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> Today I call upon the brand-name industry to cease and desist from inventing new games, that they work with us to re-balance the brand-name and generic systems, and that they return to the scientific research that they are good at and that has been their real contribution.
>
> —Representative Henry A. Waxman[1]

INTRODUCTION

The pharmaceutical industry is one of the few industries that requires patent protection to ensure the profitability of its innovative products.[2] Because the drug discovery process has a high failure rate,[3] enormous costs are associated with identification, development, and testing of new drug candidates.[4] Of course, not every approved drug

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1. Press Release, Henry A. Waxman, Representative Henry A. Waxman on the Delay of Approval of Generic Drugs (Nov. 20, 2001), *available at* http://www.citizen.org/congress/reform/drug_patents/bmsg/articles.cfm?ID=6496.

2. Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 23–25 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000) (reporting that, according to a 1994 survey, the pharmaceutical industry is one of the rare sectors that uses patents to appropriate rents); *see also* 1 FED. TRADE COMM'N, ANTICIPATING THE 21ST CENTURY: COMPETITION IN THE NEW HIGH-TECH, GLOBAL MARKETPLACE ch.6, at 7 (1996) (describing a study demonstrating that only 40% of pharmaceutical inventions would have been developed in the absence of patent protection), *available at* http://www.ftc.gov/opp/global/report/gc_v1.pdf.

3. *See* J.F. Pritchard et al., *Making Better Drugs: Decision Gates in Non-Clinical Drug Development*, 2 NATURE REV. DRUG DISCOVERY 542, 542 (2003) (describing failure risks associated with drug discovery).

4. *See* Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is*

candidate generates sufficient sales to ensure an adequate return on the pioneer's massive initial investment. According to one estimate, only three out of every ten marketed drugs are commercially successful enough for the pioneer to recoup its research and development expenses.[5] Appropriate patent protection allows drug developers to shoulder these risks by granting them exclusionary rights for a limited time.

Once a pharmaceutical product loses patent protection, competitors almost always introduce generic versions of the drug.[6] Generic drugs can capture 80–90% of the market, often within months of entering the marketplace.[7] In response to generic competition, patent holders have used a variety of controversial means to effectively extend their patent-granted monopoly.[8] While it is important that pharmaceutical pioneers remain profitable so that they have an incentive to continue developing life-saving drugs,[9] they should not be allowed to reap monopoly profits indefinitely.[10] Delays in the marketing of generic drugs directly interest consumers, since the "availability of a generic alternative can mean a price savings for consumers equal to one quarter of the price of the brand-name drug."[11] Consequently, actions by patent holders that hinder generic competition should be closely examined for impropriety.

Biotech Different?, 28 MANAGERIAL & DECISION ECON. 469, 477 (2007) (calculating average research and development costs of $1.32 billion per new molecule approved by the Food and Drug Administration (FDA)).

5. *See Paying off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 150 (2007) [hereinafter *Paying off Hearing*] (statement of Billy Tauzin, President and Chief Executive Officer, Pharmaceutical Research and Manufacturers of America).

6. *See* CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 37 n.2 (1998) (reporting that 95% of off-patent drugs had generic equivalents in 1994).

7. For example, the generic form of Prozac (fluoxetine) claimed approximately 65% of the market within a month of generic entry, 80% by the end of the first generic competitor's 180-day exclusivity period, and leveled out at almost 90% after a year of generic competition. *See* Benjamin G. Druss et al., *Listening to Generic Prozac: Winners, Losers, and Sideliners*, 23 HEALTH AFF. 210, 214 (2004).

8. Saami Zain, *Sword or Shield? An Overview and Competitive Analysis of the Marketing of "Authorized Generics,"* 62 FOOD & DRUG L.J. 739, 742 (2007) ("Recently, under the rubric of 'Lifecycle Management,' consultants and pharmaceutical executives have been encouraging various actions to squeeze the most profitability from existing drugs. Certain of these actions have been criticized as unethical, anticompetitive or even fraudulent." (footnote omitted)).

9. Carmelo Giaccotto et al., *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & ECON. 195, 195 (2005) (reporting a positive correlation between profits and research spending).

10. Note that the standard patent term is twenty years from the date when the patent application was filed. 35 U.S.C. § 154(a)(2) (2006). But because of the lengthy regulatory process, the average pioneer drug only enjoys eleven to twelve years of patent protection after FDA approval. *Paying off Hearing*, *supra* note 5, at 151–52.

11. Andrew A. Caffrey, III & Jonathan M. Rotter, Note, *Consumer Protection, Patents and Procedure: Generic Drug Market Entry and the Need to Reform the Hatch-Waxman Act*, 9 VA. J.L. &

The market for generic drugs is regulated by the Hatch-Waxman Act.[12] Paragraph IV of the Hatch-Waxman Act establishes a system whereby generic manufacturers can seek to market generic equivalents of a pioneer's patented drug prior to the patent's expiry.[13] But the original Act also contained provisions that were exploited by patent holders to delay generic competition, thereby extending their monopoly sales.[14] These techniques were harshly criticized by generic manufacturers, consumers, Congress, the Federal Trade Commission (FTC), and the President, among others.[15] In response, Congress amended the Hatch-Waxman Act in 2003 to address these practices.[16]

This Note focuses on analyzing how those amendments modified loopholes in: (1) the use of reverse payments and authorized generics to manipulate the 180-day market exclusivity given to the first generic challenger, and (2) the thirty-month stay granted to patent holders when they sue Paragraph IV generic challengers. Part I of this Note provides a brief background on the history and creation of the Hatch-Waxman Act. Part II discusses in detail how features of the original Act were exploited by patent holders to delay or thwart the entry of generic drugs. Part III then introduces the 2003 revisions to the Hatch-Waxman Act, specifically those revisions designed to counteract the abuses detailed in Part II. Finally, Part IV analyzes the actual impact the 2003 revisions have had on deterring abuse of the Act, identifies what areas are still open to abuse, and recommends further amendments to mitigate these remaining loopholes.[17]

TECH. 1, 3–4 (2004) (citing CONG. BUDGET OFFICE, *supra* note 6, at xiii).

12. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) [hereinafter Hatch-Waxman Act] (codified as amended at 21 U.S.C. § 355(j) (2006), 35 U.S.C. §§ 156, 271(e) (2006)).

13. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000) (amended 2003).

14. *See* discussion *infra* Part II.

15. *See* discussion *infra* Part III.A.

16. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 [hereinafter Medicare Modernization Act or "MMA"] (effective Dec. 8, 2003) (codified as amended in scattered sections of 21 and 42 U.S.C.).

17. It is beyond the scope of this Note to analyze the following issues related to the Hatch-Waxman Act: (1) biological generics, (2) medical devices, (3) patent term extensions due to delays in regulatory approval, (4) antitrust issues, and (5) the section 271(e)(1) safe harbor. For a discussion of biological generics, see generally Tam Q. Dinh, *Potential Pathways for Abbreviated Approval of Generic Biologics Under Existing Law and Proposed Reforms to the Law*, 62 FOOD & DRUG L.J. 77 (2007). For a discussion of medical devices, see generally Andrew J. Paprocki's Note, Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*: Can the Patent-Term Extension of the Hatch-Waxman Act Be Used as Leverage in Drug Patent Infringement Settlements?*, 46 JURIMETRICS J. 471 (2006). Paprocki discusses the unusual case where an infringing drug receives FDA approval before the patent holder's drug, thereby preventing the patent holder from getting a patent term extension upon FDA approval. *Id.* at 488 ("The [Hatch-Waxman Act] seems to permit an infringing drug developer to prevent a pioneer drug manufacturer from obtaining a patent-term extension or to withhold the patent-term extension as leverage in settlement negotiations."). For a discussion of antitrust issues, see generally John Fazzio, *Pharmaceutical Patent Settlements: Fault Lines at the Intersection of Intellectual Property*

I. HISTORY AND CREATION OF THE HATCH-WAXMAN ACT

A. REGULATION OF GENERIC PHARMACEUTICALS UNDER THE FOOD, DRUG, AND COSMETIC ACT

In order to market a new prescription drug, a pioneering pharmaceutical company must first obtain regulatory approval from the Food and Drug Administration (FDA).[18] To obtain FDA approval, the pharmaceutical company must perform extensive testing and analysis on the new drug in order to provide the FDA with data on the drug's safety, efficacy, pharmacology, and toxicology.[19] Once human clinical trials are complete, the pioneer may then file a New Drug Application (NDA) with the FDA, which "include[s] detailed reports of all animal studies and clinical testing done with the drug, reports of any adverse reactions, and any other pertinent information from worldwide scientific literature."[20] After the FDA reviews and approves the NDA, the pioneer may then commercially market its new drug.[21]

A generic drug is one that is "bioequivalent" to the brand-name drug listed in an NDA.[22] Prior to the Hatch-Waxman Act (under the Food, Drug, and Cosmetic Act ("FDCA"), as amended in 1962), the FDA required generic drug manufacturers to satisfy the same safety and efficacy requirements as new drug applicants before allowing them to market their products.[23] Generic manufacturers could not use the NDA

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and Antitrust Law Require a Return to the Rule of Reason, 11 J. TECH. L. & POL'Y 1 (2006), and C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006). For a discussion of the section 271(e)(1) safe harbor, see generally Sarah J. Chickos, *Navigating the Safe Harbor: Guidance from the Courts on Qualifying for the 35 U.S.C. 271(e)(1) Exemption from Patent Infringement of Health Care Related Inventions*, 24 J. CONTEMP. HEALTH L. & POL'Y 43 (2008).

18. *See* 21 U.S.C. § 355(a) (2006) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug.").

19. 21 C.F.R. § 312.23 (2008).

20. Pennington Parker Landen, *Federal Preemption and the Drug Industry: Can Courts Co-Regulate?*, 43 FOOD DRUG COSM. L.J. 85, 100 (1988); *see also* 21 U.S.C. § 355(a)–(b) (2006 & Supp. II 2008); 21 C.F.R. § 314.50 (2008).

21. *See* 21 U.S.C. § 355(a).

22. According to the FDA, "[a] generic drug is identical, or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price." FDA, Office of Generic Drugs Home Page, http://www.fda.gov/cder/ogd/ (last visited Nov. 13, 2008). A generic drug is

> bioequivalent to a listed drug if—
>
> > (i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses.

21 U.S.C. § 355(j)(8)(B).

23. Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-*

holder's data to demonstrate safety and efficacy, and were forced to conduct their own clinical trials.[24] The great expense of conducting these trials deterred the development of many generic drugs so much that, just before the Hatch-Waxman Act was passed, the FDA estimated there were approximately 150 brand-name drugs on the market with expired patents but no generic equivalents.[25] Congress realized that introducing generic equivalents of these off-patent drugs would save American consumers hundreds of millions of dollars.[26]

Further stifling generic drug development was the fact that performing the tests required for FDA approval during the pioneer's patent term was generally considered an infringing use. In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, the Federal Circuit held that using the active ingredient of a patented drug in tests required for FDA regulatory approval was an act of infringement and not experimental use because of its commercial purpose.[27] Consequently, generic manufacturers were forced to wait until the pioneer's patent term expired before they could begin the development and approval processes for their generic drugs. This gave pioneers a de facto extension of their patent terms during the period the generic manufacturers spent testing and seeking FDA review.[28]

B. Drug Price Competition and Patent Term Restoration Act of 1984

In 1984, Congress effectively created the modern generic pharmaceutical industry when it passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act.[29] The Act was intended "to balance two conflicting policy objectives: to induce name-brand 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."[30] Hatch-Waxman provided for an abbreviated new drug application (ANDA) for generic drugs.[31] An ANDA applicant

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Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers, 58 Food & Drug L.J. 51, 52 (2003).

24. *Id.* at 53–54.

25. H.R. Rep. No. 98-857, pt. 1, at 17 (1984).

26. *Id.*

27. 733 F.2d 858, 863 (Fed. Cir. 1984). The Hatch-Waxman Act created an experimental use exception for drug manufacturers that negated *Roche*. *See* 35 U.S.C. § 271(e)(1) (2006).

28. Mary Atkinson, *Patent Protection for Pharmaceuticals: A Comparative Study of the Law in the United States and Canada*, 11 Pac. Rim L. & Pol'y J. 181, 184 (2002).

29. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355(j) (2006), 35 U.S.C. §§ 156, 271(e) (2006)).

30. Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting); *see also* H.R. Rep. No. 98-857, pt. 1, at 14–15.

31. *See* H.R. Rep. No. 98-857, pt. 1, at 16.

is only required to demonstrate that its generic drug has the same active ingredient, the same basic pharmacokinetics, and is bioequivalent to the pioneer drug.[32] But a generic applicant is no longer required to provide independent proof of safety and efficacy, and can instead rely on the pioneer's clinical trial data.[33] The Hatch-Waxman scheme ensures the quality of generic drugs, simplifies the generic approval process, eliminates duplicative research costs associated with clinical trials, and accelerates consumer access to affordable drugs.[34] Upon ANDA approval, the generic manufacturer may begin commercially marketing its generic equivalent.[35]

The Hatch-Waxman Act also created an experimental use exception to patent infringement, providing that a "generic manufacturer may obtain a supply of a patented drug product during the life of the patent and conduct tests using that product if the purpose of those tests is to submit an application to FDA for approval."[36] This exception directly overturned the holding of *Roche*, and now insulates generic manufacturers from patent infringement liability for conducting clinical research related to ANDA applications.[37]

All ANDA applicants are required to make one of the following certifications regarding *each* patent that claims the drug they seek to copy: (I) that the drug is not patented or that patent information has not been filed; (II) that the patent has expired; (III) the date when the patent expires, and that the generic drug will not go on the market until that date passes; or (IV) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the application is submitted.[38] These are commonly called Paragraph I, II, III, and IV certifications, respectively.

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32. 21 U.S.C. § 355(j)(2)(A)(ii)–(iv).

33. *Id.* § 355(j)(2)(A).

34. *See* Requirements for Submission of In Vivo Bioequivalence Data, 68 Fed. Reg. 61,640, 61,645 (proposed Oct. 29, 2003) (to be codified at 21 C.F.R. pts. 314 & 320) (reporting estimates of ANDA preparation and filing costs between $300,000 and $1 million); Thomas Chen, Note, *Authorized Generics: A Prescription for Hatch-Waxman Reform*, 93 VA. L. REV. 459, 464 (2007).

35. *See* 21 U.S.C. § 355(a).

36. H.R. REP. No. 98-857, pt. 2, at 5; *see also* 35 U.S.C. § 271(e)(1) (2006) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.").

37. *See supra* note 27 and accompanying text. Note that it is not clear whether the section 271(e)(1) safe harbor protects researchers from infringement liability for using patented "research tools" for drug research. *See, e.g.*, Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 205 n.7 (2005); Amgen v. Int'l Trade Comm'n, 519 F.3d 1343, 1348 (Fed. Cir. 2008); Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1264 (Fed. Cir. 2008); *see also* Chickos, *supra* note 17.

38. 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV).

The certifications of primary interest are those made under Paragraph IV, which occur when a generic manufacturer seeks FDA approval to make a generic equivalent of a pioneer's drug before its patent term has expired. A patent challenge pursuant to Paragraph IV is a frequently deployed mechanism for the early introduction of generic competition.[39] When an applicant makes a Paragraph IV certification, two special features of the Act apply: the thirty-month stay and the 180-day marketing exclusivity period.[40]

1. Thirty-Month Stay of ANDA Approval

The Hatch-Waxman Act provides that making a Paragraph IV certification is itself an act of patent infringement.[41] The statute requires all Paragraph IV ANDA applicants to provide notice of the application to the challenged NDA/patent holder, including a detailed factual and legal analysis explaining why the patent is either invalid or not infringed.[42] After receiving such notice, the NDA holder has forty-five days to bring an infringement action against the ANDA applicant.[43] If suit is not filed within that time, the ANDA can be approved immediately.[44] But if suit is brought during that time, then the FDA is barred from approving the ANDA for thirty months.[45] During this thirty-month stay, the FDA can only "tentatively approve" the ANDA, such that it can become effective immediately upon expiration of the stay.[46] The only exceptions to the thirty-month stay are if either the patent expires, or there is a district court finding of patent invalidity or noninfringement during the stay, in which cases the ANDA can be approved immediately.[47]

The purpose of the thirty-month stay is to protect NDA holders with valid drug patents.[48] The stay does this by allowing the patent holder to sue the ANDA applicant for infringement before the generic challenger enters the market.[49] Congress believed that "this procedure fairly

39. *See* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 10 (2002) (reporting challenges involving 130 drugs between 1984 and 2000); *Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act": Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 113, 117 (2003) (statement of Timothy Muris, Chairman, Federal Trade Commission) (noting challenges involving more than eighty drugs between January 2001 and June 2003).

40. 21 U.S.C. § 355(j)(5)(A)–(B).

41. 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit . . . an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . .").

42. 21 U.S.C. § 355(j)(2)(B).

43. *Id.* § 355(j)(5)(B)(iii).

44. *Id.*

45. *Id.*

46. *Id.* § 355(j)(5)(B)(iv)(II)(dd).

47. *Id.* § 355(j)(5)(B)(iii)(I)–(IV).

48. H.R. REP. No. 98-857, pt. 1, at 28.

49. *Id.*

balance[d] the rights of a patent owner to prevent others from making, using, or selling its patented product and the rights of third parties to contest the validity of a patent to market a product which they believe is not claimed by the patent."[50]

2. 180-Day Marketing Exclusivity for the First ANDA Applicant

The Hatch-Waxman Act provides that the first applicant to file a Paragraph IV ANDA with the FDA will be granted 180 days of market exclusivity upon entering the market with their generic equivalent.[51] The FDA will not approve later-filed ANDAs for the same drug until 180 days after the first Paragraph IV ANDA applicant begins commercially marketing a generic equivalent of the drug.[52] The first ANDA filer gets the 180-day exclusivity even if the patent holder never sues it for infringement.[53] Therefore, during this period the first filer's product will be the only generic equivalent on the market. The simple purpose of the exclusivity period is to encourage Paragraph IV challenges by rewarding the first filing applicant—"in exchange for undertaking the costs and risks of patent litigation, the successful challenger is given [six] months of marketing without any other generic competition."[54] This exclusivity period is very valuable to generic manufacturers,[55] as they can sell their product at a price significantly higher than they could if multiple generics were on the market.[56]

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50. *Id.*

51. 21 U.S.C. § 355(j)(5)(B)(iv).

52. *Id.* Prior to the Medicare Modernization Act, this clause also permitted approval of later-filing applicants if there was a court decision of patent invalidity or noninfringement. This provision has effectively moved into the forfeiture provisions of the Medicare Modernization Act. *See* discussion *infra* Part III.C.

53. *See* Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1074 (D.C. Cir. 1998) (overturning an FDA requirement that the first filer was only entitled to the 180-day exclusivity if it successfully defended against a patent infringement suit by the NDA holder); *see also* Purepac Pharm. Co. v. Friedman, 162 F.3d 1201, 1205 (D.C. Cir. 1998).

54. Representative Henry Waxman, Speech at the Generic Pharmaceutical Association's First Annual Policy Conference: Securing the Future of Affordable Medicine (Sept. 20, 2005), *available at* http://www.house.gov/waxman/news_files/news_statements_generic_pharmaceutical%20_association_9.20.05.htm.

55. *See* Leila Abboud, *Drug Makers Use New Tactic to Ding Generics*, WALL ST. J., Jan. 27, 2004, at B1 ("In 2002, when Barr successfully challenged the patent protection on Eli Lilly & Co.'s big antidepressant Prozac, Barr got revenue of about $368 million from the new drug, or 31% of its total for the year.").

56. For example, when generic Prozac (Fluoxetine) entered the market, the first generic challenger sold it at $1.91/capsule, or 12% below the cost of brand-name Prozac. Two months after the exclusivity period expired, multiple generics had entered the market and the price of generic Prozac had dropped to $0.32/capsule. Druss et al., *supra* note 7, at 213–14.

II. LOOPHOLES IN THE HATCH-WAXMAN ACT AND RELATED SETTLEMENT AGREEMENTS

A. INTRODUCTION

The onset of generic competition can be financially devastating to pioneers while producing sizable profits for generic manufacturers.[57] Naturally, patent holders have looked for ways to strategically exploit the law to delay this competition. Representative Waxman has quipped that "some of the most outstanding research happening at certain brand-name drug companies is in the field of law."[58] There has long been a concern that patent holders have used loopholes in the Hatch-Waxman Act to deter or delay generic competition.[59] Additionally, an FTC study specifically found that the provisions of the Act pertaining to 180-day market exclusivity and the thirty-month stay were susceptible to abusive strategies that delayed the approval of generic drugs.[60] These abusive strategies are described in detail in the following sections.

B. THIRTY-MONTH STAY OF ANDA APPROVAL

As discussed above, a patent holder may sue a Paragraph IV ANDA applicant for patent infringement if suit is filed within forty-five days of receiving notice of the certification.[61] If the suit is filed, the FDA will stay approval of the ANDA for thirty months, or until a court decides the patent is not infringed or invalid, whichever is earlier.[62] This thirty-month stay provides the pioneer with a way to effectively extend the period of market exclusivity beyond their normal patent term.[63]

One abusive strategy pioneers used was to obtain multiple thirty-month stays through the use of so-called "sham" patents, which claim features peripherally related to the patented drugs, such as metabolites, intermediates, and packaging features.[64] First, the pioneer obtained the "sham" patent and then submitted it for listing in the FDA's *Orange Book*.[65] When making a Paragraph I through IV certification, the ANDA

57. CONG. BUDGET OFFICE, *supra* note 6, at 28–31.

58. Waxman, *supra* note 1.

59. *See, e.g.*, Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 414–19 (1999).

60. *See* FED. TRADE COMM'N, *supra* note 39, at i.

61. 21 U.S.C. § 355(j)(5)(B)(iii) (2006).

62. *Id.*

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

64. *See* Soehnge, *supra* note 23, at 73. The term "sham patent" is somewhat misleading and is not meant to imply that the U.S. Patent & Trademark Office is improperly issuing invalid patents. In this context, it is meant to refer to a patent that is filed for the purpose of engaging in "sham" litigation, i.e., litigation that is baseless and pursued only for the purpose of interfering with a competitor's business. *See In re* Buspirone Patent & Antitrust Litig., 185 F. Supp. 2d 363, 368 (S.D.N.Y. 2002).

65. The "*Orange Book*" is the common name for the FDA publication *Approved Drug Products*

applicant must rely on *Orange Book* listings to determine what patents cover the pioneer's drug. Consequently, after getting the sham patent listed in the *Orange Book*, the NDA holder could claim that sale of a generic equivalent would infringe the newly listed patent.[66] Regardless of the merits of this argument, the generic company was forced to make a Paragraph IV certification, allowing the pioneer company to sue the ANDA applicant and delay generic competition for up to thirty months.[67] A sham patent could even be filed after a generic challenger has filed a Paragraph I, II, or III certification, forcing the generic to file a revised ANDA with a Paragraph IV certification.[68] Used this way,

> the *Orange Book* can be a strategic weapon . . . giving the patent/NDA holder almost automatic injunctive relief for even marginal infringement claims. Adding to a patentee/NDA holder's advantage is FDA's long-standing policy of avoiding patent disputes, as evidenced by its willingness to list in the *Orange Book* virtually any patent submitted by an NDA holder and its refusal to hear any challenge to the adequacy or completeness of a generic applicant's Paragraph IV certification.[69]

Furthermore, the patent holder could obtain multiple thirty-month stays by submitting new sham patents over time, thereby delaying generic competition for several years.[70] This loophole was harshly criticized because, "[b]y the time the litigation plays out, even if the generic company prevails, enough time has gone by for the pioneer company to realize substantial continued profits on its drug product, perhaps far above its costs of litigation against the generic competitor."[71]

Additionally, if the pioneer's patent expires before the first generic challenger receives final ANDA approval, the challenger must amend its

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with Therapeutic Equivalence Evaluations, which is published monthly. OFFICE OF GENERIC DRUGS, FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2008) [hereinafter *Orange Book*], *available at* http://www.fda.gov/cder/ob/docs/preface/ecpreface.htm. The FDCA requires a patent holder to include in its NDA

> the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(b)(1). The patent numbers and expiration dates are then published in the *Orange Book*. Process patents and certain composition of matter patents are precluded from being listed in the *Orange Book*, though generic manufacturers may still be sued for infringing these unlisted patents. *See infra* notes 99, 181 and accompanying text.

66. Brian Porter, Comment, *Stopping the Practice of Authorized Generics: Mylan's Effort to Close the Gaping Black Hole in the Hatch-Waxman Act*, 22 J. CONTEMP. HEALTH L. & POL'Y 177, 181 (2005).

67. Soehnge, *supra* note 23, at 71–72.

68. *See, e.g.*, Mylan Pharm., Inc. v. Thompson, 268 F.3d 1323, 1330–31 (Fed. Cir. 2001).

69. Terry G. Mahn, *Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process*, 54 FOOD & DRUG L.J. 245, 250 (1999) (citing 59 Fed. Reg. 50,345 (Oct. 3, 1994)).

70. *See* Soehnge, *supra* note 23, at 72.

71. *Id.* (citing Glasgow, *supra* note 63).

certification from a Paragraph IV to a Paragraph II, and will no longer be entitled to the 180-day exclusivity upon ANDA approval.[72] Consequently, generic challengers facing multiple thirty-month stays risked wasting millions of dollars in litigation and losing the benefit of exclusive marketing if they failed to resolve litigation before the pioneer's patent expired.[73]

C. Reverse Payments and 180-Day Exclusivity Bottlenecks

As discussed above, the first generic manufacturer to file a Paragraph IV ANDA is entitled to 180 days of market exclusivity once it enters the market.[74] Until the exclusivity period runs, the FDA is barred from approving ANDAs by later-filing applicants.[75] But patent holders have been able to manipulate the trigger of the exclusivity period, and thereby delay the entry of generic competitors indefinitely.[76] In litigation related to a Paragraph IV certification, the parties can settle so that the first filer agrees to delay marketing its generic equivalent until a later date (often till right before the patent expires).[77] Since the first filer never enters the market, the 180-day exclusivity period does not run and generic entry becomes bottlenecked because the FDA cannot approve later-filed ANDAs.[78]

These settlements often involve so-called "reverse payments," which are cash payments by the patent holder to the generic challenger.[79] Such payments effectively allow pioneers to avoid competition by sharing their monopoly profits with generic challengers. Surprisingly, reverse payments are generally not found to violate antitrust laws, despite their anticompetitive effect of excluding or delaying entry of generics.[80] This is especially ironic since the patent holder is able to avoid competition even though the challenged patent would likely have been either invalidated

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72. *See* 21 U.S.C. § 355(j)(5)(D)(i)(VI) (2006). Recall that ANDAs for expired pioneer patents require Paragraph II certifications. *Id.* § 355(j)(2)(A)(vii)(II); *see also supra* note 38 and accompanying text.

73. *See, e.g.*, Dr. Reddy's Labs., Inc. v. Thompson, 302 F. Supp. 2d 340, 350–57 (D.N.J. 2003). One practioner suggests that this structure encourages earlier challenges to drug patents, which advances the public's interest in invalidating weak patents, and that generic manufacturer can avoid this risk by submitting ANDAs earlier. E-mail from Dr. Michael Shuster, Partner, Fenwick & West LLP, to Author (Mar. 23, 2008, 18:00:40 PST) (on file with author).

74. 21 U.S.C. § 355(j)(5)(B)(iv); *see also supra* notes 51–53 and accompanying text.

75. 21 U.S.C. § 355(j)(5)(B)(iv).

76. *See* Soehnge, *supra* note 23, at 74.

77. *Id.*

78. *See id.*

79. *See, e.g.*, *In re* Buspirone Patent Litig., 185 F. Supp. 2d 363, 365–67 (S.D.N.Y. 2002). Commentators refer to such settlements as "reverse payments" because they involve payments from the plaintiff to the defendant—i.e., from the patentee to the generic manufacturer. *See* James C. Burling, *Hatch-Waxman Patent Settlements: The Battle for a Benchmark*, 20 Antitrust 41, 41 (2006).

80. *Id.* Discussions of antitrust violations are outside the scope of this Note. For further discussion, see generally Fazzio, *supra* note 17, and Hemphill, *supra* note 17.

by a court or found not to cover the generic product.[81] "Pay-for-delay" settlements are arguably an abuse of the Hatch-Waxman Act because they inhibit competition by generic manufacturers.[82] Indeed, Senator Orrin Hatch, coauthor of the Act, has condemned such settlements, stating that he "find[s] these types of reverse payment collusive arrangements appalling."[83]

D. "AUTHORIZED" GENERIC COMPETITION DURING THE EXCLUSIVITY PERIOD

Alternatively, when faced with a generic challenge, the NDA/patent holder can license another party to use its NDA to manufacture so-called "authorized generics."[84] An authorized generic drug is manufactured by the NDA holder, but distributed through a licensee, who packages the drug with its own label and FDA identification number.[85] Therefore, the authorized generic drug is the same drug the brand-name pharmaceutical sells, simply repackaged, marketed as a generic, and sold at a lower price. Because the 180-day exclusivity period only bars ANDA applicants, the authorized generic manufacturer can market its drug during this period. Consequently, when a Paragraph IV ANDA applicant prevails in infringement litigation, it immediately faces competition from the authorized generic manufacturer, effectively nullifying the benefit of the 180-day exclusivity period and severely cutting into the ANDA applicant's profits.[86] Adding insult to injury, the patent holder recoups

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81. *See Paying off Hearing*, *supra* note 5, at 131–32 (statement of Comm'r Jon Leibowitz, Federal Trade Commission). According to the FTC, generic challengers prevail 73% of the time in litigation filed pursuant to Paragraph IV ANDAs. FED. TRADE COMM'N, *supra* note 39, at 13.

82. *See* 148 CONG. REC. S7565-66 (daily ed. July 30, 2002) (statement of Sen. Hatch) (asserting that pay-for-delay settlements were an unanticipated outcome of the Hatch-Waxman Act); *see also* S. REP. NO. 107-167, at 4 (2002) ("Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law . . . ."). *But see* Burling, *supra* note 79, at 44 (arguing in support of reverse payments as a valid form of risk aversion by patent holders).

83. 148 CONG. REC. S7566 (daily ed. July 30, 2002) (statement of Sen. Hatch).

84. The FDA has defined "authorized generic" as "any marketing by an NDA holder or authorized by an NDA holder, including through a third-party distributor, of the drug product approved under the NDA in a manner equivalent to the marketing practices of holders of an approved ANDA for that drug." Letter from William K. Hubbard, Assoc. Comm'r for Policy and Planning, Food & Drug Admin., to Stuart A. Williams, Chief Legal Officer, Mylan Pharm., Inc., and James N. Czaban, Heller Ehrman LLP (July 2, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/july04/070704/04p-0075-pdn0001.pdf.

85. *See id.*

86. The Pharmaceutical Research and Manufacturers of America (PhRMA) sponsored a study looking at the effect of authorized generics on drug prices. IMS CONSULTING, IMS HEALTH, ASSESSMENT OF AUTHORIZED GENERICS IN THE U.S. (2006), *available at* http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf. The study compared drugs where an authorized generic was launched during the first ANDA applicant's 180-day exclusivity period, with drugs where no authorized generic was marketed during the exclusivity period. *See id.* at 6–7. The effect of the authorized generics on drug prices was evaluated by comparing the price difference between generic and branded drugs in both cases. *Id.* at 7. The study found that where no authorized

some of its losses via licensing fees from the authorized generic manufacturer. The authorized generic scenario is illustrated by Johnson & Johnson's (J&J) licensing of the drug Ortho-Tricyclen to Watson Pharmaceuticals in the face of a Paragraph IV challenge by the generic manufacturer Barr Pharmaceuticals:

> Barr, a unit of Barr Pharmaceuticals Inc., had spent five years working on copying Ortho-Tricyclen, the most widely prescribed oral contraceptive, and challenging J&J's patents on the drug in court.
>
> But when Barr launched its product Dec. 29, [2003,] it wasn't alone. A competitor, Watson Pharmaceuticals Inc., had cut a deal with J&J to put out an authorized copy of Ortho-Tricyclen, agreeing to share some of its revenue from the drug. The authorized generic drove down prices and cut into sales of the Barr drug, costing it hundreds of millions of dollars.[87]

Generic companies argue that the use of authorized generics by patent holders impedes competition by reducing the monetary incentive for generic companies to challenge the pioneer company's patents via the ANDA process.[88] In the long term, this disincentivizing could result in fewer generic companies challenging patents via Paragraph IV certifications.[89] Ironically, authorized generics are pro-competitive from the consumer's perspective, since they increase the number of competitors in the market more quickly. The FDA agrees, stating that "marketing of authorized generics increases competition, promoting lower prices for drugs, particularly during the 180-day exclusivity period in which the prices for generic drugs are often substantially higher than after other generic products are able to enter the market."[90] However, while authorized generics may increase short-term competition, it is possible that they will decrease competition in the long term by deterring Paragraph IV challenges.[91]

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generic was marketed during the exclusivity period, the generic drug sold for 23% less than the branded drug. *See id.* at 10. But where an authorized generic was marketed during the exclusivity period, the discount between generics and the branded drug increased to 38%. *See id.* at 9. In contrast, the Generic Pharmaceutical Association (GPhA) sponsored an identical study, which found that authorized generics had almost no effect on generic drug prices during the exclusivity period. *See* AIDAN HOLLIS & BRIAN LIANG, AN ASSESSMENT OF THE EFFECT OF AUTHORIZED GENERICS ON CONSUMER PRICES 18 (2006), *available at* http://www.gphaonline.org/AM/Template.cfm?Section=Home&Template=/CM/ContentDisplay.cfm&ContentID=2647.

87. Abboud, *supra* note 55.

88. *Agency Views on Authorized Generics a Boon to Brands*, WASH. DRUG LETTER, Oct. 11, 2004, at 9.

89. *Id.*

90. *Id.* (internal quotation marks omitted).

91. *See* Petition from Mylan Pharm., Inc. to Food & Drug Admin., Citizen Petition No. 2004P-0075, at 2 [hereinafter Mylan Pharm. Petition] (Feb. 17, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/feb04/021804/04p-0075-cp00001-vol1.pdf.

III. REVISIONS TO THE HATCH-WAXMAN ACT IN 2003

A. THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

In response to the antitrust litigation spawned by the loopholes described above, the FTC initiated a study to examine whether the Hatch-Waxman 180-day market exclusivity and thirty-month stay provisions facilitated anticompetitive behavior.[92] The FTC released its report in July 2002 with two major recommended amendments to the Hatch-Waxman Act: (1) that the FDA should allow only one thirty-month stay per ANDA application; and (2) that pioneer drug companies provide agreements relating to the manufacture, marketing, or sale of a generic drug, or to the 180-day market exclusivity to the FTC and the Department of Justice.[93]

Responding to the FTC study and pressure from the executive branch,[94] in 2003 Congress amended the FDCA by enacting the Medicare Prescription Drug, Improvement, and Modernization Act (Medicare Modernization Act or "MMA") in order to, inter alia, curb the abuses described above.[95]

B. LIMITING USE OF THE THIRTY-MONTH STAY (MMA SECTION 1101)

Under the Medicare Modernization Act, when the pioneer sues a generic challenger in response to a Paragraph IV ANDA, the pioneer cannot obtain more than one thirty-month stay of approval of the ANDA.[96] Congress reasoned that a single thirty-month stay should not cause significant delay in generic market entry because the stay runs concurrently with FDA approval of the ANDA, which generally takes eighteen to twenty-five months.[97]

The revised statute also limits abuse of the thirty-month stay caused by filing "sham" patents. Generic challengers now only need to certify to patents that were listed in the *Orange Book* at the time their ANDA was filed.[98] This means that generic challengers no longer need to modify

92. FED. TRADE COMM'N, *supra* note 39, at i.

93. *Id.* at ii–viii.

94. *See* President George W. Bush, Remarks by the President on Prescription Drugs (Oct. 21, 2002) (proposing new FDA regulations to expedite generic drug approvals), *available at* http://whitehouse.gov/news/releases/2002/10/20021021-2.html.

95. Pub. L. No. 108-173, 117 Stat. 2066 (effective Dec. 8, 2003) (codified as amended in scattered sections of 21 and 42 U.S.C.).

96. SmithKline Beecham Corp. v. Apotex Corp., 383 F. Supp. 2d 686, 691 n.3 (E.D. Pa. 2004); *see also* 21 U.S.C. § 355(c)(3)(C) (2006).

97. Press Release, Sen. Judd Gregg, Breakthrough, Bipartisan Legislation to Make More Prescription Drugs Affordable, Available Gets Boost (Jun. 11, 2003), *available at* http://www.senate.gov/~gregg/press/2003/presso61103.pdf.

98. Medicare Modernization Act, § 1102(a)(2)(A) (codified as amended at 21 U.S.C. § 355(j)(5)(B)(iii) (2006)); *see also* Barry J. Marenberg, *Changes to the Hatch-Waxman Act Following*

their ANDA in response to later filed patents. Furthermore, the FDA also revised its regulations to address this abuse, and now limits the types of patents that can be listed in the *Orange Book*, specifically precluding the listing of patents claiming metabolites, intermediates, or packaging features.[99]

C. Forfeiture of 180-Day Exclusivity (MMA Section 1102)

Under the terms of the 2003 amendments, the 180-day exclusivity period commences when the first ANDA applicant begins commercial marketing of either its own generic version of the listed drug or an "authorized" private label version of the drug.[100] This amendment codified a 2001 district court decision holding that the "commercial marketing" trigger for the 180-day exclusivity period begins when the first-filing Paragraph IV ANDA applicant begins selling either its own generic equivalent of the pioneer's drug or a private label version of the product.[101] Therefore, if an ANDA applicant enters into a settlement agreement with the patent holder to become an authorized generic manufacturer under the pioneer's NDA, its actions trigger the 180-day exclusivity period. This amendment prevents the pioneer from stopping further generic competition by keeping the first-filing generic manufacturer from selling the drug under the pioneer's NDA.

Congress also added new provisions whereby the first Paragraph IV ANDA applicant will forfeit its rights to the 180-day exclusivity period if a specified "forfeiture event" occurs.[102] Certain forfeiture events were specifically designed to force generic manufacturers to promptly enter the market upon approval of the ANDA application, and to prevent the pioneer from stopping generic competition by paying the first-filing ANDA applicant to delay the launch of their generic drug.[103] These complex "failure to market" provisions stipulate that the first generic

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the "Medicare Prescription Drug, Improvement and Modernization Act of 2003," 23 Biotech. L. Rep. 277, 277 (2004).

99. 21 C.F.R. § 314.53(b)(1) (effective Aug. 19, 2003).

100. 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2006). The revised Act now provides that,

> [i]f the [ANDA] contains a [Paragraph IV] certification . . . and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is one hundred and eighty days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

Id. Unlike the pre-MMA version of the Act, a court decision does not by itself start the 180-day period. *Cf.* 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000) (amended 2003) (permitting trigger of the 180-day period by "a decision of a court . . . holding the patent which is the subject of the certification to be invalid or not infringed").

101. Mylan Pharm., Inc. v. Thompson, 207 F. Supp. 2d 476, 488 (N.D.W. Va. 2001); *see also* Erika King Lietzan, *A Brief History of 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, 59 Food & Drug L.J. 287, 304 (2004).

102. *See* 21 U.S.C. § 355(j)(5)(D) (2006).

103. A detailed presentation and analysis of these provisions is given in Part IV.B, *infra*.

challenger will forfeit the 180-day exclusivity period if it fails to market the generic version of the pioneer drug by the later of: (1) seventy-five days after the ANDA is approved, or thirty months after the ANDA was filed, whichever is earlier; or (2) seventy-five days after one of the following has occurred: (i) the Federal Circuit holds that the pioneer's patent either invalid or not infringed, (ii) a district court approves a settlement agreement that includes a finding that the pioneer's patent either invalid or not infringed, or (iii) the NDA/patent holder withdraws its patent information from the *Orange Book*.[104]

The MMA also created the following miscellaneous forfeiture events: (1) the first ANDA applicant withdraws its application, (2) the first applicant withdraws its Paragraph IV certification by amending it to another certification (e.g., a Paragraph I through III certification), (3) the first applicant fails to obtain "tentative approval" of its ANDA within thirty months of filing, (4) the first applicant enters into an agreement with either the NDA/patent holder or another generic challenger that either the FTC or a court finds to be in violation of federal antitrust laws, or (5) all the patents related to the Paragraph IV certification(s) have expired.[105]

If the first applicant forfeits its 180-day exclusivity, any later-filed ANDAs may be approved and made effective immediately.[106] In all forfeiture cases, the 180-day exclusivity never applies to subsequent ANDA applicants.[107]

D. Other Revisions

A generic manufacturer that is sued for patent infringement in response to a Paragraph IV ANDA filing may now bring a counterclaim to delist the patent from the *Orange Book*.[108] If the pioneer's patent is found either to not cover the listed drug or to cover only an invalid method of using the listed drug, the pioneer can be forced to withdraw the patent listing from the *Orange Book*, allowing the generic challenger to amend its application to a Paragraph I certification and thereby avoid litigation.[109]

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104. 21 U.S.C. § 355(j)(5)(D)(i)(I).

105. *Id.* § 355(j)(5)(D)(i)(II)–(VI).

106. *Id.* § 355(j)(5)(D)(iii)(I).

107. *Id.* § 355(j)(5)(D)(iii)(II).

108. *Id.* § 355(j)(5)(C)(ii) ("If an owner of the [patent holder] brings a patent infringement action against the [ANDA] applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder . . . on the ground that the patent does not claim either—(aa) the drug for which the application was approved; or (bb) an approved method of using the drug."). Note that this is not an independent cause of action and can only be raised as a counterclaim.

109. *Id.* It is beyond the scope of this Note to provide a full analysis of this provision. But it seems unlikely that the first ANDA applicant would ever file such a counterclaim, since they would either (1)

Also, where the NDA/patent holder does not bring an infringement action within forty-five days of receiving notice of the Paragraph IV certification, the ANDA applicant may bring a "[c]ivil action to obtain patent certainty."[110] In this case, the ANDA applicant may seek a declaratory judgment that the patent at issue is invalid or will not be infringed by the drug for which the applicant seeks approval.[111] In exchange, the ANDA applicant must offer the NDA-holder confidential access to its application so it can determine whether there is possible infringement.[112]

In an attempt to thwart possible anticompetitive settlements between pioneers and generic challengers, section 1112 of the MMA provides that certain types of agreements must be filed with both the FTC and the Department of Justice.[113] Where the settlement is between a patent holder and a Paragraph IV ANDA applicant, it must be reported to the antitrust agencies if it relates to either: (1) the "manufacture, marketing or sale" of the patented drug or its generic equivalent; or (2) the 180-day exclusivity period for that drug.[114] If the settlement is between two Paragraph IV ANDA challengers, it only needs to be reported if it relates to the 180-day exclusivity period for the drug they are challenging.[115] The purpose of these reporting requirements was to deter anticompetitive agreements by giving the antitrust agencies "access to information about secret deals between drug companies that keep generic drugs off the market."[116]

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forfeit the exclusivity period by amending to a Paragraph I certification, or (2) trigger a forfeiture event. Exercising this counterclaim option would only be useful for later-filing applicants, who could possibly deprive the first filer of the exclusivity period by forcing the NDA holder to delist their patent from the *Orange Book*.

110. Medicare Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066, § 1101(a), (d) (effective Dec. 8, 2003) (codified at 21 U.S.C. § 355(j)(5)(C) (2006), 35 U.S.C. § 271(e)(5) (2006)).

111. 21 U.S.C. § 355(j)(5)(C)(i); 35 U.S.C. § 271(e)(5). Despite Congress' explicit attempt to grant generic challengers declaratory judgment jurisdiction, the Federal Circuit held that such actions failed to meet the Constitution's Article III "case or controversy" requirement. *See* Teva Pharm. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1334 (Fed. Cir. 2005). But after the Supreme Court's decision in *MedImmune v. Genentech*, 127 S. Ct. 764 (2007), the Federal Circuit revised its position and now allows generic challengers to bring declaratory judgment actions even when the patent holder has granted the generic a covenant not to sue. *See* Caraco Pharm. Labs. v. Forest Labs, 527 F.3d 1278, 1290–91 (Fed. Cir. 2008); Teva Pharm. USA v. Novartis Pharm. Corp., 482 F.3d 1330, 1340 (Fed. Cir. 2007). But recent cases suggest that declaratory judgment actions brought by later-filing ANDA applicants may fail the "case or controversy" requirement. *See* Janssen Pharm. v. Apotex, Inc., No. 2008-1062, 2008 U.S. App. LEXIS 18822 (Fed. Cir. Sept. 4, 2008); Merck & Co. v. Apotex, Inc., No. 2007-1362, 2008 U.S. App. LEXIS 15014 (Fed. Cir. July 16, 2008).

112. 21 U.S.C. § 355(j)(5)(C)(i)(III).

113. Medicare Modernization Act § 1112 (effective Dec. 8, 2003) (codified at 21 U.S.C. § 355 nt.).

114. *Id.* § 1112(a).

115. *Id.* § 1112(b).

116. 148 CONG. REC. S11340 (daily ed. Nov. 18, 2002) (statement of Sen. Leahy).

IV. IMPACT OF THE MEDICARE MODERNIZATION ACT ON ABUSE OF THE HATCH-WAXMAN ACT

The 2003 amendments attempted to address many of the abuses previously described. When the MMA was approved, Senator Bill Frist stated that the bill took "steps to reduce or eliminate the delays in the movement of generic drugs to the marketplace,"[117] and Senator Charles Schumer stated that the revisions were designed to ensure that the 180-day exclusivity period "cannot be used as a bottleneck" to generic drug entry.[118] The amendments were very effective in closing some loopholes, have proven ineffective in closing others, and failed to address some abuses altogether. Additionally, the amended statutory language has spawned a host of new interpretative questions for patent holders to manipulate.

A. MULTIPLE THIRTY-MONTH STAYS BARRED

Among all of the amendments under the Medicare Modernization Act, the revisions targeting abuse of the thirty-month stay have been the most effective. By only requiring ANDA applicants to certify to patents listed in the *Orange Book* at the time of filing and limiting the patent holder to only one thirty-month stay, the MMA has eliminated the patent holder's practice of gaining multiple stays to keep generic challengers off the market.[119]

While the major abuse of the thirty-month stay has been resolved, some minor problems remain unaddressed. First, the duration of the thirty-month stay is arbitrary. Originally, the proposed duration of the stay was eighteen months, but it was increased to thirty months due to the lobbying efforts of the pharmaceutical industry.[120] Because the average ANDA takes only 25.5 months to get approved, the typical applicant is kept off the market for several months while waiting for the thirty-month stay to expire.[121]

Second, the MMA failed to address the problem created when the pioneer's patent expires before the FDA approves the first filer's Paragraph IV ANDA. If the generic challenger cannot get final ANDA approval before the patent expires, it will be forced to amend its ANDA from a Paragraph IV to a Paragraph II certification, thereby forfeiting its right to the 180-day exclusivity period.[122] Consequently, the generic challenger will have little incentive to bring a Paragraph IV challenge if

117. 149 CONG. REC. S15761 (daily ed. Nov. 24, 2003) (statement of Sen. Frist).

118. *Id.* at S15746 (statement of Sen. Schumer).

119. Marenberg, *supra* note 98, at 277.

120. Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 190 (1999).

121. *See* FED. TRADE COMM'N, *supra* note 39, at iii.

122. *See* 21 U.S.C. § 355(j)(5)(D)(i)(III) (2006).

the patent is set to expire within thirty months. For example, a generic challenger could file a Paragraph IV ANDA twenty-eight months before the pioneer's patent expires. The FDA could then tentatively approve the ANDA after eighteen months. But because of the thirty-month stay, the generic challenger will be unable to get final approval before the patent expires.[123] Once the patent expires, it will be forced to forfeit the exclusivity period by amending its ANDA to a Paragraph II certification. In these situations, a generic challenger risks expensive litigation where, even if it would likely succeed on the merits, it might lose the benefit of marketing exclusivity due to lengthy litigation.

Because the thirty-month stay effectively functions like an injunction against the generic manufacturer, preventing it from possibly infringing the pioneer's patent,[124] one solution would be to stay ANDA approval until there is a court decision or a settlement. But this scheme would be problematic where the patent holder purposefully draws out the litigation. If the generic challenger has a particularly strong case, it may want to launch "at-risk" as soon as the ANDA is approved, despite the fact that litigation is still pending.[125] Therefore, an alternate solution would be to eliminate the thirty-month stay altogether and to allow the market to run its course. This would allow a generic challenger to enter the market as soon as the ANDA is approved, even though litigation is still pending, and if the pioneer prevails in litigation, the generic would simply be liable for damages.[126] Pioneers would naturally object to the latter solution, since the damages they could recover if they prevailed in litigation may not compensate them for the profits lost due to early generic competition.[127] Consequently, the thirty-month stay may be the best compromise between these two extreme alternatives.

B. REVERSE PAYMENT SETTLEMENTS

1. Post-MMA Litigation Splits on Legality of Reverse Payments

While the Medicare Modernization Act attempted to address the negative effects of pay-for-delay settlements—e.g., through the exclusivity forfeiture provisions—it did not expressly bar reverse payments by patent holders to generic challengers to delay market entry. Instead, the MMA simply requires that drug companies report certain

123. This example also assumes that the generic challenger could not conclude litigation before the patent expires.

124. Caffrey & Rotter, *supra* note 11, at 23.

125. Yana Pechersky, Note, *To Achieve Closure of the Hatch-Waxman Act's Loopholes, Legislative Action Is Unnecessary: Generic Manufacturers Are Able to Hold Their Own*, 25 CARDOZO ARTS & ENT. L.J. 775, 796 (2007). Marketing a generic drug while related Paragraph IV litigation is pending is considered "at-risk" because the generic challenger risks liability for the pioneer's lost profits if the generic loses the patent case. *See id.*

126. Caffrey & Rotter, *supra* note 11, at 23.

127. *Id.* at 43.

types of settlement agreements to both the FTC and the Department of Justice.[128]

> At the time the MMA filing requirement went into effect, the FTC had investigated and brought several enforcement actions based on the theory that a payment from a brand firm to a generic company, in the context of a patent settlement, had likely anticompetitive effects where the payment caused a delay of the generic's entry into the market. As a consequence, Congress likely perceived that the FTC possessed sufficient legal authority to continue challenging potentially anticompetitive pharmaceutical settlements, and thereby simply required parties to provide *notice* of such settlements.[129]

But Congress incorrectly assumed that the FTC would be able to stop pay-for-delay settlements. This harmful practice has proceeded unabated in light of a split among the federal circuit courts of appeals on whether such payments are antitrust violations.[130] Three circuits have allowed pay-for-delay settlements absent direct evidence of patent invalidity or infringement,[131] while other circuits have deemed such settlements per se illegal.[132] In light of these decisions, the general rule seems to be that for a reverse payment to be found legal, its terms must stay within the scope of the patent—that is, the reverse payment settlement must not extend the patent holder's monopoly beyond the normal patent term.[133] Currently, the FTC appears to be bringing cases in an effort to create a split among the circuits and thereby force review by the United States Supreme Court.[134]

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128. Medicare Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066, § 1112 (effective Dec. 8, 2003) (codified at 21 U.S.C. § 355 nt. (2006)).

129. Seth Silber & Matthew Bye, *Is That Everything? Antitrust Filing Obligations for Pharmaceutical Settlement Agreements*, ANTITRUST COMPLIANCE BULL., Mar. 2008, at 39 (footnote omitted).

130. *See* BUREAU OF COMPETITION, FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2007 at 2 (2008) (finding that 42% of settlement agreements between pioneers and generic manufacturers during fiscal year 2007 included some form of reverse payment).

131. *See In re* Ciprofloxacin Hydrochloride Antitrust Litigation, No. 2008-1097 (Fed. Cir. Oct. 15, 2008); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006), *cert. denied sub nom.* Joblove v. Barr Labs, Inc., 127 S. Ct. 3001 (2007); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1304, 1312–13 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004).

132. *See In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003), *cert. denied sub nom.* Andrx Pharm., Inc. v. Kroger Co., 543 U.S. 939 (2004); Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 809–12 (D.C. Cir. 2001) (dicta), *cert. denied*, 535 U.S. 931 (2002).

133. Pechersky, *supra* note 125, at 795.

134. For example, the FTC recently filed suit in the D.C. District Court against Cephalon for entering into pay-for-delay settlements with four ANDA applicants. *See* Complaint for Injunctive Relief at 9, FTC v. Cephalon, Inc., No. 1:08-cv-00244 (D.D.C. Feb. 13, 2008). Review of any decisions from this court would go to the D.C. Circuit Court of Appeals, which is considered a sophisticated antitrust court, and possibly cause a split with the decisions of the Second and Eleventh Circuits. Client Alert, Seth Silber, Wilson Sonsini Goodrich & Rosati PC, FTC Sues Cephalon for "Reverse

2. Settlements Where the Challenger Retains 180-Day Exclusivity

The MMA attempted to address situations where pay-for-delay settlements "bottleneck" generic competition because the first ANDA applicant receives 180-day market exclusivity but never enters the market.[135] The revised Act provides that exclusivity is forfeited if the first applicant does not enter the market within "75 days after the date on which the approval of the application of the first applicant is made effective."[136] However, in practice, where a settlement occurs and the first applicant does not enter the market, the 180-day exclusivity has not been forfeited due to a loophole found when interpreting the forfeiture provisions.[137]

In a typical pay-for-delay settlement, the first filer receives ANDA approval, but agrees not to enter the market for several years, and the settlement does not include a finding that the pioneer's patent is invalid or not infringed. In such a case, later-filing applicants will not be able to enter the market until the first filer expends or forfeits the exclusivity period. The forfeiture provisions state that the first filer's 180-day exclusivity is lost if, inter alia, there is a "failure to market" event.[138] The Act defines "failure to market" as follows:

> (I) FAILURE TO MARKET. The first applicant fails to market the drug by the *later of*—
>
> (aa) the *earlier of* the date that is—
>
> (AA) 75 days after the date on which the [application of the first applicant is approved]; or
>
> (BB) 30 months after the date of submission of the application of the first applicant; *or*
>
> (bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is *75 days after* the date as of which . . . *at least 1 of the following has occurred*:
>
> (AA) In an infringement action . . . or in a declaratory judgment action . . . [the Federal Circuit finds on appeal] that the patent is invalid or not infringed.
>
> (BB) In an infringement action or a declaratory judgment action . . . a court signs a settlement order or consent decree that enters a final judgment that *includes a finding that the patent is invalid or not infringed.*

Payment" Patent Settlements with Four Generic Pharmaceutical Firms 4 (Feb. 19, 2008), *available at* http://www.wsgr.com/publications/pdfsearch/clientalert_cephalon.pdf.

135. *See* 21 U.S.C. § 355(j)(5)(D) (2006).

136. *Id.* § 355(j)(5)(D)(i)(I)(aa)(AA).

137. E-mail from Seth Silber, Of Counsel, Wilson Sonsini Goodrich & Rosati PC, to Author (Feb. 22, 2008, 06:58:04 PST) (on file with author).

138. 21 U.S.C. § 355(j)(5)(D)(i)–(ii).

> (CC) [The patent holder delists the patent from the *Orange Book*].[139]

Interpreting the failure to market provisions requires a series of "earlier of"/"later of" analyses.[140] The FDA must look to the later of the dates determined by applying subparts (aa) and (bb). In the typical scenario, the first filer will already have its ANDA approved by the time they enter a settlement with the patent holder. Therefore, under subpart (aa), the "earlier of" date is typically seventy-five days after the FDA approved the ANDA. Next, subpart (bb) requires the FDA to determine if any of three scenarios has occurred. But in a typical reverse payment settlement, none of the events will have happened yet—there will be no court finding that the relevant patent is invalid or not infringed, and the patent will remain listed in the *Orange Book*. On January 17, 2008, the FDA explained its interpretation of the forfeiture provisions:

> We find that under the plain language of the statute, 180-day exclusivity is not forfeited for failure to market when an event under subpart (aa) has occurred, but—as in this case—none of the events in subpart (bb) has occurred. The "failure to market" provision results in forfeiture when there are two dates on the basis of which FDA may identify the "later" event as described in section 505(j)(5)(D)(i)(I). The provision does not effect a forfeiture when an event under subpart (aa) has occurred, but no event under subpart (bb) has yet occurred.[141]

Therefore, the problem is that even if an event in subpart (aa) has happened, it is impossible to determine the "later of" event since any of the events listed in subpart (bb) could happen in the future.[142] It is possible that pending or future litigation would lead to a finding of invalidity or noninfringement, or that the NDA holder might one day delist the patent. But it is impossible for the FDA to determine whether any of these events will or will not ever happen.

For example, event (bb)(AA) could feasibly occur if a later-filing ANDA applicant brings a declaratory judgment action against the patent holder to demonstrate that the pioneer's patent is invalid or not infringed.[143] But it is unlikely that a later filer would ever initiate such

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139. *Id.* § 355(j)(5)(D)(i)(I) (emphasis added).

140. Letter from Gary J. Buehler, Dir., Office of Generic Drugs, Ctr. for Drug Evaluation and Research, to Marc A. Goshko, Executive Dir., Teva N. Am. 4 [hereinafter Buehler Letter] (Jan. 17, 2008), *available at* www.fda.gov/ohrms/DOCKETS/DOCKETS/07n0389/07n-0389-let0003.pdf.

141. *Id.* at 5.

142. *Id.*

143. Ironically, in light of *Janssen v. Apotex*, No. 2008-1062, 2008 U.S. App. LEXIS 18822 (Fed. Cir. Sept. 4, 2008), later-filing ANDA applicants are probably unable to bring declaratory judgment actions because they cannot satisfy the Article III "case or controversy" requirement. *See* discussion *supra* note 111. Alternatively, in response to a later-filed ANDA application, the patent holder could sue the later-filer under 35 U.S.C. § 271(e)(2)(A), initiating litigation that could lead to a finding of invalidity or noninfringement. But this is also unlikely since the pioneer loses nothing by effectively

litigation, because, even if the later filer prevailed in court, it would not be entitled to the 180-day exclusivity. Since the exclusivity period is solely held by the first filer and does not "roll over" to later filers, even when forfeited by the first filer, there is no incentive for later filers to bear the cost of litigation. The FDA commented in a footnote that:

> Inherent in the structure of the "failure to market" forfeiture provisions is the possibility that a first applicant would be able to enter into a settlement agreement with the NDA holder or patent owner in which a court does not enter a final judgment of invalidity or non-infringement (i.e., without a forfeiture event under subpart (bb) occurring), and that subsequent applicants would be unable to initiate a forfeiture with a declaratory judgment action. This inability to force a forfeiture of 180-day exclusivity could result in delays in the approval of otherwise approvable ANDAs owned by applicants that would market their generic drugs if they could but obtain approval. This potential scenario is not one for which the statute currently provides a remedy.[144]

Consequently, the FDA's interpretation of the MMA forfeiture provisions means that the first filer will almost never forfeit the exclusivity period in either reverse payment situations or otherwise. The FDA has not yet drafted regulations covering the new forfeiture provisions of the MMA and continues to resolve these issues on a case-by-case basis.[145] If the FDA fails to promulgate such regulations, it is likely that the interpretative questions surrounding the forfeiture provisions will be resolved by the courts in future litigation.[146] Until then, the problem remains that "the 180-day exclusivity, *which Congress created to reward generics for entering early*, does precisely the opposite: it extends the brand's monopoly, forcing consumers to pay excessive prices for [drugs] throughout the span of these illegal deals."[147]

3. Settlements Where the Challenger Withdraws Its ANDA

The reverse payment problem is exacerbated by the fact that only the first ANDA applicant can take advantage of the 180-day settlement.[148] Even if the first applicant withdraws its ANDA, the

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ignoring the later-filing. Even if the later-filer's ANDA is approved, it will be prevented from entering the market because of the bottleneck caused by the pioneer's pay-for-delay settlement with the first filer.

144. Buehler Letter, *supra* note 140, at 5 n.6.

145. *Id.* at 1.

146. FDA Solicits Public Comment on Yet Another 180-Day Generic Drug Exclusivity Issue, FDA Law Blog, http://www.fdalawblog.net/ (Oct. 12, 2007, 10:48 EST).

147. Statement of Jon Leibowitz, Commissioner, Fed. Trade Comm'n, Concurring in Part and Dissenting in Part in the Matter of Cephalon, Inc. 2 (Feb. 13, 2008), *available at* http://www.ftc.gov/os/caselist/0610182/080213comment.pdf.

148. The Hatch-Waxman Act provides that if "a previous application has been submitted," a subsequent ANDA filer must wait until 180 days after the "first commercial marketing of the drug under the previous application" or a favorable court decision, whichever is earlier. 21 U.S.C. 355(j)(5)(B)(iv) (2006). FDA regulations have interpreted this language to mean that the only

exclusivity period will never apply to later-filing applicants.[149] Consequently, if the first applicant settles and withdraws its ANDA, there is no incentive for another generic company to make a Paragraph IV filing because, even if they succeed in patent litigation, they will fail to gain market exclusivity.[150] This problem of penalizing meritorious second filers could be fixed by creating a "rolling exclusivity" procedure. The Hatch-Waxman Act should be revised so that if the first Paragraph IV challenger settles and does not enter the market, the 180-day exclusivity would instead be granted to the next challenger.[151] Granting the exclusivity period to the first *successful* generic challenger would simplify the Act and deter reverse payment settlements since it would be less feasible for the patent holder to enter such settlements with multiple generic challengers.

4. Banning Reverse Payments

As discussed above, despite the Medicare Modernization Act amendments, pay-for-delay settlements continue to inhibit generic competition. One solution to the reverse payment problem would be to completely prohibit any type of settlement between ANDA applicants and patent holders in Paragraph IV infringement litigation. This theory holds that "there should be a duty either to litigate such suits to a judgment of infringement/noninfringement or validity/invalidity or to dismiss them."[152] A more narrowly tailored solution would be to allow settlements, but to create an absolute ban on reverse payments as part of the settlements.[153] The nature of patent monopolies creates an incentive for both parties in Paragraph IV infringement litigation to find a way to settle and split the monopoly profits. It is argued that, "[b]ecause such splitting is contrary to the antitrust laws and the purposes of the Hatch-Waxman Act, it simply should not be permitted."[154] The incentives to enter into anticompetitive agreements indicate that some regulation of reverse payments is needed. Currently, the FTC reviews all reverse payment settlements and can challenge those settlements it thinks are

"previous" application that triggers the 180-day delay is the first application. *See* 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,874 (Aug. 6, 1999).

149. 21 U.S.C. § 355(j)(5)(D)(iii) (stating that if the first applicant withdraws, "no applicant shall be eligible").

150. *See* Erika Lietzan & David E. Korn, *Issues in the Interpretation of 180-Day Exclusivity*, 62 FOOD & DRUG L.J. 49, 72 (2007).

151. Ashlee B. Mehl, Note, *The Hatch-Waxman Act and Market Exclusivity for Generic Drug Manufacturers: An Entitlement or an Incentive?*, 81 CHI.-KENT L. REV. 649, 674 (2006).

152. Caffrey & Rotter, *supra* note 11, at 40.

153. This solution has been proposed in legislation. *See* Preserve Access to Affordable Generics Act, S. 316, 110th Cong. § 3(2) (2007) (barring settlement agreements if the "ANDA filer receives anything of value" and in exchange "agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time").

154. Caffrey & Rotter, *supra* note 11, at 40–41.

anticompetitive,[155] but this oversight is clearly insufficient in light of the split among the circuit courts.[156]

Commentators have argued that some reverse payments are reasonable and that an outright ban would be inappropriate.[157] Generic manufacturers have an enormous incentive to challenge patent holders since they have "relatively little to lose in litigation precipitated by a paragraph IV certification beyond litigation costs and the opportunity for future profits from selling the generic drug."[158] The average profit of a successful generic equivalent is exponentially greater than the cost of litigation.[159] Consequently, the more profitable the drug is for the pioneer, the greater the incentive is for a generic manufacturer to challenge the patent. A generic company with a weak case may nonetheless have a strong incentive to file a Paragraph IV ANDA, and a patent holder with a strong case still runs an enormous risk by proceeding to trial.[160] In high stakes litigation, the party with the most to lose has the greatest incentive to settle. But even where a patent holder believes it has a 90% chance of succeeding in litigation, the expected value associated with the 10% risk of losing is so substantial that it is arguably justified for the patentee to pay the ANDA applicant to settle as a means of risk management, especially where the patentee is risk-averse.[161]

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155. *See* Silber & Bye, *supra* note 129.

156. *See supra* notes 131–32 and accompanying text.

157. *See generally, e.g.*, Sheila Kadura, Note, *Is an Absolute Ban on Reverse Payments the Appropriate Way to Prevent Anticompetitive Agreements Between Branded- and Generic-Pharmaceutical Companies?*, 86 TEX. L. REV. 647 (2008).

158. *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 206–07 (2d Cir. 2006).

159. Gardiner Harris & Joanna Slater, *Bitter Pills: Drug Makers See 'Branded Generics' Eating into Profits*, WALL ST. J., Apr. 17, 2003, at A1 ("[T]he average profit over the life of a drug following a successful court case can be more than 10 times the cost of litigation." (quoting the president of generic manufacturer Dr. Reddy's Laboratories)).

160. Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 FED. CIR. B.J. 617, 631 (2006).

161. *See* Kadura, *supra* note 157, at 659–60. But a recent case may change the calculus generics use when determining whether to file a Paragraph IV challenge. A recent district court ruling required two generic companies to pay a pioneer's attorney fees because they filed baseless Paragraph IV challenges in violation of their "duty of care" under the Hatch-Waxman Act. *See* Takeda Chem. Indus. v. Mylan Labs., Inc., 459 F. Supp. 2d 227, 230–31 (S.D.N.Y. 2006). The case is currently on appeal to the Federal Circuit, in which the Generic Pharmaceutical Association (GPhA) filed an amicus brief arguing that "[r]eversal is vital because this aspect of the district court's ruling will undermine the efficacy of the Hatch-Waxman scheme by deterring future ANDA filings by many companies, keeping generic drugs off the market and increasing the cost of drugs to the consumers who depend on them." Brief for the Generic Pharm. Ass'n as Amici Curiae Supporting Appellants at 7, Takeda Chem. Indus. v. Mylan Labs., Inc., Nos. 2007-1269, 2007-1270 (Fed. Cir. Feb. 21, 2008). If the decision is upheld on appeal, it may serve to thwart potential generic competitors with weak cases.

C. AUTHORIZED GENERICS NOT ADDRESSED BY THE MMA

Neither the Hatch-Waxman Act, nor the Medicare Modernization Act addressed the issue of authorized generics directly. Because Congress has remained silent on this issue, courts cannot effectively deal with this problem since the statutes make it clear that the exclusivity provisions only apply to generic manufacturers who enter the market via ANDA applications. The market exclusivity provisions do not prohibit pioneers from marketing authorized generics during the first ANDA applicant's 180-day exclusivity period.[162]

In 2004, two generic manufacturers, Mylan Pharmaceuticals and Teva Pharmaceuticals, filed citizen petitions with the FDA,[163] arguing that authorized generics should be considered "generic" drugs and barred from being marketed during the first applicant's exclusivity period.[164] The FDA denied both petitions on July 2, 2004, stating that the agency "does not regulate drug prices and has no legal basis on which to prevent an innovator company from marketing its approved NDA product at a price that is competitive with that charged by a first generic applicant to the market."[165] Both generic manufacturers brought suit to challenge the FDA's ruling, and in both cases federal district court judges held in the FDA's favor.[166] Mylan appealed to the Fourth Circuit, and Teva appealed to the D.C. Circuit, and both courts of appeals affirmed the district court rulings that the FDA lacks the power to prohibit the marketing of authorized generics during the 180-day exclusivity period.[167]

While these circuit court rulings are undoubtedly correct, the outcome is unfortunate since the "emerging trend" of marketing authorized generics "will negatively affect the incentive given to generic manufactures to challenge drug patents."[168] This disincentivizing could be prevented by barring the marketing of authorized generics from the time the first Paragraph IV ANDA is filed until the 180-day exclusivity has

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162. *See* Teva Pharm. Indus., Ltd. v. Crawford, 410 F.3d 51, 55 (D.C. Cir. 2005).

163. A citizen petition is a petition that any person may submit to the FDA to request the FDA Commissioner to "issue, amend, or revoke" a regulation or order, or to request the Commissioner to "take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.30 (2008).

164. Mylan Pharm. Petition, *supra* note 91; Petition from Teva Pharm. U.S., Inc. to Food & Drug Admin., Citizen Petition No. 2004P-0261 (June 9, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/June04/061004/04p-0261-cp00001-01-vol1.pdf.

165. Letter from William K. Hubbard, Assoc. Comm'r for Policy and Planning, Food & Drug Admin., to Stuart A. Williams, Chief Legal Officer, Mylan Pharm., Inc., and James N. Czaban, Heller Ehrman LLP (July 2, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/july04/070704/04p-0075-pdn0001.pdf.

166. Teva Pharm. Indus. v. FDA, 355 F. Supp. 2d 111, 119 (D.D.C. 2004); Mylan Pharm., Inc. v. FDA, No. 1:04cv174 (N.D.W. Va. Aug. 30, 2004) (notice of voluntary dismissal without prejudice).

167. Mylan Pharm., Inc. v. FDA, 454 F.3d 270, 276–77 (4th Cir. 2006); Teva Pharm. Indus., Ltd. v. Crawford, 410 F.3d 51, 55 (D.C. Cir. 2005).

168. Petition from Mylan Pharm., Inc. to Food & Drug Admin., *supra* note 39, at 2.

expired.[169] Such a solution is justified under the argument that authorized generics clearly contravene Hatch-Waxman's goal of incentivizing generic drug marketing.[170] But because authorized generics also help consumers by lowering short-term prices, they are not necessarily predatory or anticompetitive, and are arguably a legitimate strategy to protect the innovator's profits. Empirical studies on the economic impact of authorized generics have been inconclusive, with studies finding both ways with respect to whether authorized generics harm competition.[171] The FTC has been studying the situation, but the results of its study have not yet been published.[172] Consequently, the solution to the authorized generic problem is not clear, and would require a thorough analysis of the policies and economics governing the pharmaceutical industry.[173]

D. Other Loopholes

1. *Generic Entry Bottlenecks Due to Litigation*

The Medicare Modernization Act also failed to address bottlenecks created by ongoing litigation between the pioneer and the first generic challenger. The MMA provides that forfeiture is triggered seventy-five days after the date of a final court decision "from which *no appeal* (other than a petition to the Supreme Court for a writ of certiorari) *has been or can be taken*" holding the NDA-holder's patent invalid or not infringed.[174] But this provision has been criticized as being ineffective because the statute requires a final ruling on patent invalidity or noninfringement from the Federal Circuit before forfeiture is triggered.[175] Even where the trial court finds in favor of the first ANDA applicant in the infringement or declaratory judgment suit, the applicant will often be hesitant to begin marketing its generic drug for fear of having the finding reversed by the Federal Circuit.[176] This means generic entry can be delayed for years while the first ANDA filer waits for an appellate court

169. Chen, *supra* note 34, at 511–12.

170. Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990); *see also* H.R. Rep. No. 98-857, pt. 1, at 14–15 (1984).

171. Chen, *supra* note 34, at 469.

172. *See* Notice of Authorized Generic Drug Study, 71 Fed. Reg. 16,779, 16,780 (Apr. 4, 2006), *available at* http://www.ftc.gov/os/2006/03/P062105AuthorizedGenericDrugStudyFRNotice.pdf.

173. In depth analysis of this issue is beyond the scope of this Note. *But see* Chen, *supra* note 34, at 478. Chen argues that the authorized generic practice clearly harms competition. *See id.* Since authorized generics generally enter the market before the ANDA applicant's equivalent, the authorized generic will gain the "first mover" advantage and the ANDA applicant will be burdened with the "switching costs" of late entry. *Id.* at 478–79. "Because second place is only marginally better but immensely more expensive than third place, there is no incentive to bear the risks and costs of a pre-expiration patent challenge. The result is that rational generic firms may forego potential Paragraph IV challenges when faced with this unfavorable cost-benefit calculus." *Id.* at 479.

174. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (2006) (emphasis added).

175. Interview with Seth Silber, Of Counsel, Wilson Sonsini Goodrich & Rosati PC, in Wash., D.C. (Feb. 21, 2008).

176. *Id.*

ruling. Arguably, this problem could be fixed by having forfeiture of the exclusivity period triggered by a district court ruling, instead of restricting it to an appellate court ruling. But because the Federal Circuit frequently reverses lower court rulings on patent claims construction,[177] both generics and patent holders may be dissatisfied with a solution prone to so much error.[178]

2. *Voluntary Delisting of Patents from the* Orange Book *After Paragraph IV Certification Filing*

Another method that pioneers have been using to deter generic challengers is to voluntarily delist their patents from the *Orange Book* after a Paragraph IV certification has been filed.[179] Once a patent is removed from the *Orange Book*, the generic challenger must amend its ANDA from a Paragraph IV to a Paragraph I certification.[180] Since only Paragraph IV applicants are entitled to the 180-day exclusivity period, by voluntarily delisting its patent, the patent holder is able to prevent the first generic challenger from securing marketing exclusivity. Furthermore, even if the first filer's ANDA is approved, the first filer may be hesitant to begin competing with the patent holder because the patentee can still sue for infringement once the first filer starts selling its generic drug.[181] Generic manufacturers almost never enter the market until at least a district court has held the NDA holder's patent is invalid or not infringed.[182] Additionally, the revised Act provides that delisting the patent from the *Orange Book* is a forfeiture event, which would force a first-filing applicant with an approved ANDA to enter the market within seventy-five days in order to avoid forfeiting the exclusivity period.[183]

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177. *See* Kimberly A. Moore, Markman *Eight Years Later: Is Claim Construction More Predictable?*, 9 LEWIS & CLARK L. REV. 231, 234–36 (2005) (reviewing empirical studies showing that the Federal Circuit overturns 25–50% of district court claims construction decisions); *see also* Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1476 (Fed. Cir. 1998) (en banc) (Judge Rader asserting that the Federal Circuit had overturned 40% of district court claims construction decisions).

178. Interview with Seth Silber, *supra* note 175.

179. *See* Lietzan & Korn, *supra* note 150, at 67–69.

180. 21 C.F.R. § 314.94(a)(12)(viii)(B) (2008). Recall that Paragraph I ANDAs are used when the pioneer's drug is not patented or no patent information has been filed with the FDA. 21 U.S.C. § 355(j)(2)(A)(vii)(I) (2006); *see also supra* note 38 and accompanying text.

181. It is beyond the scope of this Note to analyze the issues related to manipulation of the *Orange Book* by NDA holders. The Author's understanding is that if a pioneer's patent is not listed in the *Orange Book*, the pioneer can only avail itself of normal infringement actions under 35 U.S.C. § 271 of the Patent Act. But if the pioneer's patent is listed in the *Orange Book*, then it can take advantage of the Hatch-Waxman provisions, such as the thirty-month stay, etc. *See generally* Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165 (2005).

182. *See* FED. TRADE COMM'N, *supra* note 39, at vii.

183. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC) (stating that the exclusivity period is forfeited seventy-five days after "[t]he patent information submitted under subsection (b) or (c) is withdrawn by the [NDA] holder").

In *Ranbaxy Laboratories Ltd. v. Leavitt*, the D.C. Circuit Court of Appeals addressed the question of "whether the FDA may delist a patent upon the request of the NDA holder after a generic manufacturer has filed an ANDA containing a paragraph IV certification so that the effect of delisting is to deprive the applicant of a period of marketing exclusivity."[184] Recognizing that the "FDA's delisting policy diminishes the incentive for a manufacturer of generic drugs to challenge a patent listed in the *Orange Book*," the court held that the FDA may not delist a patent from the *Orange Book* after the submission of an ANDA with a Paragraph IV certification to that patent.[185]

Notwithstanding the D.C. Circuit's holding in *Ranbaxy*, the issue of whether NDA holders may delist their patents from the *Orange Book* still seems to be an open issue at the FDA. On March 22, 2005, Cobalt Pharmaceuticals filed a Paragraph IV ANDA for Precose (acarbose tablets), a diabetes treatment marketed by Bayer Pharmaceuticals.[186] Bayer never sued Cobalt for infringement, and in April 2007, Bayer requested that its patent for Precose be delisted from the *Orange Book*.[187] In a startling decision, the FDA allowed Bayer to delist its patent and then declared that Cobalt forfeited its 180-day exclusivity for failing to market its generic equivalent within seventy-five days of the patent delisting.[188] In the decision, the Agency explained that Bayer could delist its patent for Precose because *Ranbaxy* does not apply to post-MMA

184. 469 F.3d 120, 125 (D.C. Cir. 2006); FDA Solicits Comments on 180-Day Exclusivity Forfeiture & Orange Book Patent "Delisting" Issues, FDA Law Blog, http://www.fdalawblog.net/ (Sept. 26, 2007, 01:36 EST).

185. *Ranbaxy*, 469 F.3d at 126 (emphasis added); Kurt R. Karst, Teva Sues FDA After the Agency Refuses to Relist RISPERDAL Patent and Recognize the Company's 180-Day Exclusivity Eligibility, FDA Law Blog, http://www.fdalawblog.net/ (Mar. 7, 2008, 08:06 EST).

186. Letter from Gary J. Buehler, Dir., Office of Generic Drugs, Ctr. for Drug Evaluation and Research, to Anonymous ANDA Applicant (Sept. 26, 2007), *available at* http://www.fda.gov/ohrms/dockets/dockets/07n0417/07n-0417-let0001-vol1.pdf [hereinafter Buehler, FDA Letter to Cobalt 2007].

187. *Id.*

188. Letter from Gary J. Buehler, Dir., Office of Generic Drugs, Ctr. for Drug Evaluation and Research, to William A. Rakoczy, Rakoczy, Molino, Mazzochi & Siwik LLP, at 12 (May 7, 2008), *available at* http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064805526 5c&disposition=attachment&contentType=pdf [hereinafter Buehler, FDA Letter to Cobalt 2008]; *see also* Kurt R. Karst, FDA Determines that Cobalt Forfeited 180-Day Exclusivity for Generic PRECOSE; Agency is Sued Yet Another Time, FDA Law Blog, http://www.fdalawblog.net/ (May 11, 2008, 07:58 EST). Note that as of September 26, 2007, Cobalt's ANDA had not yet been approved. Buhler, FDA Letter to Cobalt 2007, *supra* note 186. On that day, FDA sent a letter to Cobalt soliciting its opinion on whether it was permissible for the FDA to delist Bayer's patent because more than thirty months had passed since Cobalt's first filing and it had failed to enter the market. *Id.* In applying the forfeiture provisions, the FDA found the "earlier of" date under subpart (aa) was September 22, 2007 (thirty months after the ANDA was filed). Buehler, FDA Letter to Cobalt 2008, *supra*, at 6. Similarly, the "later of" date under subpart (bb) was June 30, 2007 (seventy-five days after Bayer delisted its patent). *Id.* at 7. Therefore, Cobalt forfeited their exclusivity as of September 22, 2007, the "later of" date under 21 U.S.C. § 355(j)(5)(D)(i)(I). *Id.* at 7–8; *see also supra* notes 138–41 and accompanying text.

cases.[189] In response, Cobalt filed suit against the FDA seeking declaratory and injunctive relief.[190] As of this writing, the suit against the FDA is pending, but it is clear that the interpretative issues surrounding manipulation of *Orange Book* patent listings are still being used to discourage generic challengers. To prevent this abuse, Hatch-Waxman should be revised to either (1) explicitly prohibit an NDA holder from delisting its patent after a Paragraph IV ANDA is filed, or (2) allow the first filer to retain the 180-day exclusivity if the NDA holder voluntarily delists its patent. Both revisions would align with Congress' intent to promote the timely marketing of generic drugs.

CONCLUSION

The Medicare Modernization Act has failed to remedy exploitation of the Hatch-Waxman Act by pharmaceutical patent holders. Prior to the MMA, the main areas of abuse by pioneers consisted of (1) using multiple thirty-month stays to keep generic challengers from getting ANDA approval, (2) delaying generic competition by entering into reverse payments with generic challengers, and (3) responding to imminent generic competition by launching authorized generics. The MMA succeed in eliminating the first problem by limiting patent holders to a single thirty-month stay. But it has been tragically unsuccessful at addressing the remaining problems. The MMA attempted to remedy bottlenecks in ANDA approval by creating provisions that would lead to the forfeiture of the 180-day exclusivity period, but these flawed provisions are easily avoided by drafting settlement agreements that contain no finding of patent invalidity or noninfringement. Furthermore, Congress's hope that the FTC would be able to stop anticompetitive pay-for-delay settlements was misguided in light of the split that has developed among the federal circuit courts. Congress clearly needs to return to this area to correct the flawed forfeiture provisions and to directly address the legality of pay-for-delay settlements. Additionally, the MMA completely ignored the issue of authorized generics, such that the practice has thrived and expanded in the ensuing years.[191] This area is complicated by the fact that it is not clear whether authorized generics actually help or hurt consumers. Hopefully, the pending FTC study will answer this issue and provide Congress with guidance on how to regulate this area.

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189. Buehler, FDA Letter to Cobalt 2008, *supra* note 188, at 8 ("[T]he Ranbaxy court noted that the decisions rendered by the FDA and the district court had been made pursuant to the Act 'as it stood before the MMA and, because the MMA was not made retroactive . . . this decision is also geared to the Act pre-MMA.'" (citing Ranbaxy Labs. Ltd. v. Leavitt, 469 F.3d 120, 122 (D.C. Cir. 2006))).

190. Complaint at 2, Cobalt Labs. Inc. v. FDA, No. 1:08-cv-00798-RBW (D.D.C. May 8, 2008).

191. *See generally* Robert P. Reznick & James B. Kobak, Jr., *Authorized Generics: Still Legal—and Holding*, PHARM. EXEC., Sept. 1, 2006.