

A prescription for change: How the Medicare Act revises Hatch-Waxman to speed market entry of generic drugs

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A PRESCRIPTION FOR CHANGE: HOW THE MEDICARE ACT REVISES
HATCH-WAXMAN TO SPEED MARKET ENTRY OF GENERIC DRUGS

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A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs

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ABSTRACT

The Drug Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act (“Hatch-Waxman” or “Hatch-Waxman Act”), was passed to bring generic drugs to market more quickly. While recognizing the need to maintain incentives for pioneer research and innovation in the pharmaceutical industry, Hatch-Waxman greatly benefits the generic drug industry by providing a method for expedited review and approval of generic products by the Food and Drug Administration (FDA). Although Hatch-Waxman has been successful in substantially increasing generic competition, evidence suggests that manufacturers of brand-name drugs have discovered loopholes in the Act and have engaged in tactics to “game the system” to prolong the life of patents, thereby delaying the market entry of generic competitors. Generic manufacturers have also been accused of abusing provisions of Hatch-Waxman to the detriment of competitors and consumers. Provisions of the Act may tempt generic manufacturers to enter into collusive agreements with brand-name manufacturers. In December of 2003, President Bush signed into law the Medicare Prescription Drug and Modernization Act of 2003. Title XI of the Act amends Hatch-Waxman, in an effort to close loopholes that delay the market entry of generic drugs. The new legislation implements two major changes in the Hatch-Waxman process of generic drug approval and patent challenges. First, the law prevents the innovator drug patentee from filing multiple patents with the FDA, in the hopes of triggering Hatch-Waxman’s thirty-month stay provision. When a generic applicant seeks FDA approval of its product and claims that its product will not infringe a patent or that the patent is invalid, an innovator that files a patent infringement suit is granted an automatic thirty-month stay of FDA approval. This provision has enticed innovators to list with the FDA those patents that may not properly claim the drug in question. The improper listing of patents has allowed innovators to stack successive thirty-month stays to delay market entry of generic competition. The new legislation allows an innovator the benefit of only one thirty-month stay per generic applicant per drug. Second, the law prevents collusive agreements between innovator and generic manufacturers as well as such agreements between generic manufacturers that might delay market entry of generic products. The first generic applicant that challenges an innovator’s patent and receives FDA approval is entitled to 180 days of market exclusivity under Hatch-Waxman. Subsequent generic applicants may not receive FDA approval for their products until this 180-day exclusivity period has run. New provisions in the law subject agreements that relate to the 180-day exclusivity period to FTC scrutiny. Furthermore, new provisions ensure timely market entry of generic products by specifically enumerating incidents that trigger the

commencement of the 180 day exclusivity period and incidents that cause the generic applicant to forfeit its 180-day monopoly.

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I. INTRODUCTION

In 2002, the Federal Trade Commission (FTC) published a study investigating the behavior of brand-name pharmaceutical companies and their generic competitors with regard to the market entry of generic drugs.¹ The FTC Study sought to determine whether drug companies, both brand-name and generic, were taking advantage of loopholes in the laws to delay the market entry of generic drugs in the market. The FTC Study concluded that several provisions of the Hatch-Waxman Act, the law that regulates the approval process for brand-name and generic drugs, were exploited by both brand-name companies and generic drug companies, costing consumers billions of dollars. Based on its Study, the FTC made several recommendations to curb such abuse. The FTC's Study and recommendations served as the basis for changes in the Hatch-Waxman Act that were signed into law by President George W. Bush on December 8, 2003 as Title XI of the Medicare Prescription Drug and Modernization Act of 2003 (the Medicare Act).²

Title XI of the Medicare Act, referred to as the "Access to Affordable Pharmaceuticals Act," seeks to prevent needless delays in getting more affordable generic drugs to market. Delay in market entry of generic competition is widely viewed as one way to combat the skyrocketing cost of prescription drugs. A Congressional Budget Office (CBO) study based on retail pharmacy data from 1993 and 1994 shows that the average price of a generic prescription is approximately half of the average price of a brand-name prescription and that in 1994, the availability of generic drugs saved purchasers between \$8 and \$10 billion.³ The Bush administration estimates that provisions in the Medicare Act to prevent delays in the market entry of generic drugs will save an additional \$3 billion in drug costs per year.⁴

Questions regarding the behavior of pharmaceutical companies arise under both patent laws and the Federal Food Drug and Cosmetic Act (FFDCA).⁵ In 1984, Congress amended both the patent laws and the FFDCA to substantially enhance the opportunities for generic drugs to enter the market. The Drug Price Competition and Patent Term Restoration Act of 1984,⁶ commonly known as the Hatch-Waxman Act, after its sponsors, Senator Orrin Hatch (R-Utah) and Representative Henry Waxman (D-Cal.), was passed to bring generic drugs to market more quickly⁷ while maintaining incentive

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1. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, (July 2002) [hereinafter FTC Study], available at www.ftc.gov/os/2002/07/genericdrugstudy.pdf. (last visited Sept. 16, 2004).

2. Pub. L. No. 108-173, Title XI, §§ 1101, 1102 (codified as amended at 21 U.S.C. 355 (j)(2) and (5) (2004)).

3. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), at 28-31, [hereinafter CBO Study], available at <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0> (last visited Sept. 16, 2004).

4. See Scott Lindlaw, *New Rules Would Speed Generic Drug Availability*, BOSTON GLOBE, Oct. 21, 2002, at A3.

5. See 21 U.S.C.S. §§ 321-397 (Law. Co-op. 2002).

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

7. Title I of the Act aimed "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." H.R. Rep. No. 857 (Part I), 98th Cong., 2d Sess. at 14 (1984).

for drug research and innovation.⁸ Hatch-Waxman was successful in its goal of cost containment as the number of generic drug products brought to market soared after its implementation. The market share held by generic pharmaceuticals more than doubled in the decade following passage of the Act, rising from approximately nineteen to forty-three percent.⁹

The brand-name pharmaceutical industry has remained strong even with increased generic competition.¹⁰ Despite a downturn in the United States economy, the pharmaceutical industry has suffered substantially less than most industries, with prescription drug sales growing 12% in 2002.¹¹ Nevertheless, brand-name manufacturers cite the high cost of developing a new prescription drug as exceeding \$802 million dollars.¹² Furthermore, concerns about patent expiration on blockbuster drugs, dry spells in research, competition from generic drug manufacturers, and price controls in the European market¹³ may tempt drug companies to take aggressive and sometimes illegal measures to protect the monopolies afforded by valuable patents that may yield millions of dollars per day to a company.

The tension between brand-name drug companies and generic drug manufacturers is evident; as the patents on brand-name drugs expire, generic versions of the drug enter the market at a greatly reduced price, taking away close to half of the drug's market.¹⁴ The first generic version of a brand-name drug usually costs thirty to forty percent less than the brand-name drug. As more generic versions become available, the price can drop as much as seventy to eighty percent of the initial cost. Because the cost of litigation is minimal compared to the benefits gained from delaying generic entry, pioneer drug

8. See *id.* at 15 (1984) ("The purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket governmental approval.").

9. See FTC Study, *supra* note 1.

10. The pharmaceutical industry is ranked as the country's richest industry. See Donald L. Barlett and James B. Steele, *Why We Pay So Much for Drugs*, TIME, Feb. 2, 2004, at 45, 47 (citing a Fortune 500 survey identifying the drug industry as "the most profitable of all businesses in the U.S.").

11. See Gardiner Harris, *Drug Firms' 'Bad' Year Wasn't So Bad*, WALL ST. J., Feb. 21, 2003, at B4 (discussing the production cost of new prescription drugs).

12. See, e.g., Tufts Center for the Study of Drug Development, *Background: A Methodology for Counting Costs for Pharmaceutical R & D* (2001) (describing the analysis of data from ten pharmaceutical companies that produced an average cost of development of a new drug at \$802 million), available at [http://csdd.tufts.edu/NewsEvents/Recent News.asp?newsid=5](http://csdd.tufts.edu/NewsEvents/Recent%20News.asp?newsid=5) (last visited Jan. 16, 2005). But see MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES 37-46 (2004) (discrediting the \$802 million dollar figure).

13. See National Institute for Health Care Management, *Prescription Drugs and Intellectual Property Protection* 3 (Aug. 2000) (describing the methods drug companies use to maintain and raise prices of name-brand drugs in the United States), available at <http://www.nihcm.org/prescription.pdf> (last visited Jan. 15, 2005); Vanessa Fuhrmans & Gautam Naik, *Drug Makers Fight to Fend Off Cuts In European Prices*, WALL ST. J., June 7, 2002, at A1 (discussing drug makers' need to raise prices in the United States to compensate for government price reductions in Europe).

14. CBO Study, *supra* note 3, at 1. In the next three years, seventeen brand name drugs are scheduled to come off patents by such pharmaceutical giants as Eli Lilly, Schering Plough, GlaxoSmithKline and Bristol-Myers Squibb. Between 2001 and 2005, brand name drugs with sales in the United States close to \$20 billion will go off patent. See Timothy J. Muris, Chairman, Federal Trade Commission, *Competition and Intellectual Property Policy*, Prepared Remarks Before American Bar Association (Nov. 15, 2001) (noting FTC investigations of the conflict between name brand and generic pharmaceutical manufacturers), available at <http://www.ftc.gov/speeches/muris/intellectual.htm> (last visited Jan. 16, 2004).

manufacturers may be tempted to “game the system” to prolong the patent period and generic manufacturers may, for a price, be tempted to go along for the ride.

Both brand-name manufacturers and generic manufacturers of pharmaceutical products have manipulated the Hatch-Waxman Act in a manner not contemplated by Congress, resulting in harm to competition, and consequently, to consumers. This Article addresses two key provisions of the statutory scheme: the thirty-month stay and the 180-day exclusivity period. More specifically, the Article addresses how these provisions have been abused, and how the courts, the FTC, the FDA, and Congress have responded to such abuse. Part II introduces the Hatch-Waxman regulatory scheme and how the thirty-month stay may allow innovators to extend improperly the monopoly granted by patent law. Part III details cases that illustrate how the thirty-month stay has often frustrated generic applicants and how the courts have been unsuccessful in providing remedies for the improper listing of patents. Part IV summarizes the FTC’s findings and recommendations regarding the thirty-month stay, and how the FDA and the new legislation respond to those recommendations. Part V discusses problems associated with the 180-day exclusivity period and who is entitled to that period. Problems with the 180-day exclusivity period have led to collusive agreements between drug manufacturers. Private antitrust actions arising from such collusive agreements are also discussed in Part V. Part VI details proposed solutions to problems associated with the 180-day exclusivity period. The FTC, through actions brought against companies involved in collusive agreements, and through recommendations in its study, has taken the lead in overseeing patent settlement agreements that may violate antitrust laws. Part VI details the substantial changes Article XI of the Medicare Act makes to Hatch-Waxman regarding the 180-day exclusivity period. The Article concludes that Article XI of the Medicare Act provides much needed improvements to restoring the balance originally contemplated by Hatch-Waxman, but that the complexity of the regulatory scheme may raise unexpected problems that may necessitate further amendments.

II. THE HATCH-WAXMAN PROCESS AND PROVISIONS SUBJECT TO ABUSE

A. The Approval Process

Competition between brand-name drugs and generic versions of those drugs was negligible before the Hatch-Waxman Act was passed in 1984. Prior to 1962, the FDA approval process was relatively simple. The manufacturer of a new pioneer drug had to submit a New Drug Application (NDA) to the FDA, showing the safety of the drug. Marketing could begin sixty days after the NDA was submitted, unless the FDA disapproved the NDA.¹⁵ But in 1962, a more extensive and costly process was implemented, requiring affirmative FDA approval based on proof of the drug’s safety and efficacy.¹⁶ Under the new regulations, the time lag between the submission of a pioneer drug to the FDA and approval for introduction to the marketplace could take more than

15. See *Roche Products, Inc. v. Bolar Pharm. Co., Inc.*, 733 F.2d 858, 864 (Fed. Cir. 1984) (explaining Section 505 of the FDCA, ch. 675, 52 Stat. 1052 (1938)).

16. See *id.* (referring to Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780).

three years.¹⁷ The time lost and the expense incurred by the new regulatory approval process led to sharp increases in the price of drugs. Competition from generic drug manufacturers during this period was limited because patent law required that a generic manufacturer wait until the pioneer drug patent had expired before it could even begin to test its generic version. This interpretation of the law was confirmed by the Federal Circuit's 1984 decision in *Roche Products v. Bolar Pharmaceutical Company*,¹⁸ the same year Hatch-Waxman was passed. Before the Hatch-Waxman Amendments, generic competition was limited not only by time, but also by cost, as generic drug manufacturers were subject to the same strict and expensive approval process as pioneer drug manufacturers. Generic drug manufacturers and consumer groups complained that patent holders were granted de facto patent extensions because manufacturers could not begin preparation for competing generic products without infringing patents of the pioneer drug. Patent holders, meanwhile, complained that they lost years of patent protection while products underwent the FDA's approval process. Hatch-Waxman addressed both complaints.

The Hatch-Waxman Amendments overturned the *Bolar* decision by allowing generic drug manufacturers to begin making, testing, and seeking FDA approval of a generic product before the patents on the pioneer drug expired, without being sued for patent infringement. This provision, referred to as the Bolar Amendment, carves out a unique exception to the patent laws. Patent law provides that "whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent."¹⁹ The Bolar Amendment provides an exception to patent law, or a safe harbor against patent infringement, by providing, "[i]t shall not be an act of infringement to make, use, offer to sell, or sell . . . 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 . . ."²⁰ Consequently, under Hatch-Waxman, the time needed to develop the generic version of a drug may run simultaneously with the patent term, as long as the activities are reasonably related to securing regulatory approval. Before Hatch-Waxman, even limited use of a patented drug for testing and investigation necessary for the FDA approval process constituted infringement.²¹

The Hatch-Waxman Amendments save the generic manufacturers even more time, not to mention money, in the approval process by granting the generic manufacturer an expedited review process. This expedited process allows the generic manufacturer to rely

17. See Matthew Hinsch, Article, *Intellectual Property*, Hoechst-Roussel Pharm., Inc. v. Lehman, 13 BERKELEY TECH. L.J. 163 (1998) (stating that a drug cannot be marketed until several years after the term of its patent begins).

18. 733 F.2d 858, 864 (Fed. Cir. 1984).

19. 35 U.S.C.S. § 271(a) (Law. Co-op. 2004). This provision states: "Whoever without authority makes, uses or sells any patented invention, within the United States, [or imports into the United States any patented invention], during the term of the patent therefore, infringes the patent." *Id.*

20. 35 U.S.C.S. § 271(e)(1) (Law. Co-op. 2000 & Supp. 2004).

21. *Roche Products, Inc. v. Bolar Pharm. Co., Inc.*, 733 F.2d 858, 861 (Fed. Cir. 1984). In *Integra Lifesciences I, Ltd. v. Merck KGaA*, the Federal Circuit addressed the extent to which the safe harbor provision of § 271(e)(1) covers the development and identification of new drugs. 331 F.3d 860 (Fed. Cir. 2003). The court held that the exemption does not "encompass drug development activities far beyond those necessary to acquire information for FDA approval of a patented pioneer drug already on the market." *Id.* at 867.

on the clinical data of the pioneer manufacturer. Whereas the pioneer drug manufacturer must incur great expense and undergo rigorous scrutiny when it files an NDA to secure FDA approval, a generic manufacturer may file an Abbreviated New Drug Application (ANDA) in which it may take advantage of the NDA holder's time and expense. Generic drugs typically contain the same active ingredients but not necessarily the same inactive ingredients as the brand-name original.²² The ANDA applicant must show that its proposed generic drug product has the same active ingredient, route of administration, dosage form and strength, and proposed labeling as the brand-name drug product.²³ Because the ANDA process may be conducted while the pioneer patent is still effective, the generic manufacturer may obtain FDA approval and be ready to go to market with its product the moment the patent expires.

When they were proposed, the brand-name drug companies opposed provisions of the Hatch-Waxman Act that expedited generic entry, arguing that strengthening the generic drug industry would weaken incentive for innovation. Recognizing that Hatch-Waxman impaired the patent rights of the brand-name companies, Congress addressed the pioneer drug industry's longstanding complaints about the patent term time lost to regulatory approval by including provisions that allow time lost during clinical trials and the FDA approval process to be restored to the patent term.²⁴ A pioneer drug receives a half day in restored patent life for every day the product is in clinical trials prior to FDA review and a complete day of restoration for every day under FDA review.²⁵

Thus, Hatch-Waxman benefits generic manufacturers by speeding the entry of generic drugs to the market. The Act promotes generic competition by allowing generic manufacturers to begin developing their products before patents expire, sparing the generic manufacturer a substantial portion of the costs associated with drug development and testing, and allowing an expedited review process. To balance these advantages, the Act restores patent term time to the drug innovator. In addition to patent term restoration, Hatch-Waxman also contains provisions that protect unexpired patents that generic

22. See *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998) (citing *United States v. Generix Drug Corp.*, 460 U.S. 453, 455 (1983)).

23. See 21 U.S.C.S. § 355(j) (Law. Co-op. 1998 & Supp. 2004). The NDA must contain reports of the drug's safety and effectiveness; a list of the articles used as components in the drug; a statement of the composition of the drug; a description of the methods, facilities, and controls used in the manufacture, processing, and packaging of the drug; samples of the drug or components, if necessary; and samples of the proposed labeling. 21 U.S.C.S. § 355(b)(1) (Law. Co-op. Supp. 2004).

24. Five conditions must be met for patent term restoration: (1) the term of the patent has not expired; (2) the term of the patent has not previously been extended; (3) an application has been submitted by the owner of the patent or its agent as described in § 156(d); (4) the product has been subject to regulatory review prior to its commercial use; and (5) the commercial use is the first commercial use of the product unless the product is made by a new biotechnological procedure. 35 U.S.C.S. § 156(a) (Law. Co-op. 2000 & Supp. 2004). A patent granted before June 8, 1995, has a term of 17 years from the day it was issued. See 35 U.S.C.S. § 154(c)(1) (Law. Co-op. Supp. 2004). Since June 8, 1995, when the Uruguay Round Agreements Act went into effect, the term of a patent is 20 years from the day the inventor files a patent application with the Patent and Trademark Office. See *id.* Under the Best Pharmaceuticals for Children Act, (Pub. L. No. 107-109, § 1, 115 Stat. 1408 (2002)), the FDA may grant a drug manufacturer an additional six months of market exclusivity if the manufacturer conducts acceptable pediatric studies for its drug. See also *Pfizer, Inc. v. Dr. Reddy's Laboratories, Ltd.*, 359 F.3d 1361, 1364-65 (Fed. Cir. 2004) (discussing the purpose of patent term restoration).

25. See CBO Study, *supra* note 3, ch. 4, at 2. Nevertheless, the total time restored to patent life may not exceed five years and the effective life of a patent may not exceed fourteen years.

manufacturers may challenge. Nevertheless, if a generic manufacturer successfully challenges a listed patent, the statute rewards the generic manufacturer with a period of exclusive market share. These provisions are addressed in the next sections.

B. Orange Book Listings and the Thirty-Month Stay

In addition to patent term restoration, Hatch-Waxman recognizes the importance of protecting patents by ensuring that the pioneer drug manufacturer and NDA holder are notified and have the opportunity to sue for infringement when a generic manufacturer applies for FDA approval. When a pioneer drug manufacturer is notified that a generic manufacturer has filed for FDA approval and a patent related to the drug in question has not expired, the pioneer may sue the generic and the FDA may not approve the generic manufacturer's application for a period of thirty months or until the patent dispute is resolved.²⁶ This section explains the process in detail to make clear the potential for abuse and the difficulty in redressing such abuse.

When submitting an application, the NDA holder, usually the drug manufacturer, patent holder, or a licensee, must list all of the patents that claim the drug.²⁷ Upon approval of its application, the NDA holder must amend the list so that only those patents that claim the approved drug are listed.²⁸ The name of the patent owner, the patent numbers, and the date each patent expires are listed by the FDA in the *Approved Drug Product with Therapeutic Equivalence Evaluations* publication, more commonly known as the Orange Book.²⁹ The Orange Book lists all approved drug products with their therapeutic equivalence codes as well as the products' patents.

When a generic applicant submits an ANDA, the applicant must check all patents claimed by the innovator or NDA holder of a drug that are listed in the Orange Book. A single drug may include various patents in addition to the crucial patents for the active ingredient, such as a new active ingredient, formulation, preparation, or method of use.³⁰ The ANDA applicant must certify that its generic drug product will not infringe any patents claimed by the NDA holder's drug listed in the Orange Book or that the listed patent is invalid or unenforceable.³¹ The ANDA applicant must select one of four possible types of certification.³² A Paragraph I certification is appropriate if no patents are listed for the pioneer drug. A Paragraph II certification is filed when all patents claiming the listed drug have expired. Applications with Paragraph I or II certifications

26. 21 U.S.C.S. § 355(j)(5)(B)(iii) (Law. Co-op. 2004).

27. The claims of a patent determine the property right from which others can be excluded. *Novo Nordisk of North America, Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1369 (Fed. Cir. 1996).

28. 21 C.F.R. § 314.53(c)(2)(ii) (2002).

29. 21 U.S.C.S. § 355(b)(1) (Law. Co-op. 2002).

30. Pharmaceutical patents are chemical patents which are a subset of utility patents. Pharmaceutical patents fall into four categories: drug substance, method of use, formulation, and process. Drug substance patents cover the compound or active ingredient in the drug product, such as fluoxetine hydrochloride, which is the active ingredient in Prozac. Method of use patents cover the use of the product to treat certain health problems, such as depression or asthma. Formulation patents cover the physical composition or delivery mechanism of the drug product, such as an extended release tablet or capsule. Process patents generally cover the procedure to make the active ingredient. See FTC Study, *supra* note 1, at 41.

31. See 21 U.S.C.S. § 355(j) (Law. Co-op. 1998).

32. See *id.*

may be approved immediately by the FDA if all other requirements are satisfied.³³ An ANDA applicant files a Paragraph III certification to indicate that it will not market its generic version of the listed drug until the date the listed patent expires; approval may be effective on that date.³⁴ A Paragraph IV certification is essentially a challenge to the validity of a listed patent, in which the ANDA applicant claims either that its product will not infringe the listed patent or that the listed patent is invalid.³⁵ If a pioneer drug manufacturer lists additional patents in the Orange Book while an ANDA application is pending, the applicant is required to make certifications for the new listings.³⁶

Most litigation involving Hatch-Waxman abuse has involved Paragraph IV certification (ANDA IVs), where the generic manufacturer maintains that there is something wrong with the patent listed or with its relationship with the drug it claims.³⁷ The Act requires an ANDA applicant to notify the patent holder and the NDA holder of its Paragraph IV filing with a detailed statement of the factual and legal basis for its assertion that the patent is invalid or will not be infringed.³⁸ Although Hatch-Waxman protects the generic applicant from a patent infringement suit up to the time it files its ANDA, the Paragraph IV certification is considered a technical act of infringement because it indicates that the ANDA applicant intends to market its product before the patent in question expires.³⁹ The ANDA IV applicant must notify both the NDA holder and the patent holder of the Paragraph IV certification, who then have forty-five days after receipt of the notice to file an infringement suit. During this forty-five day period, the FDA may not approve the ANDA nor may the generic manufacturer seek a declaratory judgment regarding the validity of the patent in question.⁴⁰ If the pioneer manufacturer chooses to file a patent infringement suit against the ANDA applicant within this forty-five day window, an automatic thirty-month stay of approval is triggered. The ANDA cannot be approved until the thirty month period expires, the patent litigation is resolved, or the patent expires.⁴¹ Nothing in the Act prohibits successive thirty-month stays.

C. The 180-Day Exclusivity Period

Another important aspect of the FDA approval process is the 180-day exclusivity period awarded to the first generic manufacturer to file an ANDA challenging the validity

33. 21 U.S.C.S. § 355(j)(5)(B)(i) (Law. Co-op. 1998).

34. 21 U.S.C.S. § 355(j)(5)(B)(ii) (Law. Co-op. 1998).

35. 21 U.S.C.S. § 355 (j)(2)(A)(vii)(IV) (Law. Co-op. 1998).

36. 21 C.F.R. § 314.94(a)(12) (2003).

37. *See, e.g.,* *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998) (involving a suit between the first and second ANDA IV filers, which was allowed to proceed irrespective of outcome of the first filer's defense against the patent holder's infringement action).

38. *See* 21 U.S.C.S. § 355(j)(2)(B) (Law. Co-op. 2004); 21 C.F.R. § 314.95 (2004).

39. 35 U.S.C.S. § 271 (e)(2) (Law. Co-op. 2000).

It shall be an act of infringement to submit . . . [an ANDA] . . . if the purpose of such submission is to obtain approval [under the FFDC] to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

Id.

40. 21 U.S.C.S. § 355(j)(5)(B)(iii) (Law. Co-op. 1998).

41. *Id.*

of a listed patent through a Paragraph IV certification. The exclusivity period is a reward to the first successful ANDA applicant for the time and expense invested in the patent litigation. During the exclusivity period, the FDA may not approve the ANDA of a subsequent generic applicant; consequently, the new generic product competes with only the brand-name manufacturer for 180 days.⁴² In addition to problems with one ANDA applicant holding up the approval of subsequent ANDAs, there are also questions about when the 180-day exclusivity period is triggered. Hatch-Waxman provides that the 180-day period begins either on the date of the first commercial marketing of the generic drug or the date of a court decision declaring the patent invalid or not infringed, whichever is sooner.⁴³ The meaning of the term "court decision" has been particularly troublesome.⁴⁴

After the 180-day period of market exclusivity has expired, other generic competitors may enter the market. A court decision resulting in a finding of invalidity or non-infringement in a case brought by subsequent ANDA filers may also trigger the 180-day waiting period. This rule prevents the previous ANDA applicant's protracted litigation from holding up subsequent ANDA applicants who believe their product is non-infringing.⁴⁵

The 180-day exclusivity period has spawned considerable litigation. Brand-name manufacturers and ANDA filers have entered into agreements, ostensibly to settle patent disputes, that have the effect of delaying market entry by a potential competitor. Such agreements not only delay the entry of the first approved generic competitor but, because the FDA cannot approve subsequent ANDAs until the 180-day exclusivity period has run, may also create a bottleneck to prevent the approval of subsequent ANDAs. When several ANDAs have been filed for a particular product, generic manufacturers may end up in litigation over which applicant is entitled to the exclusivity period, as FDA rules are not clear on this point.

III. ABUSE OF THE THIRTY-MONTH STAY

Controversy surrounding the thirty-month stay begins with Orange Book listings. Because the thirty-month stay provides an inducement to innovators to file additional patents to extend their monopoly, generic competitors seeking FDA approval for competing products are often frustrated by what they view as invalid patents listed by innovators with the express purpose of delaying generic competition. Before new FDA rules were passed and Hatch-Waxman was amended by Title XI of the Medicare Act, generic applicants had no way to effectively challenge patents listed with the FDA, even

42. 21 U.S.C.S. 355(j)(5)(B)(iv) (Law. Co-op. 1998).

43. *Id.*

44. See discussion *infra* Part V.A.

45. See *Minnesota Mining and Mfg. Co. v. Barr Laboratories*, 289 F.3d 775, 780 (Fed. Cir. 2002), cited with approval in *Teva Pharm., USA, Inc. v. FDA*, 182 F.3d 1003, 1010 (D.C. Cir. 1999).

To start, or trigger, the period of market exclusivity by a "court decision," an ANDA applicant need only obtain a judgment that has the effect of rendering the patent invalid or not infringed with respect to itself; the statute does not require . . . the patent to be invalidated as to any and all ANDA applicants.

Id. For a history regarding the confusion over when the 180 day period is triggered, see James T. O'Reilly, *Prescription Pricing & Monopoly Extension: Elderly Drug Users Lose the Shell Game of Post-Patent Exclusivity*, 29 N. KY. L. REV. 413 (2002).

if they believed the patents were invalid or that their product would not infringe the patents. Without an efficient method for challenging these patents, generic competitors were forced to file Paragraph IV certifications and endure the inevitable patent infringement suit and thirty-month stay or stays that ensued. The following sections introduce evidence of how the thirty-month stay has been abused by NDA holders and how ANDA IV applicants have been powerless to challenge deliberate attempts to delay market entry of generic alternatives to brand-name products.

A. Court Decisions Involving Challenges to Orange Book Listings

Three cases decided by federal circuit courts of appeal illustrate the difficulty pharmaceutical companies encounter in challenging procedures under Hatch-Waxman. If an NDA holder abuses the Orange Book listing system to delay generic competition, the generic competitor has few options. As the *Mylan* and *Andrx* cases discussed in this section illustrate, patents listed inappropriately in the Orange Book have the same power to trigger a thirty-month stay as any validly listed patent, thereby delaying generic entry, costing consumers money without justification. The Federal Circuit has suggested that drug companies may challenge FDA actions, such as improper Orange Book listings, under the Administrative Procedure Act (APA), but a case from the Fourth Circuit indicates that such actions may be futile. This section details recent cases decided by the Court of Appeals for the Federal Circuit and the Fourth Circuit to illustrate the scope of the Orange Book listing problem, abuse of the thirty-month stay and the lack of meaningful alternatives for generic drug manufacturers challenging improperly listed patents.

1. Mylan Pharmaceuticals v. Thompson: An ANDA Applicant Has No Private Cause of Action to Delist a Patent

In *Mylan Pharmaceuticals v. Thompson*,⁴⁶ generic drug manufacturers, including Mylan Pharmaceuticals (Mylan), alleged that Bristol Myers Squibb (BMS) improperly availed itself of Hatch-Waxman provisions by misrepresenting the scope of a patent in order to obtain an Orange Book listing and delay generic entry.⁴⁷ The Court of Appeals for the Federal Circuit held that a generic drug manufacturer could not challenge the propriety of an Orange Book listing by seeking a declaratory judgment.⁴⁸ Furthermore, the Court held that delisting of an Orange Book entry was not an available remedy.⁴⁹ The Federal Circuit's ruling overturned the decision of the district court for the District of Columbia which had directed the FDA to delist the challenged patent from the Orange Book and to approve Mylan's ANDA IV.⁵⁰

46. 268 F.3d 1323 (Fed. Cir. 2001).

47. *Id.* at 1331-32.

48. *Id.*

49. *Id.*

50. *Mylan Pharm., Inc. v. Thompson*, 139 F. Supp. 2d 1, 8 (D.D.C. 2001), *rev'd* 268 F.3d 1323 (Fed. Cir. 2001). The patent in question was delisted following the district court's decision. After the Federal Circuit's decision, BMS continued its patent infringement suit against Mylan but chose not to relist the patent. Consequently, generic buspirone remained on the market. See Def.'s Mot. to Dismiss, *In re Buspirone Patent Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (MDL No. 1410) (allowing generic Buspirone to remain on the

BMS owned a patent for the treatment of anxiety through buspirone hydrochloride, U.S. Patent No. 4,182,763 (the '763 patent). This patent was listed in the Orange Book as covering the FDA approved drug BuSpar. BMS began selling BuSpar in 1986, and had significant commercial success with the product, selling more than \$600 million of the product in 1999.⁵¹ With the patent set to expire on November 21, 2000, Mylan Pharmaceuticals, Inc., the nation's largest generic drug manufacturer, had its trucks loaded with generic buspirone tablets, ready for shipment the moment the patent expired. Mylan had obtained FDA approval of its generic product after filing a Paragraph III certification, which made market entry contingent only on expiration of the patent. Twelve hours before the '763 patent was to expire, however, BMS had delivered a just-issued patent, U.S. Patent No. 6,150,365 (the '365 patent), to the FDA to be listed in the Orange Book, as claiming BuSpar.⁵² The '365 patent claims the administration of a compound that is one of the metabolites produced in the body following the administration of buspirone.⁵³ The listing of the '365 patent caused a suspension of the approval process for Mylan's generic version of BuSpar.⁵⁴ Mylan and other ANDA applicants challenged the FDA listing of the new patent, maintaining that the new patent, which was for a metabolite of buspirone, "could not 'claim a listed drug' within the meaning of the statute."⁵⁵ The FDA, in a role it describes as purely ministerial, asked BMS for clarification about its listing, accepted the proffered clarification at face value, and listed the patent in the Orange Book.⁵⁶ Mylan filed suit against the FDA and BMS, seeking the delisting of the '365 patent and FDA approval of its ANDA.⁵⁷ The district court, finding that Mylan was likely to succeed on the merits, granted the relief requested.⁵⁸

Key to the district court's decision was its conclusion that the case was a patent case, not an administrative law case.⁵⁹ Although the district court recognized that the FFDCA does not allow a private cause of action, it viewed the suit as a defense to anticipated patent litigation.⁶⁰ According to the district court, Mylan was not seeking to enforce the FFDCA but rather to get relief from BMS for its improper submission of the patent for listing.⁶¹ The district court viewed the FDA as a defendant necessary to the suit only for

market).

51. See *Mylan*, 139 F. Supp. 2d at 7.

52. *Id.* at 16.

53. *Id.* at 17.

54. *Id.* at 18.

55. *Id.* at 9.

56. *Mylan*, 139 F. Supp. 2d at 9-10.

57. *Id.* at 3.

58. *Id.* at 29.

59. *Id.* at 16-17.

60. *Id.* at 10-11; see 21 U.S.C. § 337(a) (1998) (indicating that "proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States"). In a suit filed by other ANDA applicants seeking to market generic versions of buspirone, the U.S. District Court for the District of Maryland, held that the suit against the FDA was an attempt for judicial review of an agency's final decision. *Watson Pharm., Inc. & Danbury Pharmacal, Inc. v. Henney*, 194 F. Supp. 2d 442, 445 (D. Md. 2001). Finding that the FDA's actions were not "unreasonable, arbitrary, or capricious," the Maryland court granted summary judgment for the FDA, citing the deference owed to agency determinations under *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 937 (1984), and the FDA's limited, ministerial role. *Id.* at 442.

61. *Mylan*, 139 F. Supp. 2d at 12.

the purpose of ensuring that any relief granted by the court would be carried out by the agency.⁶² The district court granted a preliminary injunction to Mylan finding that Mylan was likely to succeed on the merits because the '365 patent did not meet the statutory listing requirements that the patent "claim the drug" or a "method of using" the drug for which FDA approval had been granted.⁶³ Furthermore, the court found that the patent did not meet the listing requirement that a claim for infringement could be asserted against an authorized user, maker, or seller of the approved drug.⁶⁴ In a preliminary construction of the '365 patent claim, the district court found that during the patent prosecution, BMS had expressly surrendered the uses it subsequently claimed were covered by the newly listed patent.⁶⁵ The district court concluded that delisting the '365 patent and approving Mylan's ANDA served the public interest by increasing the public's access to low cost drugs and preventing BMS from "creating new—and probably impermissible—ways to extend its monopoly."⁶⁶

The Court of Appeals for the Federal Circuit reversed the district court's ruling, finding that neither the patent laws nor the Hatch-Waxman Amendments contemplate a private cause of action to delist a patent from the Orange Book.⁶⁷ The Federal Circuit rejected the district court's approach to the case as a patent case, seeing the action as an attempt to assert a private right of action under the FFDCA.⁶⁸ Although the Federal Circuit recognized the threat of a patent infringement suit, it found that improper listing of a patent in the Orange Book is not a proper defense in such a suit.⁶⁹ The Federal Circuit found no provisions in the Hatch-Waxman Amendments that allow an accused infringer to challenge a patent listed in the Orange Book.⁷⁰ If an ANDA applicant has filed a Paragraph IV certification, challenging the validity of a patent listed in the Orange Book, the Amendments provide that an action for declaratory judgment regarding the listed patent may not be filed until forty-five days after the patent owner receives notification of the Paragraph IV certification.⁷¹ Mylan argued that this provision did not cover its action because it had filed a Paragraph III, not a Paragraph IV, certification.⁷² But the Federal Circuit disregarded this argument, finding that the Amendments indicate "Congress only envisioned that recognized defenses could be raised in declaratory judgments in patent infringement actions."⁷³ The Court recognized that it may be

62. *Id.*

63. *Id.* at 18-19, 29. Mylan maintained that the patent did not "'claim the drug' or 'a method of using' the drug for which Bristol had gained FDA approval" as required by 21 U.S.C.S. § 355(b)(1) (Law. Co-op. 2000). *Id.* at 18-19.

64. *Id.* at 18-19, 24.

65. *Mylan*, 139 F. Supp. 2d at 12.

66. *Id.* at 29.

67. *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1329-33 (Fed. Cir. 2001).

68. *Id.* at 1332.

69. *Id.* at 1331. The court noted that the statutory defenses in a patent suit are set forth in 35 U.S.C. § 282 and include non-infringement, absence of liability for infringement, unenforceability, and invalidity. The court listed equitable defenses as unclean hands, unenforceability of the patent for fraud and inequitable conduct, misuse, and delay in filing suit resulting in laches or estoppel. *See id.*

70. *Id.*

71. 21 U.S.C.S. § 355(j)(5)(B)(iii) (Law. Co-op. 1998).

72. *Mylan*, 268 F.3d at 1332.

73. *Id.*

appropriate to order a patent to be delisted in the context of a properly filed patent suit,⁷⁴ but concluded that there is no independent cause of action seeking delisting.⁷⁵

2. *Andrx Pharmaceuticals, Inc. v. Biovail: The Problem of Multiple Thirty-Month Stays*

The Court of Appeals for the Federal Circuit again addressed issues involving Orange Book listings in *Andrx Pharmaceuticals, Inc. v. Biovail*.⁷⁶ As in the *Mylan* case, the conflict involved the validity of a late-listed patent, one listed after the ANDA application was filed with the FDA, which caused suspension of the approval of a generic drug product. Biovail's prescription drug, Tiazac, used to treat hypertension and angina, was approved by the FDA in 1995. In 1998, Andrx, a generic drug manufacturer, filed a Paragraph IV certification, maintaining that its product would not infringe Biovail's U.S. Patent No. 5,529,791 (the '791 patent). Biovail responded by filing a suit for infringement and, consequently, Andrx's ANDA approval was stayed for thirty months or until resolution of the infringement suit, pursuant to provisions in the Hatch-Waxman Act.⁷⁷ At trial, the district court found that the '791 patent was not infringed by Andrx's generic version and the Court of Appeals for the Federal Circuit affirmed.⁷⁸ But Andrx's introduction of its product was further delayed because, while the patent suit was pending, Biovail obtained an exclusive license to U.S. Patent No. 6,162,463 (the '463 patent) which claimed an extended release formula for the active ingredients of Tiazac. The new listing required Andrx to make a certification addressing the '463 patent.⁷⁹ Andrx, understandably frustrated by the filing of the new patent and the specter of a second thirty-month delay,⁸⁰ sued Biovail and the FDA, seeking a declaratory judgment of non-infringement, patent invalidity, and antitrust and state law violations. Andrx sought the delisting of the '463 patent and a shortening of the thirty-month statutory period. After the '463 patent was listed in the Orange Book, Andrx filed its Paragraph IV certification with respect to that patent, and Biovail filed suit for infringement.

The District Court for the Southern District of Florida considered together Andrx's suit seeking declaratory judgment and Biovail's claim of infringement.⁸¹ In so doing, the district court dismissed the petition to delist the '463 patent,⁸² correctly anticipating the *Mylan* ruling by the Federal Circuit that Hatch-Waxman does not contemplate a private right of action apart from the patent infringement suit. Nevertheless, the district court allowed the declaratory judgment counts for non-infringement and invalidity to be treated as counterclaims to Biovail's infringement suit.⁸³ Most importantly, the district court found that in obtaining the new patent, and in changing the formulation of the approved

74. See *Abbott Lab. v. Novopharm Ltd.*, 104 F.3d 1305, 1309 (Fed. Cir. 1997) (FDA ordered to delist a patent, which the court determined had expired).

75. *Mylan*, 268 F.3d at 1332.

76. 276 F.3d 1368 (Fed. Cir. 2002).

77. See 21 U.S.C.S. § 355(j)(5)(B)(iii) (Law. Co-op. 2000).

78. *Biovail Corp. Int'l v. Andrx Pharm., Inc.*, 239 F.3d 1297 (Fed. Cir. 2001).

79. See 21 C.F.R. § 314.94(a)(12)(vi) (2002).

80. The FDA would have approved Andrx's ANDA on or about February 14, 2001, if not for the listing of the '463 patent.

81. *Andrx Pharm. Inc. v. Biovail Corp.*, 175 F. Supp. 2d 1362 (S.D. Fla. 2001).

82. *Id.* at 1369.

83. *Id.* at 1372.

drug, Tiazac, Biovail had impeded or delayed the resolution of the patent action.⁸⁴ The statute provides that the FDA's approval of the generic drug application

shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under Paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action⁸⁵

Relying on this provision, the district court shortened the statutory thirty-month period and ordered the FDA to approve Andrx's ANDA.⁸⁶ According to the district court, Biovail failed to cooperate in resolving the patent issues by listing the '463 patent without disclosing the manufacturing change it made to the approved drug Tiazac.⁸⁷

The Federal Circuit, however, found that the district court interpreted the statute in an overly broad manner and exceeded its authority in shortening the thirty-month stay.⁸⁸ The Federal Circuit found that the district court erred in focusing on the relationship between the patent in question and the drug being marketed as opposed to the relationship between the patent and the drug substances covered by the NDA.⁸⁹ Furthermore, the Court held that, under its decision in *Mylan*, "the district court has no authority in the infringement action . . . to shorten the thirty-month stay because of allegedly improper conduct before the FDA."⁹⁰ According to the Federal Circuit, the ability to shorten the thirty-month stay pertains only to the "particular infringement action" not to the "resolution of the overall patent dispute."⁹¹ Thus, Andrx, like *Mylan*, was required to delay market entry of its competing product until resolution of the patent suit or expiration of the automatic thirty-month stay of FDA approval.

The *Andrx* decision suggests, in dicta, however, that an ANDA applicant may bring an action under the Administrative Procedure Act (APA),⁹² to compel the FDA to approve the ANDA if the FDA's denial was "arbitrary, capricious, or not in accordance with law."⁹³ The Federal Circuit vacated and remanded the district court's order, leaving Andrx the option to amend its complaint to include allegations that the FDA acted arbitrarily or capriciously in denying its ANDA.⁹⁴ However, this option appears unlikely to provide much relief as the discussion of the next case indicates.

84. *Id.* at 1373-76.

85. 21 U.S.C.S. § 355(j)(5)(B)(iii) (Law. Co-op. 2000).

86. *Andrx*, 175 F. Supp. 2d at 1368. The court ordered the waiting period to end on September 27, 2001. *Id.*

87. *Id.* at 1375.

88. *Andrx Pharm., Inc. v. Biovail Corp.* 276 F.3d 1368, 1376 (Fed. Cir. 2002).

89. *Id.*

90. *Id.*

91. *Id.*

92. See 5 U.S.C.S. §§ 702-706 (Law. Co-op. 1989) (describing the right, standard, and scope of review for the Administrative Procedure Act).

93. *Andrx*, 276 F.3d at 1378.

94. *Id.* at 1380.

3. *aaiPharma, Inc. v. Thompson: The FDA's Role is Purely Ministerial and It Has No Duty to List a Patent*

Although the Federal Circuit suggested that generic manufacturers could challenge improper Orange Book listings by suing the FDA under the APA, the FDA's passive role in administering the Orange Book system leaves little room for interpreting the FDA's behavior as arbitrary, capricious, or not in accordance with the law. Whether the FDA has a duty to ensure the accuracy of Orange Book listings was the issue addressed by the Court of Appeals for the Fourth Circuit in *aaiPharma, Inc. v. Thompson*.⁹⁵ AaiPharma held U.S. Patent No. 6,258,853 (the '853 patent) for a polymorphic variant of the active ingredient in Prozac, Eli Lilly & Company's antidepressant drug. When the patent on Prozac expired on August 2, 2001, generic manufacturers were prepared to market their versions of Prozac. AaiPharma sought to have its '853 patent listed in the Orange Book, to claim Prozac. According to FDA rules, the listing would require manufacturers of generic versions of Prozac to certify to aaiPharma that their products did not infringe the '853 patent. Although aaiPharma did not have a drug that used its patent ready to market, the Court recognized that a third party patent holder of an approved drug is entitled to the protection of Hatch-Waxman, including the thirty-month stay.⁹⁶ Lilly, as the NDA holder of the claimed drug Prozac, had the power to list aaiPharma's patent, but it refused, for reasons unknown, to do so.⁹⁷ When aaiPharma asked the FDA to intervene to compel the listing, the FDA maintained that its role in Orange Book listings was purely ministerial. Regulations promulgated by the FDA state that if the accuracy of a listing is challenged, the affected party must notify the FDA and the FDA

will then request of the applicable new drug application holder that the correctness of the patent information or omission of patent information be confirmed. Unless the application holder withdraws or amends its patent information in response to the FDA's request, the agency will not change the patent information in the list.⁹⁸

AaiPharma maintained that the FDA's refusal to list its patent violated section 706(2)(A) of the APA by improperly delegating the agency's statutory duties to the NDA holder.⁹⁹

The Fourth Circuit analyzed the FDA's interpretation of the statute according to the two step analysis articulated by the Supreme Court in *Chevron U.S.A., Inc. v. Natural Resource Defense Council, Inc.*¹⁰⁰ First, the Court considered "whether Congress has directly spoken to the precise question at issue."¹⁰¹ To support its passive role, the FDA relied on language in Hatch-Waxman which states "[u]pon submission of patent

95. 296 F.3d 227 (4th Cir. 2002).

96. *AaiPharma*, 296 F.3d at 236.

97. If aaiPharma's patent was listed as claiming Prozac, ANDA applicants would have been required to file Paragraph IV certifications, thereby triggering the 30-month stay of ANDA approval, a development that would have been serendipitous for Lilly. In a footnote, the Court noted that there was "nothing in the record to indicate why Lilly refused aaiPharma's request despite this financial incentive." *Id.* at 233 n.4.

98. 21 C.F.R. 314.53(f) (2004).

99. See *aaiPharma*, 296 F.3d at 233 n.90 (aaiPharma claimed that the FDA should have required Lilly to list the '853 patent in the Orange Book according to the APA).

100. 467 U.S. 837, 842-45 (1984).

101. *AaiPharma*, 296 F.3d at 237-38 (quoting *Chevron USA, Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-45 (1984)).

information under this subsection, the [FDA] shall publish it.”¹⁰² AaiPharma, however, cited two different sections of Hatch-Waxman to support its view that the FDA has discretion in listing patents. Section 355(d)(6) instructs the FDA to refuse to approve an application if “the application failed to contain the patent information prescribed by subsection (b) of this section.”¹⁰³ Under subsection (b), an NDA is required to submit “the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application”¹⁰⁴ AaiPharma also relied on section 355(e) which states that the FDA “shall . . . withdraw approval of an application,” if it finds that “the patent information prescribed by subsection (c) of this section was not filed within thirty days after the receipt of written notice from the [FDA] specifying the failure to file such information.”¹⁰⁵ According to aaiPharma, these two sections indicate that the FDA has a duty to ensure that the NDA holder submits all patents eligible for listing.¹⁰⁶ Because the provisions relied on by the parties appear to conflict, the court concluded that Congress did not clearly express its intent on the FDA’s role in assessing Orange Book listings and moved on to the second *Chevron* consideration, to determine whether the FDA’s interpretation was based on a “permissible” construction of the statute.¹⁰⁷

The court found the FDA’s interpretation of its role as ministerial to be reasonable because the provisions requiring submission of a list could only be interpreted to mean that a list of patents must be filed.¹⁰⁸ The court found it implausible that Congress intended to burden the FDA with the chore of insuring that all patents that could pertain to the new drug application were filed.¹⁰⁹ The court stated that it was reasonable for the FDA to read the statute as requiring it to ensure that an NDA either submits a list of patents claiming the drug or declares that it has no patents to list.¹¹⁰

Several other factors also persuaded the Fourth Circuit Court of Appeals that the FDA’s interpretation of its role as purely ministerial was reasonable. First, the court noted that aaiPharma’s interpretation that the FDA has a duty to ensure that all appropriate patents are listed ignores the problem that arises more frequently and more perniciously—delisting patents that have been improperly listed.¹¹¹ The court stated that “it is hard to believe that Congress would impose a duty on the FDA to police the improper refusal to list patents without also imposing a duty to police the improper listing of patents.”¹¹² Secondly, aaiPharma’s arguments were weakened because the FDA has no expertise in making patent judgments; its role is to insure the safety and efficacy of the products it regulates.¹¹³

102. 21 U.S.C.S. § 355(c)(2) (Law. Co-op. 2000).

103. 21 U.S.C.S. § 355(d)(6) (Law. Co-op. 2000).

104. 21 U.S.C.S. § 355(b)(1) (Law. Co-op. 2000).

105. 21 U.S.C.S. § 355 (e)(4) (Law. Co-op. 1998).

106. *AaiPharma*, 296 F.3d at 238.

107. *Id.*

108. *Id.* at 239-40.

109. *Id.*

110. *Id.* at 241.

111. *AaiPharma*, 296 F.3d at 241.

112. *Id.*

113. *Id.*

4. *Purepac v. Thompson: Court Orders Delisting of Patent Where the Method of Use is Not Approved*

The FDA's role in assessing Orange Book listings was again at issue in *Purepac Pharmaceutical Company v. Thompson*.¹¹⁴ In this case, a generic manufacturer, Purepac, seeking FDA approval of a generic form of Warner-Lambert's patented drug gabapentin, chose a route alternative to the Paragraph IV certification. The FDA regulations allow a generic manufacturer to make a section viii statement when the patent involved is a method of use patent that does not claim the use for which the ANDA applicant is seeking approval.¹¹⁵ In a section viii statement, the ANDA applicant is not challenging the validity of the patent as it would in a Paragraph IV certification, but merely maintaining that the use for which it seeks approval is not a use claimed by any listed, unexpired patent. An ANDA applicant must elect either a Paragraph IV certification or a section viii statement, as the FDA emphasizes that "either the applicant is seeking approval for the use claimed in the patent, or it is not."¹¹⁶ The section viii statement, unlike a Paragraph IV certification, does not require notice to the NDA holder and does not entitle the NDA holder to an automatic stay if it files a patent infringement suit. In this sense, a section viii statement can be viewed as an "escape hatch" from the problems associated with the thirty-month stay. This advantage is offset by the fact that section viii statements do not entitle the ANDA applicant to the benefit of the 180-day exclusivity period.

Warner-Lambert's patent on the active ingredient in gabapentin and its method of use patent for the treatment of epilepsy expired in 2000.¹¹⁷ Warner-Lambert had listed additional patents in the Orange Book, including a method of use patent for gabapentin used in treating neurodegenerative disorders, U.S. Patent No. 4,084,479 (the '479 patent).¹¹⁸ Use of gabapentin for treatment of neurodegenerative disorders is not an FDA-approved use. The drug is FDA-approved only as a treatment for epilepsy.¹¹⁹ Despite FDA requirements that Orange Book listings may include patents only for FDA approved uses, the FDA listed Warner-Lambert's '479 patent, which indicated that its use was for the treatment of neurodegenerative disorders. Thus, in listing the unapproved use, the FDA overlooked the unapproved use, merely assuming that Warner-Lambert was complying with the listing requirements. Purepac sought approval for use of its generic form of gabapentin only for the treatment of epilepsy.¹²⁰ Nevertheless, the FDA denied Purepac's section viii statement, accepting at face value Warner-Lambert's declaration and confirmation of the validity of its patent.¹²¹ Presuming the listed patent to be valid, the FDA maintained that Purepac had to submit a Paragraph IV certification. Arguing that the FDA's rejection of its section viii statement was arbitrary and capricious, Purepac sought a preliminary injunction requiring the FDA to approve its section viii

114. *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002), *aff'd* 354 F.3d 877 (D.C. Cir. 2004).

115. 21 U.S.C.S. § 355(j)(2)(A)(viii) (Law. Co-op. 1998).

116. *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 77 (D.D.C. 2003).

117. *Purepac*, 238 F. Supp. 2d at 197.

118. *See id.* at 197-98.

119. *See id.* at 199.

120. *See id.*

121. *See id.*

statement.¹²²

In granting Purepac's request, the United States District Court for the District of Columbia was critical of the FDA's actions in this case and clearly articulated the potential for abuse in Orange Book listings. Nevertheless, beyond recognition of Orange Book problems, the court's ruling is confined to the unique factual circumstances of the case and does not offer solutions to other circumstances in which abuse of the Orange Book listing process occurs. The court recognized the FDA's position that patent disputes should be settled between the private parties and that the agency has neither the resources nor the expertise to review patents proposed for listing for accuracy or relevancy.¹²³ In this APA case, however, the court found the FDA's refusal to accept Purepac's section viii statement was arbitrary and capricious, a "clear error in judgment," because there was no real conflict between the parties regarding the scope of the patent.¹²⁴ Purepac relied on Warner-Lambert's claim that the '479 patent claimed a method of use for treating neurodegenerative diseases, not epilepsy. It was clear, the court stated, that the '479 patent does not cover use of gabapentin to treat epilepsy, as evidenced by Warner-Lambert's unambiguous descriptions of the method of use of the '479 patent.¹²⁵ Furthermore, the court stated, the FDA's understanding of the patent's scope is evidenced by the code it assigned to the patent on listing, the code for treatment of neurodegenerative disorders.¹²⁶

To allow the FDA to hide behind its policy of accepting the NDA holder's assurance that its listings are accurate creates a fictitious premise, according to the court. The FDA cannot substitute "hope for reality" the court admonishes, and must recognize that although only approved uses are supposed to be in the Orange Book, unapproved uses are also listed, contrary to FDA regulations.¹²⁷ Despite the court's recognition of the dilemma involving the integrity of Orange Book listings, it offers no remedy beyond that provided in this particular case.

B. Discussion of the Case Law

Generic drug manufacturers have employed various litigation strategies to combat the problem of late-listed patents, as well as patents that purport to claim an approved drug, or method of using the drug, that do not properly claim the drug or its approved use. Despite several district court opinions that recognize the plight of the ANDA applicants and make accommodations for them, the circuit courts of appeal have been unwilling or unable to stretch Hatch-Waxman to accommodate the deserving interests of the generic drug manufacturers. Constrained by the language of Hatch-Waxman, the FDCA's prohibition against private actions, and the FDA's inability to evaluate patents listed, the courts have left generic drug manufacturers with no choice but to endure multiple thirty-month stays and defend patent infringement suits. This stay allows brand-name manufacturers to impermissibly extend their monopolies and forces consumers to pay the

122. See *Purepac*, 238 F. Supp. 2d at 201.

123. See *id.* at 205 n.20.

124. See *id.* at 210-12.

125. *Id.*

126. *Id.* at 210.

127. See *Purepac*, 238 F. Supp. 2d at 208.

high prices commanded by products without competition.

The cases decided involving Orange Book listings illustrate that the balance contemplated by Hatch-Waxman is not working. The courts failed to find any effective mechanism in Hatch-Waxman for insuring the accuracy of Orange Book listings or challenging patents that generic manufacturers suspect are blatant attempts to extend a monopoly, where the new patent filed does nothing to encourage innovation or to benefit the consumer. One problem is that the statute assumes the good faith compliance of NDA holders and ANDA applicants, ignoring the obvious tension in the parties' goals. With no easy mechanism for challenging suspect patents, and nothing to deter the pioneer's conduct, patent attorneys are encouraged to anticipate "Hatch-Waxman events" in the drafting and prosecution phases.¹²⁸ One attorney, explaining how the Orange Book can be an effective weapon in prolonging market exclusivity, describes the Orange Book as the provider of an "automatic injunction" for the patentee.¹²⁹ FDA rules, he maintains, encourage NDA holders to "evergreen" their drug patents, by "filing and refiling 'improvement' patents for the same basic drug product," so as to create "a minefield for generic applicants."¹³⁰ This practice is further encouraged by court decisions that indicate there is no effective mechanism for removing a listed patent from the Orange Book and by the fact that the FDA has never sanctioned anyone for an unauthorized filing.¹³¹ At least two courts have upheld the FDA's position that it will not change patents in the Orange Book information; the FDA will merely seek confirmation of the information from the brand-name company.¹³²

These cases indicate a need for some punishment or deterrent to prevent the improper listing of patents, the frivolous patent infringement suits that ensue, and the attending thirty-month stays. But the cases also illustrate that the FDA is not the appropriate party to administer any system of deterrence because the agency is not equipped to assess the validity of Orange Book patent listings or Paragraph IV notifications that challenge the validity of such patents. The FDA's role is to evaluate the safety and efficacy of both new and generic drugs. The agency views its role as "purely ministerial" with regard to Orange Book listings and the certification procedure and the courts have supported this interpretation.¹³³ APA challenges to FDA actions involving patent listings are not likely to be helpful, as the *aaiPharma* decision illustrates.¹³⁴ Unless the FDA fails to follow its own procedures, or treats applicants in an inconsistent manner, there is little likelihood a court could determine its actions to be arbitrary, capricious or contrary to law. The FDA has acted with consistency in refusing to interfere with the listing process.¹³⁵ As the regulations provide, the FDA merely notifies the NDA holder that an ANDA has raised questions about an Orange Book listing, accepts the

128. See Terry G. Mahn, *Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process*, 54 FOOD DRUG L.J. 245, 250 (1999) (describing the advantages to the patent-holder in the current generic application process).

129. *Id.*

130. *Id.*

131. *Id.* at 251.

132. See *aaiPharma, Inc. v. Thompson*, 296 F.3d 227 (4th Cir. 2002) (recognizing the FDA's limited ministerial role in patent disputes); *Watson Pharm., Inc. v. Henney*, 194 F. Supp. 2d 442 (D.Md. 2001) (same).

133. See *aaiPharma Inc.*, 296 F.3d at 230.

134. *Id.* at 227.

135. See *id.*

response from the NDA holder, and lists the patent.¹³⁶ Although the court did find that the FDA acted arbitrarily and capriciously in the *Purepac* case, it confined its ruling to the unique facts of that case and agreed with other courts that the FDA's role regarding listing patents is "purely ministerial."¹³⁷ Unlikely to obtain redress from the FDA in an APA action, ANDA applicants have no choice but to litigate the patent infringement suit. Hatch-Waxman requires the ANDA applicant to certify to each patent listed "despite any disagreement as to the correctness of the patent information."¹³⁸ Efforts to delist a patent have been unfruitful as courts have held that there is no private right of action under Hatch-Waxman.¹³⁹

Attempts by generic applicants to find shortcuts to resolve patent listing issues have been unsuccessful. Mylan sought to avoid the mandatory thirty-month stay triggered by a Paragraph IV notice by bypassing the certification and notice provision and seeking a declaratory judgment, outside of the statute so to speak. But the Court found this attempt to be an obvious circumvention of the statutory scheme.¹⁴⁰ Although the statute allows a court to shorten or lengthen the thirty-month stay of FDA approval if either party fails "to reasonably cooperate in expediting the action . . .,"¹⁴¹ the Federal Circuit interpreted this provision to apply only to conduct relating to the overall patent litigation.¹⁴² Thus, shortening the thirty-month stay is not a remedy available for an improper Orange Book listing. In short, court decisions involving Orange Book listings indicate that, under the original Hatch-Waxman regulatory scheme, the ANDA applicant had little choice but to go through the process of resolving a patent suit, no matter how suspect the patent listed.

IV. SOLVING PROBLEMS ASSOCIATED WITH THE ORANGE BOOK LISTING AND THE THIRTY-MONTH STAY

A. FTC Actions

The FTC has recognized the potential for abuse associated with Orange Book listings and the thirty-month stay. Actions by the FTC against brand-name pharmaceuticals have included charges of anticompetitive behavior in violation of the antitrust laws and unfair competition laws.¹⁴³ The FTC has also conducted an extensive study of problems associated with improper Orange Book listings and the thirty-month stay and made recommendations on how to curb abuses associated with these provisions of Hatch-Waxman and the FDA rules.¹⁴⁴

136. See 21 C.F.R. § 314.53(f) (2004).

137. *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191, 208 (D.D.C. 2002), *aff'd* 354 F.3d 877 (D.C. Cir. 2004).

138. 21 C.F.R. § 314.53(f) (2004).

139. *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002); *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1323 (Fed. Cir. 2001).

140. See *Mylan*, 268 F.3d at 1332 (holding that a patent holder's failure to comply with the listing requirements of § 355 is not a defense to patent infringement).

141. 21 U.S.C.S. § 355(j)(5)(B)(iii) (Law. Co-op. 1998).

142. See *Andrx*, 276 F.3d at 1376.

143. See, e.g., *In the Matter of Biovail Corp.*, File No. 011-0094 (Oct. 2, 2002) (slip opinion), available at <http://www.ftc.gov/os/2002/04/biovailcomplaint.htm> (last visited Jan. 26, 2005).

144. See generally FTC Study, *supra* note 1.

The FTC brought an action against Biovail for illegal acquisition of an exclusive license patent and wrongful listing of a patent in the Orange Book for the express purpose of blocking generic competition.¹⁴⁵ The FTC maintained that Biovail acquired and submitted a patent for listing that it knew did not cover the form of Tiazac it was marketing.¹⁴⁶ The complaint alleged that Biovail violated Section Five of the FTC Act and Section Seven of the Clayton Act by raising substantial barriers to entry into the relevant market through the unlawful acquisition of the exclusive license patent and its willful attempts to maintain a monopoly in the market for Tiazac.¹⁴⁷ The FTC action resulted in a consent order that requires Biovail to divest the illegally acquired patent to its original owner and to dismiss its infringement case against Andrx, the first ANDA IV filer, thereby allowing entry of generic Tiazac.¹⁴⁸ The order also requires Biovail to give the FTC prior notice of any patents that it will list in the Orange Book for Biovail's FDA approved products.¹⁴⁹

B. FTC Recommendations

The FTC responded to concern over Hatch-Waxman abuse by conducting a study that aimed to determine the extent of abuse caused by the thirty-month stay and the 180-day exclusivity period.¹⁵⁰ This section summarizes the findings of that study regarding the thirty-month stay provision and the FTC's recommendations to prevent delay of generic competition in pharmaceuticals. The FTC's Study focused on cases involving ANDA applicants that challenged the validity of patents through a Paragraph IV certification and was limited to the time period beginning January 1, 1992 and ending prior to January 1, 2001. Based on its study, the FTC recommended that only one thirty-month stay per generic application be permitted and that the FDA clarify Orange Book listing requirements.

The FTC found that although the overall number of patent suits triggered by Paragraph IV certifications is relatively small compared with the total number of ANDAs filed, the problems posed by misuse of the listing system and the thirty-month stay are significant because strategies used to benefit from these provisions are used in connection with the most profitable drug products. According to the Study which included 104 drug products:

[f]or the 75 drug products where patent litigation was brought, the median net sales in the year the first generic applicant filed its ANDA were \$190 million per year. By contrast, the majority of the 29 ANDAs for which no suit was filed had net sales of less than \$100 million in the year the generic applicant filed its

145. In the Matter of Biovail Corp., File No. 011-0094 (Oct. 2, 2002) (slip opinion), available at <http://www.ftc.gov/os/2002/04/biovailcomplaint.htm> (last visited Jan. 26, 2005). The FTC action arises from the same facts as those in *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002) discussed *supra* text accompanying notes 76-94.

146. *Id.*

147. *See id.*

148. *Id.*; see also In the Matter of Biovail Corp., File No. 011-0094 (April 23, 2002) (consent order), available at <http://www.ftc.gov/OS/2002/04/biovaildecision.htm> (last visited Jan. 26, 2005).

149. *Id.*

150. FTC Study, *supra* note 1.

application.¹⁵¹

Particularly subject to abuse are drugs which the FTC identified as “blockbuster” drugs—those which appear in the top twenty as ranked by annual gross sales during at least one year covered in its study.¹⁵²

Of the drug products studied, the FTC found that 72% involved patent infringement suits initiated after Paragraph IV certification by an ANDA applicant.¹⁵³ In twenty-two of thirty cases (73%) for which a court decision had been reached at the time of the FTC Study, the court held for the generic manufacturer.¹⁵⁴ Furthermore, the FTC Study noted an increase in the number of patents listed after an ANDA is filed and that such later-listed patents often do not claim the approved drug product or an approved use of the product.¹⁵⁵ Eight drug products were identified that delayed FDA approval from four to forty months beyond the first thirty months granted by the statute.¹⁵⁶ The study notes that in the four cases decided to date, the patents in question were all found either invalid or not infringed by the generic applicant.¹⁵⁷

The FTC considered the problems of the initial thirty-month stay and successive thirty-month stays separately. The initial thirty-month stay raises problems of abuse because the system assumes that the patents listed in the Orange Book are valid and that they properly claim the approved drug. As the cases discussed in Part III.A above indicate, patents may not be validly listed. Moreover, because the FDA is not equipped to evaluate whether patents are properly listed, no efficient means exists for an ANDA applicant to challenge suspect patents. Despite problems with the thirty-month stay, the FTC Study concludes that an initial thirty-month stay does not necessarily delay market entry of generic competition, even when a patent is invalid or would not be infringed by the ANDA, because the thirty-month stay approximates the length of time for FDA approval.¹⁵⁸ Although the FTC concedes that the number of patents listed for a drug product has increased the amount of time necessary to resolve patent suits, it does not offer recommendations beyond limiting the thirty-month stay to one per ANDA.¹⁵⁹

The FTC’s recommendations directly address the problems associated with successive thirty-month stays. Successive thirty-month stays occur when an NDA holder submits patents after the ANDA has filed with the FDA, requiring new certifications to the late-listed patents. Although the FTC’s Study reported only eight cases in the years from 1998 to 2001 in which successive thirty-month stays were invoked, these cases involved the most profitable drugs.¹⁶⁰ One of the most striking cases involving successive thirty-month stays involved GlaxoSmithKline’s (GSK) blockbuster drug,

151. *Id.* at 14.

152. *See id.* at ii n.2. Capoten, Cardizem CD, Cipro, Claritin, Lupron Depot, Neurontin, Paxil, Pepcid, Pravachol, Prilosec, Procardia XL, Prozac, Vasotec, Xanax, Zantac, Zocor, Zolofit, and Zyprexa are those cited in the study. *Id.* at 10-11.

153. *Id.* at 14.

154. FTC Study, *supra* note 1, at 15.

155. *Id.* at 40.

156. *Id.*

157. *Id.*

158. *See id.* at 39. *See* FTC Study, *supra* note 1, at 39.

159. FTC Study, *supra* note 1, at 39-40.

160. *See id.* at 39. For example, Paxil (paroxetine hydrochloride) and Neurontin (gabapentin).

Paxil.¹⁶¹ The FDA approved the drug in 1992. At that time, the patent covering Paxil's active ingredient had already expired. GSK, however, listed another patent for a different form of the active ingredient. This patent was challenged in 1998 by the generic manufacturer Apotex. During the thirty-month stay triggered by Apotex's Paragraph IV certification and the ensuing patent infringement suit, GSK listed nine additional patents in the Orange Book. Apotex dutifully filed Paragraph IV certifications for these late-listed patents, with the result that four additional thirty-month stays were triggered. The approval of generic Paxil was delayed for over five years.¹⁶²

The FTC's recommendation that only one thirty-month stay per ANDA per drug be allowed should, according to the agency, eliminate most of the abuses associated with this provision while still allowing the brand-name manufacturer to protect its patents. According to the proposed approach, patents that are listed after an ANDA application is submitted would still require the ANDA applicant's certification but the certification would not trigger an automatic thirty-month stay of approval. The patent holder could, of course, still sue for patent infringement and could seek a preliminary injunction to prevent the generic manufacturer from launching its product.¹⁶³

The FTC's Study also noted problems with the Orange Book listing process. First, the study noted the increase in the number of patents listed in the Orange Book, particularly for blockbuster drugs.¹⁶⁴ According to the FTC, data indicates that the increased number of patents filed leads to litigation involving multiple patents and a longer period of time required for resolution. Moreover, in analyzing late-listed patents, the FTC recognized that several categories of patents raised significant issues concerning whether they were properly listed within the meaning of the statute.¹⁶⁵ Because generic applicants have little recourse when patents are improperly listed, the FTC recommended that the FDA clarify listability requirements. The FTC Study revealed that listing issues frequently involve three categories of patents: first, those that may not properly claim the drug formulation or method of use approved by the NDA (including metabolite patents, drug intermediate patents, and polymorph patents); second, product-by-process patents; and third, patents that raise issues of double-patenting.¹⁶⁶ While recognizing that the FDA cannot evaluate all patents because of the required complex interpretation of chemistry, patent law and FDA law, the FTC Study nevertheless stated that some patents are relatively straightforward and requested the FDA to clarify the scope of patents that may be listed.¹⁶⁷

161. *See id.* at 51.

162. *See id.*

163. *See Purdue Pharma L.P., v. Boehringer Ingelheim GmbH*, 98 F. Supp. 2d 362 (S.D.N.Y. 2000), *aff'd* 237 F.3d 1359, 1363 (Fed. Cir. 2001) (discussing preliminary injunction that was granted to enjoin infringement on patent); *Glaxo Group Ltd v. Ranbaxy Pharms., Inc.*, 262 F.3d 1333, 1338 (Fed. Cir. 2001) (discussing district court's decision to grant preliminary injunction because generic manufacturer could not pay NDA holder's potential damages). There are not many cases on preliminary injunctions for pharmaceutical companies.

164. *See* FTC Study, *supra* note 1, at 51.

165. *See id.* at 52.

166. *See id.* at 54-55.

167. *See id.* at 55.

C. New FDA Rules on Listing Requirements

In response to the FTC's study and recommendations, the FDA passed new rules to reduce litigation associated with improper Orange Book listings. Before the new rules were implemented, Hatch-Waxman required that an NDA filer

shall file with the application 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.¹⁶⁸

The new FDA rules add some more precise rules to this requirement.

The new FDA rules, which became effective June 18, 2003, are designed to "prevent innovator drug companies from submitting certain new patent claims that are unlikely to represent substantial new innovation in order to extend their marketing protection, thus delaying the approval of a generic equivalent."¹⁶⁹ The new rules specify which types of patents may be listed and which may not.¹⁷⁰ The regulations allow patents for drug product (active ingredients), drug substances (formulation and composition) and method-of-use patents (tablet, capsule).¹⁷¹ The regulations do not allow process patents to be submitted to the FDA. Furthermore, since the FTC noted that many listing problems occurred with method-of-use patents, the new FDA rules specify that such patents may be submitted only on those patents that claim indications or other conditions of use on a pending or approved application.¹⁷² New FDA rules also respond to problems identified in the FTC Study by prohibiting the submission of patents claiming packaging, intermediates, or metabolites and requiring more detailed information for patents claiming a different polymorphic form of the active ingredient described in the NDA.

Because the FDA does not have the time or expertise to review patent submissions, the new rules have changed the submission process by requiring NDA applicants to complete a specific declaration form that requires information about the type of patent being submitted.¹⁷³ The patent submission declarations are more detailed, with check boxes that attempt to screen out patents that are not allowed by the regulations. The rules also require a signed attestation that the information is accurate and complies with the requirements of the regulations.¹⁷⁴

The FDA followed the FTC's recommendation that the thirty-month stay be limited to one per ANDA per drug.¹⁷⁵ Under the new FDA rule, ANDA applicants must still certify to all patents listed in the Orange Book, but notice to the NDA holder is only required in the initial Paragraph IV certification.¹⁷⁶ Thus, if a brand-name manufacturer

168. 21 U.S.C.S. § 355(b)(1) (Law. Co-op. 1998).

169. *FDA's New Regulation to Speed Access to Lower Cost Generic Drugs About to Take Effect* (August 8, 2003), available at www.fda.gov/bbs/topics/NEWS/2003/NEW00932.html (last visited Sept. 16, 2004).

170. 21 C.F.R. § 314.53(b) (2002).

171. *Id.*

172. *Id.*

173. 21 C.F.R. § 314.53(c) (2002).

174. *Id.*

175. 21 C.F.R. § 314.53(b) (2002).

176. *Id.*

lists patents subsequent to filing of an ANDA IV, no further Paragraph IV certification is required. This change directly impacts the thirty-month stay. Because notice is only required after the first Paragraph IV certification, the thirty-month stay can only attach following that first notice. The FDA sought to tie the triggering of the thirty-month stay to the notification of Paragraph IV certification. Legislation was not yet finalized when the FDA passed its rules. Although the FDA rules agree in most respects with the final provisions of the Medicare Act, the new law ties the triggering of the thirty-month stay to the certification date rather than the notice date as the FDA rule would have.¹⁷⁷

D. The Medicare Act

Following the FTC's recommendations, the Medicare Act amends the FDCA by allowing only one thirty-month stay per ANDA.¹⁷⁸ This change in the law ends the problem of successive thirty-month stays that may occur when innovators list patents after an ANDA is filed. The new law allows a thirty-month stay only for infringement suits filed regarding patents listed in the Orange Book at the time the ANDA was filed.¹⁷⁹ The provisions also change notification procedures in the interest of resolving ANDA IV issues. When an ANDA makes a Paragraph IV certification, it must notify the NDA holder and the patent owners within twenty days of receiving notice from the FDA that its application has been filed.¹⁸⁰ If the certification is an amendment or supplement to the application, the applicant must give notice to the NDA holder and patent owners simultaneously with the submission of its amendment or supplement.¹⁸¹ Previously, the statute did not mention a time period for notifying the NDA and patent holders. The patent holder still has forty-five days in which to sue if it wants the benefit of the thirty-month stay. Previously, the forty-five day period was not triggered until the patent holder and NDA holder were notified, so a substantial period of time could expire before patent litigation ensued. The notice provision pertains to all Paragraph IV certifications submitted on or after August 18, 2003. Paragraph IV certifications are still required for later-listed patents and patent holders may sue for infringement on those later-listed patents. In such cases, however, no thirty-month stay would be triggered.

The Medicare Act allows an ANDA applicant to bring a declaratory judgment action that the challenged patent is invalid or will not be infringed by the drug for which the applicant seeks approval.¹⁸² The declaratory judgment action may be brought against an NDA holder or patent owner, provided that party has not instituted a patent infringement lawsuit within forty-five days of notification of a Paragraph IV certification.¹⁸³ Before the Medicare Act revised the FDCA, the generic applicant was barred from bringing a civil action to determine patent certainty. If the NDA holder did not bring suit, the applicant would have to complete the approval process with the FDA and proceed to market its drug, without judicial certainty as to whether its product could be subject to an

177. Medicare Act of 2003, (codified as amended at 21 U.S.C.S. § 355 (Law. Co-op. 2004)).

178. *Id.*

179. *Id.*

180. *Id.*; 21 U.S.C.S. § 355(b)(3)(2)(i) (Law. Co-op. Supp. 2004).

181. *Id.*

182. *Id.*

183. *Id.*

infringement suit. The new provision affords the ANDA applicant the opportunity to obtain legal certainty while it seeks FDA approval, before it takes the risk of selling a potentially infringing product. If the ANDA applicant maintains that its product will not infringe the listed patent, it must make an offer of confidential access to its application so that the NDA holder and patent owners may determine whether to bring an infringement suit.¹⁸⁴ If the generic manufacturer is claiming only invalidity of the patent, it does not have to make an offer of confidential access. In theory, this provision offers the generic applicant some comfort. In reality, however, this provision may not be available because courts have found that cases in which a generic applicant is seeking patent certainty may not present an actual case or controversy as required by the Declaratory Judgment Act.¹⁸⁵

The Medicare Act allows the generic manufacturer to bring a counterclaim to correct or delete patent information from the Orange Book on the grounds that the listed patent either does not claim the drug for which the NDA was approved or an approved method of using the drug.¹⁸⁶ This provision solves the problem encountered in cases which did not allow the counterclaim because there is no private right of action under the FFDCA.¹⁸⁷ The availability of a delisting counterclaim could allow more expeditious resolution of suits because a court may determine whether the listed patents claim the NDA drug or a method of using the drug more quickly than the infringement issue. Nevertheless, the delisting action can only be brought as a counterclaim in a patent infringement suit, not as an independent cause of action, and the only remedy is the removal of the patent from the Orange Book. This provision does not allow the generic applicant to collect money damages.¹⁸⁸

184. Medicare Act of 2003, *supra* note 177.

185. 28 U.S.C. § 2201(a) (1994); *see* *Teva Pharm. USA, Inc. v. Pfizer Inc.*, Civil Action No. 03-CV-10167-RGS, 2003 U.S. Dist. LEXIS 21940, Mem. Op. (D. Mass. Dec. 8, 2003); *Dr. Reddy's Labs., Ltd. v. Pfizer Inc.*, 2003 WL 21638254 (D.N.J. July 8, 2003). In both cases, declaratory judgment actions filed by generic applicants challenging a patent listed in the Orange Book were dismissed because of the lack of an actual controversy. In patent cases, two criteria must be met to present an actual controversy. First, there must be "an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit;" second, there must be "present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999) (quoting *BP Chems. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993)). The first prong of this test is met when an ANDA applicant files a Paragraph IV certification because Hatch-Waxman states that such a certification constitutes an act of infringement. 35 U.S.C.S. § 271 (e)(2)(A) (Law. Co-op. 2004). The problem, however, is that the second prong may be difficult to prove. In *Dr. Reddy's v. Pfizer*, the court found that although filing a Paragraph IV certification satisfied the first prong of the case in controversy test, the second prong regarding reasonable apprehension of suit was not satisfied. *Dr. Reddy's* maintained that its generic version of Zolofit would not infringe on a polymorph patent held by Pfizer that expired in 2010. The court held that *Dr. Reddy's* motion for declaratory judgment failed because it did not allege objective words or actions by Pfizer that demonstrated an intent to enforce its polymorph patent. Although *Dr. Reddy's* insisted that actions by Pfizer such as listing of the patent in the Orange Book, refusing to provide a covenant not to sue, and suing the first generic manufacturer were actions that indicated reasonable apprehension to sue, the court held that this evidence did not rise to a level that indicated Pfizer would seek to enforce its patent. 2003 U.S. Dist. LEXIS 24367 at *22.

186. 21 U.S.C.S. § 355(j)(5)(C)(ii) (Law. Co-op. 2004).

187. *See Mylan and Andrx*, discussed *supra* at Part III.A.

188. 21 U.S.C.S. § 355(j)(5)(C)(ii)-(iii) (Law. Co-op. 2004).

V. ABUSE OF THE 180-DAY EXCLUSIVITY PERIOD

A. Background

The 180-day period of market exclusivity awarded to ANDA applicants that challenge the validity of listed patents through a Paragraph IV certification is the second provision of Hatch-Waxman that has been attacked as a loophole exploited by both brand-name and generic manufacturers. Hatch-Waxman provides that the first generic applicant is allowed to sell the only generic substitute for a brand-name drug product for 180 days after the first commercial marketing by the first generic applicant, or after a decision of a court holding the relevant patents to be invalid or not infringed.¹⁸⁹ The exclusivity period provides a significant incentive for generic manufacturers to challenge weak or narrow drug patents and to design generic products that do not infringe existing patented products.¹⁹⁰ When a generic manufacturer is successful in challenging a patent, consumers benefit because the lower priced generic versions of drugs become available sooner.

The FTC, consumers, and competitors have claimed that brand-name manufacturers and ANDA applicants have entered into collusive agreements that harm consumers and competition by delaying the market entry of generic products. Such agreements may take a variety of forms but the general pattern involves a “pay for delay” agreement in which the brand-name manufacturer pays the ANDA IV applicant to cooperate by not entering the market. The 180-day exclusivity period plays a prominent role in such agreements because the FDA can not approve subsequent ANDA applications until the first ANDA IV filer has enjoyed its 180 days of market exclusivity. Thus, the first ANDA IV filer, by deliberately delaying, or “parking,” its 180 days of exclusivity, may create a bottleneck that prevents other generic competitors from getting FDA approval.

Understanding what triggers the running of the 180 day exclusivity period is critical to understanding the allegations that pharmaceutical companies have colluded to delay generic competition. Before the Medicare Act was passed, Hatch-Waxman provided that the 180-day exclusivity period was calculated from either the date of the first commercial marketing of the generic drug or the date of a court decision declaring the patent invalid or not infringed, whichever was sooner.¹⁹¹ If a patent owner did not file an infringement suit against the ANDA IV applicant, the 180-day exclusivity period began to run on the first date of commercial marketing by the generic applicant. If an ANDA IV was challenged, the 180 days began to run once a court decision had been reached. The FDA initially interpreted this language to mean that, if sued, the first generic applicant could be eligible for the exclusivity period only if it successfully defended against a patent infringement suit.¹⁹² The courts, however, struck down the FDA’s “successful defense” regulation as inconsistent with the plain language of the Hatch-Waxman Amendments.¹⁹³

189. 21 U.S.C.S. § 505(j)(5)(B)(iv) (Law. Co-op. 2004).

190. See *Mova v. Shalala*, 140 F.3d 1060, 1075 (D.C. Cir. 1998).

191. 21 U.S.C.S. § 355(j)(5)(B)(iv) (Law. Co-op. 2004).

192. 21 C.F.R. § 314.107(c)(1)(ii) (2002).

193. See *Mova v. Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997) *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998). As

The statutory term “court decision” continued to cause confusion. FDA regulations interpreted the term “court decision” to mean “the court that enters final judgment from which no appeal can or has been taken.”¹⁹⁴ In *Mylan Pharmaceuticals, Inc. v. Shalala*,¹⁹⁵ the District Court for the District of Columbia found that the FDA’s interpretation of “court decision” was incorrect and that the language referred to a district court decision. Consequently, the FDA amended its rules to implement the *Mylan* decision by defining the “court decision” that triggers the running of the 180-day exclusivity period as the decision of the district court, not a decision from which no appeal could be taken. The FDA now considers the 180-day exclusivity period to be triggered by *any* district court judgment holding the patent invalid, not infringed, or unenforceable. Moreover, a court decision regarding patent validity or non-infringement need not be the court hearing the infringement suit against the first filer. A court decision reached in a suit filed by another party challenging the patent’s validity is sufficient to trigger the beginning of the first filer’s 180 days of exclusivity.¹⁹⁶ The FDA revised its regulations to reflect the *Mylan* decision, but made the new definition of “court decision” applicable to ANDA IV applicants that filed with the FDA after March 2000.¹⁹⁷

Under the original Hatch-Waxman statute, subsequent court decisions and FDA rules, a generic applicant may begin marketing its product once a district court has found the challenged patent invalid or not infringed. The applicant does not have to wait for an appellate court decision. The generic manufacturer could choose, however, to delay market entry if unwilling to risk the damages it could incur if the district court’s ruling of invalidity or non-infringement is overturned on appeal. The generic manufacturer’s decision to begin marketing its product or wait for the outcome of an appeal involves the weighing of this risk against the rewards of the 180 days of market exclusivity. The manufacturer that plays it safe awaiting appeal may watch the 180 day period evaporate long before the appeal is decided.

The difficulty of determining when a 180-day period of exclusivity begins and who is entitled to this period has led to manipulation of the regulatory scheme by brand-name and generic manufacturers. Parties have colluded to delay generic competition by entering into settlements or interim agreements that require the generic competitor to cooperate, for a price, so as to stall the exclusivity period. Parties to such agreements benefit while consumers suffer the high price of brand-name drugs. Private antitrust actions as well as actions by the FTC have challenged such agreements as violating antitrust and unfair competition laws. The FTC Study also led to recommendations that

the first ANDA filer *Mova* argued that a subsequent filer that was not sued by the patent holder could not get FDA approval until 180 days after *Mova* had begun marketing its product or a court had held the patent invalid or not infringed. The court recognized that its interpretation allowed subsequent ANDA filers to be “hostage” to the first ANDA filer’s patent litigation, but concluded that Congress, not the court, would have to remedy such possibilities. *Mova*, 955 F. Supp. at 131.

194. See *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 33-34 (D.D.C. 2000) (referring to 21 C.F.R. § 314.107(e) (1999)).

195. 81 F. Supp. 2d 30 (D.D.C. 2000).

196. See *Granutec, Inc. v. Shalala*, 1998 U.S. App. LEXIS 6685, Nos. 97-1873 & 97-1874, 1994 WL 153410, *8-9 (4th Cir. 1998) (unpublished table decision reported at 139 F.3d 889).

197. See FDA, Guidance for Industry, Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (Mar. 2000) (extending *Mylan*’s definition of “court” to prospective cases only).

the FDA and Congress have acted on. The next sections discuss the success and problems of antitrust actions by both private parties and the FTC and how the FTC, the FDA, and the Medicare Act attempt to resolve these issues.

B. Private Antitrust Actions

“Pay for delay” agreements between brand-name pharmaceuticals and generic competitors have spawned private litigation. Plaintiffs include generic competitors that are held up by an agreement that delays the triggering of the 180-day exclusivity period as well as direct and indirect purchasers who are economically harmed by the delay of a less expensive generic alternative. Plaintiffs bringing antitrust claims against parties involved in “pay for delay” agreements have been successful in establishing that they suffered the required antitrust injury and that their antitrust suits are not protected by the *Noerr-Pennington* doctrine,¹⁹⁸ which protects those who petition the government from antitrust challenges. Although district courts agreed that agreements involving payments from the brand-name company to potential generic competitors are illegal per se, in violation of § 1 of the Sherman Antitrust Act, the Courts of Appeals for the Sixth and Eleventh Circuits have split on the appropriate antitrust analysis of agreements in the Hatch-Waxman context.¹⁹⁹ The per se analysis was upheld by the Court of Appeals for the Sixth Circuit, but the Court of Appeals for the Eleventh Circuit disagreed with per se analysis in the Hatch-Waxman patent context. The different approaches taken by the Sixth and Eleventh Circuits illustrate the tension between competing policies in patent and antitrust law.²⁰⁰

1. *Andrx Pharmaceuticals, Inc. v. Biovail Corp.: Collusive Agreements Establish Antitrust Injury and are Not Immune From Suit Under The Noerr-Pennington Doctrine.*

In *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*,²⁰¹ a second ANDA applicant, Biovail, sued the first ANDA applicant, Andrx, claiming that Andrx entered into a “pay for delay” agreement with the brand-name manufacturer, Hoechst, Marion, Roussel, Inc. (HMRI). Biovail maintained that the agreement violated the Sherman Antitrust Act and caused it to suffer antitrust injury. The controversy arose when HMRI sought to delay

198. See, e.g., *In re Cardizem Antitrust Litigation*, 105 F. Supp. 2d 618 (E.D. Mich. 2000); *In re Buspirone Antitrust Litigation*, 185 F. Supp. 2d 340 (S.D.N.Y. 2002) and discussion *infra* note 217. See also FTC Complaints cited *infra* note 245.

199. See *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003) (indicating that agreements involving payments from a brand name company to a potential generic competitor are illegal per se); *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) (same); *In re Terazosin Hydrochloride Antitrust Litigation*, 164 F. Supp. 2d 1340 (S.D. Fla. 2000) (applying per se analysis to “pay for delay” agreements); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003) (rejecting per se analysis as inconsistent with exclusivity granted by patent).

200. See Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 750 (2002) (arguing that public policy toward “exit payments” should consider three policies—“pro-competition, pro-patent, and pro-settlement—and formulate rules leading to the lowest net social cost when all relevant costs are factored”). *Id.* See also Laura J. Robinson, *Analysis of Recent Proposals to Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47, 60 (2003) (arguing that incentives to settle patent litigation must be considered in the context of antitrust claims and that per se analysis should not apply automatically in patent disputes or where “payment traveled from patentee to the infringer”).

201. 256 F.3d 799 (D.C. Cir. 2001).

market entry of generic versions of its brand-name prescription drug, Cardizem CD, a drug widely prescribed for treatment of chronic chest pains and hypertension as well as for the prevention of heart attacks and strokes. On September 22, 1995, Andrx filed an ANDA, seeking approval of its generic version of Cardizem CD. Following notice of Paragraph IV certification, HMRI sued Andrx, thereby triggering the thirty-month stay of FDA approval. Biovail was the second generic applicant to submit an ANDA and Paragraph IV certification for a generic version of Cardizem CD. HMRI, however, did not sue Biovail. Nevertheless, because the FDA cannot approve any ANDAs during the thirty-month stay, Biovail's approval was held up by the patent litigation between HMRI and Andrx.

Biovail sued Andrx because HMRI and Andrx entered into an interim agreement, which prohibited Andrx from selling its generic product until a specific date.²⁰² The agreement specified that Andrx would continue to pursue its ANDA and would not transfer the 180 days of market exclusivity it was entitled to as the first ANDA filer. The agreement also provided that HMRI would make payments to Andrx in the amount of \$40 million a year, payable quarterly, beginning on the date Andrx received FDA approval for its generic product and ending either on the date Andrx began to sell its generic version or on the date Andrx lost the patent infringement suit.²⁰³

Andrx filed suit against the FDA and other ANDA applicants, including Biovail, to clarify its rights as the first ANDA applicant. Specifically, Andrx wanted to be assured it was entitled to the 180-day exclusivity period and that the FDA would not approve subsequent ANDAs until after Andrx had enjoyed the 180 days of market exclusivity. Biovail counterclaimed, alleging that Andrx's agreement with HMRI violated Sections 1 and 2 of the Sherman Act.²⁰⁴ The FDA granted final approval of Andrx's ANDA on July 3, 1998. The thirty month period had expired, allowing Andrx to begin selling its product. But, pursuant to its agreement with HMRI, Andrx did not begin marketing its product, and HMRI began making the quarterly payments of \$10 million.²⁰⁵ HMRI and Andrx terminated their agreement in 1999, and entered into a stipulation settling the patent dispute. On June 23, 1999, Andrx began marketing its generic version of Cardizem CD and the 180-day exclusivity period began to run.²⁰⁶ The FDA gave tentative approval to Biovail's ANDA in October and final approval in December of 1999.

In addressing the antitrust claims by Biovail against Andrx, the district court dismissed the case with prejudice, stating that Biovail could not show antitrust injury "causally linked to Andrx's alleged[ly] anticompetitive behavior."²⁰⁷ But the Court of Appeals for the District of Columbia held that Biovail could have shown antitrust injury and that the district court should have dismissed the case without prejudice to allow Biovail an opportunity to show antitrust injury.²⁰⁸ The Court of Appeals found that Biovail could plead an injury or threatened injury because it had the required intent and preparedness to enter the Cardizem CD market, as evidenced by the FDA's approval of

202. *Id.* at 803.

203. *Id.*

204. *Id.* at 804.

205. *Id.*

206. *Andrx*, 256 F.3d at 804.

207. *Id.*

208. *Id.* at 806.

its ANDA.²⁰⁹ Although the district court found that Biovail had failed to establish the requisite causal connection between its injury and the alleged anticompetitive behavior, the Court of Appeals found that a reasonable juror could conclude that the HMRI/Andrx Agreement prevented Biovail from entering the market.²¹⁰ The court stated that “payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties in entering the agreement and rent-preserving effect of that agreement.”²¹¹ In response to Andrx’s contention that it was exercising rights it had under Hatch-Waxman, the Court responded, “[a]lthough it is true that the first to file an ANDA is permitted to delay marketing as long as it likes, the statutory scheme does not envision the first applicant’s agreeing with the patent holder of the pioneer drug to delay the start of the 180-day period.”²¹² Thus, the court found that Andrx’s commitment to delay the commencement of the 180-day period could have caused Biovail’s injury.²¹³

Andrx argued that Biovail could have sought a “court decision” such as a declaratory judgment, which would have triggered the running of the 180-day period, but the substantial time involved in securing such a judgment led the court to conclude that this proposed remedy was not fully available to Biovail.²¹⁴ The Court also found that Biovail could not petition the FDA to approve its ANDA because Andrx was “not actively pursuing approval of its abbreviated application.” This solution was not available, however, because the agreement specifically stated that Andrx would pursue approval of its ANDA.²¹⁵ The Court of Appeals found that Biovail’s alleged injury is the type that the antitrust laws are designed to prevent because Andrx and HMRI combined to achieve an unlawful objective, Biovail could show that its injury flowed from that unlawful combination²¹⁶ and the Andrx/HMRI Agreement neither enhanced competition nor benefited consumers.

Andrx further defended by claiming that the agreement was litigation-related conduct exempted from antitrust liability by the *Noerr-Pennington* doctrine. This doctrine, grounded in the First Amendment right to petition the government, may insulate competitors’ decisions to combine, even if their underlying intention is to restrain competition or gain advantage over competitors.²¹⁷ The Court of Appeals for the District of Columbia indicated that the HMRI/Andrx Agreement was most likely a market allocation agreement not a petition for government protection. Consequently, the Court

209. *Id.* at 807. The district court was not aware of the FDA’s approval of Biovail’s ANDA, but the Court of Appeals held that even probable approval was sufficient to show intent and preparedness to enter the market. *Id.* at 808.

210. *Andrx*, 256 F.3d at 809.

211. *Id.* (citing David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 335 (2000)).

212. *Andrx*, 256 F.3d at 809.

213. *Id.* at 810.

214. *Id.* at 811-12. In *Teva Pharm. USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999), the Court held that successful resolution or dismissal of a declaratory judgment action is a “court decision” within the meaning of the statute. *Id.* at 1007-08.

215. *Andrx*, 256 F.3d at 811-12.

216. *Id.* at 815.

217. *Id.* at 817.

held that it could not seek protection under the *Noerr-Pennington* doctrine.²¹⁸

2. In re Cardizem CD Antitrust Litigation: *Pay for Delay Agreements Between Brand-name and Generic Manufacturers are Illegal Per Se According to the Sixth Circuit.*

The agreement between HMRI and Andrx also gave rise to an antitrust suit brought by direct and indirect purchasers of Cardizem CD.²¹⁹ The plaintiffs claimed that the defendants Hoeschst Marion Roussel, Inc. (HMRI), the manufacturer of the prescription drug Cardizem CD, and Andrx Pharmaceuticals, Inc. (Andrx), then a potential manufacturer of a generic version of that drug, entered into an illegal agreement that violated federal and state antitrust laws. The plaintiffs maintained that but for the agreement that paid Andrx \$40 million not to enter the Cardizem CD market, Andrx would have entered the market much sooner, allowing purchasers to acquire the generic equivalent of Cardizem CD at a much better price.²²⁰ Furthermore, Andrx's decision not to enter the market delayed the entry of subsequent generic competitors, because the FDA cannot approve subsequent ANDAs until the first filer has enjoyed its 180 days of exclusivity.²²¹

The FDA approved Andrx's ANDA on July 9, 1998. HMRI began making its quarterly payments and Andrx, pursuant to the agreement, did not begin marketing its

218. *Id.* at 818. The *Noerr-Pennington* doctrine is named for two Supreme Court cases that protect the First Amendment right to petition the government from antitrust action. See *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) ("The Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or monopoly."). *Id.* at 136; *United Mine Workers v. Pennington*, 381 U.S. 657 (1965) (holding that juries should be instructed that joint efforts to persuade public officials are not illegal under antitrust law). The United States District Court for the Southern District of New York addressed the *Noerr-Pennington* doctrine more fully in an antitrust case involving Orange Book listings. See *In re Buspirone Antitrust Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002). Bristol Meyers Squibb defended against a claim that its improper listing of patents claiming BuSpar was an illegal attempt to restrain trade in the market for buspirone by claiming that the Orange Book listings were petitions protected by the *Noerr-Pennington* doctrine. *Id.* at 368. In concluding that *Noerr-Pennington* does not apply to Orange Book listings, the court emphasized the non-discretionary, regulatory role of the FDA in listing patents in the Orange Book, as distinct from cases in which petitions are intended to persuade government officials. *Id.* at 378. The court also emphasized that a party may lose *Noerr-Pennington* immunity if it knowingly and willfully engages in fraud or if the patent infringement suit is a sham, motivated by a desire to impose competitive injury rather than to obtain a justifiable remedy. *Id.* at 373-76. Finally, the court found that improper Orange Book listings satisfied the two criteria of the "sham" exception to the *Noerr-Pennington* doctrine, articulated by the Supreme Court in *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49, 60-61 (1993). According to the *Professional Real Estate* case, two criteria create an exception to *Noerr-Pennington* immunity. First, the court must determine whether the lawsuit is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits"; second the court must find that the "baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor [through the] use of the governmental process—as opposed to the outcome of the process—as an anticompetitive weapon.'" *Id.* at 60-61 (citing *Eastern R.R. v. Noerr Motor*, 365 U.S. 127, 144 (1961)); *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380 (1991)). In concluding that BMS's actions satisfied both criteria, the court stated that BMS had no objective basis that the patent it listed was valid because it knew that the patent did not claim the use of buspirone. *In re Buspirone Antitrust Litigation*, 185 F. Supp. 2d at 376.

219. *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003).

220. *Id.* at 904.

221. *Id.* at 907.

product.²²² In June of 1999, Andrx and HMRI settled the patent dispute for \$50.7 million and Andrx began marketing a reformulated FDA approved product which it maintained did not infringe Cardizem CD's unexpired patents. In total, HMRI paid Andrx \$89.93 million.²²³

The Court of Appeals for the Sixth Circuit addressed the question on interlocutory appeal whether the agreement "constitutes a restraint of trade that is illegal per se under section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1"²²⁴ The court held that the Agreement between HMRI and Andrx was illegal per se because the payments by HMRI to Andrx of \$40 million a year not to enter the market for Cardizem CD and its generic equivalents amounted to a horizontal market allocation agreement that eliminated competition in the market for Cardizem CD throughout the United States.²²⁵ The court refused to consider any pro-competitive effects of the Agreement, following the Supreme Court's reasoning that "[t]he anticompetitive potential inherent in all price-fixing agreements justifies their facial invalidation even if pro-competitive justifications are offered for some."²²⁶

The conclusion reached by the Sixth Circuit that agreements between brand-name and generic manufacturers met with disagreement in the Court of Appeals for the Eleventh Circuit. The case discussed in the next section is based on facts similar to those in the Cardizem CD litigation. The court's analysis, however, is quite different.

3. Valley Drug v. Geneva Pharmaceuticals, Inc.: *Eleventh Circuit Rejects Per Se Analysis for Pharmaceutical Patent Settlements*

In a case involving two patent settlement agreements between a brand-name manufacturer and two generic manufacturers, the Court of Appeals for the Eleventh Circuit held that per se analysis is inappropriate in agreements involving the settlement of patent litigation.²²⁷ The agreements that were the subject of the lawsuit were between the brand-name manufacturer Abbott Laboratories and two generic manufacturers, Zenith Goldline Manufacturers (Zenith) and Geneva Pharmaceuticals (Geneva). Abbott initially sued both Zenith and Geneva following ANDA IV applications for approval of a generic version of Abbott's successful product Hytrin, which is used for treating hypertension and enlarged prostate.²²⁸

The patent for the compound used in Hytrin had expired when Zenith filed its ANDA, but Abbott had other patents for various crystalline forms of the compound as well as various patents on methods of using and preparing the compound. Zenith brought a preliminary injunction suit to get the patents delisted but the suit was not successful and was appealed.²²⁹ On March 31, 1998, Zenith and Abbott entered into an agreement

222. *Id.* at 903.

223. *Id.* at 907.

224. *Cardizem*, 332 F.3d at 900.

225. *Id.* at 908.

226. *Id.* at 909 (citing *Arizona v. Maricopa Cty. Med. Soc.*, 457 U.S. 332, 351 (1982)).

227. *Valley Drug v. Geneva Pharm., Inc.* 344 F.3d 1294 (11th Cir. 2003).

228. Hytrin generated \$540 million in sales for Abbott in 1998 alone. *Valley Drug v. Geneva Pharm., Inc.*, 350 F.3d 1181, 1184 (11th Cir. 2003) (discussing class certification issues).

229. *See Zenith Labs. v. Abbott Labs.*, No. 96-1661, 1997 U.S. Dist. LEXIS 23954 (D.N.J. Oct. 1, 1997) (denying Zenith's motion for a preliminary injunction).

whereby Zenith agreed to dismiss the delisting claims that were on appeal and acknowledge the validity of Abbott's patents and that its proposed product would infringe.²³⁰ Zenith also agreed not to sell or distribute a competing generic product until Abbott's patents expired or until someone else introduced a competing generic product. Zenith agreed not to assist any company in developing a competing product and not to assign any of its rights to potential competitors.²³¹ In exchange for Zenith's acknowledgements and promises, Abbott agreed to pay Zenith \$3 million up front, \$3 million after three months, and \$6 million every three months until March 1, 2000, or until the Agreement otherwise terminated.²³² If another generic manufacturer got FDA approval and successfully went to market with a 180-day exclusivity period, Abbott's payments would be halved until the period expired.²³³

On April 1, 1998, Abbott and Geneva entered into an agreement to settle the patent litigation. Geneva agreed not to sell its generic product until Abbott's patent expired, until another generic manufacturer introduced a competing generic product, or until Geneva got a court decision of non-infringement or invalidity which was final through certiorari to the United States Supreme Court.²³⁴ Geneva also agreed not to sell its rights to a 180-day exclusivity period and agreed to oppose the approval of other ANDAs. In exchange for these promises, Abbott agreed to pay \$4.5 million each month to Geneva until someone else brought a generic version of Hytrin to market or Abbott won on its infringement claims.²³⁵ According to its terms, the Abbott-Geneva agreement terminated on January 10, 2000 when the Supreme Court denied certiorari to review decisions of lower courts which had found the patent was invalid. The agreements terminated even before the date the Supreme Court denied certiorari due to the terms of an FTC consent settlement reached in August of 1999.²³⁶

The district court granted summary judgment to the plaintiffs, finding that the agreements were illegal per se because they were geographic market allocations.²³⁷ According to the district court, Abbott, Geneva, and Zenith were horizontal competitors who conspired to allocate the entire United States market for Hytrin to Abbott. Moreover, the payments received by Zenith and Geneva amounted to participation in the profits of the allocation agreement.²³⁸

The Court of Appeals for the Eleventh Circuit, however, rejected the conclusion that the agreements were illegal per se, stating that the district court failed to consider the exclusionary power of Abbott's patents in its antitrust analysis.²³⁹ Reasoning that an unexpired patent gives its owner the "lawful right to exclude others," the Eleventh Circuit

230. *Valley Drug*, 344 F.3d at 1300.

231. *Id.*

232. *Id.*

233. *Id.*

234. *Id.* The agreement provided that if Geneva prevailed in district court, the \$4.5 million monthly payments would go into escrow pending resolution on appeal.

235. *Valley Drug*, 344 F.3d at 1300.

236. See *In re Abbott Labs.*, No. C-3945, 2000 WL 681848 (May 22, 2000), available at <http://www.ftc.gov/os/2000/05/c3945.do.htm> (last visited Jan. 26, 2005) (outlining the terms of the FTC order).

237. *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1348-49 (S.D. Fla. 2000) (discussing anticompetitive effects and per se illegality of geographic market allocations).

238. See *id.* (outlining the agreement and its anticompetitive effects).

239. See *Valley Drug*, 344 F.3d at 1304-05 (explaining boundaries of the power to exclude).

noted that the Zenith and Geneva agreements were no broader than the potential exclusionary effect of the challenged patent.²⁴⁰ Although the patents that were the subject of the agreements were eventually held to be invalid, the Eleventh Circuit maintained that subsequent invalidity should not be considered in analyzing the antitrust claim. According to the court, unless the plaintiffs had evidence that the patent was procured by fraud or that the defendants knew the patent was invalid, the exclusionary effect of the patent, presumed to be valid at the time of the agreements in question, must be considered.²⁴¹ The court stated that “[e]xposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives.”²⁴² The Court conceded that the size of a payment, a “reverse payment,” or “exit payment,” raises suspicion that parties lacked faith in the patent’s validity, but objected to *per se* antitrust analysis solely on the basis of such payments.²⁴³

In considering the antitrust implications of settlements of pharmaceutical patent litigation, the Eleventh Circuit proposed the following analytic framework that recognizes the patent exception to antitrust liability: (1) Identify protection afforded by the patent and compare to protections afforded by preliminary injunction and stay mechanisms in light of the defendant’s obtaining such protections; (2) Apply traditional antitrust analysis to any provisions of the agreement that go beyond the exclusionary effect of the patent to determine anticompetitive effects; and (3) Identify with specificity which provisions are illegal and the nature of the anticompetitive effects.²⁴⁴ This framework requires a considerably more detailed analysis of the settlement than the *per se* analysis favored by the Court of Appeals for the Sixth Circuit.

VI. SOLVING PROBLEMS ASSOCIATED WITH THE 180-DAY EXCLUSIVITY PERIOD

A. FTC Actions

The FTC has taken an active role in cases involving Hatch-Waxman abuse. Antitrust laws currently provide the best remedy for generic manufacturers or purchasers who claim harm from either improper Orange Book listings or improper agreements that delay the triggering of the 180-day period of market exclusivity. The FTC believes it can ensure efficient operation of the Hatch-Waxman process directly through vigorous enforcement of the antitrust laws.²⁴⁵ The FTC has issued complaints against several

240. *Id.* (citing 35 U.S.C.S. §§ 271(a) & 283 (Law. Co-op. 2003)). See also *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 249 (E.D.N.Y. 2003) (finding agreements not illegal *per se* and stating that “when patents are involved . . . the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is *per se* illegal”).

241. See *Valley Drug*, 344 F.3d at 1306-07. See also H. HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION, ¶1780a (2d ed. 2000) (indicating that antitrust and patent law share the same goal of protecting the public welfare); see also Crane, *supra* note 200, at 748, n.1 (noting the shared common objectives of antitrust and patent law).

242. *Valley Drug*, 344 F.3d at 1308.

243. *Id.* at 1309-11 (explaining that the size of the payments does not mean that they were illegitimate).

244. *Id.* at 1312-13 (describing the appropriate analysis).

245. Prepared Statement of the Federal Trade Commission, Before the Committee on Commerce, Science, and Transportation, United States Senate, Washington, D.C. (April 23, 2002).

companies alleging that they have used negotiation settlements during patent infringement litigation as a pretext for creating agreements that pay off generic manufacturers to delay or refrain from putting a competing drug on the market.²⁴⁶ In evaluating such settlements, the FTC has identified several provisions that may signal that the agreements are anticompetitive. Provisions that provide for reverse payments from the patent holder to the alleged infringer; provisions that restrict the generic manufacturer's ability to enter the market with noninfringing products; and provisions that restrict the generic manufacturer's ability to assign or waive its 180-day marketing exclusivity rights all trigger antitrust scrutiny by the FTC. Two FTC actions, one successful, the other unsuccessful, illustrate how the FTC has proceeded to reign in anticompetitive behavior of pharmaceutical companies in cases involving collusive agreements to delay entry of generic competition.

1. Abbott Laboratories

The FTC alleged that Abbott Labs paid approximately \$4.5 million per month to Geneva Pharmaceuticals to delay the generic version of its branded drug Hytrin, a product used to treat enlarged prostate and hypertension.²⁴⁷ Geneva was the first ANDA applicant to file a Paragraph IV certification and was well-prepared to launch a generic version of its product when it received FDA approval in 1998. Nevertheless, on the very day the FDA granted approval to market its product, Geneva contacted Abbott and announced that it would launch its product unless paid not to do so.²⁴⁸ According to the agreement, Geneva agreed not to enter the market with any generic Hytrin product, including a noninfringing product, until either the patent litigation was resolved, including review through the Supreme Court, or another generic Hytrin manufacturer entered the market. Geneva also agreed not to transfer its 180-day market exclusivity rights.²⁴⁹ As the first ANDA IV filer, Geneva was in a position to hold up FDA approval of subsequent generic filers by failing to trigger the 180-day exclusivity period either by marketing its product or getting a court decision that found the patent invalid or not infringed. For Geneva, the agreement was the "best of all worlds," because it was assured a risk-free payment until the litigation was resolved, while retaining its rights to enjoy the

246. See, e.g., Abbott Laboratories, No. C-3945 at <http://www.ftc.gov/os/2000/05/c3945complaint.htm> (last visited Sept. 16, 2004); Geneva Pharm., Inc., No. C-3946 (alleging restraint of trade in agreement pursuant to which Geneva agreed not to enter the market to compete with Abbott's product Hytrin in exchange for payments of \$4.5 million per month), at <http://www.ftc.gov/os/2000/05/c3946complaint.htm> (last visited Sept. 16, 2004); Hoechst Marion Roussel, Inc., No. 9293 (charging HMRI and Andrx with anticompetitive practices in connection with an agreement in which HMRI paid Andrx \$10 million per quarter to stay out of the Cardizem CD market), at <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm> (last visited Sept. 16, 2004); Schering-Plough Corp., No. 9297 (charging Schering-Plough, Upsher-Smith, and American Home Products with unlawfully agreeing to delay generic entry of competition for Schering's product K-Dur20), at <http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf> (last visited Sept. 16, 2004).

247. See Abbott Laboratories, No. C-3945, at <http://www.ftc.gov/os/05/c3945complaint.htm> (last visited Sept. 16, 2004). According to the complaint, "Abbott estimated Geneva's revenues from launching [its generic product] at \$1 million to \$1.5 million per month, but was willing to pay Geneva a 'premium over that not to compete.'" *Id.*

248. See *id.*

249. See *id.*

180-day market exclusivity period.²⁵⁰ Although the United States District Court for the Northern District of Illinois granted summary judgment to Geneva in the patent infringement suit and the Court of Appeals for the Federal Circuit affirmed, Geneva, pursuant to the agreement, did not begin to market its product.²⁵¹

According to the FTC, “the agreement was not justified by any countervailing efficiency” and the agreement imposed restraints beyond what would have been available in a court-ordered preliminary injunction.²⁵² The agreements prevented Geneva from relinquishing its exclusivity rights and from developing and marketing even noninfringing products. The FTC’s complaint alleged that the agreement was an unreasonable restraint of trade and a conspiracy to monopolize the relevant market in violation of Section Five of the Federal Trade Commission Act.²⁵³ The FTC investigation led to a consent order, which barred the parties from entering into similar agreements in the future. In particular, the order prohibited agreements that would not allow a party to relinquish its right to the 180-day exclusivity period or required the first ANDA IV filer to refrain from marketing or selling a non-infringing product.²⁵⁴

2. Schering-Plough

FTC investigations of anticompetitive behavior are not without significant hurdles. A decision by an administrative law judge involving an action by the FTC against Schering-Plough (Schering) and UpsherSmith (Upsher) illustrates some problems that the FTC might encounter in antitrust actions involving patent settlements.²⁵⁵ In a case similar to that brought against Abbott and Geneva, the FTC alleged that Schering-Plough conspired with two generic manufacturers to keep a generic version of its prescription drug K-Dur 20, a potassium supplement, from entering the market, costing consumers an estimated \$100 million.²⁵⁶ Generic manufacturer Upsher had sought FDA approval to manufacture and distribute a generic version of the drug. Schering sued Upsher for patent infringement but the two companies settled in 1997, with Upsher agreeing not to sell any generic version of Schering’s drug until September 2001, and Schering agreeing to license five drugs from Upsher for \$60 million. The administrative law judge dismissed the FTC’s antitrust complaint, finding that there was insufficient evidence to conclude that the payment involved was for delaying market entry of the generic product. Schering’s patent did not expire until 2006, and the judge found that there was no basis to presume the patent was invalid.²⁵⁷ Furthermore, the court found that the evidence supported a conclusion that the payments from Schering to Upsher were part of an arms length transaction for the licenses to Upsher’s five products.²⁵⁸ Although the FTC viewed

250. *See id.*

251. *See* Abbott Laboratories, No. C-3945, at <http://www.ftc.gov/os/05/c3945complaint.htm> (last visited Sept. 16, 2004).

252. *Id.*

253. *Id.*

254. *Id.*

255. Schering-Plough Corp., No. 9297 (F.T.C. June 27, 2002) (initial decision), at <http://www.ftc.gov/os/adjpro/d9297/020627jd.pdf> (last visited Sept. 16, 2004).

256. *Id.*

257. *Id.*

258. *Id.* Particularly persuasive was the fact that one of the products licensed was a promising cholesterol

the payments by Schering as an inducement to prevent Schering from pursuing approval of its generic version of the drug, the FTC was not able to prove that the payments made by Schering for the five licenses were a sham intended only to keep Upsher off the market.

The Commission, however, overturned the decision of the administrative law judge, finding that the settlement agreement involving payments by Schering constituted unfair competition.²⁵⁹ The opinion states that, “[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.”²⁶⁰ Although the Commission recognized the pro-competitive objectives of patent settlement, it found insufficient evidence to support such a defense.²⁶¹ The Commission disagreed with the conclusions of law and fact in the opinion issued by the administrative law judge. According to the Commission, the evidence indicated that the \$60 million paid to Upsher was not for the licenses but for delay, and, consequently, an impermissible restraint on trade.²⁶²

FTC investigations have most likely already had an impact on the type of agreements that brand-name pharmaceutical companies and their generic competitors enter into. Interim agreements such as the Abbott/Geneva agreement have not surfaced since the FTC began its antitrust investigations in this area in 1999.²⁶³ More creative agreements such as the Schering Plough agreement may be more difficult for the FTC to police.²⁶⁴ Nevertheless, the FTC has demonstrated a strong commitment to ferreting out the motives and consequences of conduct that delay generic entry and cause harm to consumers.

B. FTC Study and Recommendations on the 180-Day Exclusivity Period

The FTC Study recommends that agreements between pharmaceutical companies affecting the marketing of generic drugs be reviewed by the FTC and the Justice Department and that the triggering events for FDA approval and the commencement of the 180-day exclusivity period be modified.²⁶⁵ The FTC also believes that notification of agreements between first generic applicants and brand-name companies to the FTC and the United States Department of Justice would allow early identification of antitrust issues that such agreements might raise.²⁶⁶ Agreements that should be filed include those

lowering drug. Although the product was subsequently abandoned, the evidence indicated that Schering had pursued licensing opportunities for a similar drug and that it hoped to gain experience in the cholesterol lowering market in anticipation of marketing its own cholesterol lowering drug.

259. See *Schering-Plough Corp.*, No. 9297 (F.T.C. Dec. 18, 2003) (opinion of the Commission), at <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf> (last visited Sept. 16, 2004).

260. *Id.* at 26.

261. *Id.*

262. *Id.*

263. See FTC Study, *supra* note 1, at 63.

264. See Crane, *supra* note 200, at 749 (noting that restrictive rules regarding patent infringement settlements may “force patent litigants—often horizontal competitors—into licensing relationships that may impose greater social costs than exit payments”); Robinson, *supra* note 200, at 63 (stating that “the FTC is limited in what it can achieve in the complex area of . . . patent infringement litigation[]”).

265. FTC Study, *supra* note 1.

266. *Id.*

that relate in any way to the 180-day exclusivity period.

The FTC notes that the 180-day exclusivity period gives generic manufacturers an economic incentive to be the first ANDA IV filer and the first to market a generic product alternative.²⁶⁷ During the period of the FTC Study, from 1992 through 2000, the FDA granted 180 days of exclusivity to 31 out of 104 ANDA IV filers.²⁶⁸ Recognizing that the original rules allow first ANDA IV filers to “park” their exclusivity period, thereby blocking FDA approval of subsequent generic applicants, the FTC Study recommends ways to ensure that either the commercial marketing trigger or the court decision trigger will encourage timely marketing of the first FDA approved generic drug product.²⁶⁹

Of the 31 FDA grants of exclusivity covered in the FTC Study, the FTC noted that nineteen of the generic drug products triggered the commencement of the 180-day period by commercial marketing and twelve were triggered by a court decision favorable to the generic applicant.²⁷⁰ ANDA IV filers that are not sued generally begin commercial marketing shortly after FDA approval so that the 180-day period begins to run and the door is open for FDA approval of subsequent generic competitors.²⁷¹ In cases where the first ANDA filer is sued as well as in cases involving settlements or interim agreements, the FTC notes confusion about when the 180-day exclusivity period is triggered. The FTC Study makes three minor recommendations to clarify when the 180-day exclusivity period should be triggered.

First, the FTC recommends legislation to “[c]larify that ‘commercial marketing’ includes the first generic applicant’s marketing of the brand-name product.”²⁷² Some companies enter into agreements whereby the brand-name company supplies the generic applicant with its own product to be marketed as a generic version. If such supply agreements do not trigger the 180 days as a first commercial marketing, subsequent applicants could be delayed indefinitely, especially if the brand-name company does not sue subsequent filers so that no court decision could serve as a trigger.²⁷³

The second minor recommendation the FTC makes is that Congress should “[c]odify that the decision of any court on the same patent being litigated by the first generic applicant constitutes a ‘court decision’ sufficient to start the running of the 180-day exclusivity period.”²⁷⁴ This provision would merely codify the current interpretations of the FDA and the courts.²⁷⁵ The third minor recommendation by the FTC is that legislation should “[c]larify that a court decision dismissing a declaratory judgment action for lack of subject matter jurisdiction constitutes a ‘court decision’ sufficient to trigger the 180-day exclusivity period.”²⁷⁶ Such a provision would support the decision

267. *Id.* at 57.

268. *Id.*

269. *Id.*

270. FTC Study, *supra* note 1, at 58.

271. *Id.* at viii.

272. *Id.* at ix.

273. *Id.* at ix.

274. *Id.* at ix-x.

275. See *Teva Pharm., USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999); *Granutec, Inc. v. Shalala*, 139 F.3d 889 (4th Cir. 1998) (unpublished decision); FDA, *Guidance for Industry: 180-Day Exclusivity under the Hatch-Waxman Amendments to the Federal Food, Drug & Cosmetic Act* (Jun. 1998), available at <http://www.fda.gov/cder/guidance/2576fml.pdf> (last visited Jan. 30, 2004).

276. FTC Study, *supra* note 1, at x.

reached in *Teva Pharmaceutical v. FDA*, in which the court held that a case dismissed for lack of case or controversy satisfies the “court decision” trigger for the 180-day period of exclusivity.²⁷⁷ In *Teva*, the generic challenger sought a declaratory judgment to gain patent certainty before marketing its product because it had not been sued by the brand-name company. The brand-name company had given assurances that it would not sue Teva. According to the FTC, the dismissal in the declaratory judgment action should act as a trigger for the 180 days so that a first ANDA filer such as Teva will bring its product to market quickly once it has assurance through the litigation that no infringement suit will be brought.²⁷⁸

C. The Medicare Act

Title XI of the Medicare Act is largely a response to the FTC Study, although it does not adopt the recommendations wholesale and makes some important changes and additions to the FTC’s recommendations. The Medicare Act follows the FTC recommendation that agreements between brand-name drug companies and generic applicants that affect the manufacturing, marketing, or sale of the brand-name drug or the generic drug that is listed in the ANDA and any agreements that affect the 180-day exclusivity period be filed with the FTC and the United States Department of Justice. The Act requires that such agreements be filed within ten days of execution and before the first commercial marketing of the drug that is the subject of the agreement.²⁷⁹ Agreements between ANDA IV filers that affect the 180-day exclusivity period are subject to this same filing requirement.²⁸⁰ This provision, effective for all agreements executed after January 7, 2004, subjects parties who fail to comply to civil penalties of not more than \$11,000 per day.²⁸¹

The Medicare Act makes significant changes regarding the triggering of the 180-day exclusivity period. The new provisions eliminate the “court decision” trigger altogether, operating instead on a “use it or lose it” premise. Focusing only on the first commercial marketing of the generic product, the Medicare Act requires the first ANDA filer to use the 180-day exclusivity period within certain time constraints or forfeit the period.²⁸² The ANDA applicant must market its product within 75 days after final FDA approval or thirty months after submission of its ANDA, whichever is earlier.²⁸³ But these triggers are superceded in that the exclusivity period will commence 75 days after a court of appeals decision on each patent for which the applicant submitted and “lawfully maintained” a Paragraph IV certification. Under the new provisions, the generic applicant need not launch at risk and will not lose all or a portion of the 180-day exclusivity period

277. 182 F.3d 1003 (D.C. Cir. 1999).

278. The FTC does not consider the case in which a generic manufacturer seeks declaratory judgment on invalidity or noninfringement of a patent and the brand-name manufacturer has not given assurance that it will not sue at a later date.

279. Medicare Act, Pub. L. No. 108-173, §§ 1112-1113, 117 Stat. 2066 (2004). The Act amends Section 505(j) of the Federal, Food, Drug & Cosmetic Act (21 U.S.C.S. 355(j)); see also <http://www.ftc.gov/os/2004/01/040106pharmrules.pdf> (last visited Sept. 16, 2004).

280. *Id.*

281. *Id.* § 1115.

282. 21 U.S.C.S. § 355(j)(5)(D) (Law Co-op. 2004).

283. *Id.*

if it decides to wait for the appellate court's decision. The court decision or order may be the result of any applicant that has received tentative approval or in a declaratory judgment action brought by any ANDA applicant against the patent owner. If a challenged patent is removed from the Orange Book, the first ANDA filer must market its product within 75 days of its removal.²⁸⁴

Under the new provisions, only the first applicant is eligible for the 180-day exclusivity period.²⁸⁵ There may, however, be more than one first ANDA filer eligible for the exclusivity period. If more than one ANDA applicant files on the same day, they share exclusivity and the 180 days begin to run on the first day of marketing by any of the first applicants, so that there is only one 180-day period. This situation must be distinguished from the case in which a later applicant is the first to file on a later-listed patent. In that situation, only the first ANDA applicant is entitled to the exclusivity period and it does not have to share with the later applicant. Subsequent ANDA filers may be eligible for the exclusivity period only if all first ANDA filers withdraw, if all first ANDA filers amend their Paragraph IV certifications, or if all first ANDA filers fail to obtain tentative FDA approval within thirty months of their ANDA filing.²⁸⁶ If the first ANDA applicant enters into an agreement with the innovator or with another applicant that violates the antitrust laws, the first ANDA applicant forfeits its exclusivity period and no one is eligible for the exclusivity period.²⁸⁷

New notice provisions also require that Paragraph IV certifications that are included in amendments or supplements to FDA filings must give simultaneous notice to NDA holders or patent owners even if notice was previously given.²⁸⁸ This provision solves the problem encountered by the United States District Court for the District of Columbia in *Purepac Pharmaceuticals Co. v. Thompson*.²⁸⁹ In *Purepac*, the court upheld an FDA decision that failure to provide simultaneous notice will not result in invalidation of the certification, but will cause the application to be deemed filed for priority purposes on the date the notice was mailed, rather than the date the application was submitted.²⁹⁰

The Medicare Act adopts the FTC's recommendation to interpret the first commercial marketing to include a supply agreement by the NDA holder. The new law states that the 180 days is triggered by the first commercial marketing by the ANDA of either its ANDA product or the NDA product. This provision prevents supply agreements between the brand-name company and a generic competitor from blocking subsequent generic competitors.

VII. DISCUSSION: STRENGTHS AND WEAKNESSES OF THE REVISED ACT

The revisions that the Medicare Act makes to the Hatch-Waxman Act should be successful in curbing the most flagrant abuses that delay market entry of generic competition. The new provisions regarding the thirty-month stay and the 180-day

284. *Id.*

285. Medicare Act, Pub. L. No. 108-173, §§ 1112-1113, 117 Stat. 2066 (2004).

286. *Id.*

287. *Id.*

288. *Id.* at § 1101.

289. 354 F.3d 877 (D.C. Cir. 2004).

290. *See id.* at 888-89.

exclusivity period respond to problems that the courts have encountered and evidence uncovered by the FTC Study. The brand-name pharmaceutical industry, of course, sees the changes as infringing on their rights, while generic manufacturers would have favored legislative proposals that went even further to promote generic competition.

The automatic thirty-month stay that NDA and patent holders are entitled to if they sue an ANDA IV applicant within forty-five days of notice has undoubtedly contributed to delaying market entry of some generic drugs. By limiting the automatic thirty-month stay to one per ANDA, the problems associated with this provision should be greatly alleviated. Supporters of the generic pharmaceutical industry have argued that the thirty-month stay should be abolished altogether, on the grounds that it grants a preliminary injunction to the patentee without judicial review.²⁹¹ Some legislative proposals included a provision that would have abolished the thirty-month stay.²⁹² The brand-name pharmaceutical industry contends that abolishing the thirty-month stay would upset the balance contemplated in Hatch-Waxman, as this provision was part of the balance which recognized the need to protect brand-name companies in light of the advantages abbreviated review granted to generic manufacturers.

Proposals for eliminating the thirty-month stay altogether would most likely have unduly upset the Hatch-Waxman balance. As the FTC Study indicates, this thirty-month period approximates the time it takes the FDA to approve the ANDA.²⁹³ Consequently, eliminating the thirty-month stay would do little to speed market entry of competing generic products, while denying brand-name companies the opportunity to protect unexpired patents.

The Medicare Act recognizes that successive thirty-month stays are the true source of unwarranted delays. The new legislation preserves the additional protection Hatch-Waxman accords to innovators through the automatic thirty-month stay, but limits the Act's protection to those patents listed at the time an ANDA is filed. Patents listed by the NDA or a patent holder after the ANDA is filed do not receive this benefit. Patent infringement suits may, of course, be brought to protect later-listed patents, but the Hatch-Waxman automatic stay will no longer apply to such patents. This new provision discourages what appears to be a trend towards listing any patent, however marginally related to the NDA, with the express purpose of stacking successive thirty month delays. As the case law illustrates, this trend has been made possible by the Orange Book listing system which permits brand-name companies to list patents without accountability or adverse consequence.²⁹⁴

Recognizing that the FDA's role as a gatekeeper for the listing of specious patents is limited, the Medicare Act encourages the FDA to do more to ensure the proper listing of

291. See Presentation to the United States Senate Commerce Committee (April 23, 2002), *Drug Pricing & Consumer Costs* (statement of Kathleen D. Jaeger, R.Ph., J.D., President & CEO, Generic Pharmaceutical Association).

292. In 2001, the Senate passed a bill to amend Hatch-Waxman. S.812, 107th Cong. (2001). The bill did not survive in the House of Representatives. H.R. 1862, 107th Cong. (2001). The Drug Price Competition Act of 2001 was also proposed. For a discussion of the proposed legislation, see Holly Soehnge, Ph.D., *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD DRUG L.J. 51, 78-79 (2003).

293. See FTC Study, *supra* note 1, at 39.

294. See Mahn, *supra* note 128 and discussion in Part III.B.

patents in the Orange Book. Furthermore, new FDA rules prohibit listing the several categories of patents that have been involved in cases alleging improper Orange Book listing and successive thirty-month stays.²⁹⁵ Although the courts have described the FDA's role in listing patents as purely ministerial, there is some evidence that the courts will require more FDA scrutiny of Orange Book listings. Courts have recognized that an ANDA applicant may bring an APA action against the FDA and, in one case, held that the FDA acted "arbitrarily and capriciously" in its treatment of an ANDA applicant where the FDA had listed a method of use patent that was not for an FDA approved use.²⁹⁶

Limiting the thirty-month stay could have had the unintended consequence of discouraging listings, leaving the ANDA applicant unable to notify under Hatch-Waxman provisions and launching its product with the threat of unforeseen infringement suits.²⁹⁷ Moreover, if a patent that claimed an NDA drug product were not listed, the ANDA would not be able to make a Paragraph IV certification, with the consequence that there could not be a 180-day exclusivity period, as an ANDA applicant must file a Paragraph IV certification to be eligible for the exclusivity reward. Because courts have recognized that the FDA does not have the power, the resources, or the expertise to compel or remove listings in the Orange Book, the provisions in the Medicare Act that compel the timely listing of patents claiming an NDA are essential to ensuring the smooth running of the ANDA approval process.

The provisions of the Medicare Act anticipated the consequences of limiting the thirty-month stay to one per ANDA applicant. The law requires NDAs to register all patents claiming the product within thirty days of FDA approval. Patents that have not been granted at the time the product is approved by the FDA must be filed within thirty days of patent approval. An NDA holder or patentee is barred from bringing a patent infringement suit based on a patent that has not been timely filed. Thus, the ANDA applicant now has increased assurance that FDA approval and commercial marketing of its product will not be delayed by late-listed patents. Although late-listed patents may still be the subject of patent infringement suits, the provisions of the Medicare Act that compel their listing allow the generic competitor to make informed decisions about launching its product. In addition to the protection that the revised Act provides, brand-name pharmaceutical companies are more likely to institute patent infringement suits before commercial marketing of the generic competitor because the generic competitor may be unable to satisfy damages the brand-name company would be entitled to if it prevailed in the infringement suit.

Delays caused by the 180-day exclusivity period should be greatly reduced as a result of revisions to Hatch-Waxman. The new law is much more specific with regard to what triggers the commencement of the exclusivity period and which ANDA applicants

295. 21 C.F.R. § 314.53(b) (2004). *But see* Robinson, *supra* note 200, at 78 (stating that the new system is unduly burdensome and that the new listing requirements may prevent legitimate product packaging patents from being listed).

296. *See* Purepac Pharm. Co. v. Thompson, 238 F. Supp. 2d 191 (D.D.C. 2002), *aff'd* Purepac Pharm. Co. v. Torpharm, Inc., 354 F.3d 877 (D.C. Cir. 2004) (holding that a manufacturer could properly certify that a method patent, listed in the Orange Book to treat "neurogenerative diseases," was not claiming use when it sought to market the drug).

297. *See* Robinson, *supra* note 200, at 78.

are entitled to its benefit. The reworking of the 180-day exclusivity provisions is intended to prevent the “parking” of this benefit, so that the first generic competitor is required to begin commercial marketing. Furthermore, the provisions seek to remove incentives for the eligible ANDA applicant to “park” its exclusivity period, a practice which delays the entry of subsequent generic competitors. Thus, the triggering and forfeiture events are precisely defined.

The Medicare Act’s removal of the “court decision” trigger for the 180-day exclusivity period should encourage earlier marketing of approved FDA generic products. The revised Act allows the first ANDA filer to wait for a court decision, including the decision of an appellate court, before launching its product. Thus, the first ANDA filer is allowed to enjoy the full benefit of its 180-day exclusivity period without risking an adverse outcome in the litigation. An ANDA applicant eligible for the exclusivity period is unlikely to delay its commercial marketing unnecessarily, however, as the law makes it clear that a court decision regarding the patent in dispute may be obtained by subsequent ANDA applicants as well. The FTC Study indicates that even when previous interpretations of Hatch-Waxman provisions allowed first ANDA filers to wait for a final, unappealable decision to trigger the 180-day period, some chose to begin commercial marketing after the district court decision.²⁹⁸ In the five cases where first ANDA filers opted to trigger the 180-day exclusivity period through commercial marketing rather than waiting for a court decision trigger, all five ANDA applicants prevailed on appeal.²⁹⁹ Abandoning the interpretation that a district court decision triggers the 180-day exclusivity period also prevents ANDA applicants eligible for the 180-day exclusivity period from losing part or all of this valuable period. The FTC Study reports two cases in which a district court decision triggered the 180-day exclusivity period.³⁰⁰ In these cases, the ANDA applicant had not yet received final FDA approval; consequently, one applicant lost 21 days of exclusivity while the other lost 120 days.³⁰¹

Although earlier proposals for revising Hatch-Waxman included a private cause of action for delisting patents from the Orange Book, the Medicare Act provides that a cause of action for delisting a patent may be allowed only as a counterclaim in a patent infringement suit.³⁰² Despite this limitation, problems related to improper listings should decrease with new FDA filing requirements as well as the limitation on thirty-month stays. The case law illustrates that claims seeking delisting are usually related to later-listed patents that trigger successive thirty-month stays.³⁰³ This provision may, at least, allow more expeditious resolution of patent infringement suits. The law makes it clear that the generic applicant may not recover any damages in a counterclaim for delisting.³⁰⁴ Nevertheless, this provision does not affect a generic applicant’s ability to

298. FTC Study, *supra* note 1, at 61.

299. *Id.*

300. *Id.*

301. *Id.*

302. Medicare Act, *supra* note 2, § 1101.

303. See, e.g., *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003) (stating that nine patents were listed following the ANDA filing, each requiring additional certifications; four triggered infringement suits and four additional thirty-month stays).

304. See Medicare Act, *supra* note 2, § 1101.

collect antitrust damages for an improper Orange Book listing.³⁰⁵

The new law allows the patent holder to seek patent certainty through an action for declaratory judgment, provided neither the NDA holder or patent owner files an infringement suit. This provision may have little impact. Only in cases where the NDA holder and the patent owner have given assurances that would estop them from later bringing an infringement suit would this action be worthwhile. Generic applicants may have difficulty seeking patent certainty in a declaratory judgment action because the case may be dismissed for failing to state an actual case or controversy.³⁰⁶ Nevertheless, the Conference Agreement for the Medicare Act states that courts should use the new declaratory judgment provision to prevent improper delays of generic entry. According to the Conference Agreement, courts should determine whether a reasonable apprehension of suit exists when an ANDA IV has been filed and the patentee has not brought an infringement suit within forty-five days of notification.³⁰⁷

VIII. CONCLUSION

Although Hatch-Waxman has been largely successful in its goals of encouraging generic competition and reducing the cost of prescription drugs, loopholes in the Act allowed both brand-name and generic companies to use certain provisions in the law and regulations to delay generic competition. Responding to problems raised in court decisions and an extensive FTC Study, the Medicare Act amends those provisions of Hatch-Waxman which contributed to the most costly delays, without trespassing on the rights of patentees. Successive thirty-month stays, made possible by specious patent listings in the FDA's Orange Book, subjected generic applicants to long and often unnecessary delays in marketing competing generic drugs. The new law alleviates this problem by limiting the thirty-month stay to one per ANDA applicant. Delays associated with improper Orange Book listings should also be reduced due to new FDA rules that require additional screening procedures to ensure that only patents properly within the scope of the legislation are listed.

Abuse of the 180-day exclusivity period awarded to the first ANDA filer that challenges a patent as invalid or not infringed by its generic product has been largely deterred by provisions that require the commercial marketing of the generic product within a specific time frame. The confusing "court decision" trigger for this period has been eliminated. The new provisions make it clear that the incentive associated with the 180-day exclusivity period is tied to bringing the generic product to market as soon as is reasonably possible.

Antitrust issues remain an important issue in the context of pharmaceutical patent disputes. Collusive agreements between brand-name and generic companies, as well as those between two or more generic manufacturers, should be halted by the new provision that all such agreements must be filed with the FTC and the United States Department of Justice. Some patent settlement agreements, as well as licensing agreements, may be

305. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Conference Agreement (2003) (noting that Congress intended not to limit recovery of "anti-trust or any other damages" for improper Orange Book listing), available at <http://world.std.com/~goldberg/hr1confpt.html> (last visited Jan. 16, 2004).

306. See *supra* note 185 and accompanying text.

307. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, *supra* note 305.

more difficult for the government to police. Private antitrust litigation remains an important remedy for both companies and consumers who claim that improper Orange Book listings or agreements that manipulate the 180-day exclusivity period operate as an illegal restraint on trade. Plaintiffs in such cases have overcome hurdles such as proving antitrust injury and defending against claims that the *Noerr-Pennington* doctrine immunizes defendants from suit. The Circuit Courts of Appeal have disagreed, however, on whether per se analysis is appropriate in the context of pharmaceutical patent litigation.

The complexity of the Hatch-Waxman regulatory scheme will inevitably invite creative methods of advancing the different interests of brand-name and generic manufacturers. The revisions of the Medicare Act, however, clearly target the areas that are likely to be manipulated and their clarity and intent should provide guidance to the courts where there is need for further interpretation.