHEMISTRY 2535, 2535 (2006). “Pharmacokinetics” is defined as “the study of the action of drugs within the body, which can, in many respects, be envisioned more accurately as the actions of the body on an administered drug. It includes studies of the mechanisms of drug absorption, distribution, metabolism, and excretion; onset of action; duration of effect; biotransformation; and effects and routes of excretion of the metabolites of the drug.” MOSBY’S DICTIONARY OF MEDICINE, NURSING & HEALTH PROFESSIONS 1439 (8th ed. 2008).

⁷⁶ See Chen, *supra* note 61, at 464.

⁷⁷ § 355(j)(5)(B)(iv); Pous, *supra* note 54, at 304–05.

be infringed if a generic version of its drug entered the market before the expiration of each patent.⁷⁸ The FDA maintains a list of all its approved pharmaceuticals in a publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the “Orange Book.”⁷⁹ Subsequent ANDAs filed by generics seeking to replicate the drug in question must reference these Orange Book patents and make one of four “certifications” for each patent.⁸⁰

The amended ANDA process benefits generics by giving them a unique incentive to challenge patents’ validity: successful Paragraph IV litigation proving invalidity or noninfringement rewards the generic manufacturer with a 180-day marketing exclusivity period, during which time the FDA is prohibited from approving any other generic versions of that drug.⁸¹ This 180-day period of exclusivity constitutes immense profit potential and handsomely rewards the first generic manufacturer who takes the risk of a Paragraph IV challenge. The incentive to challenge patents further promotes consumer interests by creating a “patent-quality oversight mechanism” that accelerates the provision of generic alternatives to market.⁸²

Therefore, the provisions of the Hatch–Waxman Act alternate their focus between the interests of generics and branded companies. They serve the Act’s ultimate harmonizing purpose of maintaining economic incentives for both pioneer research and development and affordable generic alternatives.⁸³ Branded interests benefit from the new statutory potential to extend market exclusivity through both a term extension under § 156 and a thirty-month stay under the revamped ANDA process.⁸⁴ Generics, in contrast, benefit from the reversal of the *Roche* ruling and the corresponding easing of regulatory testing standards, as well as the 180-day exclusivity grant to the first successful Paragraph IV challenger of a patented product.⁸⁵ These special concessions to the pharmaceutical industry have prompted criticism of the Act, which contrasts the generally rigid application of the patent regime over other industries’ innovation interests. Arguably, however, the unique aspects of the pharmaceutical

⁷⁸ § 355(j)(2)(A)(vii)(IV); *see also* note 66 and accompanying text.

⁷⁹ CTR. FOR DRUG EVALUATION & RESEARCH, FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (32d ed. 2012), *available at* <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>; *see also* Pous, *supra* note 54, at 304–05.

⁸⁰ *See* § 355(j)(2)(A)(vii)(I)–(IV); Pous, *supra* note 54, at 305.

⁸¹ Chen, *supra* note 61, at 465.

⁸² *Id.*

⁸³ H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48.

⁸⁴ *See* § 355(j)(5)(B)(iii); Wheaton, *supra* note 16, at 465–66; *supra* note 68 and accompanying text.

⁸⁵ *See* Chen, *supra* note 61, at 465; *see also* Wheaton, *supra* note 16, at 458.

industry—including its immense research-and-development costs as well as the social value of its products—make such special provisions necessary.⁸⁶

The patent system as a whole and the limited monopolies it grants are usually justified by reference to their use in promoting and stimulating research and invention. The biopharmaceutical industry, necessitating unusually intensive investments of time and capital, therefore seems a worthy subject for unique treatment by the system.⁸⁷ Highlighting the pharmaceutical industry as an outlier in terms of research costs, a 2006 study by the Congressional Budget Office found that pharmaceutical firms invest as much as five times more in research and development relative to sales than the average U.S. manufacturing firm.⁸⁸ Indeed, it has been estimated that the pharmaceutical industry's research-and-development costs for the year 2003 were over \$17 billion, representing an average increase of 5% per year in real terms since 1980.⁸⁹ A widely cited 2003 study further estimated that the average cost of successfully developing a new drug, including the indirect costs incurred by a firm through spending on failed drug projects, was \$802 million in the year 2000.⁹⁰ The pharmaceutical industry as a whole estimates it spent \$49.4 billion on research and development in 2010 alone.⁹¹

With the average time period necessary to develop a new drug hovering at approximately twelve years,⁹² the opportunity cost of such an investment escalates as firms' time and resources are rerouted from other projects.⁹³ Such dramatic economic statistics bolster the argument that the pharmaceutical industry warrants special treatment by the U.S. patent system due to its unique cost challenges. Without an adequate economic incentive to innovate, such as a substantial period of marketing exclusivity, major pharmaceutical players would surely exit the market, resulting in

⁸⁶ Wilson, *supra* note 7, at 509–10 (discussing how § 271(e)(1) is unique to the pharmaceutical industry because all other patent holders are entitled to exclusive use of their patented product for the full length of the patent term, and therefore contributes to the dulling of the incentive to innovate new pharmaceuticals).

⁸⁷ Aljalian, *supra* note 19, at 2–3 (quoting Abraham Lincoln as describing the patent system as “add[ing] the fuel of interest to the fire of genius” (internal quotation marks omitted)).

⁸⁸ CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 9 (2006), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugrd.pdf>.

⁸⁹ *Id.* at 7–8 (quoting National Science Foundation estimates).

⁹⁰ Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003).

⁹¹ PHARM. RESEARCH & MFRS. OF AM., *supra* note 56. In fact, the Obama Administration recently pledged \$1 billion towards a national drug development center due to concerns that rising research costs will slow the pace of pharmaceutical innovation. See Gardiner Harris, *A New Federal Research Center Will Help to Develop Medicines*, N.Y. TIMES, Jan. 23, 2011, at 1.

⁹² CONG. BUDGET OFFICE, *supra* note 88, at 2, 31.

⁹³ DiMasi, *supra* note 90, at 152.

fewer new and improved drug products.⁹⁴ This cost-deterrent argument not only justifies specialized treatment for pioneer companies but also for their generic imitators, as illustrated by the substantial decline in the number of generic products brought to market after the enactment of the 1962 FDCA Amendments.⁹⁵ As previously discussed, the substantial costs of replicating the efficacy and safety tests performed on a branded drug compound were simply prohibitively large for many generic companies to enter the market competitively.⁹⁶ Therefore, from a pure cost-of-innovation standpoint, a convincing argument emerges justifying the exclusive tailoring of the Hatch–Waxman Act for the pharmaceutical industry because of its high research costs.

In addition to this economic justification, a more policy-driven argument can be made for specialized treatment of the pharmaceutical industry given the high social value of the products it develops.⁹⁷ While the U.S. patent system exists by virtue of Congress’s general power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries,”⁹⁸ the high social utility of the pharmaceutical industry’s products justifies its disparate treatment among the other useful arts and sciences.

Indeed, congressional concern over the complex interplay of the profit motives of firms, immense research-and-development costs, and consumer demand for high quality, lower cost medicines motivated the passage of the Hatch–Waxman Act in 1984.⁹⁹ As articulated by Senator Hatch, “With the stakes so high, it is imperative that our intellectual property laws provide the proper incentives to facilitate a new era in our understanding of human biology, health, and disease.”¹⁰⁰ Thus, both economic-incentive considerations and a more theoretical championing of the high social utility of the pharmaceutical industry’s products justify its disparate treatment within the patent regime. However, it remains an important check on the pro-innovation provisions of the Hatch–Waxman system that, to the

⁹⁴ Wilson, *supra* note 7, at 496 (“Diminishing the effective patent term will reduce the incentive to develop pioneer drugs and may result in fewer new and improved medications.”).

⁹⁵ Gorlin, *supra* note 18, at 827.

⁹⁶ *Id.* (noting, as evidence of the prohibitive nature of these costs, that by the early 1980s nearly 150 post-1962 off-patent drugs were without generic competition).

⁹⁷ Wilson, *supra* note 7, at 516 (recognizing the need for adequate patent protection to spur drug innovation by stating that “[s]ociety has patent terms to thank for the availability of beneficial new drugs”).

⁹⁸ U.S. CONST. art. I, § 8, cl. 8.

⁹⁹ See *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Hearing Before the S. Comm. on the Judiciary*, 107th Cong. 3–4 (2001) (statement of Sen. Orrin G. Hatch, Chairman, S. Comm. on the Judiciary).

¹⁰⁰ *Id.* at 4.

American consumer, “an unaffordable medication may be the same as no medication at all.”¹⁰¹

II. DEFINING “PRODUCT” IN THE HATCH–WAXMAN ACT

The inherent tension between pioneer and generic companies’ interests therefore underlies much of the Hatch–Waxman legislation, despite its creators’ best efforts to balance the ultimate benefits each industry enjoys. The inconsistent application of the patent-term-extension statute reflects the continuing struggle between generic and pioneer interests as courts wrestle with the proper meaning of “product.”¹⁰² Although the consistency of the recent Federal Circuit trend favoring extensions is desirable, a return to the court’s previous line of reasoning defining “product” to rein in extensions on related compounds is necessary to protect the balance between generics and pioneers.¹⁰³

Section 156 states that an extension shall be granted if, among other requirements: “the product has been subject to a regulatory review period before its commercial marketing or use . . . [and] the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product.”¹⁰⁴ It is unsurprising that the “product” definition has posed such a stumbling block for the Federal Circuit over the years, given the ambiguity of the deceptively simple term in both a legal and scientific sense. Section 156 defines “product” vaguely as “[a] drug product,”¹⁰⁵ a clarification that is “far from enlightening.”¹⁰⁶ The statute then defines “drug product” as “the active ingredient of . . . a new drug . . . including any salt or ester of the active ingredient.”¹⁰⁷ While this definition is an improvement on the previous one, it too lacks the requisite specificity to give it true utility because “active ingredient” is also a term riddled with ambiguity.¹⁰⁸

In a general chemical sense, an “active ingredient” is the component of a drug compound that provides the biological activity that causes an effect

¹⁰¹ *Id.* at 3.

¹⁰² Paul Burgess & John Lucas, *Which Generic Drug Would You Want to Use? The Federal Circuit’s Interpretation of “Active Ingredient,” “Active Moiety” and “Approved Product,”* 87 J. PAT. & TRADEMARK OFF. SOC’Y 11, 26 (2005) (concluding that the Federal Circuit’s decision in *Pfizer v. Dr. Reddy’s* was an “unfortunate failure to settle a legal uncertainty [that] may result in even greater litigation in a field already plagued”).

¹⁰³ For examples of the Federal Circuit’s previous, extension-limiting treatment of the term “product,” see, e.g., *Pfizer Inc. v. Dr. Reddy’s Labs., Ltd.*, 359 F.3d 1361, 1367 (Fed. Cir. 2004), and *Fisons plc v. Quigg*, 876 F.2d 99, 101 (Fed. Cir. 1989).

¹⁰⁴ 35 U.S.C. § 156(a)(4)–(5)(A) (2006).

¹⁰⁵ *Id.* § 156(f)(1)(A).

¹⁰⁶ Burgess, *supra* note 102, at 17.

¹⁰⁷ § 156(f)(2).

¹⁰⁸ See Burgess, *supra* note 102, at 17.

on a structure or function of the body.¹⁰⁹ Without the active ingredient, the drug compound would not have the desired effect on a patient. This concept of active ingredient is also referred to as the “active moiety” of the drug, meaning the “molecule or ion responsible for the physiological or pharmacological action of the drug substance.”¹¹⁰ An “active moiety” view of active ingredient is concerned only with the main molecule causing the desired effect within the body, rather than the generic salt or ester characteristics appended to it.¹¹¹

In contrast, others conceive of “active ingredient” as referring to the approved product as it exists in the actual drug compound. This definition includes any variation on the main, pharmacological-effect-producing molecule itself.¹¹² If this molecule were formulated as one of its salt forms in the approved drug compound, under this view the active ingredient would be the salt form itself and not just the underlying parent compound at the root of that salt formulation.¹¹³ In this way, this definition of “active ingredient” isolates “product” to mean only the specific structure, derivative form and all, found within the drug compound. In contrast, under the previous definition linking “active ingredient” with “active moiety,” “product” would encompass both a salt and ester formulation of the main, pharmacological-effect-producing molecule. Different packaging as various derivative forms would not exclude these formulations from the umbrella “product” classification.

Pioneer and generic interests usually divide predictably in their preferences for one definition over the other. Pioneers have a strong financial interest in lengthening their patent terms through extensions.¹¹⁴ Therefore, a pioneer company seeking to gain an extension over a drug whose ester derivative has already been patented and marketed individually would advocate for the narrow interpretation isolating “product” to the specific derivative structure at hand. In contrast, a generic firm seeking to block a pioneer product from gaining a term extension will seek to challenge the extension by arguing that “product” should be interpreted broadly to cover the underlying active ingredient under the “active moiety” definition.

The Federal Circuit has adopted both definitions at different times, creating much uncertainty and unnecessary litigation regarding the

¹⁰⁹ See *Drugs@FDA Glossary of Terms*, FDA, <http://www.fda.gov/Drugs/informationondrugs/ucm079436.htm> (last visited July 26, 2012).

¹¹⁰ Burgess, *supra* note 102, at 17.

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ See *id.*

¹¹⁴ Wilson, *supra* note 7, at 496 (“A secure patent term provides an incentive for pioneer drug manufacturers to spend money on new and better medications because it increases the probability that a profit can be made after the large research and development costs are recovered.”).

suitability of extension grants over particular compounds.¹¹⁵ In doing so, the Federal Circuit has at times deferred to the FDA and USPTO's readings of "product," and at other times rejected these agencies' argued expertise regarding the term's definition.¹¹⁶ The court has similarly contradicted itself in its interpretations of the statute's "plain language." In one case, it held that reading "product" to mean only the approved formulation or one of its esters or salts conflicted with the plain meaning of § 156, and in a later case ruled that the plain meaning of "product" within the statute could not be expanded beyond the approved product's active ingredient, or an ester or salt thereof.¹¹⁷ The Federal Circuit's inconsistent treatment of related compounds in the patent-term-extension context therefore reflects the court's struggle concerning its position on the generic and pioneer debate at the heart of the Hatch–Waxman Act.

III. PAST TREATMENT OF RELATED COMPOUNDS IN THE HATCH–WAXMAN REGIME

A primary example of the line of reasoning the Federal Circuit endorsed before the recent *Ortho–McNeil* and *PhotoCure* decisions can be seen in *Fisons plc v. Quigg*.¹¹⁸ The plaintiff in *Fisons* appealed the USPTO's denial of his patent-term-extension application on a new human-drug product containing cromolyn sodium as its active ingredient.¹¹⁹ Fisons argued that the denial was based on an incorrect interpretation of "product" under § 156, leading to the extension denial because of the prior presence of a highly related drug on the market.¹²⁰ The court affirmed the denial, reasoning that Fisons's interpretation of "product" construed the statutory term too narrowly to comply with the plain meaning of the statute, and thus adopted the active moiety view of "product."¹²¹

¹¹⁵ Compare *Fisons plc v. Quigg*, 876 F.2d 99, 100–01 (Fed. Cir. 1989) (adopting the "active moiety" definition of product), with *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 397–98 (Fed. Cir. 1990) (adopting the "approved product" reading of product within the statute).

¹¹⁶ Compare *Ortho–McNeil Pharm., Inc. v. Lupin Pharm., Inc.*, 603 F.3d 1377, 1380–81 (Fed. Cir. 2010) (declining to adopt defendant Lupin's interpretation of "product" as it "would change the long-standing term-extension policy of the FDA and the PTO"), with *Glaxo*, 894 F.2d at 399 ("Consequently, we will give great deference to the Commissioner's determinations as to which patented chemical compounds fall within Congress' definition of 'products,' but little or no deference to the Commissioner's surmise of Congress' intent in framing its definition.").

¹¹⁷ Compare *Fisons*, 876 F.2d at 101 ("Fisons' proposed interpretation [reading product as the approved drug compound only] conflicts with the plain meaning of the statutory language."), with *Glaxo*, 894 F.2d at 395 (stating that the "ordinary, contemporary, common meaning" of the term "product" meant active ingredient or salts or esters thereof only (internal quotation marks omitted)).

¹¹⁸ *Fisons*, 876 F.2d at 101 (rejecting the plaintiff's reading of the statute limiting "product" to only that drug form actually found in the approved product).

¹¹⁹ *Id.* at 100.

¹²⁰ *Id.* at 100–01.

¹²¹ *Id.* at 101.

Under such an interpretation, Fisons's new drug compounds did not qualify as the first permitted commercial marketing of their common active ingredient cromolyn sodium, thereby foreclosing the availability of the term extension.¹²² Fisons argued that this reading of "product" was erroneous and should be substituted for an understanding equating "product" with the particular drug formulation that had been approved.¹²³ Fisons cited the last sentence of § 156(a), which states: "The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the 'approved product.'"¹²⁴ The plaintiff argued that "product" within the previous paragraphs of § 156 must refer to the entire composition of the drug product, not just the active ingredient, because the product is "approved" in its entirety and not just as an active ingredient.¹²⁵

The court found Fisons's interpretation too convoluted to harmoniously exist with the plain language of the statute, pointing out that the supposedly clarifying statement introducing the phrase "approved product" was followed by, not preceded by, the relevant first commercial marketing requirement.¹²⁶ Per the court's opinion, "[i]t would do violence to the plain language [of § 156] to make the last sentence into a substantive definition to be read back into paragraph (5). . . . Accordingly, we cannot agree with Fisons' position."¹²⁷ The extension was accordingly denied, and the Federal Circuit formally endorsed the definition of "product" that describes the term as the underlying active ingredient of the drug compound.¹²⁸

However, just one year later the court followed Fisons's unsuccessful argument in *Glaxo Operations UK Ltd. v. Quigg*, affirming a patent extension over the antibiotic cefuroxime axetil.¹²⁹ Cefuroxime axetil is a derivative ester form of cefuroxime, an organic acid. Cefuroxime and its salts were claimed in a patent owned by Glaxo, but only two salts were FDA-approved and ultimately marketed under the names Zinacef and Kefurox. The parent acid molecule cefuroxime was never approved by the FDA.¹³⁰ The USPTO Commissioner denied Glaxo's application for a patent term extension over cefuroxime axetil, the ester of cefuroxime, explaining that its marketing was not the first permitted commercial marketing or use of the "product" because Zinacef and Kefurox, salts of cefuroxime, had

¹²² *Id.*

¹²³ *Id.* at 100–01.

¹²⁴ 35 U.S.C. § 156(a) (2006).

¹²⁵ *Fisons*, 872 F.2d at 101.

¹²⁶ *See id.*

¹²⁷ *Id.*

¹²⁸ *Id.* at 102.

¹²⁹ 894 F.2d 392, 393–94 (Fed. Cir. 1990).

¹³⁰ *Id.* at 394.

previously been approved.¹³¹ Therefore, according to the Commissioner, the correct definition of “product” was the underlying active ingredient cefuroxime—the active moiety of the drug compound. This interpretation of “product” followed the reasoning of the majority in *Fisons*.¹³²

Glaxo appealed this decision, arguing that “product” was properly defined as the specific formulation of the approved drug product, cefuroxime axetil, and not the parent active moiety, cefuroxime. To support its position, Glaxo noted that “product” is defined in § 156(f)(2) as “the active ingredient of a new drug . . . including any salt or ester of the active ingredient.”¹³³ Neither Zinacef nor Kefurox contains cefuroxime axetil or a salt or ester of cefuroxime axetil as an active ingredient; these previously marketed drugs are salts of cefuroxime itself.¹³⁴ Accordingly, Glaxo argued that its patent represented the “first permitted commercial marketing or use” of the “product” cefuroxime axetil, and was deserving of a term extension.¹³⁵

The Commissioner asserted that Congress intended the definition to mean any “new chemical entity” or “new active moiety,” encompassing all salt or ester forms of a single therapeutically active ingredient.¹³⁶ This interpretation better facilitates the introduction of generic drugs to the marketplace, a primary goal of the Hatch–Waxman Act, and has furthermore been adopted by the FDA in its own interpretations of Title I of the Act.¹³⁷ While acknowledging that Zinacef and Kefurox themselves are not salts or esters of cefuroxime axetil itself, the Commissioner based his argument against extension on the nevertheless highly related nature of the compound cefuroxime.¹³⁸

The Federal Circuit ultimately disagreed with the Commissioner’s characterization of “product” and reversed his decision prohibiting the term extension, now endorsing the narrower “product” definition.¹³⁹ Although the court agreed that the Commissioner’s interpretation of § 156 was consistent with the general purpose of the Act to increase generic availability while still maintaining economic incentives to innovate, the court adhered to the

¹³¹ *Id.*

¹³² *See Fisons*, 872 F.2d at 101.

¹³³ *Glaxo*, 894 F.2d at 394 (omission in original) (quoting 35 U.S.C. § 156(f)(2) (2006)) (internal quotation marks omitted).

¹³⁴ *See id.*

¹³⁵ *Id.* at 394–95.

¹³⁶ *Id.* at 394.

¹³⁷ *Id.* at 395–96.

¹³⁸ *See id.* at 394 (“It is undisputed that cefuroxime axetil is the active ingredient of CEFTIN tablets. Moreover, the Commissioner does not appear to contest that ZINACEF and KEFUROX are neither salts nor esters of cefuroxime axetil.”).

¹³⁹ *Id.* at 399–400.

literal meaning of the statute, reasoning that the means through which the goals of the Act were to be achieved was a query for Congress.¹⁴⁰

Finally, the court rejected the Commissioner's argument that his interpretation was due deference if it was "reasonable" and not clearly contrary to Congress's intent.¹⁴¹ Ironically, the "plain meaning" the court saw as so unambiguous as to justify this lack of agency deference is the opposite of the "plain meaning" it found the statute to possess in *Fisons*.¹⁴² In *Fisons*, the Federal Circuit found the plain meaning of § 156(a)(5)'s reference to "product" to be the underlying active ingredient rather than the specific formulation found in the approved product; here, the court found the plain meaning of "product" to be the specific derivative form of the underlying active moiety found in the approved product.¹⁴³ With little explanation given as to why it was now using a different interpretation, the court dismissed the Commissioner's remaining arguments as policy concerns best left to Congress.¹⁴⁴

This conflict of precedent was further convoluted with the decision in *Pfizer Inc. v. Dr. Reddy's Laboratories, Ltd.*¹⁴⁵ Pfizer received a patent term extension on its patent for the drug amlodipine besylate, while Dr. Reddy's Laboratories had applied for a patent for amlodipine maleate, a different salt form of the underlying active moiety amlodipine.¹⁴⁶ Pfizer subsequently sued Dr. Reddy's, claiming that Dr. Reddy's amlodipine maleate patent would infringe Pfizer's patent on amlodipine besylate.¹⁴⁷ Dr. Reddy's countered by asserting that the term extension covered only the approved formulation of the active ingredient present in the marketed compound—amlodipine besylate—and that its patent on amlodipine maleate did not infringe.¹⁴⁸

This case presented the Federal Circuit with the same question posed in *Glaxo* and *Fisons*: what is the meaning of "product" within § 156? According to its stance in *Glaxo*, "product" refers to the approved

¹⁴⁰ See *id.* at 396 ("The Commissioner merely argues . . . that fewer patents should be eligible for extensions than the plain meaning of that section suggests, and that his interpretation attains a better balance between the competing purposes of the Act. Congress, however, may decide, and here clearly did decide, how to best accommodate the conflicting objectives.").

¹⁴¹ *Id.* at 398–99 (citing *Chem. Mfrs. Ass'n v. NRDC*, 470 U.S. 116, 126 (1985); *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 842–43 (1984)).

¹⁴² Compare *Glaxo*, 894 F.2d at 395, with *Fisons* *plc v. Quigg*, 876 F.2d 99, 101 (Fed. Cir. 1989).

¹⁴³ *Glaxo*, 894 F.2d at 395; *Fisons*, 876 F.2d at 101.

¹⁴⁴ Burgess, *supra* note 102, at 20 ("Without any explanation as to why the term active ingredient should mean 'approved product' rather than 'active moiety' the [*Glaxo*] court found that the statutory terms had a plain meaning. . . . The court made it clear that 'striking balances in legislative language is Congress' job' not the court's." (quoting *Glaxo*, 894 F.2d at 395, 399)).

¹⁴⁵ *Pfizer Inc. v. Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361 (Fed. Cir. 2004).

¹⁴⁶ *Id.* at 1363–64.

¹⁴⁷ See *id.*

¹⁴⁸ Burgess, *supra* note 102, at 16.

formulation of the active ingredient actually found in the drug compound, or an ester or salt thereof. Therefore, the term extension would only cover amlodipine besylate or a salt or ester of amlodipine besylate (none of which implicate amlodipine maleate) and Dr. Reddy's patent would not infringe. However, according to the reasoning articulated in *Fisons*, "product" refers to the underlying active moiety regardless of its derivative form. Therefore, the term extension would cover amlodipine and any salts or esters thereof, including amlodipine maleate and making Dr. Reddy's guilty of infringement.¹⁴⁹ Thus, *Pfizer* presented the court with a chance to definitively settle the definition of "product" between the two interpretations, whose differences held drastically different consequences for the application of the provision.¹⁵⁰

The district court ruled that the proper § 156 interpretation aligned "product" with the specific formulation of the active ingredient found in the approved product, and accordingly dismissed the infringement charge.¹⁵¹ The Federal Circuit, however, reversed the lower court and ruled that the patent term extension applied to the underlying active moiety and all salt and ester forms, thus covering Dr. Reddy's maleate form.¹⁵² In reaching this decision, the Federal Circuit was guided by the general purpose of the Hatch–Waxman Act: "to benefit makers of generic drugs, research-based pharmaceutical companies, and not incidentally the public."¹⁵³ Cognizant of the benefit the patent-term-extension provision conveys to branded companies, the court ultimately reasoned that the "product" in this case was amlodipine, regardless of the salt or ester derivative form.¹⁵⁴

In ruling that "product" referred to the underlying active moiety amlodipine, the court returned to the definition of "product" as referring to the active ingredient of the product, or any salt or ester of that active ingredient.¹⁵⁵ The court appeared to be swayed by Pfizer's argument that changing the derivative form of the drug compound does not affect the therapeutically active agent, which is the same amlodipine, whether formulated as the salt amlodipine maleate or fellow salt amlodipine besylate.¹⁵⁶ To allow Dr. Reddy's to narrowly define the relevant "product" of Pfizer's extension as amlodipine besylate and to thereby escape an

¹⁴⁹ *Id.* at 16–17.

¹⁵⁰ *Id.* at 17.

¹⁵¹ See *Patent Term Extension Is Held to Include the Active Ingredient of the Drug Product and All of Its Salts and Esters Under the Hatch–Waxman Act*, 13 FED. CIR. B.J. 765, 766 (2004).

¹⁵² See *Pfizer*, 359 F.3d at 1366–67.

¹⁵³ *Id.* at 1364 (quoting *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) (internal quotation mark omitted)).

¹⁵⁴ *Id.* at 1366.

¹⁵⁵ *Id.*; see 35 U.S.C. § 156(f)(2) (2006) ("The term 'drug product' means the active ingredient of— (A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) . . .").

¹⁵⁶ See *Pfizer*, 359 F.3d at 1365.

infringement charge on amlodipine maleate would be to ignore the foresight of the legislation's drafters, who clearly anticipated potential manipulation of the salt or ester form of an active ingredient in order to dodge this caveat.¹⁵⁷

While this case may at first appear to be a successful attempt to settle the inconsistent rulings of past term-extension disputes, it fails to conclusively define "product" for purposes of future extensions.¹⁵⁸ The case fails to make any mention of its earlier, opposite take on the definition of "product" within *Glaxo*, an omission which proves problematic since both the *Glaxo* and *Pfizer* decisions were made by three-judge panels.¹⁵⁹ The Federal Circuit declined the opportunity to settle the "product" issue definitively with an en banc ruling.¹⁶⁰ Therefore, the Federal Circuit's ruling in *Pfizer* left *Glaxo* still standing as precedent, perpetuating overall uncertainty regarding the meaning of "product."¹⁶¹

IV. THE RECENT TREND TOWARD EASING EXTENSIONS: *ORTHO-MCNEIL* AND *PHOTOCURE*

With these inconsistent rulings as a backdrop, the Federal Circuit recently reexamined the definition of "product" in two separate cases, ultimately granting extensions in both.¹⁶² In *PhotoCure ASA v. Kappos* and *Ortho-McNeil Pharmaceutical, Inc. v. Lupin Pharmaceuticals, Inc.* the Federal Circuit held that new active ingredients which were separately patentable and subject to regulatory review satisfied the § 156 requisite as the first permitted commercial marketing of the drug product despite highly related compounds already existing on the market.¹⁶³ These cases represent a shift in the Federal Circuit's treatment of such compounds and seem to facilitate extension grants. They have dangerous implications for the already fragile balance between generics and pioneers crafted by the Hatch-Waxman Act.¹⁶⁴

¹⁵⁷ *Id.* As the court stated, "The statute foresaw variation in the salt or ester of an active ingredient, and guarded against the very loophole now urged." *Id.* at 1366 (citing 21 U.S.C. § 355(j)(5)(D)(i), (v) (2006); 35 U.S.C. § 156(f)).

¹⁵⁸ Burgess, *supra* note 102, at 26.

¹⁵⁹ *See id.* at 25–26 ("Under the rules of procedure, a three judge panel may not overturn a prior three judge panel decision."); *see also* FED. R. APP. P. 35(a)(1) (stating that en banc rehearings may be ordered when "necessary to secure or maintain uniformity of the court's decision").

¹⁶⁰ Burgess, *supra* note 102, at 26.

¹⁶¹ *Id.*

¹⁶² *See Ortho-McNeil Pharm., Inc. v. Lupin Pharm., Inc.*, 603 F.3d 1377 (Fed. Cir. 2010); *PhotoCure ASA v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2010).

¹⁶³ *See Ortho-McNeil*, 603 F.3d at 1378; *PhotoCure*, 603 F.3d at 1377.

¹⁶⁴ Warren, *supra* note 12, at 3 ("These holdings . . . may provide opportunities for patentees to extend patent term for new drug products . . . even if the drug candidates are related as polymorphs, protected forms, and different stereoisomeric combinations of a previously patented and approved product.").

In *PhotoCure*, the chemical entity at issue was methyl aminolevulinate hydrochloride (MAL hydrochloride), a methyl ester of the known compound aminolevulinic acid hydrochloride (ALA hydrochloride).¹⁶⁵ Both are used to treat precancerous skin growths, though MAL hydrochloride achieved separate patentability due to its improved therapeutic properties and was subject to its own regulatory testing requirements, a process which erased four-and-a-half years of its patent term.¹⁶⁶ The plaintiff applied to the USPTO for a patent term extension, which the agency denied, ruling that MAL hydrochloride was the “same ‘product’” as ALA hydrochloride by virtue of the shared “underlying [ALA] molecule.”¹⁶⁷ Because a product containing ALA hydrochloride was already commercially available, the FDA’s marketing approval of the MAL hydrochloride product was not the first commercial use of that “product,” and therefore the plaintiff’s application failed to meet the statutory requirements for an extension.¹⁶⁸

This ruling was supported by the FDA, who had advised the USPTO that MAL hydrochloride was an ester of the previously FDA-approved ALA hydrochloride, and proposed that the requirements of § 156 were not met.¹⁶⁹ The district court, however, was unmoved by the line of reasoning endorsed by these two agencies and granted the extension as it found that the “product” within the drug at issue was MAL hydrochloride and not the parent ALA hydrochloride.¹⁷⁰ As a result, the USPTO and district court once again found themselves on opposite sides of the “product” definition debate, with the USPTO supporting an “active moiety” definition and the district court looking to the actual formulation present in the approved product.

The Federal Circuit sided with the district court, adopting the strict “product” interpretation instead of the “active moiety” theory. The court was especially persuaded by the fact that MAL hydrochloride qualified as a separately patentable drug warranting its own regulatory testing, despite the similarity of its chemical structure to the already marketed ALA hydrochloride.¹⁷¹ The court also appeared to adopt the reasoning proffered

¹⁶⁵ *PhotoCure*, 603 F.3d at 1374.

¹⁶⁶ *See id.* at 1374–75.

¹⁶⁷ *In re Patent Term Extension Application for U.S. Patent No. 6,034,267*, 2008 WL 5598280, at *3, *6 (Comm’r Pat. May 13, 2008) (“ALA is simply formulated differently in the two different drugs . . .”).

¹⁶⁸ *PhotoCure*, 603 F.3d at 1375.

¹⁶⁹ *See id.* The USPTO had consulted with the FDA in accordance with the *Memorandum of Understanding Between the Patent and Trademark Office and the Food and Drug Administration*, 52 Fed. Reg. 17,830 (May 12, 1987), when making its term extension decision.

¹⁷⁰ *PhotoCure*, 603 F.3d at 1375–76.

¹⁷¹ *Id.* at 1375.

in *Glaxo*: that “a compound can only qualify as the ‘active ingredient’ of a drug if that compound itself is present in the drug.”¹⁷²

The court distinguished *Glaxo* and the present case from *Pfizer* by emphasizing that *Pfizer* dealt with the scope of a term extension rather than an issue of extension eligibility.¹⁷³ The court read *Pfizer* as standing for the principle that an extension “was not intended to be defeated by simply changing the salt,” when the changed salt left the “active moiety” of the product unchanged.¹⁷⁴ *Pfizer* did not conflict with the *Glaxo* ruling because *Pfizer* did not deal with a molecule of separate patentability.¹⁷⁵ Therefore, the court returned to the line of reasoning it adopted in *Glaxo* and similarly granted the term extension over the drug in question, despite its highly related nature to an already marketed drug.¹⁷⁶

In *Ortho-McNeil*, the Federal Circuit continued in this vein, again allowing an extension over a derivative form of a known compound.¹⁷⁷ The drug product in *Ortho-McNeil* was levofloxacin, a single enantiomer of a known racemic mixture, ofloxacin, a known antibacterial agent.¹⁷⁸ Levofloxacin’s manufacturer, Ortho-McNeil, secured a patent for the enantiomer based upon its superior therapeutic ability and applied for an extension to compensate for regulatory delay.¹⁷⁹ The USPTO, with the support of the FDA, granted the extension, relying on the Federal Circuit’s interpretation of “product” as articulated in *Glaxo*.¹⁸⁰ Defendant Lupin initiated Paragraph IV litigation, stipulating to the validity, enforceability, and infringement of the levofloxacin patent, but contesting whether it was entitled to the term extension.¹⁸¹ The district court affirmed the extension, relying on the *Glaxo* precedent and citing the “great deference” due the USPTO in regards to “product” determinations.¹⁸²

¹⁷² *Id.* at 1375–76 (quoting *PhotoCure ASA v. Dudas*, 622 F. Supp. 2d 338, 347 (E.D. Va. 2009) (citing *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 393 (Fed. Cir. 1990), *aff’d sub nom.* *PhotoCure ASA v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2010)) (internal quotation marks omitted).

¹⁷³ Burgess, *supra* note 102, at 20.

¹⁷⁴ *PhotoCure*, 603 F.3d at 1376 (quoting *Pfizer Inc. v. Dr. Reddy’s Labs., Ltd.*, 359 F.3d 1361, 1366 (Fed. Cir. 2004)) (internal quotation marks omitted).

¹⁷⁵ *Id.*

¹⁷⁶ *See id.* at 1376–77.

¹⁷⁷ *Ortho-McNeil Pharm., Inc. v. Lupin Pharm., Inc.*, 603 F.3d 1377, 1378 (Fed. Cir. 2010).

¹⁷⁸ *Id.* A racemate is a mixture consisting of equal amounts of molecules known as enantiomers, which share the same chemical composition but are mirror images of each other. Despite their shared chemical composition, enantiomers and racemates may produce different physical, chemical, or biological properties. *See* INT’L UNION OF PURE & APPLIED CHEMISTRY, *supra* note 10, at 1223.

¹⁷⁹ *Ortho-McNeil*, 603 F.3d at 1378–79.

¹⁸⁰ *Id.* at 1379 (discussing the FDA’s recommendation to the PTO that “[o]ur records also indicate that [levofloxacin] represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the [appellate and district] courts in [*Glaxo*]”).

¹⁸¹ *Id.*

¹⁸² *Id.* at 1380 (quoting *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 399 (Fed. Cir. 1990)) (internal quotation marks omitted).

Lupin argued on appeal that since an enantiomer is half of its racemate, levofloxacin was present as an “active ingredient” in the previously marketed racemate ofloxacin.¹⁸³ According to Lupin, levofloxacin should be considered the same “drug product.”¹⁸⁴ Furthermore, since ofloxacin was already available on the market, Ortho’s application to market levofloxacin did not satisfy “the first permitted commercial marketing or use of the product” requisite of § 156.¹⁸⁵ The Federal Circuit was not persuaded, however, that the enantiomer’s presence within the already marketed mixture disqualified it from a term extension, emphasizing its separate patentability and regulatory testing requirements.¹⁸⁶ Echoing *PhotoCure*, the court affirmed the grant of Ortho’s application.¹⁸⁷

Together, *PhotoCure* and *Ortho–McNeil* represent a shift from the prior inconsistent treatment of highly related compounds by the Federal Circuit to a more predictable management of these products in a patent-extension context. This consistency is certainly not undesirable.¹⁸⁸ However, facilitating patent extensions by interpreting “product” to refer only to the approved formulation of a broader underlying active moiety is contrary to the greater harmonizing purposes of the Hatch–Waxman Act.¹⁸⁹ These rulings, and the trend they espouse, encourage patentees to apply to extend patent terms on new drug compounds despite their shared “chemical, biological, or pharmacological properties” with previously patented and approved drug products, “even if the drug candidates are related as polymorphs, protected forms, and different stereoisomeric combinations of a previously patented and approved product.”¹⁹⁰

While the patent-term-extension provision was intended to be a boon for branded pharmaceutical companies, to be balanced out by the safe harbor provision and 180-day exclusivity measure allotted to generics, interpreting its terms to expansively facilitate extensions transforms it into a windfall for branded companies. The Federal Circuit should abandon its current trend interpreting “product” so narrowly as to allow highly related compounds to gain individual extensions, and return to its previous line of

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* at 1382.

¹⁸⁸ See, e.g., Burgess, *supra* note 102, at 26 (lamenting the “legal uncertain[ty]” of the product debate, which “may result in even greater litigation in a field already plagued with patent litigation”).

¹⁸⁹ H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48.

¹⁹⁰ Warren, *supra* note 12, at 3; see also Terry G. Mahn, *Patenting Drug Products: Anticipating Hatch–Waxman Issues During the Claims Drafting Process*, 54 FOOD & DRUG L.J. 245, 247 (1999) (“A drafting strategy that is designed to maximize Hatch–Waxman benefits will . . . mak[e] certain that different active ingredients are claimed in *separate* patents in order to preserve the possibility of extending the patent life for each ingredient.”).

reasoning reining in extensions in better furtherance of the Hatch–Waxman Act’s harmonizing goals.¹⁹¹

V. THE “GAMING” OF THE PATENT SYSTEM BY BRANDED PHARMACEUTICAL COMPANIES

In addition to threatening the balance between pioneer and generic companies the Hatch–Waxman Act aims to create, the shift in the treatment of related drug compounds in *Ortho–McNeil* and *PhotoCure* represents a new opportunity for major pharmaceutical companies to “game” the system. While overall the Hatch–Waxman Act is considered to successfully foster greater competition in the pharmaceutical industry while maintaining a high level of innovation, both pioneer and generic drug manufacturers have worked to circumvent the provisions they find unsympathetic, ultimately decreasing the availability of low-cost generics to the public.¹⁹² With disingenuous and anticompetitive incentives already being fostered, albeit inadvertently, by certain provisions of the Hatch–Waxman Act, major pharmaceutical companies are hardly in need of another legislative loophole to exploit.¹⁹³ A return to the Federal Circuit’s previous treatment of related compounds is necessary to foster a more beneficial balance between the incentive to innovate and consumer protection, and thus foreclose another opportunity for potential gaming of the patent system.

As Senator Schumer stated in a 2001 Senate hearing: “[T]he balance [of the Hatch–Waxman Act] has been thrown out of whack in recent years. The large pharmaceutical companies basically have been playing by their own rules. As the stakes and profits have become higher, lawyers for that industry have picked the Hatch–Waxman law clean.”¹⁹⁴ There are a number of popular strategies employed by brand-name pharmaceutical companies under the Hatch–Waxman regime to extend their patent lifetimes that abide by the letter of the statute but not its spirit.¹⁹⁵ Examples include companies seeking to extend patents through manipulation of legislative loopholes and lobbying,¹⁹⁶ through initiating litigation alleging patent infringement, and

¹⁹¹ See, e.g., *Fisons plc v. Quigg*, 876 F.2d 99, 100–01 (Fed. Cir. 1989) (rejecting plaintiff’s arguments that “product” should be read to mean only the approved formulation of an active ingredient, rather than its underlying active moiety).

¹⁹² Soehnge, *supra* note 3, at 51.

¹⁹³ See *id.* at 70.

¹⁹⁴ *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Hearing Before the S. Comm. on the Judiciary*, *supra* note 99, at 7 (statement of Sen. Charles E. Schumer, Member, Comm. on the Judiciary).

¹⁹⁵ See Wirz, *supra* note 5, at 4 (“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 . . .”).

¹⁹⁶ Glasgow, *supra* note 55, at 237 (referring to proposed legislation aggressively supported by Claritin manufacturer Schering–Plough through lobbying efforts as the “Claritin Monopoly Relief Act”).

through strategic temporal layering of patents over different aspects of one drug product.¹⁹⁷

Perhaps the most egregious of these tactics is the reverse-settlement phenomenon, a practice that has garnered much attention from the Federal Trade Commission in recent years as it has grown in popularity with drug companies.¹⁹⁸ Reverse-settlement payment agreements are essentially anticompetitive settlements in which the generic Paragraph IV winner refrains from entering the market and triggering the 180-day exclusivity period in exchange for a hefty settlement from the branded company whose patented product it seeks to imitate.¹⁹⁹ Because a single 180-day period can realize significant profits for the pioneer, it is often worth the branded company's while to compensate the generic generously to maintain a few more months of exclusivity since "[the generic] will not make as much as the pioneer will lose."²⁰⁰

Thus, reverse payments are technically effective settlement tools since they do achieve peace between the respective generic and branded parties. But there are also "potential negative consequences that extend beyond the immediate parties involved" and which accrue to the American consumer, whose access to lower-cost generic alternatives is delayed.²⁰¹ The Medicare Prescription Drug, Improvement, and Modernization Act of 2003²⁰² seeks to reduce the threat of these anticompetitive settlements by requiring "pioneer and generic firms to notify the FTC and Department of Justice within 10 days of any agreements involving the 180-day exclusivity period,"²⁰³ and additionally requiring that generics must "exploit their exclusivity period within certain time limits or risk forfeiture of their reward."²⁰⁴

Further manipulations of Hatch–Waxman provisions can be found in the practice of strategically layering patents and in the authorized generic market. Temporally layering patents over different aspects of a single drug is a common tool branded pharmaceutical companies use to extend the patent lifetime of a product.²⁰⁵ Such layering ensures that with the expiration

¹⁹⁷ See *id.* at 232–33.

¹⁹⁸ Bulow, *supra* note 18, at 145–46.

¹⁹⁹ Chen, *supra* note 61, at 466–67.

²⁰⁰ Catherine E. Creely, Comment, *Prognosis Negative: Why the Language of the Hatch–Waxman Act Spells Trouble for Reverse Payment Agreements*, 56 CATH. U. L. REV. 155, 161–62 (2006) (quoting Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II*, FED. TRADE COMM'N, <http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.shtml> (last modified June 25, 2007)).

²⁰¹ *Id.*

²⁰² Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified in scattered sections of U.S.C.).

²⁰³ Chen, *supra* note 61, at 467 (citing §§ 1111–1113, 117 Stat. 2066, 2461–63).

²⁰⁴ *Id.* (citing § 1102, 117 Stat. 2066, 2457–60 (codified as amended at 21 U.S.C. § 355(j)(d)(5) (2006))).

²⁰⁵ Glasgow, *supra* note 55, at 234.

of one patent over a drug, another feature's patent protection triggers and prevents the drug from going off-patent.²⁰⁶

Authorized generics are brand-name drugs sold under generic labels, manufactured by the brand but marketed and sold by the generic company during their period of 180-day exclusivity. A source of much controversy, courts have reluctantly allowed the sale of authorized generics because there is no statutory provision prohibiting them since the Hatch–Waxman Act only restricts other generic manufacturers during the 180-day exclusivity period.²⁰⁷ Because the authorized generics are priced like generics, they allow the brand-name company to compete in both markets. As a result, brand-name companies that manufacture authorized generics are criticized for manipulating the 180-day provision in an attempt to discourage generics from pursuing Paragraph IV entry.²⁰⁸ However, the ultimate legality of this practice of branded manufacturers remains unclear and continues to be challenged by generic companies.²⁰⁹

The application of the Hatch–Waxman provisions has therefore, at times, “turn[ed] the [A]ct on its head,” creating an environment in which anticompetitive agreements and strategic maneuvering of intellectual property are encouraged and rewarded.²¹⁰ While patent protection is certainly of unparalleled importance in the pharmaceutical industry due to the economic incentive it provides to counter research-and-development costs,²¹¹ the inherent difficulties of the industry do not excuse manipulation of the legislation meant to balance its concerns with those of the public. Vigilant policing of the Hatch–Waxman provisions by the courts is necessary to prevent further “gaming” of the system by pharmaceutical companies in search of profit. The patent-term-extension provision of § 156 is no exception: it should be interpreted according to the Federal Circuit’s previous line of reasoning defining “product” in such a way as to rein in patent extensions, thus continuing to encourage generic competition in the industry.

CONCLUSION

The Hatch–Waxman Act was designed with the interests of the branded drug manufacturer, the generic counterpart, and the consumer in

²⁰⁶ *Id.* SmithKline successfully employed this layering strategy to ensure its antibiotic Augmentin will stay on patent until 2017, a full fifteen years after its original patent expired. *Id.*

²⁰⁷ Chen, *supra* note 61, at 468 (noting that critics argue that “in the long term, authorized generics will reduce the profitability of Paragraph IV entry and ultimately eliminate the incentive to pursue such patent challenges”).

²⁰⁸ *Id.* at 461.

²⁰⁹ Pous, *supra* note 54, at 311–12.

²¹⁰ See *supra* note 4 and accompanying text.

²¹¹ Wheaton, *supra* note 16, at 434–35.

mind.²¹² By providing generics with a simplified route to market and economic incentives to successfully challenge weak drug patents, the Act ensures consumer access to lower cost alternatives to branded drugs. Simultaneously, the Act restores patent life lost to branded companies because of regulatory testing to ensure the economic drive behind innovation remains strong.²¹³ While the Act has generally been successful in maintaining a workable balance between these competing entities, prompting tremendous increases in generic market share while still promoting a high level of pioneer research and development, that balance has been threatened by branded entities' manipulation.²¹⁴ Scrutiny of the recent developments in patent-term-extension case law is warranted, as it could have positive effects on the larger Hatch–Waxman balance.

The *PhotoCure* and *Ortho–McNeil* decisions signal a shift in an inconsistent history of the Federal Circuit's treatment of the term drug "product" for purposes of patent-term-extension analysis. A continuation of this current trend of facilitating extensions signals dangerous consequences for an already strained pharmaceutical patent system and should be abandoned for the Federal Circuit's previous line of reasoning defining "product" more broadly so as to limit term extensions.²¹⁵

The Patent Term Extension statute, 35 U.S.C. § 156, was created with the aim of restoring a portion of the patent life and bolstering the economic incentive for the development of new drugs, lost during the often lengthy period of regulatory review.²¹⁶ Given the broader harmonizing goals of the Hatch–Waxman Act regarding generic and pioneer companies, it seems unlikely that Congress intended to provide pioneers with another means to block generic market entry by allowing highly related compounds to gain respective term extensions as different "products."

With the Hatch–Waxman Act's provisions already being distorted from their original harmonizing purpose through such tactics as reverse payments, patent layering, and authorized generics, the Federal Circuit should tighten term-extension grants to ensure major pharmaceutical companies cannot abuse another provision to their benefit.²¹⁷ A possible, if improbable, solution outside of the judicial process may lie in the provision of increased funding to the FDA to expedite the regulatory process in the

²¹² H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48.

²¹³ Soehnge, *supra* note 3, at 53 (stating the Hatch–Waxman provisions benefit pioneer drug manufacturers by "helping to offset the tremendous expense of time and money required for FDA approval").

²¹⁴ Behrendt, *supra* note 4, at 248 ("[T]he Act has provided an environment in the high stakes drug business wherein 'crafty, albeit industrious market players' prevail." (quoting Mylan Pharm. Inc. v. Henney, 94 F. Supp. 2d 36, 54 (D.D.C. 2000))).

²¹⁵ For examples of this older line of cases, see, e.g., *Pfizer Inc. v. Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361, 1365–66 (Fed. Cir. 2004), and *Fisons plc v. Quigg*, 876 F.2d 99, 101 (Fed. Cir. 1989).

²¹⁶ Behrendt, *supra* note 4, at 252.

²¹⁷ See Wirz, *supra* note 5, at 3.

first place.²¹⁸ However, such a remedy would address only the symptom of the underlying tension between generic and pioneer interests motivating such “gaming” of the system. Conversely, amending the Hatch–Waxman Act itself should also be approached with caution, as the Act has been generally successful and any legislative tinkering “risk[s] triggering the law of unintended consequences, which could . . . result in less research or fewer generic drugs.”²¹⁹ For these reasons, a return to the Federal Circuit’s previous narrow treatment of related compounds limiting extensions is the most feasible means to foster a more beneficial balance between the incentive to innovate and consumer protection with the least disturbance to the current patent regime.

²¹⁸ Behrendt, *supra* note 4, at 270.

²¹⁹ *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Hearing Before the S. Comm. on the Judiciary*, *supra* note 99, at 39 (statement of Sen. Sam Brownback, Member, Comm. on the Judiciary).