

DIGITAL ACCESS TO SCHOLARSHIP AT HARVARD
DASH.HARVARD.EDU

HARVARD LIBRARY


The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond

Citation

Colleen Kelly, The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond (April 2011).

Link

http://nrs.harvard.edu/urn-3:HUL.InstRepos:8965629

Terms of use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material (LAA), as set forth at

https://harvardwiki.atlassian.net/wiki/external/NGY5NDE4ZjgzNTc5NDQzMGIzZWZhMGFlOWI2M2EwYTg

Accessibility

https://accessibility.huit.harvard.edu/digital-accessibility-policy

Share Your Story

The Harvard community has made this article openly available.
Please share how this access benefits you. Submit a story

The Balance Between Innovation and Competition:

The Hatch-Waxman Act, the 2003 Amendments, and Beyond

Colleen Kelly

Harvard Law School

Class of 2011

April 2011

This paper is submitted in satisfaction of both the course requirement and the third year written work requirement.

Abstract

In 1984, Congress passed the Hatch-Waxman Act, a landmark statute designed both to encourage innovation by pioneer drug companies and to increase competition by generic drug companies. After the enactment of the Act, scholars, industry members, and federal agencies, including FDA and the FTC, noted that both innovator and generic companies engaged in strategic behavior attempting to "game" the regulatory regime to their respective economic advantage. In 2003, FDA promulgated a final rule and Congress passed the Medicare Modernization Act, amending the Hatch-Waxman Act. Both the regulatory and statutory changes attempted to address the loopholes in the statutory structure, provide clarity to the Hatch-Waxman framework, and achieve the balance between innovation and competition.

This paper provides a comprehensive look at the 2003 statutory and regulatory changes, examining the issues that the 2003 amendments definitively resolved and analyzing the outstanding issues and the unintended consequences of these changes. First, the paper analyzes the history, goals, and provisions of the original Hatch-Waxman Act and the issues that arose after its enactment. Second, the paper discusses the passage of the 2003 FDA final rule and the 2003 Medicare Modernization Act, which were designed to settle some of these issues. Next, this paper demonstrates that although the 2003 amendments may have definitively resolved some preexisting disputes between drug companies, the amendments did not resolve all interpretive issues of the Hatch-Waxman Act and have even led to unintended consequences and further disputes between drug companies. In particular, this paper discusses several areas of current controversy, including the effect of patent delisting and patent expiration on 180-day exclusivity, the interpretation of the patent delisting counterclaim provision, the application of the declaratory judgment action provision, the legality of patent settlement agreements, and the appropriateness of authorized generics. Finally, this paper assesses the potential for future reform of the Hatch-Waxman Act, including several proposed avenues to address current disputes. This paper concludes that maintaining Hatch-Waxman's balance between promoting innovation and increasing generic competition has been and will likely remain a daunting task for legislators and regulators in the future.

TABLE OF CONTENTS

I. Introduction 1
II. The Hatch-Waxman Act of 1984 5
A. Background and History of Drug Regulation 5
B. Provisions of the Hatch-Waxman Act 9
III. Successes and Controversies Stemming from the Hatch-Waxman Act 17
A. The Achievement of Increased Generic Drug Competition 17
B. Controversies Arising Out of the Hatch-Waxman Act 19
1. Patent Listing and the Thirty-Month Stay Provision 20
2. 180-Day Exclusivity and Patent Settlement Agreements 24
IV. The 2003 Amendments: FDA's Final Rule and the Medicare Modernization Act 29
A. 2003 FDA Regulation 30
B. Legislative Background 34
C. Medicare Modernization Act of 2003 41
D. Issues Definitively Resolved by the 2003 FDA Final Rule and the 2003 MMA 50
V. Recent Hatch-Waxman Controversies after the Enactment of the MMA 52
A. The Effect of Patent Delisting on 180-Day Exclusivity 54
1. Background on Patent Delisting 56
2. *Teva v. Sebelius* 58
3. Reaction to *Teva v. Sebelius* 61
B. The Effect of Patent Expiration on 180-Day Exclusivity 62
1. FDA's Decision Letter on the Expiration of Merck's '075 Patent 62
2. Aftermath of FDA's Decision Letter 64
C. Patent Delisting Counterclaim Provision 65
1. *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.* 65
2. Aftermath of *Novo Nordisk* 71
D. Declaratory Judgment Actions 73
1. *Teva Pharmaceuticals, USA, Inc. v. Pfizer, Inc.* 74
2. *MedImmune, Inc. v. Genentech, Inc.* 75
3. Recent Court Decisions: Covenants Not to Sue 77
E. Patent Settlement Agreements 81
1. Scholarly Debate over Patent Settlement Agreements 83
2. The FTC's Position 85
3. Recent Litigation in the Courts 86
4. The Failure to Market Provision and Patent Settlement Agreements 87
5. *Arkansas Carpenters Health and Welfare Fund v. Bayer AG* 88
F. Authorized Generic Drugs 91
1. The Position of FDA and the Courts 93
2. The Position of Generic Drug Companies and Other Scholars 95
3. Legislative Action 97
4. The FTC Study 98
VI. Avenues for Future Reform 100
A. Authorized Generics 100
B. Patent Settlement Agreements 103
C. 180-Day Exclusivity Provision 105

D. Failure to Market Forfeiture Provision 106
E. Innovation 107
VII. Conclusion 109

I. Introduction

> "FDA has tried to maintain a balance between protecting innovation in drug development and in expediting the approval of lower-cost generic drugs. . . . But let me say that there is no way, through rulemaking or through legislation, to avoid all opportunities for gaming. . . . [T]here are unforeseen circumstances and unintended consequences."[1]
>
> -- Daniel E. Troy, Chief Counsel of FDA, 2003

In September 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984,[2] the landmark legislation commonly known as the Hatch-Waxman Act. The Act was a compromise designed to balance the competing interests of research-based pharmaceutical companies ("innovators" or "pioneers") and generic drug manufacturers ("generics"). On the one hand, the Act was designed to encourage innovators to continue investing in the research and development of new drugs, and on the other hand, the Act was intended to increase generic drug competition in the pharmaceutical drug market, thereby lowering drug prices and consumer costs for drugs.

The Hatch-Waxman Act "effectively created the modern generic pharmaceutical industry."[3] In amending the Federal Food, Drug, and Cosmetic Act[4] (FD&C Act), the Hatch-Waxman Act created a complex regulatory scheme governing the approval of generic drugs by the Food and Drug Administration ("FDA"). The Act provides for an Abbreviated New Drug

---

[1] *Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace*: *Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 8, 14 (2003) [hereinafter 2003 Hearing] (statement of Daniel E. Troy, Chief Counsel, FDA).

[2] Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360 (cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

[3] Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 175 (2008).

[4] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. § 301 *et seq.*).

Application ("ANDA") process for generic drug manufacturers.[5] Instead of having to submit lengthy preclinical and clinical data demonstrating the drug's safety and efficacy to FDA, like that required in an innovator's New Drug Application ("NDA"), the only scientific data that a generic manufacturer must submit to FDA is data that the drug is "bioequivalent" to the pioneer drug.[6] Congress designed this ANDA process "to make available more low cost generic drugs"[7] to American consumers. This goal has arguably been achieved given the explosion in the growth of the generic drug industry since the passage of the Act. Today, seven out of 10 prescriptions in the United States are for generic drugs.[8] As of 2007, of the 12,751 listed drugs in the Orange Book,[9] 10,072 of the listed drugs have generic counterparts.[10] In 2007, brand pharmaceutical sales totaled $228 billion, while generic pharmaceutical sales totaled $58.5 billion.[11]

The other goal of the Hatch-Waxman Act was to encourage research-based companies to continue investing in the research and development of new drugs to cure or ameliorate medical problems – also a very important goal to American consumers. The lengthy FDA premarket approval process was substantially decreasing the effective life of a drug

---

[5] *See* 21 U.S.C. § 355(j). The Act also provides for an alternative route of generic drug approval through the submission of a "paper NDA," now commonly called a section 505(b)(2) NDA. *See* 21 U.S.C. § 355(b)(2). As most generic drugs are approved through the ANDA process, this paper will focus on the ANDA approval process.

[6] *See* 21 U.S.C. § 355(j)(2)(A)(iv).

[7] H.R. REP. No. 98-857, pt. 1, at 14 (1984). The House Report also stated, "The availability of generic versions of pioneer drugs approved after 1962 would save American consumers $920 million over the next 12 years." *Id.* at 17.

[8] Susan Okie, *Multinational Medicines–Ensuring Drug Quality in an Era of Global Manufacturing*, 361 NEW ENG. J. MED. 737, 738 (2009).

[9] The Orange Book makes publicly available a list of all FDA-approved drugs. *See* FDA, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

[10] *See* Generic Pharmaceutical Association (GPhA), Facts at a Glance, http://www.gphaonline.org/about-gpha/about-generics/facts.

[11] *Id.*

patent,[12] thus discouraging pioneer companies' incentives to innovate. In order to restore patent protection and encourage innovation, the Act provides that FDA may not approve an ANDA until all patent protection and market exclusivity periods have expired.[13] Additionally, the Act provides for patent term extension for drugs that were subject to regulatory review before the drug's commercial marketing.[14] The concern over the "erosion in pharmaceutical innovation"[15] is all the more present today, given the high costs of research and the long length of regulatory review. "On average, it now takes 10 to 15 years to develop a new chemical entity (NCE) new drug."[16] Additionally, only 5 of 5,000 chemicals that begin preclinical testing are approved by FDA, and "an approved NDA today costs well over $1 billion."[17]

The Hatch-Waxman Act was a carefully constructed piece of legislation designed to achieve this fine balance between the interests of generic and pioneer drug companies. However, as one commentator predicted, given that the "Act is lengthy and complex . . . [n]o doubt many controversies will arise over FDA's interpretations and implementation of the statute."[18] This prediction turned out to be true, as much controversy and litigation arose in the years after the Act's passage, with many commentators noting that both innovator and generic

---

[12] Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 301 (1985).

[13] *See* Peter Barton Hutt, *Landmark Pharmaceutical Law Enacted*, 1 HEALTH SCAN, No. 3 (1984).

[14] *See* 35 U.S.C. § 156.

[15] Flannery & Hutt, *supra* note 12, at 301.

[16] PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 577 (3d ed., Foundation Press 2007).

[17] *Id.*

[18] Flannery & Hutt, *supra* note 12, at 271.

drug companies were trying to "game" specific Hatch-Waxman provisions to their benefit,[19] at times with anticompetitive effects.[20] To provide clarity to the Hatch-Waxman process and to decrease the drug companies' strategic behavior, both FDA and Congress made significant amendments to the Hatch-Waxman scheme in 2003. This paper provides a comprehensive overview of the changes made in FDA's 2003 regulation and Congress's Medicare Modernization Act of 2003 ("MMA"). This paper identifies the issues that the 2003 amendments definitively resolved and identifies the unintended consequences and new controversies that have arisen since the 2003 changes. These new problems illustrate that achieving the balance originally struck by the Act may be a continually daunting task for both Congress and FDA.

This paper proceeds in five parts. Part II provides a brief overview of the history and goals of the original Hatch-Waxman Act and then discusses the specific provisions of the Act. Part III identifies controversies stemming from the Hatch-Waxman Act that arose prior to 2003. Part IV describes FDA's promulgation of a final rule in 2003 and then discusses the legislative history and particular provisions of the 2003 MMA that amended the Hatch-Waxman Act. This part also identifies the issues that the MMA and FDA final rule definitively resolved. Part V identifies both the new controversies that arose between drug companies as a result of the 2003 MMA and the issues that the statutory amendments left outstanding. This part discusses six of the unresolved issues regarding the Hatch-Waxman Act: (1) patent delisting and its effect

---

[19] *See generally* Matthew Avery, *supra* note 3; Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA – J.L. & Tech. 164 (2004); Ankur N. Patel, *Delayed Access to Generic Medicine: A Comment on the Hatch-Waxman Act and the "Approval Bottleneck,"* 78 FORDHAM L. REV. 1075, 1109 (2009).

[20] *See generally* Federal Trade Commission, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (July 2002) [hereinafter FTC Study], *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

on 180-day exclusivity; (2) patent expiration and its effect on 180-day exclusivity; (3) the patent delisting counterclaim provision; (4) generic companies' declaratory judgment actions; (5) patent settlement agreements; and (6) authorized generics. Part VI identifies possible solutions and reforms to the Hatch-Waxman Act that might ameliorate current disputes.

II. The Hatch-Waxman Act of 1984

In order to provide context, section A provides a concise background and history of drug regulation in the United States prior to the passage of the Hatch-Waxman Act. Section B presents an overview of the main provisions of the Hatch-Waxman Act and their effect on the new and generic drug approval process.

A. Background and History of Drug Regulation

In 1906, Congress passed the Pure Food and Drugs Act,[21] which did not mandate a federal premarket approval or notification system for new drugs.[22] However, in 1938, Congress replaced the 1906 Act with the Federal Food, Drug, and Cosmetic Act[23] ("FD&C Act"). The FD&C Act established a premarket notification process, in which a pioneer drug manufacturer must submit to FDA safety data of its drug in a new drug application ("NDA"). Under the FD&C Act, FDA now performed a gatekeeping role, as the Act "authorized FDA to prevent marketing if the safety testing did not demonstrate the safety of the new drug."[24] If the FDA did not reject the NDA within 60 days, the pioneer drug manufacturer was free to market the drug.[25] FDA designated some pioneer drugs as generally recognized as safe "old drugs"

---

[21] 34 Stat. 768 (1906).

[22] Flannery & Hutt, *supra* note 12, at 272.

[23] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. § 301 *et seq.*).

[24] Flannery & Hutt, *supra* note 12, at 272.

[25] HUTT, MERRILL & GROSSMAN, *supra* note 16, at 577.

between 1938 and 1962, and allowed generic versions of these drugs to be marketed without having generic companies submit NDAs for the drugs.[26]

In 1962, Congress passed the Drug Amendments of 1962,[27] which immensely strengthened FDA's regulatory authority. The amendments fundamentally altered the drug review process from a simple premarket notification system to a more complex premarket approval system.[28] Under the amendments, a pioneer drug manufacturer must submit to FDA its own preclinical and clinical data demonstrating the drug's safety and efficacy and then must receive FDA's affirmative approval of the NDA before marketing its drug.[29] For FDA, with this new authority came great responsibility. As Richard Merrill stated, "FDA is believed to have a different role, a responsibility to prevent harm before it occurs. . . . FDA is repeatedly reminded, and often reminds us, that it shares responsibility for any drug that causes harm."[30]

After the passage of the 1962 Amendments, FDA adopted several different procedures for the approval of generic copies of pioneer drugs. For pre-1962 pioneer drugs that FDA found to be safe and effective under its Drug Efficacy Study Implementation ("DESI") program,[31] FDA created an abbreviated new drug application ("ANDA") process whereby a generic company need only submit bioavailability and bioequivalence data demonstrating that its generic drug is as safe and effective as the pioneer drug.[32] For post-1962 pioneer drugs, generic drug manufacturers were required to submit a full NDA, including clinical data demonstrating

---

[26] 40 Fed. Reg. 26,142 (1975).

[27] Pub. L. No. 87-781, 76 Stat. 780 (1962).

[28] *See* Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753 (1996).

[29] *Id.*

[30] *Id.*

[31] *See* Flannery & Hutt, *supra* note 12, at 273.

[32] 21 C.F.R. § 314.2*; see also* Flannery & Hutt, *supra* note 12, at 274, 277.

the drug's safety and efficacy. FDA then established a "paper NDA" process for generic versions of both pre-1962 and post-1962 pioneer drugs in 1980. "A paper NDA is a full NDA and must satisfy all of the same requirements as a pioneer NDA;"[33] however, a generic manufacturer could demonstrate the safety and effectiveness of a drug by pointing to published scientific literature, instead of conducting its own clinical trials.[34] In 1983, FDA then proposed a regulation to the Department of Health and Human Services ("HHS") that would create an ANDA process for post-1962 prescription drugs.[35] The generic drug manufacturers filed a lawsuit asking the court to compel FDA to create this ANDA process for post-1962 new drugs.[36] Ultimately, the case was dismissed with the enactment of the Hatch-Waxman Act,[37] which superseded all of FDA's prior regulations and proposals regarding the approval of generic drugs.[38]

The Hatch-Waxman Act "resolve[d] fifteen years of controversy about FDA's policies and procedures governing the marketing approval for generic drugs."[39] The title of the Act, The Drug Price Competition and Patent Term Restoration Act of 1984, reveals Congress's twin purposes in passing the Act. The Act was designed as a compromise to accommodate the opposing interests of innovator companies and generic companies. The Act was designed to "strike a balance between two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug

---

[33] Flannery & Hutt, *supra* note 12, at 277.

[34] 45 Fed. Reg. 82,052 (1980); 46 Fed. Reg. 27,396 (1981); *see also* Flannery & Hutt, *supra* note 12, at 275.

[35] *See* Flannery & Hutt, *supra* note 12, at 276.

[36] Nat'l Ass'n of Pharm. Mfrs., Inc. v. Heckler, 83 Civ. 4817 (WCC) (S.D.N.Y.).

[37] *See* Flannery & Hutt, *supra* note 12, at 276.

[38] HUTT, MERRILL & GROSSMAN, *supra* note 16, at 759.

[39] *See* Flannery & Hutt, *supra* note 12, at 271.

products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."[40]

The legislative history of the Act, although "relatively sparse,"[41] provides some insight into Congress's dual motivations in passing the Act. On June 21, 1984, the House Committee on Energy and Commerce issued a Report that analyzed the ANDA process and patent term restoration features of the Act.[42] First, with regard to the ANDA procedure, Congress aimed to increase generic drug entry into the pharmaceutical market in order to drive down drug prices and consumer drug costs. The House Report noted that it was not beneficial or efficient for generic drug manufacturers to submit full NDAs, which must include their own human clinical studies, for post-1962 drugs. The Report declared that "FDA considers such retesting to be unnecessary and wasteful because the drug has already been determined to be safe and effective. Moreover, such retesting is unethical because it requires that some sick patients take placebos and be denied treatment known to be effective."[43] Additionally, the Report recited the fact that 150 post-1962 pioneer drugs were on the market, off-patent, and with no generic equivalent, [44] thus illustrating the need for a streamlined process to increase the number of generic drugs on the market. Furthermore, the House Report stated, "The availability of generic versions of pioneer drugs approved after 1962 would save American consumers $920 million

[40] aaiPharma Inc. v. Thompson, 296 F.3d 227, 230 (4th Cir. 2002).

[41] Flannery & Hutt, *supra* note 12, at 271. For instance, the Senate did not issue a report. *Id.*

[42] H.R. REP. No. 98-857, pt. 1 (1984).

[43] *Id.* at 16.

[44] *Id.* at 17.

over the next 12 years."[45] Not only would the Act save American consumers a significant amount of money, but state and national governments would benefit greatly in cost savings.[46]

Second, the House Report provided insight into Congress's goal of increasing the incentives for research-based companies to innovate and develop new drugs. The House Report asserted that "[t]he incentive is the restoration of some of the time lost on patent life while the product is awaiting pre-market approval. Under current law, a patent continues to run while the maker of the product is testing and awaiting approval to market it."[47] The Report noted the testimony from pharmaceutical company representatives that said that although the patent term was 17 years,[48] the effective patent term was much less than that, given the research trials and regulatory review process.[49] Thus, in order to stem the reduction in the effective patent term for drug products, Congress adopted the patent term restoration feature of the Act.

B. Provisions of the Hatch-Waxman Act

The Hatch-Waxman Act revised section 505 of the FD&C Act, which regulates the approval of new drugs, and added section 505(j) to the FD&C Act, which established the

---

[45] *Id.*

[46] *Id.*

[47] *Id.* at 15.

[48] In 1994, Congress extended the length of the patent term to 20 years from the date of patent filing. *See* Uruguay Round Agreements Act, 108 Stat. 4809 (codified at 35 U.S.C. § 156) (1994).

[49] H.R. REP. No. 98-857, pt. 1, at 17. In 1980, the House Subcommittee on Science, Research, and Technology issued a Report stating that it takes seven to thirteen years for a pioneer drug manufacturer to undergo the research and clinical testing and NDA approval process mandated by FDA. *See* THE FOOD AND DRUG ADMINISTRATION'S PROCESS FOR APPROVING NEW DRUGS, REPORT BY THE SUBCOMM. ON SCIENCE, RESEARCH, AND TECHNOLOGY, 96th Cong. 2d Sess. (1980). Thus, the effective patent life is "less than half the seventeen years" provided under patent law. Flannery & Hutt, *supra* note 12, at 30.

ANDA approval process for generic drugs.[50] The Hatch-Waxman Act also amended the Patent Act in several respects.

The Hatch-Waxman Act amended section 505(b) of the FD&C Act, which determines the information that a pioneer manufacturer must submit to FDA in its NDA for the approval of its new drug.[51] As mentioned in the previous section, the NDA is a lengthy document, which must include animal and human studies showing the drug's safety and effectiveness. Submitting an NDA takes much time and expense: "[d]evelopment of the average NCE ANDA drug takes some 15 years from preclinical research through NDA approval and costs in excess of $1.5 billion."[52] Under revised section 505(b), an innovator company must also provide to FDA "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."[53]

This revision of section 505(b) was made pursuant to Hatch-Waxman's addition of new section 505(j), specifically section 505(j)(7). Section 505(j)(7) mandated that FDA publish a publicly available list of all FDA-approved drugs,[54] with each drug listing containing the patent listings claiming the drug or its method of use. The list of approved drugs must contain those approved by full NDAs, paper NDAs, and ANDAs.[55] One purpose of this public

---

[50] 21 U.S.C § 355(j).

[51] *See* 21 U.S.C. § 355(b).

[52] HUTT, MERRILL & GROSSMAN, *supra* note 16, at 764 n.6.

[53] 21 U.S.C. § 355(b)(1).

[54] FDA-approved NDA drugs are known as "listed drugs" under the statute. *See* 21 U.S.C. § 355(j)(2)(A)(i).

[55] *See* Flannery & Hutt, *supra* note 12, at 293.

listing of approved drugs was for generic companies to "identify[] drugs eligible for abbreviated NDAs."[56] Pursuant to this section, FDA created the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, commonly known as the Orange Book.[57] Along with a list of approved drugs, the Orange Book also contains "an evaluation of the therapeutic equivalence of the [generic] drug products."[58] A therapeutic equivalence rating of "A" in the Orange Book means that FDA considers the drug to be therapeutically equivalent, while a therapeutic equivalence rating of "B" means that FDA finds bioequivalence problems with the drug.[59] In accordance with the statute, FDA must update the list every thirty days with newly approved drugs and with revised patent information.[60]

In the Hatch-Waxman Act, Congress created two options for generic companies to gain approval of their generic versions of pioneer drugs. The Act retained FDA's distinction between an ANDA and a paper NDA. Thus, a generic company can file an ANDA with FDA under section 505(j),[61] or it can file a paper NDA under section 505(b)(2).[62] As most generic

---

[56] *See* HUTT, MERRILL, & GROSSMAN, *supra* note 16, at 757.

[57] The publication was called the "Orange Book" because of the color of its cover. *See* 68 Fed. Reg. 36,676 (June 18, 2003). The Orange Book is now electronic and can be found on FDA's website. *See* FDA, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

[58] *See* HUTT, MERRILL, & GROSSMAN, *supra* note 16, at 757.

[59] *See id.*

[60] *See* Flannery & Hutt, *supra* note 12, at 293.

[61] An ANDA can be submitted to FDA under two circumstances. First, where the generic drug is the "same" as the pioneer drug "in all material respects," the generic drug manufacturer can submit an ANDA directly to FDA. HUTT, MERRILL, & GROSSMAN, *supra* note 16, at 760. Second, where the generic drug is "different' from the innovator drug in a material respect, the generic drug manufacturer must submit a "suitability petition" to FDA, "demonstrating that the difference between the drugs is not sufficient to preclude an abbreviated NDA, and that additional studies to show safety and effectiveness are not needed." *Id.* If FDA grants the suitability petition, the generic manufacturer can submit the ANDA, but if FDA does not grant the petition, the generic manufacturer must submit a full NDA or a section 505(b)(2) NDA. *Id.*

manufacturers have utilized the ANDA process and the ANDA process is central to this paper's analyses in the sections below, only the ANDA process will be described in detail.[63] Congress created the ANDA process to streamline the generic drug approval process for generic drug manufacturers.[64] The Act states that "[a]ny person may file with the Secretary an abbreviated application for the approval of a new drug."[65] Under this process, instead of having to supply FDA with clinical data demonstrating the safety and effectiveness of the drug, the only scientific study that generic manufacturers need to submit to FDA is one demonstrating that the generic drug is "bioequivalent" to the listed drug.[66] Additionally, in an ANDA, the generic manufacturer must include information to show that: (1) the active ingredient of the generic drug is the same as that of the pioneer drug;[67] (2) the generic drug has the same route of administration, dosage form, and strength as the pioneer drug;[68] and (3) the generic drug's labeling must be same as the labeling of the pioneer drug. [69]

---

[62] Recall from the preceding section, *supra* notes 33 – 34 and accompanying text, that paper NDAs, now called section 505(b)(2) NDAs, are like full NDAs, except generic manufacturers are allowed to use published scientific literature to demonstrate the safety and efficacy of their generic drug. "[T]he section 505(b)(2) NDA is mid-way between a full NDA and an abbreviated NDA." HUTT, MERRILL, & GROSSMAN, *supra* note 16, at 771.

[63] The Hatch-Waxman Act of 1984 applies "the same rules to both" ANDAs and section 505(b)(2) NDAs. Hutt, *supra* note 13.

[64] *See supra* notes 42 – 46 and accompanying text.

[65] 21 U.S.C. § 355(j)(1).

[66] 21 U.S.C. § 355(j)(2)(A)(iv). Under 21 U.S.C. §355(j)(8)(B)(i), a drug is considered to be "bioequivalent" to a listed drug if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses."

[67] 21 U.S.C. § 355(j)(2)(A)(ii).

[68] 21 U.S.C. § 355(j)(2)(A)(iii).

[69] 21 U.S.C. § 355(j)(2)(A)(i). Certain exceptions to this requirement can apply.

Furthermore, as part of the ANDA application, generic manufacturers are required to file one of the following four certifications for *each* Orange Book patent listing covering the listed drug: (I) the patent information has not been filed with FDA; (II) the patent has expired; (III) the date when the patent expires; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.[70] When the generic manufacturer seeks to market a generic equivalent of an innovator's drug before the expiration of an Orange Book patent listing covering that drug, the generic company submits a Paragraph IV certification.[71] An ANDA applicant filing a Paragraph IV certification must notify both the patent owner and the NDA holder of the certification and "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."[72] If an NDA holder lists additional patents in the Orange Book after the ANDA was filed with FDA, the ANDA applicant must make additional certifications within thirty days of the listing of the new patent.[73]

The Hatch-Waxman Act revised the Patent Act to provide that the filing of an ANDA with a Paragraph IV certification is treated as a technical act of patent infringement.[74] The Hatch-Waxman Act added this artificial infringement provision to protect NDA patent holders, so that the infringement dispute could be resolved before the generic drug hits the

---

[70] 21 U.S.C. § 355(j)(2)(A)(vii).

[71] *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[72] 21 U.S.C. § 355(j)(2)(B)(iv)(II).

[73] *See* Derzko, *supra* note 19, at 174.

[74] *See* 21 U.S.C. § 271(e)(2). Also, the Hatch-Waxman Act amended the Patent Act at 35 U.S.C. § 271(e)(1), so that it is not an act of infringement for a generic drug manufacturer to use a patented drug (prior to the patent's expiration) solely for testing purposes in order to satisfy FDA's submission requirements. This provision overturned the Federal Circuit's decision in *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed Cir. 1984).

market.[75] Also, as stated by one commentator, "From society's perspective, early resolution of such patent disputes is generally considered beneficial since it helps clear the way for generic drug entry if a patent is in fact invalid, or if a patent is found to be valid but not infringed."[76] After receiving notice, if the NDA holder brings a patent infringement action against the ANDA applicant within forty-five days, FDA is barred from approving the ANDA for thirty months from the date of the receipt of the notice.[77] However, if the patent expires or if a court rules that the patent is invalid or not infringed, FDA can then immediately approve the ANDA.[78] Additionally, the statute provides that "[t]he court may increase or decrease the 30-month period specified in the statute if it determines that either party has failed to expedite the proceeding."[79] If the NDA holder does not bring suit against the ANDA applicant within forty-five days, FDA may approve the ANDA immediately.[80]

Additionally, if the listed drug contains a method of use patent "which does not claim a use for which the [ANDA] applicant is seeking approval," the ANDA applicant must submit "a statement that the method of use patent does not claim such a use."[81] This statement is commonly known as a "section viii" statement, and does not constitute an act of infringement like a Paragraph IV certification.

The Hatch-Waxman Act also provides that the first ANDA applicant to file with FDA a Paragraph IV certification to a patent covering a pioneer drug will be granted 180 days of

---

[75] *See* Flannery & Hutt, *supra* note 12, at 285.

[76] Derzko, *supra* note 19, at 239.

[77] *See* 21 U.S.C. § 355(j)(5)(B)(iii).

[78] *Id.*

[79] *See* Flannery & Hutt, *supra* note 12, at 285.

[80] 21 U.S.C. § 355(j)(5)(B)(iii). If the ANDA contains just Paragraph I or Paragraph II certifications, FDA may approve the ANDA immediately. 21 U.S.C. § 355(j)(5)(B)(i).

[81] 21 U.S.C. § 355(j)(2)(A)(viii).

generic marketing exclusivity.[82] FDA will not approve subsequent ANDAs for the same pioneer drug until the expiration of the 180 days.[83] Under the Hatch-Waxman Act, the first Paragraph IV ANDA filer's 180-day exclusivity is triggered by either the commercial marketing of the generic drug or a court decision finding the patent invalid or not infringed, whichever is earlier.[84] This 180-day exclusivity is very profitable for generics,[85] and as such, the provision is meant to "encourage generic applicants to challenge weak or questionable patents."[86]

The Hatch-Waxman Act provided a mechanism to accelerate generic drug entry into the pharmaceutical market, but the Act also added increased patent protection and periods of market exclusivity for NDA holders. The Act provides that FDA may not approve an ANDA until all patent protection and market exclusivity periods have expired.[87] In terms of market exclusivity, for a new chemical entity ("NCE") NDA, a generic manufacturer cannot submit an ANDA to FDA until five years after FDA approval of the NCE NDA (or four years if the generic company is challenging a pioneer drug's patent as invalid or not infringed).[88] For a non-NCE NDA, a generic manufacturer cannot submit an ANDA to FDA until three years after FDA

---

[82] *See* 21 U.S.C. § 355(j)(5)(B)(iv).

[83] *See id.*

[84] *Id.*

[85] "An important feature of the regime is a large incentive to litigate the validity and scope of an innovator's patents, a "bounty" worth hundreds of millions of dollars for a major drug." C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1560 (2006).

[86] Mary W. Bourke & M. Edward Danberg, *Current Trends in Hatch-Waxman Patent Litigation: A System Still in Flux*, 878 PRACT. L. INST. – PAT. 939, 960 (2006); *see also* 2003 Hearing, *supra* note 1, at 5 (statement of Timothy J. Muris, Chairman of the FTC) ("[The 180-day exclusivity] provision provides an incentive for companies to challenge patent validity and to design around patents.").

[87] *See* Hutt, *supra* note 13.

[88] *See id.*

approval of the non-NCE NDA.[89] These periods of market exclusivity apply even if the patents of the pioneer NDA have expired.[90] Additionally, as discussed above, if an ANDA filer makes a Paragraph IV certification to one of the NDA holder's patents, the NDA holder can institute an infringement action within forty-five days and receive a thirty-month stay.[91] Thus, if an NCE NDA holder commences an infringement action, FDA may not approve an ANDA until seven and a half years after FDA approval of the NCE NDA.[92]

Additionally, in amending the Patent Act, the Hatch-Waxman created the opportunity for patent term restoration for a drug patent, in order to remedy the decline in the patent's life due to the lengthy testing and FDA premarket approval process.[93] The patent term extension provision applies to product, method of use, and process patents, subject to five requirements.[94] The statute provides that "[t]he term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued."[95] This extension of the patent term by the regulatory review period is subject to four limitations. First, the statute defines the regulatory review period as half of the investigational phase, plus the entire length of

---

[89] *Id.*

[90] *See id.*

[91] *See supra* notes 77-80 and accompanying text.

[92] *See* Flannery & Hutt, *supra* note 12, at 292. However, if a court in the infringement action rules that all of the challenged patents are invalid or not infringed before the end of the thirty-month stay, FDA can approve the ANDA. *Id.*

[93] 35 U.S.C. § 156.

[94] 35 U.S.C. § 156(a). These five requirements include that: (1) the patent has not expired; (2) the patent has not been previously extended; (3) the patent holder has submitted an appropriate patent extension application; (4) the product was subject to a regulatory review period prior to its commercial marketing; and (5) the commercial marketing was the first such marketing permitted by statute (with certain exceptions). *Id.*

[95] 35 U.S.C. § 156(c).

time that FDA is assessing whether to approve a filed NDA.[96] Second, the patent extension is limited to five years for each patent. "Third, the total effective patent life of the product, after the patent term is extended, cannot exceed fourteen years."[97] Fourth, the statute provides that the regulatory review period will be reduced for any period of time the NDA applicant did not act with "due diligence."[98] Finally, within 60 days of FDA approval of the NDA, the NDA patent holder must submit an application to the Patent Office in order to be eligible to receive patent term restoration.[99]

III. Successes and Controversies Stemming from the Hatch-Waxman Act

Section A of this Part briefly discusses the changed landscape of the pharmaceutical drug market after the passage of the Hatch-Waxman Act, including increased drug competition and decreased drug costs. Section B details several of the controversies that arose after the enactment of the Hatch-Waxman Act, particularly pertaining to innovator and generic drug companies' "gaming" of several of the Act's provisions, including the thirty-month stay provision and the 180-day exclusivity provision.

A. The Achievement of Increased Generic Drug Competition

In crafting a streamlined ANDA approval process for generic drugs, the Hatch-Waxman Act spurred the development and growth of the generic drug industry. In contrast to the extraordinary length of time and cost it takes to develop and receive FDA approval of an NCE NDA pioneer drug,[100] the development and FDA approval of an ANDA drug takes only

---

[96] 35 U.S.C. § 156; *see also* Flannery & Hutt, *supra* note 12, at 304.

[97] Flannery & Hutt, *supra* note 12, at 304; *see also* 35 U.S.C. § 156(c)(3).

[98] 35 U.S.C. § 156(c)(1).

[99] 35 U.S.C. § 156(d)(1).

[100] *See supra* note 52 and accompanying text.

three to five years and costs the generic drug manufacturer only up to $500,000.[101] This shorter, less-expensive ANDA mechanism for receiving drug approval has created a boom in the generic drug industry. "Since 1984, the generic industry has grown to more than $16 billion in annual sales, representing more than 53% of all prescriptions filled in 2004."[102] With the entry of more generic drugs onto the market, increased competition has led to the reduction of drug prices. An FDA study demonstrates that the entry of generic drugs onto the market drives down prices dramatically.[103] When the first generic drug enters the market, there is only a five percent decrease in the innovator drug price. However, the entry of the second generic competitor leads to a fifty percent decrease in the pioneer drug price, and the sixth generic competitor leads to a seventy-five percent decrease in the pioneer drug price.[104]

This downward pressure on drug costs translates into significant savings for consumers, state governments, and the federal government. A 1998 Congressional Budget Office ("CBO") Study calculated that in 1994, for drug sales at pharmacies, consumers saved $8 billion to $10 billion on drug costs by substituting generic versions for the innovator drugs.[105] In 2003, FDA's Chief Counsel, Daniel Troy, highlighted this achievement of the Hatch-Waxman Act when he stated, "[S]ince its enactment in 1984, Hatch-Waxman has become an extremely valuable tool in making medications more affordable to American citizens. . . . To date, FDA has approved more than 10,000 generic drug products, providing high-quality, lower-cost

---

[101] *See* HUTT, MERRILL, & GROSSMAN, *supra* note 16, at 764 n.6.

[102] Bourke & Danberg, *supra* note 86, at 950.

[103] FDA, Generic Competition and Drug Prices (Apr. 4, 2006).

[104] *Id.*

[105] CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY ix (JULY 1998), *available at* http://www.cbo.gov/showdoc.cfm?index=655&sequence=0.

prescription drugs to millions of consumers."[106] Thus, the Act has been a success in increasing generic competition in the pharmaceutical market and driving down drug prices.

B. Controversies Arising Out of the Hatch-Waxman Act

However, given the complexity, length, and sometimes ambiguous language of the Hatch-Waxman Act, several controversies arose after its passage. Many commentators asserted that both innovator and generic drug manufacturers engaged in "gaming" the Act, exploiting several of the Act's provisions to their favor,[107] sometimes with anticompetitive consequences.[108] One scholar stated, "[C]ertain aspects of the Hatch-Waxman Act came under intense scrutiny because observers found that both innovators and generics were engaging in strategic behavior within the Hatch-Waxman scheme to better their own economic positions. As a result, the entry of certain generic drugs into the marketplace may have been delayed."[109] Senator Hatch, one of the original authors of the Hatch-Waxman Act, declared that "anticompetitive behaviors [were] made possible in part by the sometimes complex and admittedly confusing text of [the] law."[110] Furthermore, he stated that "some research-based and

[106] 2003 Hearing, *supra* note 1, at 6 (statement of Daniel E. Troy, Chief Counsel, FDA).

[107] *See* Avery, *supra* note 3, at 179 ("There has long been a concern that patent holders have used loopholes in the Hatch-Waxman Act to deter or delay generic competition."); Derzko, *supra* note 19, at 175 ("The rules encouraged innovative companies and generic companies to behave strategically to their own benefit but at the expense of consumer interests.").

[108] *See* 2003 Hearing, *supra* note 1, at 33 (prepared statement of the FTC) ("[T]he Commission has observed through its investigations, law enforcement actions, and industry-wide study that some brand-name and generic drug manufacturers may have "gamed" these two provisions, attempting to restrict competition beyond what the Amendments intended."); *see also id.* at 6 (statement of Daniel E. Troy, Chief Counsel, FDA) ("Of course, there are two provisions that have been associated with some anticompetitive behavior – the submission of brand name drug patents for listing by FDA, and the role of these patents in generating 30-month stays in the approval of generic drugs while patent infringement issues are litigated.").

[109] Derzko, *supra* note 19, at 167.

[110] 2003 Hearing, *supra* note 1, at 1 (statement of Sen. Orrin G. Hatch).

generic drug firms were attempting to game the system to avoid competition in the marketplace."[111]

In July 2002, the Federal Trade Commission ("FTC") released a study called GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY ("FTC Study") that examined generic drug manufacturers' attempts to enter the pharmaceutical market *prior* to the expiration of the NDA holder's drug patents.[112] Thus, the FTC analyzed only those generic companies' ANDAs containing Paragraph IV certifications. The FTC analyzed 104 brand-name drugs between 1992 and 2000 to determine whether any anticompetitive behavior by innovator and generic drug companies was systematically occurring to keep generic drugs off the market.[113] This Part analyzes the main controversies that arose after the passage of the Hatch-Waxman Act, which were detailed extensively in the FTC Study, regarding: (1) patent listing and thirty-month stays; and (2) 180-day exclusivity and patent settlement agreements.

1. Patent Listing and the Thirty-Month Stay Provision

Since 1984, FDA has maintained that it performs a completely ministerial role with respect to Orange Book patent listings. Thus, the agency does not evaluate the sufficiency or correctness of the patent information submitted by the NDA holder; it relies instead on the NDA holder to submit the required information correctly. In its 1994 regulation, FDA stated that the "agency believes that its scarce resources would be better utilized in reviewing applications

[111] *Id.* at 2.

[112] *See* FTC Study, *supra* note 20; *see also* 2003 Hearing, *supra* note 1, at 40 (prepared statement of the FTC).

[113] *See* FTC Study, *supra* note 20; *see also* 2003 Hearing, *supra* note 1, at 4 (statement of Timothy J. Muris, Chairman of the FTC).

rather than reviewing patent claims. . . . FDA does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA."[114]

The Hatch-Waxman Act and FDA regulations implementing the Act did not provide clear guidance on what patents NDA holders should and should not list in the Orange Book.[115] For instance, "the regulations did not provide any guidance as to whether patents directed to metabolites, polymorphs . . . or drug delivery modalities could be appropriately listed."[116] This lack of guidance on what patents should be listed in the Orange Book became of extreme importance because of the nexus between patent listings and the thirty-month stay provision. Patents listed in the Orange Book *after* the filing of an ANDA, or "late-listed" patents, could trigger an additional thirty-month stay of FDA approval of the ANDA. If an NDA holder files a patent with FDA after an ANDA applicant had already filed its ANDA, the ANDA applicant must make a certification to the newly listed patent.[117] If the ANDA filer makes a Paragraph IV certification to the late-listed patent, the NDA holder can file an infringement suit against the ANDA applicant within forty-five days to receive an additional thirty-month stay.

FDA's unclear rules regarding patent listing, coupled with the availability of another thirty-month stay after a Paragraph IV certification is made to a late-listed patent, "created a tremendous incentive for innovative companies to broadly interpret the law governing

---

[114] Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,343 (Oct. 3, 1994).

[115] *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(b) (2002). Under the statutory language, "The applicant 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." 21 U.S.C. § 355(b)(1).

[116] Derzko, *supra* note 19, at 190.

[117] *See* 21 U.S.C. § 355(j)(5)(B)(iii).

what types of patents could be listed."[118] Thus, pioneer companies frequently listed "improvement" patents in the Orange Book, such as those "for disectable tablets and special coatings, new formulations, crystalline forms of the same drug, and variations on drug delivery systems."[119] With each late-listed patent, the innovator company could receive another thirty-month stay of FDA approval of the Paragraph IV ANDA filer's application. This practice of gaining multiple thirty-month stays through the late-listing of patents in the Orange Book has been termed "evergreening."[120] For instance, one prominent example of this "evergreening" practice relates to SmithKline Beecham Corporation's brand-name drug Paxil. Paxil, used to treat obsessive-compulsive disorder, was a $2.1 billion blockbuster drug. After instituting its first patent infringement action against a Paragraph IV ANDA filer, SmithKline filed nine late-listed patents and obtained *five* additional 30-month stays.[121]

This "evergreening" practice led to antitrust litigation. One scholar noted that "[i]t is now common that ancillary to patent litigation initiated under the Hatch-Waxman Act, antitrust claims will be filed against the pharmaceutical patentee, either during the infringement action itself or in subsequent class action suits."[122] Allegations of misrepresentation or fraud in connection with the patents listed in the Orange Book have given rise to antitrust charges against

---

[118] Derzko, *supra* note 19, at 176.

[119] Terry G. Mahn, *Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process*, 54 FOOD & DRUG L.J. 245, 250 (1999).

[120] Derzko, *supra* note 19, at 186. One commentator claimed that "the Orange Book can be a strategic weapon . . . giving the patentee/NDA holder almost automatic injunctive relief for even marginal infringement claims." Mahn, *supra* note 119, at 250.

[121] *See* 2003 Hearing, *supra* note 1, at 18 (statement of Sen. Charles E. Schumer); *see also* Derzko, *supra* note 19, at 176.

[122] Esther H. Steinhauer, *Is Noerr-Pennington Immunity Still a Viable Defense Against Antitrust Claims Arising from Hatch-Waxman Litigation*, 61 FOOD DRUG L.J. 679, 679 (2006).

the NDA holder.[123] For instance, in *In re Buspirone Patent & Antitrust Litigation*,[124] Bristol-Myers listed a new patent in the Orange Book the day before the expiration of a listed patent and then initiated infringement litigation against generic manufacturers who made Paragraph IV certifications to this patent. Allegations were made that Bristol-Myers "knew that the newly asserted patent did not cover any of the approved uses for buspirone . . . [and] that Bristol-Myers misrepresented this issue to the FDA when requesting Orange Book listing of the patent."[125] Bristol-Myers moved to dismiss the Orange Book patent listing antitrust claims on the basis of *Noerr-Pennington* immunity, which means that "those who petition government for redress are generally immune from antitrust liability."[126] However, the court dismissed Bristol-Myers's claim for immunity because an Orange Book patent listing "does not require the FDA to perform an independent review of the validity of the statements made in support of the patent's scope."[127] Because Orange Book patent listing is more similar to filing a tax than petitioning the government, the court held that Orange Book listing can lead to antitrust liability.

The FTC Study investigated the occurrence of this "evergreening" practice in order to examine whether there was an anticompetitive effect on generic competition from the late-listing of patents in the Orange Book. The Study noted that for eight of the brand-name drug products, innovator companies filed late-listed patents and received an additional thirty-month stay.[128] The additional thirty-month stay caused a delay – ranging from four to forty months – in

[123] *Id.* at 680.

[124] 185 F. Supp. 2d 363 (S.D.N.Y. 2002).

[125] Steinhauer, *supra* note 122, at 685.

[126] *Id.* at 681.

[127] *Id.* at 686.

[128] *See* FTC Study, *supra* note 20, at iii.

FDA approval of the ANDA.[129] Furthermore, out of these eight cases, four courts have ruled on the validity of the late-listed patent and all have found that the patent was either invalid or not infringed.[130] Due to these findings, the FTC recommended that "only one 30-month stay be permitted per drug product per ANDA to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant's ANDA."[131] The study also recommended that FDA revise and clarify its patent listing requirements.[132]

Given the unclear statutory and regulatory provisions regarding Orange Book patent listing and the high stakes of each listing due to the possibility of additional thirty-month stays, much controversy existed between generic and innovator companies prior to 2003 regarding the appropriateness of many Orange Book patent listings. Generic companies often believed that the innovator companies were filing "sham" patents in order to delay generic drug approval. Between 1984 and 2003, generic companies attempted to prevent multiple thirty-month stays by challenging the pioneer companies' Orange Book patent listings and requesting delisting of the patents as a remedy. However, in *Mylan Pharmaceuticals, Inc. v. Thompson*,[133] the Federal Circuit held that the Hatch-Waxman Act did not provide a private cause of action against an NDA holder for the delisting of an Orange Book patent. Thus, under the Hatch-Waxman Act, generic companies were left without a mechanism to correct or delist patents they believed to be inaccurate or inappropriately listed.

2. 180-Day Exclusivity and Patent Settlement Agreements

---

[129] *Id.* at iii.

[130] *Id.* at iii-iv.

[131] *See* 2003 Hearing, *supra* note 1, at 40 (prepared statement of the FTC); *see also* FTC Study, *supra* note 20, at ii.

[132] *See* FTC Study, *supra* note 20, at v.

[133] 268 F.3d 1323, 1327 (Fed. Cir. 2001).

Another major controversy that arose after the passage of the Hatch-Waxman Act concerned the 180-day market exclusivity provision. This provision grants to the first generic applicant who files an ANDA with a Paragraph IV certification a period of 180 days of market exclusivity during which FDA may not approve another ANDA for the same drug.[134] The 180-day market exclusivity is triggered by the date of the commercial marketing of the generic drug or the date of a court ruling that the patent is invalid or not infringed, whichever is earlier.[135] Several issues arose surrounding the interpretation and application of this provision. First, in 1994, FDA issued a final regulation stating that it would only grant 180-day exclusivity to the first Paragraph IV ANDA applicant who was sued in a patent infringement action by the pioneer drug company and successfully defended against the claim.[136] According to FDA, the "successful defense" requirement served to eliminate ANDA applicants' incentive to file "frivolous claims of patent invalidity or noninfringement."[137] However, in *Mova Pharmaceuticals, Corp. v. Shalala*,[138] the D.C. Circuit rejected FDA's "successful defense" requirement as contrary to the plain text of the Hatch-Waxman Act.[139] In light of the *Mova* decision, FDA eliminated the "successful defense" requirement from its rule[140] and instead adopted an approach consistent with the plain language of the statute – "a first-to-file basis," [141]

---

[134] *See* 21 U.S.C. § 355(j)(5)(B)(iv).

[135] *Id.*

[136] *See* 59 Fed. Reg. 50338 (Oct. 3, 1994).

[137] *Id.* at 50353.

[138] 955 F. Supp. 128, 130 (D.D.C. 1997), *aff'd* 140 F.3d 1060 (D.C. Cir. 1998).

[139] *Mova*, 140 F.3d at 1069.

[140] *See* FDA, GUIDANCE FOR INDUSTRY: 180-DAY GENERIC DRUG EXCLUSIVITY UNDER THE HATCH-WAXMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 4 (June 1998), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatory Information/Guidances/ucm079342.pdf.

[141] *See* Derzko, *supra* note 19, at 195.

in which the first generic applicant to submit an ANDA with a Paragraph IV certification to a patent would receive 180-day exclusivity.

Second, another interpretive issue arose surrounding whether a decision of a district court or appeals court was necessary to trigger a generic applicant's 180-day exclusivity. In its 1999 rulemaking, FDA interpreted "a decision of a court"[142] to mean "the court that enters final judgment from which no appeal can be or has been taken."[143] However, in *Mylan Pharmaceuticals, Inc. v. Shalala*,[144] the D.C. District Court rejected FDA's interpretation and reasoned that the appropriate court decision to trigger 180-day exclusivity was that of a district court.[145] In light of the *Mylan* decision, FDA changed its rule to reflect that a district court decision will trigger a generic applicant's 180-day exclusivity.[146]

Besides the two interpretive problems discussed above, an area of main concern was that innovator and generic companies were entering into patent settlement agreements, and in doing so, they were able to use the 180-day exclusivity provision to keep subsequent generic applicants off the market. The FTC notes that "both parties have economic incentives to collude to delay generic entry. By blocking entry, the brand name may preserve monopoly profits. A portion of these profits, in turn, can be used to fund payments to the generic manufacturer," who agrees to forgo selling its generic drug on the market.[147] In the scenario of a patent settlement agreement, there is no court decision finding that the patent is invalid or not infringed, and there is no commercial marketing of the generic drug. Hence, there is no trigger of the first generic

---

[142] 21 U.S.C. § 355(j)(5)(B)(iv).

[143] 21 C.F.R. 314.107(e)(1) (1999).

[144] 81 F. Supp. 2d 30 (D.D.C. 2000).

[145] *Id.*

[146] *See* FDA, GUIDANCE FOR INDUSTRY, *supra* note 140, at 5.

[147] 2003 Hearing, *supra* note 1, at 34 (prepared statement of the FTC).

applicant's 180-day exclusivity. Thus, FDA cannot approve subsequent generic applicants' ANDAs because the 180-day period has not run. As a result, generic competition for the drug may be delayed well into the future. Some commentators have termed this delayed entry of generic competitors into the market due to the delayed triggering of 180-day exclusivity "the approval bottleneck."[148]

The FTC Study examined the substance and effects of the patent settlement agreements entered into by drug companies between 1992 and 2000.[149] The study showed that generic applicants that submitted ANDAs containing Paragraph IV certifications "prevailed in 73 percent of the cases in which a court ha[d] resolved the patent dispute."[150] However, the FTC Study found that in twenty cases the parties entered into a patent settlement agreement.[151] In nine of these settlements, the innovator company paid the generic applicant.[152] These types of settlements, with payments flowing from the innovator company to the generic company, are sometimes called "reverse-payment settlements" or "pay-for-delay settlements."[153] In seven of these settlements, the innovator company licensed the generic applicant to use the NDA holder's patents prior to patent expiration.[154] Finally, in two of the settlements, the generic company was

---

[148] *See* Patel, *supra* note 19, at 1095 ("However, exhaustion of the exclusivity may be delayed, into the distant future, as a result of settlement. This 'approval bottleneck' effectively prevents Subsequent Paragraph IV ANDA filers from obtaining FDA approval, delaying generic entrants into the marketplace."); *see also* Avery, *supra* note 3, at 181.

[149] *See* 2003 Hearing, *supra* note 1, at 14, 19 (prepared statement of the FTC).

[150] *See* FTC Study, *supra* note 20, at vi.

[151] *Id.* at vii. The Study also identified six generic-generic settlement agreements, with "some of those [raising] anticompetitive problems." 2003 Hearing, *supra* note 1, at 15 (statement of Timothy J. Muris, Chairman of the FTC).

[152] *See* 2003 Hearing, *supra* note 1, at 45 (prepared statement of the FTC).

[153] *See* Ark. Carpenters Health and Welfare Fund v. Bayer AG, 604 F.3d 98, 102 (2d Cir. 2010); Avery, *supra* note 3, at 181 – 82.

[154] *See* 2003 Hearing, *supra* note 1, at 45 (prepared statement of the FTC).

allowed to market the brand-name drug under the pioneer company's NDA, but not under the generic's ANDA.[155]

In eight of the nine reverse-payment settlements, the generic manufacturer agreed not to manufacture or sell its generic product until the expiration of the NDA holder's patents.[156] "The range of brand payments was $1.75 million to $132.5 million, and the time between the date of the agreement and patent expiration ranged between 4 months and 10 years."[157] For instance, in one such settlement, the innovator company paid the generic company $66.4 million, with the NDA drug's patents not expiring until over nine years later.[158] Until the expiration of the drug patents, then, the generic company's 180-day market exclusivity was not triggered, and FDA could not approve subsequent generic companies' ANDAs.[159] Ultimately, the FTC Study "found 14 settlement agreements that, when executed, had the potential to park the first generic applicant's 180-day exclusivity for some time, and thus prevent subsequent generic entry."[160] The FTC concluded that, although the 180-day exclusivity provision did not create this approval bottleneck by itself, the 180-day provision coupled with the patent settlement agreements have led to delayed generic competition.[161] As a result of the study's findings, the FTC recommended that Congress enact a statute that requires innovator and generic drug companies to provide

---

[155] *See* FTC Study, *supra* note 20, at 25.

[156] *Id.* at 31.

[157] *Id.*

[158] *Id.* at 32 Table 3-3.

[159] However, if a subsequent generic Paragraph IV ANDA filer were able to obtain a court decision of patent invalidity or non-infringement with respect to the NDA holder's drug patents, then this decision would trigger the first ANDA filer's 180 day exclusivity. *Id.* at 31.

[160] 2003 Hearing, *supra* note 1, at 5 (statement of Timothy J. Muris, Chairman of the FTC); *see* FTC Study, *supra* note 20, at vii.

[161] *See* 2003 Hearing, *supra* note 1, at 46 (prepared statement of the FTC).

copies of some patent settlement agreements to the FTC and the Department of Justice ("DOJ").[162]

As demonstrated by this Part, evidence surfaced, particularly from the FTC Study, that both generic and innovator companies engaged in "gaming" certain provisions of the Hatch-Waxman Act to their advantage, sometimes with the effect of delaying generic drug entry. As such, many commentators began calling for reform of the Act, which will be discussed in Part IV of this paper.

IV. The 2003 Amendments: FDA's Final Rule and the Medicare Modernization Act

Part III described the main controversies that arose after the passage of the Hatch-Waxman Act, particularly with regard to the patent listing provision, thirty-month stay provision, and 180-day exclusivity provision. This Part discusses the changes that were made to the Hatch-Waxman scheme to correct the loopholes that led innovator and generic companies to "game" certain provisions of the Act. Section A describes FDA's 2003 rule on patent listing requirements. Section B briefly describes the legislative background leading up to the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003[163] ("Medicare Modernization Act" or "MMA"). Section C analyzes the specific provisions of the Medicare Modernization Act, which amend certain provisions of the Hatch-Waxman Act. Finally, section D assesses the issues that were definitively resolved by the 2003 final rule and the MMA.

---

[162] *See* FTC Study, *supra* note 20, at vi, viii; *see also* 2003 Hearing, *supra* note 1, at 46 (prepared statement of the FTC).

[163] Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended in scattered sections of 21 and 42 U.S.C.).

A. 2003 FDA Regulation

In response to the controversies over patent listings and thirty-month stays, and the FTC's recommendations regarding these issues,[164] FDA issued a final rule on June 18, 2003.[165] The rule contained two main changes to the Hatch-Waxman regulatory scheme. First, the rule "clarifie[d] patent submission and listing requirements, which will reduce confusion and help curb attempts to take advantage of this process."[166] Second, the rule stated that there will only be *one* thirty-month stay available for each ANDA and section 505(b)(2) application. FDA reasoned that "[e]liminating multiple 30-month stays will speed up the approval and market entry of generic drugs."[167] FDA asserted that the rule would maintain the original balance struck by the Hatch-Waxman Act.[168] Although the aspects of the final rule relating to thirty-month stays were superseded by the passage of the MMA, the aspects of the final rule pertaining to patent listing submission requirements remain in effect. As such, only those parts of the rule regarding patent listings will be discussed in this section.

---

[164] *See supra* notes 131 – 132 and accompanying text. The FTC Study recommended that FDA clarify its patent listing rules and allow for only one thirty-month stay for each ANDA or section 505(b)(2) application. *Id.*

[165] 68 Fed. Reg. 36676 (June 18, 2003) (codified at 21 C.F.R. § 314.53(b)(1)). The rule was first proposed on October 24, 2002. *See* 67 Fed. Reg. 65448 (Oct. 24, 2002).

[166] *Id.* at 36676. The Chief Counsel of FDA stated that the submission requirements and signed declaration forms "will significantly reduce opportunities to list inappropriate patents just to prevent access to low-cost generic alternatives." 2003 Hearing, *supra* note 1, at 7 (statement of Daniel E. Troy, Chief Counsel, FDA).

[167] *Id.* The Chief Counsel of FDA declared after its promulgation, "We expect th[e] rule to save patients over $35 billion in drug costs over 10 years." 2003 Hearing, *supra* note 1, at 7 (statement of Daniel E. Troy, Chief Counsel, FDA).

[168] 68 Fed. Reg. 36676 ("The final rule maintains a balance between the innovator companies' intellectual property rights and the desire to get generic drugs on the market in a timely fashion.").

The rule stated that NDA applicants must submit drug substance patents, drug product patents, and method of use patents for listing in the Orange Book.[169] The rule clarified that only method of use patents claiming approved uses are to be listed. The rule stated that patents claiming processing, packaging, intermediates, or metabolites are not to be listed in the Orange Book.[170] Additionally, "[p]atents claiming a different polymorphic form of the active ingredient described in the NDA must be submitted if the NDA holder has test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA."[171]

Also, the rule revises the patent information that a pioneer company must submit to FDA[172] and requires a pioneer company to submit this patent information on signed declaration forms both with its NDA (FDA Form 3542a) and after FDA approval of its NDA (FDA Form 3542).[173] As one commentator noted, the FDA's new rule requires "NDA applicants to make careful and more detailed representations in their patent declarations to produce greater compliance with the patent listing requirements."[174] For method of use patents claiming approved methods of use, the forms require NDA applicants to make a claim-by-claim listing.[175] The applicant must provide a description of the approved use for the use code listing, which is

---

[169] *Id.* at 36678.

[170] *Id.* at 36676.

[171] *Id.*

[172] *Id.* at 36677.

[173] *Id.* at 36686, 36707 – 36712.

[174] Barry J. Marenberg, *FDA Issues Final Rule on Patent Listing Requirements and 30-Month Stays of Approval Following Submission of Abbreviated New Drug Applications*, 23 BIOTECHNOLOGY L. REP. 48, 49 (2004).

[175] 68 Fed. Reg. at 36682.

limited to 240 characters.[176] FDA explained that this claim-by-claim listing for method-of-use patents was required in order to determine whether an ANDA applicant could "carve out" the method of use in a section viii statement, or whether it had to certify to the listed patent.[177] The declaration forms make "willful and knowingly false statements" on the forms a criminal offense.[178] The new patent listing requirements apply only to prospective patents listed after the rule came into force on August 18, 2003.[179]

In this rulemaking, FDA maintained its purely ministerial role with regard to patent listings in the Orange Book. FDA stated, "A fundamental assumption of the Hatch-Waxman Amendments is that the courts are the appropriate mechanism for the resolution of disputes about the scope and validity of patents. The courts have the experience, expertise, and authority to address complex and important issues of patent law."[180] In rejecting the suggestion to create an administrative review process for patent listings, FDA noted that "it would be inappropriate and impractical for us to create regulatory mechanisms for reviewing patent listings or permitting third parties to submit patents for listing. We lack both the resources and the expertise to resolve such matters."[181]

---

[176] *Id.* at 36686.

[177] *Id.* at 36682 ("In determining whether an ANDA applicant can "carve out" the method of use, rather than certify to the listed patent, we will rely on the description of the approved use provided by the NDA holder or patent owner in the patent declaration and listed in the Orange Book.").

[178] *Id.* at 36686.

[179] *Id.* at 36676, 36696.

[180] *Id.* at 36676, 36683.

[181] *Id*. at 36683. After the promulgation of the final rule, FDA's Chief Counsel stated in a Senate hearing, "I want to make clear that we do not undertake an independent review of the patents submitted by the NDA sponsor. We have tried in our new rule to make it clear which patents must and must not be listed, and to have a beefed-up declaration." 2003 Hearing, *supra* note 1, at 6 (statement of Daniel E. Troy, Chief Counsel, FDA).

The Hatch-Waxman Act and FDA regulations make patent listing mandatory.[182] Under the 2003 rule, NDA applicants must submit to FDA patent information related to certain patents (including drug product, drug substance, and method of use) and must not submit patent information related to other patents (such as metabolites and intermediates). However, as illustrated by the discussion above, FDA does not rigorously review the patent listing process.[183] Instead, FDA relies on the pioneer drug company to submit correct and accurate patent information, pursuant to the statute and regulations, for listing in the Orange Book.[184] Courts have upheld FDA's ministerial role with regard to patent listing.[185] Recently, in *Teva Pharmaceuticals, USA, Inc. v. Leavitt*,[186] the D.C. Circuit stated that "[w]hen it comes to the veracity of the patent information supplied by NDA holders, FDA operates in a purely ministerial role, relying on the NDA holders to provide the Agency with accurate patent information."[187] The court stated that this interpretation of FDA's role is consistent with the text of the Hatch-Waxman Act, which only requires FDA to publish patent information provided by the NDA holders.[188] The circuit court also noted that FDA's policy choice is sound and should be upheld.[189]

---

[182] *See* Derzko, *supra* note 19, at 18 ("[T]he statute mandates patent listing in accordance with the parameters set forth therein, rather than being permissive."); *see also* FDA, *Decision Letter to ANDA Applicants* (Mar. 26, 2010), at 7 n.14 ("Patent listing is not optional.").

[183] *See* FDA, *Decision Letter to ANDA Applicants* (Mar. 26, 2010), at 7 n.14 ("It is, of course, true that FDA does not have the patent expertise to enforce the statutory requirement that appropriate patents be listed or delisted.").

[184] Bourke & Danberg, *supra* note 86, at 954.

[185] *See* Apotex, Inc. v. Thompson, 347 F.3d 1335, 1348 – 49 (Fed. Cir. 2003); aaiPharm Inc. v. Thompson, 296 F.3d 227, 242 – 43 (4th Cir. 2002).

[186] 548 F.3d 103 (D.C. Cir. 2008).

[187] *Id.* at 106.

[188] *Id.* (citing 21 U.S.C. § 355(b)(1)).

[189] *Id.* at 106 – 107.

B. Legislative Background

The 107th Congress initiated attempts at reform of the Hatch-Waxman Act, with the Senate introducing bill S. 812 in 2001.[190] The White House, the FTC, and FDA opposed this bill, believing that it would encourage too much litigation.[191] Although S. 812 passed the Senate in July 2002, a similar bill died in the House.[192] The 108th Congress continued reform efforts – with the introduction of Senate bill S. 1225 in June 2003 – this time in light of the findings and recommendations of the FTC Study released in July 2002.

The FTC Study, discussed in detail above in Part III,[193] was "a key document for policymakers" in crafting the 2003 statutory amendments to the Hatch-Waxman Act.[194] The study examined whether two statutory provisions – the 180-day exclusivity and thirty-month stay provisions – were used to delay generic competition.[195] As mentioned previously, the FTC Study prepared findings demonstrating the anticompetitive effects of these provisions and made two major recommendations: (1) a limit of one thirty-month stay per ANDA to resolve the disputes of those patents listed in the Orange Book prior to the filing of the ANDA; and (2) a requirement that certain patent settlement agreements be filed with the FTC and the DOJ.[196]

---

[190] S. 812, 107th Cong. (2002); *see also* LIBRARY OF CONGRESS, BILL SUMMARY & STATUS, 107TH CONGRESS (2001-2002), S. 812, MAJOR CONGRESSIONAL ACTIONS, http://thomas.loc.gov/cgi-bin/bdquery/z?d107:SN00812:@@@R.

[191] *See* 2003 Hearing, *supra* note 1, at 12 (statement of Senator Orrin G. Hatch) ("[T]he White House cited its fear that S. 812 might encourage excessive litigation."); *id.* at 13 (statement of Daniel E. Troy, Chief Counsel, FDA) ("We certainly agree with you about S. 812 and we thought it would unduly induce too much litigation . . . .").

[192] *See* LIBRARY OF CONGRESS, BILL SUMMARY & STATUS, 107TH CONGRESS (2001-2002), H.R. 1862, MAJOR CONGRESSIONAL ACTIONS, http://thomas.loc.gov/cgi-bin/bdquery/z?d107:HR01862:.

[193] *See supra* notes 112-113, 128-132, 149-162 and accompanying text.

[194] *See* 2003 Hearing, *supra* note 1, at 3 (statement of Senator Orrin G. Hatch).

[195] *See* FTC Study, *supra* note 20, at i-ii.

[196] *See id.* at i-viii.

The FTC Study also made several minor recommendations. Regarding the 180-day exclusivity provision, the FTC made three proposals, which included clarifying that: (1) the "commercial marketing" trigger includes the generic company's marketing of the pioneer drug product; (2) the "court decision" trigger includes a *trial* court's decision on patent invalidity or non-infringement; and (3) the "court decision" trigger includes a court's dismissal of a declaratory judgment action for lack of subject matter jurisdiction.[197] These minor recommendations regarding the 180-day exclusivity provision were meant both to clarify the triggers of the exclusivity period and to prevent the 180-day exclusivity provision from contributing to an "approval bottleneck." Additionally, due to FDA's ministerial role with regard to patent listings, the FTC Study suggested that a generic Paragraph IV ANDA applicant be allowed to assert a counterclaim raising patent listing issues in a patent infringement lawsuit instituted by the NDA holder.[198]

The Senate Judiciary Committee held a hearing on June 17, 2003,[199] at which Senator Hatch, the Chairman of the FTC, the Chief Counsel of FDA, and others expressed their views on S. 1225, which contained revisions to the Hatch-Waxman Act.[200] A theme that permeated throughout the hearing was the commentators' expressed desire to maintain the balance between innovation and competition struck by the original Hatch-Waxman Act. For instance, the Chief Counsel of FDA stated that the "main goal . . . in this area is to promote innovation, while also promoting rapid access to low-cost, safe and effective generic drugs."[201] The hearing participants also acknowledged that the loopholes in the Hatch-Waxman structure

[197] *See id.* at viii-xi.

[198] *See* 2003 Hearing, *supra* note 1, at 44 (prepared statement of the FTC).

[199] *Id.*

[200] *Id.*

[201] *Id.* at 6 (statement of Daniel E. Troy, Chief Counsel, FDA).

must be fixed in order to promote competition. Senator Hatch remarked that Congress should strive "to end several mechanisms by which some research-based and generic drug firms [have attempted] to game the system to avoid competition in the marketplace."[202] To this end, most participants agreed that adopting the FTC Study's two main recommendations would help achieve this goal. Additionally, acknowledging the large sums of money at stake and the good-lawyering of Hatch-Waxman issues,[203] several participants stated their concern that adding new provisions to the Hatch-Waxman Act would create new loopholes. For instance, the Chief Counsel of FDA declared that "I know of no more of the law in which the law of unintended consequences operates with more force than this one . . . [E]ither way you tilt it, you can't write it so clearly that there are no opportunities for gaming."[204]

The hearing also contained discussion of several specific provisions in S. 1225. First, for instance, S. 1225 contained a declaratory judgment provision, which provides that an NDA holder's failure to bring a patent infringement action against a Paragraph IV ANDA filer within forty-five days of receiving notice establishes a case or controversy sufficient for the generic applicant to bring a declaratory judgment action in federal court.[205] During the hearing, a representative for DOJ stated that the department had not yet reached a conclusion regarding the constitutionality of this provision. However, Professor John Yoo stated at the hearing that he believed the declaratory judgment provision to be constitutional.[206] Second, another provision of

---

[202] *Id.* at 2 (statement of Senator Orrin G. Hatch).

[203] *Id.* at 9 (statement of Daniel E. Troy, Chief Counsel, FDA) ("There is no end to the originality of the arguments that are made in this area. The dollars are very large, the issues are extremely well-lawyered").

[204] *Id.* at 8, 15.

[205] *See* S. 1225, 108th Cong. (2003).

[206] 2003 Hearing, *supra* note 1, at 23 – 24 (statement of John Yoo, Professor of Law, Univ. of California at Berkeley).

great concern was the 180-day exclusivity provision. Senator Hatch remarked that the first-to-file system gave a "not fully justified advantage . . . to first filers" and "may already be encouraging earlier lawsuits of dubious merit."[207] Other commentators at the hearing discussed the importance of legislative efforts to prevent first generic applicants from parking their 180-day exclusivity.[208]

Soon after this hearing, the Senate decided to introduce the reforms to the Hatch-Waxman Act in S. 1, and the House was debating a similar bill, H.R. 1.[209] During the Senate's debate over S. 1, the Senators commentated on the abuses of the Hatch-Waxman Act since its enactment, particularly those causing the delay of generic competition.[210] The Senate's debate again highlighted the need to balance innovation and competition, just as in the original Hatch-Waxman Act. For instance, Senator McCain declared:

> I believe that this amendment will improve the current system while preserving the intent of Hatch-Waxman. This legislation is not an attempt to jeopardize the patent rights of innovative companies, nor does it seek to provide an unfair

---

[207] *Id.* at 12 (statement of Senator Orrin G. Hatch). Senator Hatch continued by remarking, "Now, from a policy perspective, why should a mere first filer be treated better than a party who actually wins a lawsuit?" *Id.* at 13.

[208] *Id.* at 13 (statement of Daniel E. Troy, Chief Counsel, FDA) ("That said, we are working, we think very productively with the staff on S. 1225 to embody more of a, shall we say, use it or lost it approach so that someone can't park their exclusivity.").

[209] H.R. 1 was introduced in the House on June 25, 2003. *See* LIBRARY OF CONGRESS, BILL SUMMARY & STATUS, 108TH CONGRESS (2003 – 2004), H.R. 1, MAJOR CONGRESSIONAL ACTIONS, http://thomas.loc.gov/cgi-bin/bdquery/z?d108:HR00001:@@@R. The House and Senate bills contained the Hatch-Waxman revisions, but were widely publicized due to their reform of the Medicare program, particularly regarding the Medicare Prescription Drug Benefit. *See* LIBRARY OF CONGRESS, BILL SUMMARY & STATUS, 108TH CONGRESS (2003 – 2004), H.R. 1, CRS SUMMARY, http://thomas.loc.gov/cgi-bin/bdquery/z?d108:HR00001:@@@D&summ2=m&.

[210] *See* 149 Cong. Rec. S8193 (statement of Senator Gregg) ("What we saw regrettably, under Hatch-Waxman, was there were games being played."); *see also* 149 Cong. Rec. S8190 (statement of Senator McCain) ("The amendment closes loopholes in the current food and drug laws that allow brand pharmaceutical companies to protect themselves from generic competition by unfairly extending drug patent life, maximizing company profits on the backs of American consumers.").

> advantage to generic manufacturers. Rather, the intent of this amendment is to *strike a balance between these two interests* so that we can close the loopholes that allow some companies to engage in anti-competitive actions by unfairly prolonging patents or eliminating fair competition.[211]

Additionally, Senator Frist remarked, "The Hatch-Waxman law has almost 20 years of balance, and now is the time to go back and readjust and make sure that balance is well situated going forward."[212]

The House and the Senate passed their respective bills on June 27, 2003.[213] Both of these bills contained similar provisions, including: (1) a limit of one thirty-month stay per ANDA; (2) a declaratory judgment action for a Paragraph IV ANDA filer if the pioneer company does not file an infringement suit within forty-five days of receiving notice; (3) a patent delisting counterclaim for a Paragraph IV ANDA filer in a patent infringement case; (4) various forfeiture events for a first Paragraph IV ANDA filer's 180-day exclusivity; and (5) a requirement to notify the FTC and the DOJ regarding certain patent settlement agreements.[214] However, the bills contained several differences, particularly regarding the text of the declaratory judgment and counterclaim provisions. After the Senate passed an amended version of H.R. 1, a conference committee was convened.[215]

---

[211] 149 Cong. Rec. S8190 (emphasis added).

[212] 149 Cong. Rec. S8197.

[213] *See* LIBRARY OF CONGRESS, BILL SUMMARY & STATUS, 108TH CONGRESS (2003 – 2004), H.R. 1, MAJOR CONGRESSIONAL ACTIONS, http://thomas.loc.gov/cgi-bin/bdquery/z?d108:HR00001:@@@R; LIBRARY OF CONGRESS, BILL SUMMARY & STATUS, 108TH CONGRESS (2003 – 2004), S. 1, MAJOR CONGRESSIONAL ACTIONS, http://thomas.loc.gov/cgi-bin/bdquery/z?d108:SN00001:@@@R.

[214] WENDY H. SCHACHT & JOHN R. THOMAS, HATCH-WAXMAN RELATED PROVISIONS OF THE MEDICARE PRESCRIPTION DRUG BILLS (H.R. 1 AND S. 1): A SIDE-BY-SIDE COMPARISON, CONGRESSIONAL RESEARCH SERVICE (2003), *available at* http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/rl32003.pdf.

[215] 149 Cong. Rec. H6681.

On August 1, 2003, the Senate Judiciary Committee held a hearing to analyze the differences between H.R. 1 and S. 1.[216] At this hearing, two main points of contention arose about the reform provisions. First, participants in the hearing brought up several concerns regarding the 180-day exclusivity provision and its proposed forfeiture provisions. Senator Hatch, an original draftsman of the Hatch-Waxman Act, noted that both bills contain a "first-to-file regime" to determine which Paragraph IV ANDA applicant would receive 180-day exclusivity.[217] Senator Hatch evinced his disapproval of this regime and instead advocated for a successful challenger regime:

> I am a proponent of what I call a successful challenger system. It seems to me that the first successful challenger, be it the first generic to be sued, the first to win in court, or the first to be granted a covenant not to be sued by the pioneer firm, is more deserving than a mere first filer. . . . [I]t appears to me that the 180-day marketing exclusivity provisions in the pending legislation contain perverse incentives that may result in unfortunate, if unintended, consequences.[218]

Additionally, the FTC Chairman noted his dissatisfaction with the drafting of the failure to market forfeiture provision, which he believed still left open the possibility of a generic applicant "parking" its exclusivity, thus delaying generic drug entry. The Chairman noted that in order to avoid this outcome, the FTC recommended that the failure to market provision: (1) refer to a district court decision and not an appeals court decision; and (2) state that a court decision "dismissing a declaratory judgment action for lack of subject matter jurisdiction would trigger

---

[216] *Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act," Hearing Before the S. Comm. on the Judiciary*, 108th Cong. (Aug. 1, 2003) [hereinafter Examining the Senate and House Versions Hearing].

[217] *Id.* at 2 (statement of Senator Orrin G. Hatch).

[218] *Id.* at 2 – 3.

the first applicant's 180-day period."[219] The Chief Counsel of FDA added, "We think that some of the 180-day provisions could create unintended difficulties."[220]

Second, another point of contention between the commentators at the hearing concerned the constitutionality of the declaratory judgment provision contained in S. 1. This provision in S. 1 stated that a patent owner's failure to bring a patent infringement lawsuit against the Paragraph IV ANDA applicant in forty-five days after receiving notice establishes an actual controversy under Article III, sufficient to confer subject matter jurisdiction on federal district courts to hear a generic applicant's declaratory judgment action.[221] The representative of the DOJ, Deputy Assistant Attorney General Sheldon Bradshaw, testified that DOJ viewed this declaratory judgment provision as unconstitutional.[222] Bradshaw explained that this provision "is inconsistent with Article III of the Constitution. This provision . . . attempts to vest the lower Federal courts with jurisdiction over disputes, that because of Article III's case or controversy requirement, the Constitution does not empower these courts to hear."[223] However, Senator Schumer responded to these concerns by referring to the letters of constitutional scholars John Yoo and Henry Dinger that stated that the provision was constitutional.[224] H.R. 1, instead, contained a declaratory judgment provision that only created the statutory cause of action under the Declaratory Judgment Act. Under this provision, a district court must still find that an actual case or controversy exists under Article III in order to have subject matter jurisdiction over the

[219] *Id.* at 5 (statement of Timothy J. Muris, Chairman of the FTC).
[220] *Id.* at 23 (statement of Daniel E. Troy, Chief Counsel, FDA).
[221] *Id.* at 11 (statement of Sheldon Bradshaw, Deputy Assistant Attorney General, OLC, DOJ).
[222] *Id.*
[223] *Id.*
[224] *Id.* at 15 – 16 (statement of Senator Charles E. Schumer).

action.[225] Attorney Bradshaw did not find any constitutional infirmity with H.R. 1's declaratory judgment provision.[226]

Finally, a familiar theme that again pervaded this hearing was the need to achieve the balance between innovation and competition. Senator Hatch summed up this sentiment when he stated:

> I want to make sure that when we get [these bills] done, they are constitutionally sound and that they really work and that they don't upset the balance between the need to have new, innovative drugs created at a cost of $800 million to $1 billion, where you have got to get that money back or you can't keep investing in it – the need to do that and the need to get them into generic form as quickly as possible. That is the balance of Hatch-Waxman that we worked hard to create and really has worked remarkably well, in spite of even some of these conflicts and problems that we have had.[227]

The House Conference Report No. 108-391 was filed on November 21, 2003.[228] The Report was passed by the House on November 22, 2003, and was subsequently passed by the Senate on November 25, 2003.[229] President George W. Bush signed the Medicare Modernization Act into law on December 8, 2003.[230]

C. Medicare Modernization Act of 2003

Title XI of the Medicare Modernization Act, entitled "Access to Affordable Pharmaceuticals," significantly amended the Hatch-Waxman Act of 1984. Subtitle A included reforms of the thirty-month stay and 180-day exclusivity provisions, and Subtitle B contained the

---

[225] *See id.* at 19 (statement of Sheldon Bradshaw, Deputy Assistant Attorney General, OLC, DOJ).

[226] *Id.*

[227] *Id.* at 27 (statement of Senator Orrin G. Hatch).

[228] LIBRARY OF CONGRESS, BILL SUMMARY & STATUS, 108TH CONGRESS (2003 – 2004), H.R. 1, MAJOR CONGRESSIONAL ACTIONS, http://thomas.loc.gov/cgi-bin/bdquery/z?d108:HR00001:@@@R.

[229] *Id.*

[230] *See* Statement of Pres. George W. Bush upon Signing H.R. 1, WHITE HOUSE PRESS. REL. (Dec. 8 2003), 2004 U.S.C.C.A.N. 2201.

FTC and DOJ review of certain patent settlement agreements for antitrust violations. This section provides an overview of eight of the important changes the MMA made to the existing Hatch-Waxman structure.

First, the MMA effectively limited an innovator company to one thirty-month stay per ANDA.[231] With the passage of the MMA, an innovator company can only receive a thirty-month stay for patents listed in the Orange Book *before* a generic applicant submits its ANDA.[232] Therefore, if a generic applicant submits an ANDA with a Paragraph IV certification, and the NDA holder files suit within forty-five days of receiving notice, a thirty-month stay of FDA approval of the ANDA will be triggered. If the NDA holder then lists new patents in the Orange Book after the filing of the ANDA, the generic applicant must file certifications to the new patents, but no additional thirty-month stays will be triggered even if the new certifications are Paragraph IV certifications.[233] Additionally, the MMA revised the Hatch-Waxman Act such that a *district* court decision of patent invalidity or non-infringement will end a thirty-month stay of FDA approval.[234] If the district court determines that the patent has been infringed but an appeals court reverses the district court and finds that the patent is valid or not infringed, the

---

[231] *See* 21 U.S.C. § 355(j)(5)(B)(iii). This provision superseded the part of the 2003 FDA final rule relating to thirty-month stays.

[232] *Id.*

[233] However, under the MMA, there are still some scenarios in which multiple thirty-month stays may be triggered for the same ANDA. For instance, assume a generic applicant submits an ANDA with a Paragraph IV certification to one patent and Paragraph III certifications to the other NDA holder's patents. The NDA holder files a patent infringement lawsuit against the generic applicant within forty-five days, which triggers a thirty-month stay of ANDA approval. The ANDA applicant then decides to amend its ANDA by changing one of the Paragraph III certifications to a Paragraph IV certification. Because the patent was listed in the Orange Book before the ANDA was first submitted, the NDA holder can file an infringement lawsuit against the ANDA applicant within forty-five days of receiving notice and trigger another thirty-month stay.

[234] *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I).

thirty-month stay is terminated upon the decision of the appeals court.[235] Finally, in conjunction with the new thirty month-stay provisions, the MMA added a provision that an ANDA applicant may not amend or supplement its ANDA to include a different listed drug, although the applicant may amend or supplement its ANDA to include a different drug strength.[236] This provision was intended to prevent ANDA applicants from receiving only one thirty-month stay of approval for an application that sought approval of two different drug products.[237]

Second, the MMA added a new requirement that a generic applicant that submits an ANDA with a Paragraph IV certification must notify the NDA holder and patent holder of this certification within twenty days after the FDA files the ANDA.[238]

Third, the MMA revised the trigger of the 180-day exclusivity provision. Under the original Hatch-Waxman Act, the period of 180-day exclusivity was triggered by the earlier of the date of first commercial marketing of the generic drug or of a court decision finding the patent invalid or not infringed. The MMA deleted the court decision trigger and stated that the 180-day exclusivity period is triggered by the "first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant."[239] One commentator explained that "[t]his change allows generic companies the opportunity to 'gear up' for launch after the litigation has ended."[240] Also, it is important to note that the MMA commercial marketing trigger includes the generic company's commercial marketing of the *pioneer* drug. This provision was included so that if, in a patent settlement agreement, the NDA holder granted

[235] *See* 21 U.S.C. § 355(j)(5)(B)(iii)(II).

[236] *See* 21 U.S.C. § 355(b)(4).

[237] Bourke & Danberg, *supra* note 86, at 971.

[238] *See* 21 U.S.C. § 355(j)(2)(B)(ii).

[239] 21 U.S.C. § 355(j)(5)(B)(iv).

[240] Bourke & Danberg, *supra* note 86, at 972.

the generic company a license to market the pioneer drug, the generic company's 180-day exclusivity would be triggered.

Fourth, the MMA provided that 180-day exclusivity applies *per drug product* and not per drug patent.[241] Therefore, the first generic applicant that submits a substantially complete ANDA with a Paragraph IV certification to any patent of the listed drug will be eligible for 180-day exclusivity. If a subsequent generic applicant files an ANDA application for the same drug product, but makes a Paragraph IV certification to a *different patent* than the previous ANDA, then the subsequent generic applicant is not entitled to 180-day exclusivity. Under this first-to-file regime, if two first Paragraph IV ANDA filers submit their ANDAs to FDA on the same day, then these two generic applicants will receive shared 180-day exclusivity.[242] Additionally, if the first-to-file generic applicant (or all first applicants if there is shared exclusivity) forfeits its 180-day exclusivity, then no subsequent generic applicants that filed ANDAs with Paragraph IV certifications will be eligible to receive 180-day exclusivity.[243]

Fifth, the MMA added forfeiture provisions by which the first Paragraph IV ANDA applicant will forfeit its right to the 180-day exclusivity period if a "forfeiture event" occurs.[244] The "failure to market" forfeiture provision is a complex provision that requires two dates to occur before forfeiture is triggered. The provision states that the first Paragraph IV

---

[241] *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) ("[T]he term 'first applicant' means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph 2(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph 2(A)(vii)(IV) for the drug.").

[242] *See id.*; *see also* Bourke & Danberg, *supra* note 86, at 972. This shared exclusivity begins on the day either company starts commercial marketing. *See* HUTT, MERRILL, & GROSSMAN, *supra* note 16, at 769.

[243] *See* 21 U.S.C. § 355(j)(5)(D)(iii) ("If all first applicants forfeit the 180-day exclusivity period under clause (ii) . . . (II) no applicant shall be eligible for a 180-day exclusivity period.").

[244] *See* 21 U.S.C. § 355(j)(5)(D)(i).

ANDA applicant will forfeit 180-day exclusivity if it fails to market the drug by the *later* of: (1) 75 days after the ANDA is approved, or 30 months after the ANDA is filed, whichever is earlier; or (2) 75 days after one of the following has occurred: (i) a court enters a decision, from which no appeal has been or can be taken, that finds the pioneer's patent is either invalid or not infringed; (ii) a settlement agreement is approved that includes a finding that the pioneer's patent is either invalid or not infringed; or (iii) the patent holder withdraws the patent information from the Orange Book.[245] In order to calculate the "later of" date, a date under each prong of the failure to market provision must have occurred. For instance, a first generic applicant will forfeit exclusivity if the applicant fails to market the drug within 75 days after FDA approves the ANDA and within 75 days after a court finds the patent invalid or not infringed. Note also that under the second prong of the failure to market provision, *any* generic applicant, and not just the first generic applicant, can cause the occurrence of a triggering event, such as a court decision of patent invalidity or non-infringement.[246]

The MMA also created five additional forfeiture events: (1) the first ANDA applicant withdraws its application;[247] (2) the first ANDA applicant withdraws or amends all of its Paragraph IV certifications qualifying it for 180-day exclusivity;[248] (3) the first ANDA applicant fails to obtain tentative approval of its ANDA within 30 months of filing;[249] (4) the first ANDA applicant enters into an agreement with the patent holder or another generic company that the FTC or a court finds to violate federal antitrust laws;[250] or (5) all patents to

[245] *See* 21 U.S.C. § 355(j)(5)(D)(i)(I).

[246] *See id.*; *see also* Derzko, *supra* note 19, at 244.

[247] *See* 21 U.S.C. § 355(j)(5)(D)(i)(II).

[248] *See* 21 U.S.C. § 355(j)(5)(D)(i)(III).

[249] *See* 21 U.S.C. § 355(j)(5)(D)(i)(IV).

[250] *See* 21 U.S.C. § 355(j)(5)(D)(i)(V).

which the first applicant made Paragraph IV certifications qualifying it for 180-day exclusivity have expired.[251] The MMA forfeiture provisions are intended to prevent first Paragraph IV ANDA filers from parking their 180-day exclusivity and thus delaying generic competition.

Sixth, the MMA inserted a patent delisting counterclaim provision.[252] Under this provision, if an NDA holder or patent owner sues a generic drug company for patent infringement due to the generic applicant's ANDA containing a Paragraph IV certification, then the generic company can bring a counterclaim to delist the patent or correct the patent information in the Orange Book.[253] In the counterclaim, the ANDA applicant can claim that the listed patent does not claim either the drug for which the NDA application was approved or an approved method of using the drug.[254] Furthermore, the statute provides that the ANDA applicant's action to delist or correct an Orange Book-listed patent can only be raised as a counterclaim and is not an independent cause of action.[255] Furthermore, an ANDA applicant is not entitled to damages under this counterclaim.[256]

Seventh, the MMA added a declaratory judgment provision.[257] Under this provision, if an NDA holder or patent owner does not bring a patent infringement action against a Paragraph IV ANDA filer within forty-five days of receiving notice, the ANDA filer may, in accordance with the Declaratory Judgment Act,[258] bring a declaratory judgment action regarding

---

[251] *See* 21 U.S.C. § 355(j)(5)(D)(i)(VI).
[252] *See* 21 U.S.C. § 355(j)(5)(C)(ii).
[253] *See id.*
[254] *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I).
[255] *See* 21 U.S.C. § 355(j)(5)(C)(ii)(II).
[256] *See* 21 U.S.C. § 355(j)(5)(C)(iii).
[257] *See* 21 U.S.C. § 355(j)(5)(C)(i).
[258] *See* 28 U.S.C. § 2201(a).

the invalidity or non-infringement of the patent which is the subject of the Paragraph IV certification.[259] Congress stated that the federal district courts will have subject matter jurisdiction to hear these declaratory judgment actions "to the extent consistent with the Constitution."[260] Additionally, if the ANDA applicant is claiming non-infringement of the patent, the generic applicant must include in its notice a document with an offer of confidential access to the ANDA.[261] This access to the ANDA for the NDA holder or patent owner is only to be used for "the sole and limited purpose" of determining whether a patent infringement action should be brought with respect to the patent that is subject to the Paragraph IV certification.[262] As one scholar stated, "The offer of access is not mandatory. However, if it is not proffered, the generic applicant may not seek a declaratory judgment if it is not sued."[263] The MMA also provided that an ANDA applicant is not entitled to damages in a declaratory judgment action brought under this provision.[264]

Eighth, the MMA required that certain patent settlement agreements entered into by drug companies be filed with the FTC and the DOJ.[265] Three types of agreements are

---

[259] *See* 21 U.S.C. § 355(j)(5)(C)(i)(I).

[260] *See* 35 U.S.C. § 271(e)(5). The MMA's declaratory judgment provision is *not* equivalent to the one contained in S. 1, over which the DOJ and many Senators expressed concern about the provision's constitutionality. Instead, the declaratory judgment provision is more akin to the declaratory judgment provision in H.R. 1, in which a district court must find that Article III's "case or controversy" requirement is satisfied to hear the case. The DOJ expressed no concern about the constitutionality of such a provision. *See supra* notes 225-226 and accompanying text. In changing the language of the final MMA provision, "[i]t appears that concerned Senate members felt that the ultimately enacted wording of section 1101(d) would solve [the constitutional] problem." Derzko, *supra* note 19, at 241.

[261] *See* 21 U.S.C. § 355(j)(5)(C)(i)(III).

[262] *Id.*

[263] Bourke & Danberg, *supra* note 86, at 973.

[264] *See* 21 U.S.C. § 355(j)(5)(C)(iii).

[265] MMA Title XI § 1112.

required to be submitted to the FTC and the DOJ: (1) an agreement between a generic company that has submitted an ANDA with a Paragraph IV certification and a pioneer company that pertains to: (a) the manufacture, marketing, or sale of the pioneer drug; (b) the manufacture, marketing, or sale of the generic drug; or (c) any generic company's 180-day exclusivity with respect to the pioneer drug;[266] (2) an agreement between two generic companies that have both submitted ANDAs with Paragraph IV certifications to the same listed drug that pertains to one company's 180-day exclusivity period;[267] and (3) any agreements between the parties mentioned above that are not described above "and are contingent upon, provide a contingent condition for, or are otherwise related to an agreement" that is required to be filed above.[268] Any agreement required to be filed must be filed with the Assistant Attorney General and the FTC no later than ten business days after the execution of the patent settlement agreement.[269] If any pioneer or generic company fails to comply with the filing requirements, the company shall be liable for a civil penalty if a civil suit is brought by the United States or the FTC,[270] and a federal district court can order compliance or any other equitable relief it deems appropriate, upon the application of the Assistant Attorney General or the FTC.[271]

Finally, it is important to note which suggestions made during the legislative process were *not* enacted into law by the MMA. Regarding the 180-day exclusivity provision, Senator Hatch's recommendation of a "successful challenger" regime was not enacted.[272]

---

[266] MMA Title XI § 1112(a).

[267] MMA Title XI § 1112(b).

[268] MMA Title XI § 1112(c)(2).

[269] MMA Title XI § 1113.

[270] MMA Title XI § 1115(a).

[271] MMA Title XI § 1115(b).

[272] *See supra* notes 217-218 and accompanying text.

Instead, under the MMA, 180-day exclusivity is based on a "first-to-file" regime. Additionally, Congress did not adopt the FTC's two suggestions regarding the failure to market forfeiture provision. During the August 1, 2003 Senate Judiciary Committee Hearing, the Chairman of the FTC recommended that the second prong of the failure to market forfeiture provision reference a district court decision regarding patent invalidity or non-infringement, and not an appeals court decision.[273] The FTC believed that "the district court decision trigger is important to encourage subsequent generic entry."[274] However, the MMA's failure to market forfeiture provision references an appeals court's decision. The language of the provision refers to "a court [that] enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed."[275] The FTC Chairman also recommended that the failure to market provision be amended so that court decisions dismissing a generic applicant's declaratory judgment action for lack of subject matter jurisdiction would trigger the first Paragraph IV ANDA filer's 180-day exclusivity.[276] The FTC reasoned that "[t]his change will ensure that the 180-day period does not unreasonably block a subsequent generic applicant's market entry."[277] However, when Congress enacted the MMA, the language of the failure to market provision was not amended to include this suggestion.

Furthermore, the MMA refrained from amending the Hatch-Waxman Act in several other ways, although none of the following reforms were extensively considered in Congress. First, Congress did not create an administrative review system within FDA to

[273] *See supra* note 219 and accompanying text.

[274] Examining the Senate and House Versions Hearing, *supra* note 216, at 5 (statement of Timothy J. Muris, Chairman of the FTC).

[275] 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

[276] *See supra* note 219 and accompanying text.

[277] Examining the Senate and House Versions Hearing, *supra* note 216, at 5 (statement of Timothy J. Muris, Chairman of the FTC).

evaluate the appropriateness and accuracy of patent information submitted by NDA holders. Instead, Congress included the patent delisting counterclaim provision, by which a generic applicant could assert a counterclaim to correct or delist patent information from the Orange Book in the context of a patent infringement lawsuit.[278] Second, Congress did not state that reverse-payment settlement agreements between drug companies were *per se* illegal.[279] Instead, in line with the FTC's recommendation, the MMA contained a provision that required certain patent settlement agreements between drug companies to be filed with the FTC and the DOJ for review of antitrust issues.[280] Third, Congress did not amend the patent term extension provisions of the original Hatch-Waxman Act to increase the length of patent term restoration,[281] nor did it amend the market exclusivity provisions of the Act. Thus, the MMA did not increase innovator drug companies' patent or market exclusivity protection in this round of Hatch-Waxman reform.

D. Issues Definitively Resolved by the 2003 FDA Final Rule and the 2003 MMA

The 2003 MMA and FDA final rule definitively resolved two issues of great concern that arose after the passage of the original Hatch-Waxman Act. First, prior to 2003, substantial debate existed between generic and innovator drug companies over the validity of certain patent listings in the Orange Book. However, "FDA's listing regulations, which are now in force, clarify much of the confusion that existed under the old patent listing rules."[282] The 2003 rule clearly mandates the listing in the Orange Book of patents claiming drug products,

---

[278] *See* 21 U.S.C. § 355(j)(5)(C)(ii).

[279] *See* Derzko, *supra* note 19, at 246 ("[I]t is worth noting that there has been no change in substantive law pertaining to what activities might and might not be anticompetitive. Perhaps most notably, settlement agreements between innovators and generics or between two generics in the patent law area were not, for example, declared *per se* antitrust violations.").

[280] *See* MMA Title XI § 1112.

[281] *See* Derzko, *supra* note 19, at 254 ("[T]he recent Hatch-Waxman reforms made no adjustments to the patent restoration period.").

[282] Derzko, *supra* note 19, at 214.

drug substances, and approved methods of use. The 2003 rule clearly prohibits the listing in the Orange Book of patents claiming intermediates, metabolites, processing, and packaging.[283] These bright-line rules have significantly lessened the controversies over the appropriateness of listing various kinds of patents, especially improvement patents. Additionally, the new declaration forms and the possibility of criminal penalties for listing inappropriate patent information both help to create adherence to these new rules.

Second, the MMA's revision of the thirty-month stay provision has had two beneficial consequences. The MMA effectively places a limit of one thirty-month stay per ANDA,[284] in order to resolve patent disputes over those patents listed in the Orange Book prior to the filing of the ANDA.[285] First, in conjunction with the FDA rule clarifying patent listing requirements, this reform of the thirty-month stay provision has ameliorated the contentious issues over patent listings. "[S]ince only one 30-month automatic stay will now be obtainable for an ANDA, there will be less incentive on the part of brand name companies to take a broad interpretation of what patents should be listed."[286] Second, the reform of the thirty-month stay provision has halted innovator companies' "evergreening" practice of receiving multiple thirty-month stays and thus delaying generic competition. After the filing of an ANDA, if an NDA holder decides to list a new patent in the Orange Book, the generic applicant must make a certification to this new patent, but under the MMA, the NDA holder is no longer entitled to another thirty-month stay if the generic applicant makes a Paragraph IV certification to the new

[283] *See* 21 C.F.R. § 314.53(b)(1).

[284] *See supra* note 233 for a discussion of how multiple thirty-month stays are still a possible, although rare, occurrence.

[285] *See* 21 U.S.C. § 355(j)(5)(B)(iii).

[286] Derzko, *supra* note 19, at 243.

patent. Thus, "the MMA has eliminated the patent holder's practice of gaining multiple stays to keep generic challengers off the market."[287]

Third, the MMA clarified several issues with regard to the 180-day exclusivity provision. The MMA makes clear that 180-day exclusivity is on a "first-to-file" basis per drug product and not per patent. The MMA provides that the first generic applicant who files a substantially complete ANDA containing a Paragraph IV certification to a pioneer drug's patent is eligible for the 180-day exclusivity period.[288] Additionally, if two ANDAs with Paragraph IV certifications are submitted on the same day for the same drug product, then these first generic applicants will receive "shared exclusivity." Finally, the MMA explicitly states that there is no roll-over exclusivity; if the first Paragraph IV ANDA filer loses its 180-day exclusivity, no other ANDA applicant is eligible to receive 180-day exclusivity.

However, as will be discussed in Part V of this paper, many recent controversies have arisen stemming from the 2003 statutory amendments, including controversies regarding the failure to market forfeiture provision, the patent delisting counterclaim provision, the declaratory judgment action provision, and the patent settlement agreement notification provision.

V. Recent Hatch-Waxman Controversies after the Enactment of the MMA

The Medicare Modernization Act of 2003 amended the provisions of the original Hatch-Waxman Act, and in doing so, added several new provisions, such as the patent delisting counterclaim provision, the failure to market forfeiture provision, the declaratory judgment action provision, and the patent settlement agreement notification provision. These new provisions have engendered much controversy, particularly regarding the correct interpretation

[287] Avery, *supra* note 3, at 188.

[288] *See* 21 U.S.C. § 355(j)(5)(B)(iv).

of these provisions in light of the overall Hatch-Waxman structure and the correct application of these provisions to a variety of factual scenarios. Daniel Troy, then-Chief Counsel of FDA, predicted these controversies, as illustrated by his statement during the 2003 Senate Judiciary Committee Hearing prior to the passage of the MMA: "As with the passage of most new laws, questions and ambiguities are inevitable and the courts, FDA and/or Congress will surely address these ambiguities as they arise."[289]

Coupled with the problem of ambiguity in statutory language is the recurring problem that innovator and generic drug companies are "gaming" certain provisions of the Hatch-Waxman Act to their own economic benefit. Again, then-FDA Chief Counsel Daniel Troy was particularly attuned to the likelihood of generic and innovator companies' gaming any new provisions added by the MMA to the Hatch-Waxman Act. At the Senate Judiciary Committee Hearing, Mr. Troy declared, "I know of no more of the law in which the law of unintended consequences operates with more force than this one . . . [E]ither way you tilt it, you can't write it so clearly that there are no opportunities for gaming."[290] Due to the unintended consequences of these provisions, several commentators have urged that some of these provisions, such as the failure to market forfeiture provision and the patent settlement agreement notification provision, are not achieving their intended goals, and have suggested that further legislative reform is necessary.

This next Part provides a comprehensive analysis of the new Hatch-Waxman issues that have arisen since the 2003 statutory amendments. These unintended consequences and new controversies, which will be covered in the next six sections, include: (1) the effect of

---

[289] Barry J. Marenberg, *Changes to the Hatch-Waxman Act Following the "Medicare Prescription Drug, Improvement and Modernization Act of 2003,"* 23 BIOTECH. L. REP. 277, 280 (2004).

[290] 2003 Hearing, *supra* note 1, at 8, 15 (statement of Daniel E. Troy, Chief Counsel, FDA).

patent delisting on a first generic applicant's 180-day exclusivity; (2) the effect of patent expiration on a first generic applicant's 180-day exclusivity; (3) the interpretation of the patent delisting counterclaim provision; (4) the application of the declaratory judgment action provision; (5) the legality of patent settlement agreements; and (6) the issue of authorized generics.

A. The Effect of Patent Delisting on 180-Day Exclusivity

With the passage of the MMA, Congress intended to prevent first generic applicants from "parking" their 180-day exclusivity and thus delaying the entry of generic competitors onto the market. Congress's main avenue to achieve this goal was through the addition of forfeiture events to the Hatch-Waxman Act.[291] If a forfeiture event occurred, then a first generic applicant would lose its 180-day exclusivity. The main forfeiture event is contained in the complex failure to market forfeiture provision. This provision states that the first Paragraph IV ANDA applicant will forfeit its 180-day exclusivity if it fails to market the drug by the *later* of: (1) 75 days after the ANDA is approved, or 30 months after the ANDA is filed, whichever is earlier; or (2) 75 days after one of the following has occurred: (i) a court enters a decision, from which no appeal has been or can be taken, that finds the pioneer's patent is either invalid or not infringed; (ii) a court approves a settlement agreement that includes a finding that the pioneer's patent is either invalid or not infringed; or (iii) the patent holder withdraws the patent information from the Orange Book.[292]

FDA has not yet issued regulations clarifying the scope and interpretation of the MMA failure to market forfeiture provision. However, FDA has issued several decision letters on this subject, which have shed some light on the interpretation and application of this

[291] *See* 21 U.S.C. § 355(j)(5)(D).

[292] *See* 21 U.S.C. § 355(j)(5)(D)(i)(I).

provision. For instance, in a Letter to Marc A. Goshko, Executive Director of Teva North America, FDA explained its interpretation of this complicated provision:

> We find that under the plain language of the statute, 180-day exclusivity is not forfeited for failure to market when an event under subpart (aa) has occurred, but - as in this case - none of the events in subpart (bb) has occurred. The "failure to market" provision results in forfeiture when there are two dates on the basis of which FDA may identify the "later" event as described in section 505(j)(5)(D)(i)(I). The provision does not effect a forfeiture when an event under subpart (aa) has occurred, but no event under subpart (bb) has yet occurred.[293]

Pursuant to FDA's interpretation of this provision, a date under each prong of the failure to market provision must have occurred, in order to calculate the "later of" date.

Even though FDA has clarified some aspects of the failure to market provision in individual decision letters, this provision has still led to much debate. One controversy that has arisen relates to the effect of an NDA holder's delisting of a certified patent from the Orange Book on an ANDA applicant's 180-day exclusivity. This situation arises when a first generic applicant submits an ANDA with a Paragraph IV certification to a pioneer drug's patent – making it eligible for 180-day exclusivity. The pioneer company then requests that FDA delist this patent, and FDA delists the patent. The second component of the failure to market provision is satisfied if the first generic applicant fails to market the drug within 75 days after the NDA holder withdraws the patent information from the Orange Book, or in other words, after the NDA holder delists the patent.[294] The question is, then, does the NDA holder's delisting of the certified patent destroy the generic company's Paragraph IV certification and, with it, its 180-day exclusivity? As one commentator noted, "[g]eneric firms had once championed patent delistings

---

[293] FDA, *Letter to Marc A. Goshko*, RE: Docket No. 2007N-0389, ANDA 77-165: Granisetron Hydrochloride Injection (Jan. 17, 2008), at 5. For another FDA decision letter regarding the failure to market forfeiture provision, see FDA, *Dear ANDA Applicant Letter (Hi-Tech),* RE: Docket No. FDA-2008-N-0483 (Oct. 28, 2008).

[294] *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC).

as [a] means to faster approval, but now see them as threatening their most valuable asset, 180-day exclusivity."[295] FDA and the federal courts have recently addressed this important issue.

1. Background on Patent Delisting

In *Ranbaxy Laboratories Ltd. v. Leavitt*,[296] a case involving the effect of patent delisting on a generic applicant's 180-day exclusivity prior to the MMA amendments, Ranbaxy and Ivax (the latter being acquired by Teva) submitted ANDAs containing Paragraph IV certifications to two patents covering Merck's listed drug Zocor.[297] After these filings, Merck requested that FDA delist the two challenged patents. FDA delisted the two patents from the Orange Book, resulting in Ranbaxy and Ivax losing 180-day marketing exclusivity.[298] The generic companies filed citizen petitions requesting that FDA relist the patents.[299] However, FDA rejected the petitions because Merck had not initiated patent infringement suits against Ranbaxy and Teva.[300] The generic companies sued in district court, and the court entered summary judgment for the generic companies. On appeal, the D.C. Circuit considered the *Chevron* step one question of "whether the FDA may delist a patent upon the request of the [brand manufacturer] after a generic manufacturer has filed an ANDA containing a paragraph IV certification so that the effect of delisting is to deprive the applicant of a period of marketing exclusivity."[301] The court held that FDA's delisting policy was contrary to the text and structure

---

[295] M. Nielsen Hobbs, *180-Day Exclusivity Ruling on Cosopt Signals Need for Strong Patent Challenges*, THE PINK SHEET (Nov. 3, 2008).

[296] 469 F.3d 120 (D.C. Cir. 2006).

[297] *Id.* at 121.

[298] *See* 21 C.F.R. § 314.94(a)(12)(viii)(B) (requiring that when a patent is removed from the Orange Book, the ANDA filer must delete its paragraph IV certification with regard to the delisted patent).

[299] *Ranbaxy*, 469 F.3d at 121.

[300] *Id.*

[301] *Id.* at 125.

of the Hatch-Waxman Act, and contrary to the purpose of the Act, as it "diminishes the incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book."[302] Therefore, the Court affirmed the district court and held that "FDA improperly denied Ranbaxy and Teva a period of marketing exclusivity by delisting Merck's patents."[303]

The *Ranbaxy* Court only interpreted the Hatch-Waxman Act prior to the 2003 MMA amendments. Since the 2003 amendments, three scenarios similar to the *Ranbaxy* fact pattern have arisen. The first fact pattern involved the generic company Cobalt Pharmaceuticals and Bayer's brand-name drug Precose. The second fact pattern involved the generic company Hi-Tech Pharmacal Co. and Merck's brand-name drug Cosopt. In both instances, the generic companies argued that in the revised Hatch-Waxman framework, a generic company that files an ANDA with a Paragraph IV certification to a listed patent should be entitled to exclusivity even if the NDA holder then requests that FDA delist the patent.

FDA rejected these arguments and refused to apply the *Ranbaxy* rule.[304] Instead, FDA based its decision on the failure to market forfeiture provision added by the MMA.[305] FDA stated that with respect to both Cobalt and Hi-Tech, the delisting of the patent by the NDA holder led to a forfeiture event for failure to market because "[t]he patent information submitted under subsection (b) or (c) of this section [was] withdrawn by the holder of the application approved under subsection (b)."[306] FDA stated that under the plain language of the statute, the

---

[302] *Id.* at 126.

[303] *Id.*

[304] *See* FDA, *Dear ANDA Applicant Letter* (*Hi-Tech)*, *supra* note 293; FDA, *Letter to William A. Rakoczy (Cobalt)*, RE: ANDA No. 77-532 (May 7, 2008).

[305] *See* FDA, *Dear ANDA Applicant Letter* (*Hi-Tech)*, *supra* note 293, at 16; FDA, *Letter to William A. Rakoczy (Cobalt)*, RE: ANDA No. 77-532 (May 7, 2008), at 12; *see also* 21 U.S.C. § 355(j)(5)(D)(i)(I).

[306] *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC).

second trigger under the failure to market provision is satisfied seventy-five days after the innovator company delists the challenged patent.[307] Both Cobalt and Hi-Tech sought review of FDA's policy in district court but were denied relief.

2. *Teva v. Sebelius*

The third fact pattern – in the case of *Teva v. Sebelius*[308] – involved the generic company Teva and Merck's brand-name drugs Cozaar and Hyzaar.[309] Merck's blockbuster hypertension drugs Cozaar (losartan) and Hyzaar (losartan and hydrochlorothiazide) generated $3.6 billion globally in 2008.[310] In 2003 and 2004, Teva filed ANDAs for Cozaar and Hyzaar that made Paragraph IV certifications to Merck's U.S. Patent No. 5,608,075 (the "'075 patent"), which expires in 2014.[311] After Teva filed its ANDAs, Merck chose not to initiate patent infringement litigation, and instead, in March 2005, Merck requested that FDA delist the '075 patent from the Orange Book. FDA removed the patent but did not make this action public until April 18, 2008.[312] In the meantime, FDA tentatively approved both of Teva's ANDAs for Cozaar and Hyzaar. Additionally, FDA tentatively approved Apotex's subsequent Paragraph IV ANDA for Hyzaar. However, under FDA's interpretation of the failure to market forfeiture provision as indicated in the Cobalt and Hi-Tech matters, Teva had forfeited 180-day marketing exclusivity for Hyzaar and Cozaar – seventy-five days from the date of the delisting of the

---

[307] *See* FDA, *Dear ANDA Applicant Letter* (*Hi-Tech)*, *supra* note 293, at 14 n.15 ("Section 505(j)(5)(D)(i)(I)(bb)(CC) applies to more than just those patents withdrawn as a result of a counterclaim. . . . FDA reads the plain language of 505(j)(5)(D)(i)(I)(bb)(CC) to apply whenever a patent is withdrawn (or requested to be 'delisted') by the NDA holder.").

[308] 595 F.3d 1303 (D.C. Cir. 2010).

[309] *Id.* at 1306.

[310] Brenda Sandburg, *ANDA Exclusivity Protected From Patent Delisting Under Appeals Court Ruling*, THE PINK SHEET (Mar. 8, 2010).

[311] *Sebelius*, 595 F.3d at 1307.

[312] *Id.*

patents.[313] In 2009, Teva sued the Secretary of HHS, Kathleen Sebelius, in district court seeking a declaratory judgment rejecting FDA's policy and an injunction requiring that FDA grant Teva 180-day exclusivity on April 6, 2010 (the date generic losartan competition was to begin after Merck's pediatric exclusivity expired).[314] After finding that the claim was ripe and Teva had standing, the District Court for the District of Columbia ruled in favor of FDA on the merits.[315]

The D.C. Circuit agreed with the district court that the action was justiciable but reversed the district court's decision on the merits, holding that FDA's policy was contrary to the structure of the Hatch-Waxman Act. In an opinion by Judge Williams, the court first addressed the ripeness and standing issues. In terms of ripeness, the court held that Teva's suit satisfied both the fitness and hardship prongs of the ripeness inquiry. Teva's claim was "purely legal," as it pertained solely to statutory interpretation,[316] and Teva would suffer hardship, "a near-certain loss of the first mover advantage to which the company claims entitlement," if judicial review were postponed.[317] In terms of standing, the court held that Teva had satisfied all three elements, including the injury prong. The court stated that "Teva faces an imminent threat of . . . the impending prospect of allegedly unlawful competition in the relevant market."[318] Even though the FDA policy that Teva challenges is embodied "not in a rulemaking but in two adjudications to which Teva was not a party," the circuit court held that Teva had standing.[319]

---

[313] *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC).

[314] *Sebelius*, 595 F.3d at 1304.

[315] *Id.* at 1305.

[316] *Id.* at 1308.

[317] *Id.* at 1310.

[318] *Id.* at 1312.

[319] *Id.* at 1311.

Regarding the merits of the case, Teva put forward two arguments that countered FDA's policy that an NDA holder's request for delisting of a patent constitutes a forfeiture event under the failure to market forfeiture provision. First, in a linguistic analysis, Teva argued that the patent delisting forfeiture provision of the Act[320] must be read together with the patent delisting counterclaim provision.[321] Teva explained that the 2003 MMA patent delisting counterclaim provision "is the only portion of the statute that explicitly provides for the delisting of a patent after it has been challenged in an ANDA. . . . [T]hat singular reference requires the conclusion that the counterclaim provision describes *the only scenario* in which the FDA may delist a challenged patent."[322] However, the court held that although this was a plausible reading of the Act, FDA rightly pointed out that "there is simply no express preclusion of non-counterclaim delistings, or of such delistings' triggering forfeiture."[323]

However, the court was persuaded by Teva's incentive structure argument, based on the D.C. Circuit's decision in *Ranbaxy*. In *Ranbaxy*, the court stated, "FDA may not, however, change the incentive structure adopted by the Congress."[324] The circuit court held that FDA's policy fails at *Chevron* step one because the agency's interpretation was incorrect that the failure to market forfeiture provision[325] changed the statute's incentive structure such that *Ranbaxy* no longer applies. The court explained that "the agency, however, offers *not a single cogent reason* why Congress might have permitted brand manufacturers to trigger subsection (CC) by withdrawing a challenged patent, outside the counterclaim scenario identified by

[320] 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC).

[321] 21 U.S.C. § 355(j)(5)(C)(ii)(I).

[322] *Sebelius*, 595 F.3d at 1315 (emphasis in original).

[323] *Id.* at 1315 – 16.

[324] *Id.* at 1316 (quoting *Ranbaxy*, 469 F.3d at 126).

[325] 21 U.S.C. § 355(j)(5)(D)(i)(I).

Teva."[326] The D.C. Circuit reversed the district court and remanded the case for further proceedings on appropriate relief for Teva.[327] Judge Henderson dissented, stating that the case is not ripe for review until after FDA issues its final decision either granting or denying Teva's ANDA.[328]

3. Reaction to *Teva v. Sebelius*

The Pink Sheet reported that "[t]he appeals court decision will have a broad impact as generic manufacturers will no longer be stripped of marketing exclusivity if a brand name company delists a patent in FDA's Orange Book."[329] The Pink Sheet stated that since January 27, 2009, patents covering eleven pioneer drugs had been delisted. These brand-name drugs include Merck's Vytorin to lower cholesterol, Johnson & Johnson's Risperdal Consta for schizophrenia and bipolar disorder treatment, and Amylin's Symlin for diabetes treatment.[330] One attorney stated that the *Sebelius* decision indicates the D.C. Circuit's willingness "to pay attention to Congressional intent and the impact of FDA's decision on the balance struck by Hatch-Waxman."[331] On the other hand, another attorney "said the decision 'strained the logic of *Chevron*' to get the desired result."[332] On April 5, FDA filed a petition for a panel rehearing and rehearing en banc, which the D.C. Circuit denied on May 17, 2010.[333]

---

[326] *Sebelius*, 595 F.3d at 1317 (emphasis in original).

[327] *Id.* at 1319.

[328] *Id.* (Henderson, J., dissenting).

[329] Brenda Sandburg, *ANDA Exclusivity Protected From Patent Delisting Under Appeals Court Ruling*, THE PINK SHEET (Mar. 8, 2010).

[330] *Id.*

[331] *Id.*

[332] *Id.*

[333] *Id.*

B. The Effect of Patent Expiration on 180-Day Exclusivity

Related to the issue of whether voluntary patent delisting by the NDA holder constitutes a forfeiture event is the issue of whether patent expiration (other than natural expiration) constitutes a forfeiture event under 21 U.S.C. § 355(j)(5)(D)(i)(VI). This statutory provision, added to the Hatch-Waxman Act by the MMA, states that the first Paragraph IV ANDA filer forfeits 180-day exclusivity if "[a]ll of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired."[334] FDA has recently interpreted this provision in light of the *Sebelius* decision, concluding that patent expiration for nonpayment of fees does not affect a first ANDA filer's eligibility for 180-day exclusivity. However, FDA's reasoning in its decision letter has sparked significant controversy.

1. FDA's Decision Letter on the Expiration of Merck's '075 Patent

On the same facts of *Teva v. Sebelius*,[335] Teva and other generic companies filed ANDAs for Merck's hypertension drugs Cozaar and Hyzaar, containing Paragraph IV certifications to Merck's '075 patent. While the *Sebelius* litigation concerning FDA's delisting of the '075 patent was pending, a new issue arose with respect to the '075 patent. "Apotex notified FDA on March 9, 2010, that records of the U.S. Patent and Trademark Office (PTO) showed that the '075 patent had expired no later than March 30, 2009, due to non-payment of fees."[336] On March 12, 2010, Merck informed FDA that the expiration date for the '075 patent was incorrect and should be revised from March 4, 2014, to March 4, 2009.[337] FDA then updated the Orange Book to reflect the correct March 4, 2009 expiration date.

---

[334] 21 U.S.C. § 355(j)(5)(D)(i)(VI).

[335] 595 F.3d 1303 (D.C. Cir. 2010).

[336] FDA, *Decision Letter to ANDA Applicants* (Mar. 26, 2010), at 1 n.1.

[337] *See id.* at 1.

On March 11, 2010, FDA sent a letter to ANDA applicants and opened a public docket for comments on the issue of patent expiration due to failure to pay fees and its effect on 180-day exclusivity. On March 26, 2010, FDA issued its 8-page decision letter to ANDA applicants addressing whether the expiration of patents for failure to pay fees constitutes a forfeiture event under 21 U.S.C. § 355(j)(5)(D)(i)(VI). FDA first considered the question "on a clean slate," as if the *Sebelius* decision had never occurred.[338] FDA stated that the text of the patent expiration forfeiture event provision does not distinguish between natural expiration and other types of expiration. Therefore, under a plain reading of the statute, FDA concluded that "it would interpret the statute so that patent expiration *for any reason* is a patent expiration forfeiture event."[339]

However, FDA then went on to state that it was obligated to consider the D.C. Circuit's decision in *Teva v. Sebelius* in determining whether patent expiration for failure to pay fees constitutes a forfeiture event. FDA stated that, in *Sebelius*, the court reasoned that "the structure of the MMA exclusivity provisions . . . does not permit an NDA holder to 'unilaterally' deprive the generic applicant of its exclusivity on the basis of delisting."[340] Thus, FDA concluded that this analysis "appears to preclude a forfeiture of exclusivity on the basis of a patent expiration where the expiration is in the control of the NDA holder."[341] The agency concluded that, in light of the *Sebelius* decision, the expiration of Merck's '075 patent did not result in a forfeiture of the first ANDA filer's (Teva's) eligibility for 180-day exclusivity for Cozaar and Hyzaar. FDA concluded the letter with this contentious statement: "The Agency

[338] *Id.* at 5.

[339] *Id.* (emphasis added).

[340] *Id*. at 7.

[341] *Id.*

makes this finding even though it is not the result that FDA, as the agency that administers the statute, believes is appropriate given the relevant statutory language or the policies underlying the statute."[342]

2. Aftermath of FDA's Decision Letter

One commentator noted that FDA's March 26, 2010 decision letter was an "interesting strategic move by the Agency."[343] Although ultimately concluding that patent expiration due to the failure to pay maintenance fees was not a forfeiture event, FDA spent the majority of the letter rejecting that decision. "FDA's letter decision is clearly a plea for other interested parties to challenge the Agency's decision."[344] This commentator's prediction proved to be correct. After FDA issued its decision letter, Apotex and Roxane brought suit against FDA in the U.S. District Court for the District of Columbia seeking a preliminary injunction to stop FDA from granting Teva 180-day marketing exclusivity.[345] The generic companies argued that FDA's decision letter violated the FD&C Act and the Administrative Procedure Act. Teva intervened in the case arguing against Apotex and Roxane's position that FDA's adherence to *Sebelius*'s reasoning was arbitrary and capricious.[346] On April 2, 2010, Judge Collyer issued an opinion denying the generic companies' preliminary injunction motion.[347] On April 6, 2010, FDA approved Teva's ANDAs, granting Teva 180-day exclusivity on the generic versions of

---

[342] *Id.* at 8.

[343] Kurt R. Karst, *FDA Rules Against Patent Expiration 180-Day Exclusivity Forfeiture for Generic COZAAR/HYZAAR, But in Doing So FDA Repudiates Its Own Decision and Asks to be Sued*, FDA LAW BLOG (Mar. 29, 2010, 5:36 AM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/03/fda-rules-against-patent-expiration-180day-exclusivity-forfeiture-for-generic-cozaarhyzaar-but-in-do.html.

[344] *Id.*

[345] Apotex, Inc. v. Sebelius, 700 F. Supp. 2d 138 (D.D.C. 2010).

[346] *Id.*

[347] *Id.*

Hyzaar and Cozaar.[348] Apotex appealed to the D.C. Circuit, and the D.C. Circuit affirmed the decision of the district court on July 6, 2010.[349] Apotex filed a petition for a writ of certiorari on October 4, 2010, which was denied by the Supreme Court on January 18, 2011.[350]

C. Patent Delisting Counterclaim Provision

The MMA added a provision to the Hatch-Waxman Act that allows a generic manufacturer in a Paragraph IV infringement suit to assert a counterclaim against the innovator company challenging the accuracy and correctness of the innovator drug's patent information listed in the Orange Book.[351] The provision states that the ANDA "applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either – (aa) the drug for which the application was approved; or (bb) an approved method of using the drug."[352] Recently, the scope of this counterclaim provision, as it pertained to a method of use patent, came under scrutiny by the Federal Circuit in *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*[353]

1. *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*

Novo Nordisk A/S and Novo Nordisk, Inc. ("Novo") sell the brand-name drug Prandin, which is "an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes."[354] Prandin (repaglinide) has three FDA-approved uses: (1) monotherapy (use

---

[348] Karst, *supra* note 343.

[349] Apotex, Inc. v. Sebelius, 384 Fed. Appx. 4 (D.C. Cir. 2010).

[350] *Apotex*, 131 S. Ct. 1000, 79 USLW 3246 (U.S. Jan. 18, 2011) (No. 10-453).

[351] *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I).

[352] *Id.*

[353] 601 F.3d 1359 (Fed. Cir. 2010).

[354] *Id.* at 1362.

of repaglinide by itself); (2) repaglinide in combination with metformin; and (3) repaglinide in combination with thiazolidinediones.[355] There are two patent listings for Prandin in FDA's Orange Book. U.S. Patent No. 37,035 claims the chemical composition of repaglinide, and the patent expired on March 14, 2009. U.S. Patent No. 6,677,358 (the "'358 patent") claims "[a] method for treating non-insulin dependent diabetes mellitus (NIDDM) comprising administering to a patient in need of such treatment repaglinide in combination with metformin," and the patent expires on June 12, 2018.[356] This method of use patent was assigned the use code "U-546" by FDA and the use code narrative read "[u]se of repaglinide in combination with metformin to lower blood glucose."[357] Novo does not own the patents claiming the other two FDA-approved uses of repaglinide.[358]

In February 2005, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") filed an ANDA for repaglinide, making a Paragraph IV certification to the '358 patent. Within 45 days, Novo brought a patent infringement action against Caraco. In April 2008, Caraco filed an amended ANDA to FDA: an ANDA with a Paragraph IV certification to the '358 patent and a section viii statement[359] carving out the use of repaglinide in combination with metformin.[360] Caraco also "stipulated that its ANDA would infringe the '358 patent if it included a label that discussed the combination of repaglinide and metformin."[361] FDA approved Caraco's section viii statement. Then, in May 2009, Novo updated its use code narrative in the Orange Book for

---

[355] *Id.*

[356] *Id.*

[357] *Id.* at 1362 – 63.

[358] *Id.* at 1362.

[359] *See supra* note 81 and accompanying text.

[360] *Novo*, 601 F.3d at 1363.

[361] *Id.*

the ’358 patent by submitting to FDA a changed Form 3542. Pursuant to this form, FDA changed the U-546 use code to “U-968” and inserted Novo’s new use code narrative: “A method of improving glycemic control in adults with type 2 diabetes mellitus.”[362] As a result of this broader use code narrative, FDA reconsidered Caraco’s section viii statement. FDA rejected Caraco’s carve-out label because it overlapped with the U-968 use code for the ’358 patent.[363]

In June 2009, Caraco asserted a counterclaim under 21 U.S.C. § 355(j)(5)(C)(ii), challenging Novo’s changed use code and requesting a court order that Novo change the use code for the ’358 patent back to the U-546 use code. Caraco argued that the U-968 use code was “overbroad because it incorrectly suggested that the ’358 patent covered all three approved methods of using repaglinide even though it claimed only one approved method.”[364] In addition, Caraco asserted a patent misuse defense related to the ’358 patent’s use code narrative.

The United States District Court for the Eastern District of Michigan granted Caraco’s motion for summary judgment on the counterclaim, but did not rule on the patent misuse defense. The court agreed with Caraco’s reasoning that Novo’s U-968 use code was overbroad.[365] The court stated, “Novo is not a private FDA. Novo, by the change in the use code narrative is attempting to extend the life of an expired patent.”[366] The district court held that Caraco was entitled to an injunction directing Novo to submit an amended Form 3542 to FDA to change Novo’s use code for the ’358 patent back to the U-546 use code.[367]

---

[362] *Id.*

[363] *Id.*

[364] *Id.*

[365] Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., 656 F. Supp. 2d 729, 730 (E.D. Mich. 2009).

[366] *Id.* at 732.

[367] *Id.* at 730.

A panel of the Federal Circuit granted Novo's motion for expedited review and noted that this was the first time the court had interpreted the counterclaim provision. The circuit court reversed the district court's grant of an injunction. The court reasoned that Caraco did "not have a statutory basis to assert a counterclaim requesting such injunctive relief [for the change of the use code narrative]."[368] Judge Rader wrote the opinion of the court and interpreted the counterclaim provision of the Hatch-Waxman Act. He based his holding – that Caraco was not entitled to a changed use code under the counterclaim provision – on two grounds. First, the court began by analyzing the meaning of "an approved method" in 21 U.S.C. § 355(j)(5)(C)(ii)(I). Novo argued that "an approved method" meant *any* approved method, meaning that Caraco was entitled to the counterclaim only if the patent does not claim any approved methods.[369] However, Caraco argued that "an approved method" meant *all* approved methods, such that Caraco was entitled to the counterclaim if the patent does not claim the other two approved methods.[370] Judge Rader found the statutory provision to be unambiguous, with "an" meaning "any." Additionally, the court looked at the legislative history of the counterclaim provision, which indicated that the provision was only meant to correct the specific problem in *Mylan v. Thompson*,[371] where an innovator company listed a patent unrelated to the drug product or method.[372] The *Novo* court held that the "Hatch-Waxman Act authorizes a counterclaim only if the listed patent does not claim any approved methods of using the listed drug."[373]

---

[368] *Novo*, 601 F.3d at 1360.

[369] *Id.* at 1364.

[370] *Id.*

[371] 268 F.3d 1323 (Fed. Cir. 2001).

[372] *Novo*, 601 F.3d at 1365.

[373] *Id.* at 1365.

Second, the court held that the term "patent information," as used in the counterclaim provision,[374] is defined by the Act to mean only "the patent number and the expiration date."[375] Because the statute only refers to "the patent number and the expiration date," Judge Rader stated that patent information could only mean just this information. Thus, the court found that "the counterclaim provision only authorizes suits to correct or delete an erroneous patent number or expiration date."[376] Therefore, there was no statutory authorization for Caraco to assert a counterclaim challenging Novo's use code.

In a concurrence, Judge Clevenger, agreeing with Judge Rader's statutory interpretation, stated that Caraco's complaint should not lie with Novo but with FDA. "Novo did nothing that was illegal or forbidden. . . . But FDA, acting independently, gummed up the works [by] requiring a single broad indication for repaglinide as part of the approved labeling."[377] Also, Judge Clevenger commented on the appropriate institution to correct this issue when he stated: "Congress is the appropriate entity to readjust, if necessary, the delicate balance it has struck between original drug manufacturers and their generic counterparts."[378]

In a 28-page dissent, Judge Dyk disagreed with Judge Rader's interpretation of the statutory terms "an approved method" and "patent information." Judge Dyk declared:

> Today's decision strikingly limits the counterclaim provision with the consequence that, in all likelihood, the ANDA applicant is left without any remedy to correct an erroneous Orange Book listing with respect to a method of use patent. . . . [T]he majority's crabbed view of the statute sanctions an unjustified manipulation of the Orange Book.[379]

---

[374] 21 U.S.C. § 355(j)(5)(C)(ii)(I).

[375] *Novo*, 601 F.3d at 1366.

[376] *Id.*

[377] *Id.* at 1367 – 68 (Clevenger, J., concurring).

[378] *Id.* at 1368.

[379] *Id.* at 1382 (Dyk, J., dissenting).

First, the dissent stated that, contrary to the majority opinion, there is no definition of "patent information" in the statute. Judge Dyk argued that the statutory language demands that the "scope of the patent must be accurately described," which constitutes patent information.[380] Additionally, he stated that there is no statutory language that distinguishes between drug information and method of use information, making "all Orange Book information . . . 'patent information.'"[381]

Second, the dissent disagreed with the majority's interpretation of "an approved method" as any approved method. Judge Dyk stated that "an approved method" means an approved method of use listed by the NDA holder in the Orange Book. The dissent believed that "if the submitted Orange Book information claims patent coverage for an approved drug not covered by the patent or a method of use not covered by the patent, that information may be corrected."[382] The dissent asserted that this case illustrates Novo's manipulation of the Orange Book to prevent generic competition, which "the counterclaim provision was designed to avoid."[383] Finally, Judge Dyk stated that the majority opinion is contrary to the policy of the recent D.C. Circuit decision in *Sebelius*,[384] because Judge Rader's holding that Caraco's counterclaim is not available is "unsuppoorted by any cogent reason for leaving an ANDA applicant without a remedy to correct an erroneous Orange Book patent listing with respect to a method of use patent."[385]

---

[380] *Id.* at 1371.

[381] *Id.* at 1373.

[382] *Id.* at 1377.

[383] *Id.* at 1378.

[384] 595 F.3d 1303 (D.C. Cir. 2010).

[385] *Novo*, 601 F.3d at 1382.

2. Aftermath of *Novo*

After the *Novo* decision, Caraco petitioned the Federal Circuit for a rehearing en banc. The Pink Sheet reported that "[t]he generic industry has lined up against Novo Nordisk's maneuver to keep Caraco Pharmaceuticals from getting approval," as Apotex, Mylan, Impax, Teva, and the Generic Pharmaceutical Association submitted amicus briefs in support of Caraco's petition.[386] Apotex and Impax stated that "Novo voluntarily changed its description immediately after FDA approved Caraco's request to carve out non-infringing uses of Novo's drugs."[387] The Pink Sheet observed that the generic industry believes that the *Novo* decision will have a broad impact on ANDA litigation. Caraco's attorney asserted that the "Federal Circuit decision is endorsing what seems to be a blatant regulatory abuse. If it stands, this tactic will become the next best way to block generics."[388]

The Federal Circuit denied Caraco's petition for a rehearing en banc on July 29, 2010.[389] In dissent, Judge Gajarsa, with whom Judge Dyk joined, stated that "[t]he majority's opinion construes the counterclaim provision contrary to its manifest Congressional purpose. That construction renders 21 U.S.C. § 355(j)(2)(A)(viii) ("Section viii") carve-out statements a virtual nullity and leaves generic drug manufacturers without a remedy to challenge inaccurate Orange Book listings with respect to method of use patents."[390] Caraco filed a petition for a writ

[386] Brenda Sandburg, *"The Next Best Way To Block Generics" May Be Novo's Patent Use Code Switch*, THE PINK SHEET, June 7, 2010.

[387] *Id.*

[388] *Id.*

[389] *Novo*, 615 F.3d 1374 (Fed. Cir. July 29, 2010).

[390] *Id.* at 1375 – 76 (Gajarsa, J., dissenting).

of certiorari in December 2010. On March 28, 2011, the Supreme Court asked for the United States's views on whether it should hear the case.[391]

Several commentators have noted that possible Congressional intervention may be warranted regarding the patent delisting counterclaim provision. Stemming from Judge Clevenger's statement that Congress is the appropriate body to "readjust" the balance struck by the Hatch-Waxman Act, the Orange Book Blog observed that "[p]erhaps Congress will 'readjust' the Act" with respect to the counterclaim provision.[392] The FDA Law Blog also speculated about whether Congress will further amend the Hatch-Waxman Act with regard to the patent delisting counterclaim provision.[393] The controversy over patent use codes and the patent delisting counterclaim provision might increase in the future, as one commentator noted that the number of patent use codes in the Orange Book has doubled over the past several years, from 546 in 2004 to 1026 in 2010.[394]

---

[391] *High Court Asks U.S. for Views on Use of Hatch-Waxman Counterclaim Provision*, BNA PHARM. L. & INDUS. REP. (Apr. 1, 2011).

[392] Jim Wasicak & Aaron Barkoff, *Federal Circuit Vacates Injunction that Directed Novo Nordisk to Revise Patent Use Code for Prandin*, ORANGE BOOK BLOG (Apr. 15, 2010), http://www.orangebookblog.com/2010/04/federal-circuit-vacates-injunction-that-directed-novo-nordisk-to-revise-orange-book-patent-use-code-for-prandin.html.

[393] Kurt R. Karst, *Federal Circuit Reverses District Court Decision in Patent Delisting Counterclaim Case; All Orange Book Information is Not "Patent Information,"* FDA LAW BLOG (Apr. 15, 2010 7:04 AM), http://www.fdalawblog.net/ fda_law_blog_hyman_phelps/2010/ 04/federal-circuit-reverses-district-court-decision-in-patent-delisting-counterclaim-case-all-orange-bo.html.

[394] Kurt R. Karst, *Analysis Shows Patent Use Codes Have Doubled Since August 2003*, FDA LAW BLOG (July 8, 2010 1:25 PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/07/ analysis-shows-patent-use-codes-have-doubled-since-august-2003--by-kurt-r-karst-httpwwwhpmcomvattorneycfmrid22.html.

D. Declaratory Judgment Actions

Another recent area of controversy concerns the MMA's addition of a declaratory judgment action provision to the Hatch-Waxman Act.[395] Under this provision, if the NDA holder or patent owner does not bring a patent infringement action against a Paragraph IV ANDA filer within forty-five days of receiving notice, the generic applicant can sue to obtain a declaratory judgment that the patent listed in the Orange Book is invalid or not infringed.[396] Congress extended federal subject matter jurisdiction to these civil actions "to the extent consistent with the Constitution."[397] Therefore, federal courts have jurisdiction over declaratory judgment actions that present a "case or controversy" under Article III of the Constitution.

Several commentators have noted the importance of this provision to the Hatch-Waxman scheme. One commentator noted that the declaratory judgment provision "will help resolve patent disputes and clear the way to the introduction of new generic drugs by eliminating patents that are deemed by courts to be invalid or not infringed."[398] Additionally, during a Senate Judiciary Committee Hearing before the passage of the MMA, the Chief Counsel of FDA explained that "[g]enerics, for good reasons, want more certainty . . . before they launch."[399] Furthermore, in another Senate Judiciary Committee Hearing, Senator Schumer announced the importance of the declaratory judgment action provision to the entirety of the MMA reform, "I want to stress the importance of the declaratory judgment provision in this bill. It is key to

[395] *See* 21 U.S.C. § 355(j)(5)(C)(i).

[396] *Id.*

[397] *See* 35 U.S.C. § 271(e)(5).

[398] Derzko, *supra* note 19, at 241.

[399] 2003 Hearing, *supra* note 1, at 11 (statement of Daniel E. Troy, Chief Counsel, FDA).

making the system work. There is not currently a clear pathway for a generic drug company to get a declaratory judgment to show that they do not infringe a patent."[400]

Since the passage of the MMA, substantial controversy has arisen regarding when a generic applicant meets the "case or controversy" requirement of Article III. Since 2003, the federal courts' jurisprudence over when the "case or controversy" requirement is met in declaratory judgment actions relating to patent disputes has changed substantially. This section of the paper explains the evolution of the courts' Article III jurisprudence with respect to declaratory judgment actions over patent disputes and then considers the recent controversies that have arisen regarding the declaratory judgment action provision. Particularly, after the Supreme Court broadened the declaratory judgment standard in *MedImmune, Inc. v. Genentech, Inc.*,[401] various court decisions on whether a Paragraph IV filer satisfies the "case or controversy" requirement "suggest that the law may still be unsettled in this area and that small nuances can make a big difference in results."[402]

1. *Teva Pharmaceuticals, USA, Inc. v. Pfizer, Inc.*

When the MMA was passed in December 2003, the federal courts' standard to determine whether Article III was satisfied in declaratory judgment actions over patent disputes was the "reasonable-apprehension-of-suit" test.[403] Under this test, the court determined whether the generic applicant had a reasonable apprehension that the patent owner would sue for patent infringement, and if the court determined that there was a reasonable apprehension, Article III

[400] Examining the Senate and House Versions Hearing, *supra* note 216, at 16 (statement of Senator Charles E. Schumer).

[401] 549 U.S. 118 (2007).

[402] Patel, *supra* note 19, at 1109.

[403] *See* Examining the Senate and House Versions Hearing, *supra* note 216, at 12 (statement of Sheldon Bradshaw, Deputy Assistant Attorney General, OLC, DOJ).

was satisfied.[404] This test was reaffirmed by the Federal Circuit's decision in *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*[405] The court stated that under the test, "there must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff which could constitute infringement."[406] Applying this test, the court held that it did not have subject matter jurisdiction over the declaratory judgment action because the generic company did not have a reasonable apprehension of suit by the NDA holder. One commentator stated that this test was "stringent," leading to most declaratory judgment actions being dismissed.[407]

2. *MedImmune, Inc. v. Genentech, Inc.*

In *MedImmune*, the Supreme Court rejected the reasonable-apprehension-of-suit test to determine if a justiciable controversy existed in a declaratory judgment action.[408] The Court in *MedImmune* stated that in analyzing whether a declaratory judgment action satisfies the "case or controversy" requirement under Article III, the appropriate test is based on "all the circumstances."[409] The Court determined that the analysis entails assessing "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."[410] Also, the Court explained that the dispute must be "'definite and

---

[404] *Id.*

[405] 395 F.3d 1324 (Fed. Cir. 2005).

[406] *Id.* at 1330.

[407] Patel, *supra* note 19, at 1093.

[408] *MedImmune*, 549 U.S. at 132 n.11.

[409] *Id.* at 127.

[410] *Id.*

concrete . . . and that it [must] be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character."[411]

The *MedImmune* decision "relaxed the declaratory judgment test," and therefore "declaratory judgments became a more viable option for Subsequent Paragraph IV ANDA filers."[412] In *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*,[413] the Federal Circuit applied *MedImmune*'s totality of the circumstances test to a Paragraph IV ANDA filer's declaratory judgment action.[414] In this case, Novartis's drug Famvir had five patent listings in the Orange Book. Teva filed an ANDA with Paragraph IV certifications to all five patents; however, Novartis only brought an infringement action against Teva on the base patent.[415] Teva then brought a declaratory judgment action on the unasserted patents,[416] and Novartis moved to dismiss for lack of subject matter jurisdiction, contending that there was no case or controversy under Article III. The district court dismissed the suit based on the reasonable-apprehension-of-suit test. However, on appeal, the Federal Circuit applied *MedImmune*'s test and found a justiciable controversy between the parties.[417] The court held that a "justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents."[418]

---

[411] *Id.*

[412] Patel, *supra* note 19, at 1102.

[413] 482 F.3d 1330 (Fed. Cir. 2007).

[414] *Id.* at 1342.

[415] *Id.* at 1334.

[416] *Id.* at 1335.

[417] *Novartis*, 482 F.3d at 1346.

[418] *Id.* at 1344.

3. Recent Court Decisions: Covenants Not to Sue

Since *MedImmune* and *Novartis* and the adoption of the all-the-circumstances test, some innovator companies have granted to subsequent Paragraph IV ANDA filers covenants not to sue either on all of the patents listed in the Orange Book or any patents not sued upon in infringement actions.[419] This practice of granting covenants not to sue with respect to certain patents has raised the legal question of whether covenants not to sue vitiate generic drug companies' declaratory judgment action jurisdiction. Two Federal Circuit decisions in 2008 and later district court decisions illustrate how "the treatment [by courts] of covenants not to sue seems unsettled, as it is a very new area."[420]

In *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*,[421] Forest was the innovator company for the drug Lexapro, Ivax was the first Paragraph IV ANDA filer, and Caraco was the subsequent Paragraph IV ANDA filer.[422] Forest had two patent listings for its drug Lexapro in the Orange Book, to which Ivax and Caraco filed Paragraph IV certifications. Forest sued Ivax on only one of these listed patents, which was found valid and infringed.[423] Forest sued Caraco on the litigated patent and provided Caraco a convenant not to sue on the unasserted patent.[424] Thereafter, Caraco brought a declaratory judgment action for the unasserted patent, because in order to trigger Ivax's 180-day exclusivity, Caraco had to successfully challenge both of the listed patents in the Orange Book. The Federal Circuit applied *MedImmune*'s all-the-circumstances test and found that, despite the covenant not to sue,

---

[419] *See* Patel, *supra* note 19, at 1103.

[420] *Id.* at 1104.

[421] 527 F.3d 1278 (Fed. Cir. 2008).

[422] *Id.* at 1286, 1288.

[423] *Id.* at 1286.

[424] *Id.* at 1288.

Caraco's declaratory judgment action presented a justiciable Article III controversy. The controversy "exists because Forest's actions effectively prevent the FDA from approving Caraco's ANDA and thus exclude Caraco from the drug market."[425]

However, in *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*,[426] six months after deciding *Caraco* and in a case involving another covenant not to sue, the Federal Circuit affirmed the dismissal of Apotex's declaratory judgment action. In *Janssen*, three patents were listed in the Orange Book related to Janssen's listed drug, Risperdal Oral Solution. Teva was the first Paragraph IV ANDA filer with regard to two of the patents and filed a Paragraph III certification to the third patent, the '663 patent. Janssen did not bring infringement actions against Teva for the Paragraph IV certifications. Apotex, the subsequent Paragraph IV filer, made Paragraph IV certifications to all three patents. Janssen brought an infringement action only against the'663 patent and granted a covenant not to sue with respect to the other two patents.[427] However, unlike in *Caraco*, Apotex "stipulated to the validity, infringement, and enforceability of the '663 patent."[428] Applying the all-the-circumstances test, the Federal Circuit would have found *Caraco* controlling if Apotex had not made the stipulation. Because of the stipulation, however, Apotex would not be able to obtain FDA approval until after the expiration of the '663 patent even if Apotex could prevail in its declaratory judgment action against the other two listed patents. As such, the harm that created a justiciable controversy under Article III disappeared with the stipulation.

---

[425] *Id.* at 1297.

[426] 540 F.3d 1353 (Fed. Cir. 2008).

[427] *Id.* at 1358.

[428] *Id.* at 1360.

Since *Caraco* and *Janssen*, district courts have evidenced difficulty applying the law with regard to declaratory judgment actions, demonstrating the Federal Circuit's "lack of clear direction."[429] For instance, in *Dey, L.P. v. Sepracor*,[430] the Delaware district court found that Dey's declaratory judgment action presented a justiciable Article III controversy. In the case, Sepracor listed six patents in the Orange Book regarding its brand-name drug Xopenex. Dey, the subsequent Paragraph IV ANDA filer, made Paragraph IV certifications to all six patents. Sepracor sued Dey on only five of the patents. Dey filed a declaratory judgment action regarding the unasserted patent, the '289 patent, and Sepracor granted Dey a covenant not to sue on this patent. In analyzing whether the covenant not to sue eliminated Dey's subject matter jurisdiction, the court reasoned that "the instant case is intermediate to *Caraco* and *Janssen*" and "is more like *Caraco* than *Janssen*."[431] The court stated that "unlike Apotex in the *Janssen* case, Dey has not precluded itself from going to market prior to the primary ANDA filer."[432] Thus, the court denied Sepracor's motion and concluded that there was subject matter jurisdiction to hear the case.

Recently, on October 6, 2010, the Federal Circuit held that there was subject matter jurisdiction over the declaratory judgment action in *Teva Pharmaceuticals USA, Inc. v. Eisai Co.*[433] This case concerned Eisai's brand-name drug Aricept, in which five patents were listed in the Orange Book for the drug.[434] Ranbaxy, the first Paragraph IV ANDA filer, made Paragraph IV certifications to four of the patents and a Paragraph III certification to the '841

[429] Patel, *supra* note 19, at 1109 n. 222.
[430] 595 F. Supp. 2d 355 (D. Del. 2009).
[431] *Id.* at 361 – 62.
[432] *Id.* at 362.
[433] 620 F.3d 1341 (Fed. Cir. 2010).
[434] *Id.* at 1343.

patent.[435] Ranbaxy's 180-day exclusivity has yet to be triggered. Teva, a subsequent Paragraph IV ANDA filer, submitted an amended ANDA with Paragraph IV certifications to all five patents, and Eisai only brought suit against Teva with respect to the '841 patent. When Eisai did not initiate patent infringement litigation regarding the other four patents, Teva sought a declaratory judgment of non-infringement with respect to the four patents.[436] Prior to the declaratory judgment litigation, Eisai had filed statutory disclaimers with respect to two of the declaratory judgment patents. After Teva's filing of the declaratory judgment action, Eisai granted Teva covenants not to sue with respect to the other two declaratory judgment patents. Given the statutory disclaimers and covenants not sue, Eisai argued that Teva's declaratory judgment action did not create a case or controversy under Article III.

The court stated that the case "turn[ed] on whether a subsequent Paragraph IV filer has a legally cognizable interest in when the first-filer's exclusivity period begins, such that delay in triggering that period qualifies as "injury-in-fact" for the purposes of Article III."[437] The court found that Teva's action presented an actual controversy despite the statutory disclaimers and covenants not to sue, because the patents were still listed in the Orange Book.[438] Therefore, Teva still needed to obtain a court decision of patent invalidity or non-infringement to receive FDA approval.[439] The court found the case similar to *Caraco*: "as in *Caraco*, a favorable judgment 'would eliminate the potential for the [DJ patents] to exclude [Teva] from the drug market.'"[440] The court held that it was important that the declaratory judgment patents were still

[435] *Id.* at 1344.
[436] *Id.* at 1345.
[437] *Id.* at 1343.
[438] *Id.* at 1348 n.3.
[439] *Id.*
[440] *Id.* at 1347.

listed in the Orange Book, and that if Teva were to succeed in its declaratory judgment action with respect to the four patents, it would trigger Eisai's 180-day exclusivity.

These declaratory judgment actions, mostly arising in the context of a subsequent Paragraph IV ANDA filer trying to trigger the first applicant's 180-day exclusivity, have been decided by the courts based on the specific factual circumstances of the cases under the *MedImmune* test. The courts have relied on the Federal Circuit's guidance in *Caraco* and *Janssen*, with the courts trying to determine if the case before them is more similar to *Caraco* or to *Janssen*. Given that there are no bright-line rules in the courts' declaratory judgment action jurisprudence, and that many different factual scenarios and nuances will likely develop, it will be hard to predict how the courts will rule in future cases. More contentious litigation over whether subject matter jurisdiction exists in generic companies' declaratory judgment actions will likely occur in the future, with the courts having a chance to further refine their jurisprudence.

E. Patent Settlement Agreements

After the passage of the MMA and the promulgation of the 2003 FDA final rule clarifying patent listing requirements, much of the antitrust litigation against pharmaceutical companies has not stemmed from allegations of misrepresentation or fraud with regard to an NDA holder's Orange Book patent listings. However, concern over the anticompetitive effects of patent settlement agreements, which was an issue prior to the passage of the MMA,[441] still persists today. The FTC Study of 2002 identified fourteen patent settlement agreements that had

[441] For instance, during one of the Senate debates prior to the passage of the MMA, Senator Hatch stated, "The FTC is doing the right thing in taking enforcement actions against those who enter into anti-competitive agreements that violate our Nation's antitrust laws." 148 Cong. Rec. S7348 (July 25, 2002) (statement of Senator Hatch).

the tendency to "park" a generic applicant's 180-day exclusivity.[442] The parking of a generic company's 180-day exclusivity delays the entry of generic competitors into the market, which then delays decreases in drug prices for consumers.[443]

Congress addressed the anticompetitive consequences of patent settlement agreements by passing two provisions in the MMA. First, pursuant to the recommendation of the FTC, the MMA added a notification provision in which drug companies must file with the FTC and DOJ certain types of patent settlement agreements.[444] This requirement was added so that the FTC and DOJ could review certain patent settlement agreements for violations of the federal antitrust laws and take appropriate action if necessary. Second, the MMA added forfeiture provisions to the Hatch-Waxman Act, whereby if a forfeiture event occurs, the first generic applicant loses its 180-day exclusivity.[445] Some of these forfeiture events are tied explicitly to drug companies entering into patent settlement agreements. For instance, under the failure to market forfeiture provision, the second component of the provision is satisfied if the generic company does not market the drug within seventy-five days after court approval of a settlement agreement that finds the patent to be invalid or not infringed.[446] Also, under a separate forfeiture provision of the MMA, a forfeiture event occurs if there is a final decision of the FTC or a court that finds a patent settlement agreement to be in violation of the antitrust laws.[447]

---

[442] *See supra* note 160 and accompanying text.

[443] *See id.*

[444] *See supra* notes 265-271 and accompanying text.

[445] *See* 21 U.S.C. § 355(j)(5)(D)(i)-(ii).

[446] *See* 21 U.S.C. § 355(j)(5)(D)(i)(I).

[447] *See* 21 U.S.C. § 355(j)(5)(D)(i)(V).

Although Congress attempted to address the concerns relating to reverse-payment patent settlement agreements through these MMA provisions, considerable debate exists over whether these provisions do an adequate job of remedying these agreements' anticompetitive consequences. Some commentators believe that Congress should ban reverse-payment settlement agreements or place more restrictions on them. Other commentators believe that banning reverse-payment settlement agreements would lead to anticompetitive consequences. This next section analyzes the recent controversies over patent settlement agreements, an area of great debate among regulators, legislators, drug companies, consumers, courts, and scholars.

1. Scholarly Debate over Patent Settlement Agreements

Since the 1990s, many Hatch-Waxman scholars, antitrust experts, and others have weighed in on the debate over reverse-payment patent settlement agreements. On one side of the debate, many commentators believe that patent settlement agreements between generic and innovator companies or between two generic companies should not be banned. For instance, Jonathan Lave argued that reverse-payment settlement agreements should not be deemed *per se* violations of the antitrust laws, because the "existence [of a reverse payment] does not necessarily show that the generic extracted monopoly rents from the pioneer or that the pioneer sought to protect an invalid patent. Rather, the settlement's terms may be procompetitive and rational."[448] Lave concluded that the FTC and DOJ should adopt a case-by-case approach to reverse-payment settlements, reviewing the size of the payments in the settlements and upholding only reasonable payments that are less than or equal to a generic company's expected payout from the litigation.[449]

---

[448] Jonathan M. Lave, *Responding to Patent Litigation Settlements: Does the FTC Have it Right Yet?*, 64 U. PITT. L. REV. 201, 203 (2002).

[449] *Id.* at 226.

Judge Posner of the Seventh Circuit, sitting by designation on the United States District Court for the Northern District of Illinois, stated his position on reverse-payment settlement agreements in dictum in a recent opinion. He explained that "[a] ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive."[450] Echoing this sentiment was an opinion piece recently published in the Wall Street Journal that stated "[r]everse settlements expand the options for rationally ending patent disputes. . . . Eliminating reverse settlements will reduce the incentive to challenge patents at all."[451]

On the other side of the debate, many commentators believe that there should be an outright ban on reverse-payment settlement agreements or a rebuttable presumption of their illegality. For instance, Professor C. Scott Hemphill reasoned that "a settlement should be accorded a presumption of illegality as an unreasonable restraint of trade if the settlement both restricts the generic firm's ability to market a competing drug and includes compensation from the innovator to the generic firm."[452] This presumption can be rebutted by the drug companies making a showing that there are pro-competitive consequences of the settlement.[453] Additionally, Professors Ponsoldt and Ehrenclou proposed a similar approach: reverse-payment settlement agreements that maintain the pioneer drug company's monopoly should be presumptively illegal; this presumption can be rebutted by the pioneer drug company

[450] Asahi Glass Co., Ltd. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003).
[451] *The 'Pay for Delay' Rap*, WALL STREET JOURNAL (Oct. 5, 2010).
[452] Hemphill, *supra* note 85, at 1561.
[453] *Id.* at 1596.

demonstrating that it was likely to win on the merits of the patent infringement litigation and that the settlement payment is similar to the expected litigation costs of the suit.[454]

2. The FTC's Position

The FTC has long taken the position that reverse-payment settlement agreements are *per se* antitrust violations.[455] The FTC believes that these settlements – in which the innovator company pays the generic company and the generic company agrees to stay out of the market – delay generic competition and hurt consumers. The Chairman of the FTC, Jon Leibowitz, has termed these agreements "win-win-lose" agreements: the pioneer company wins by continuing to have its monopoly, the generic company wins by being paid a large sum of money by the pioneer company, and the consumers lose by being forced to continue to pay high prices for drugs.[456]

The FTC has challenged many of these agreements as being unreasonable restraints on trade in violation of section 5 of the FTC Act.[457] In 2000 and 2001, the FTC succeeded in obtaining two consent decrees involving reverse-payment settlement agreements between innovator and generic drug companies.[458] Leibowitz declared that the FTC's actions

---

[454] James F. Ponsoldt & W. Hennen Ehrenclou, *The Antitrust Legality of Pharmaceutical Patent Litigation Settlements*, 2006 U. Ill. J.L. TECH. & POL'Y 37, 57 – 58 (2006).

[455] *See Hearing of the Senate Special Committee on Aging*, 109th Cong. (July 20, 2006) (statement of Jon Leibowitz, Commissioner of the FTC) ("For the past decade, the FTC has made challenging patent settlements that delay generic entry a bipartisan priority. In the late 1990's, when we started seeing these disturbing pharmaceutical settlement payments, we acted to stop them.").

[456] *See Official Says FTC Still Seeks to Bring Case on Reverse Payments to End Circuit Split*, BNA PHARM. L. & INDUS. REP. (Oct. 8, 2010).

[457] *See, e.g.*, *In re* Bristol-Myers Squibb Co., No. C-4076, 2003 WL 21008622 (F.T.C. Apr. 14, 2003) (consent decree); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).

[458] *See In re* Abbott Labs. & Geneva Pharm., Inc., No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000); *In re* Hoechst Marion Roussel, Inc., No. 9293, 2001 WL 333643 (F.T.C. Apr. 2, 2001).

against companies entering into these types of agreements "stopped this conduct cold. And it set forth rules that everyone understood: if you settle a pharmaceutical patent case by paying off a generic, you will face antitrust scrutiny. As a result, to the best of our knowledge there were no such settlements between 2000 and 2004."[459]

3. Recent Litigation in the Courts

Recently, however, the federal courts have not been very receptive to the FTC's position on reverse-payment settlement agreements. Currently, three circuit courts have held that reverse-payment settlement agreements are not *per se* antitrust violations. The Eleventh Circuit in *Schering-Plough Corp. v. FTC*,[460] the Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation*,[461] and the Federal Circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*[462] all held that reverse-payment settlement agreements are legal so long as the agreements do not exceed the scope of patent protection. However, the Sixth Circuit in *In re Cardizem CD Antitrust Litigation*[463] held that reverse-payment settlement agreements were *per se* illegal. The circuit court stated:

> There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade.[464]

Leibowitz stated that the court opinions upholding the reverse-payment settlement agreements "have dramatically altered the legal landscape," hurting the FTC's enforcement

---

[459] *Hearing of the Senate Special Committee on Aging*, 109th Cong. (July 20, 2006) (statement of Jon Leibowitz, Commissioner of the FTC).

[460] 402 F.3d 1056 (11th Cir. 2005).

[461] 466 F.3d 187 (2d Cir. 2006).

[462] 544 F.3d 1323 (Fed. Cir. 2008).

[463] 332 F.3d 896 (6th Cir. 2003).

[464] *Id.* at 908.

strategy.[465] Furthermore, the FTC has seen a rise in the number of reverse-payment settlement agreements being entered into by drug companies.[466] Given these federal courts' positions on reverse-payment settlement agreements, the FTC and many commentators believe that the MMA's addition of the notification provision was inadequate. Even if drug companies must file reverse-payment settlement agreements with the DOJ and the FTC, and the FTC finds that these agreements violate the antitrust laws, the FTC has been unable to prevail on these antitrust claims in court. One commentator stated that "Congress incorrectly assumed that the FTC would be able to stop pay-for-delay settlements. This harmful practice has proceeded unabated in light of a split among the federal circuit courts of appeals on whether such payments are antitrust violations."[467] In order to resolve the circuit split, the FTC has pursued the strategy of filing new suits in district courts to create a bigger split among the courts of appeals, so that the Supreme Court will be more likely to hear the issue.[468]

4. The Failure to Market Provision and Patent Settlement Agreements

In addition to the legal problems relating to the FTC's recent enforcement efforts, commentators and FDA have acknowledged a loophole in the second component of the failure to market provision relating to patent settlement agreements. The second component of the failure to market provision is satisfied if the generic company does not market the drug within seventy-five days after court approval of a settlement agreement that finds the patent to be invalid or not

---

[465] *Hearing of the Senate Special Committee on Aging*, 109th Cong. (July 20, 2006) (statement of Jon Leibowitz, Commissioner of the FTC).

[466] FTC, PAY FOR DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 1 (Jan. 2010), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

[467] Avery, *supra* note 3, at 190.

[468] *See Official Says FTC Still Seeks to Bring Case on Reverse Payments to End Circuit Split*, BNA PHARM. L. & INDUS. REP. (Oct. 8, 2010).

infringed.[469] Congress added this provision to prevent the parking of a generic company's 180-day exclusivity due to a patent settlement agreement. Under the new provision, if a generic company eligible for 180-day exclusivity and an innovator company entered into a patent settlement agreement that found the patent to be invalid or not infringed, the generic company would forfeit its 180-day exclusivity if it did not market the drug within seventy-five days of court approval of the settlement.

Several companies have circumvented this provision by entering into patent settlement agreements that do not include a finding of patent invalidity or non-infringement. Therefore, to the advantage of both the innovator company and the generic company, the generic company retains its 180-day exclusivity even after entering into the patent settlement agreement. In a 2008 decision letter, FDA acknowledged that "the structure of the 180-day exclusivity and forfeiture provisions may give rise to concerns about parking of exclusivity."[470] FDA stated:

> Inherent in the structure of the "failure to market" forfeiture provisions is the possibility that a first applicant would be able to enter into a settlement agreement with the NDA holder or patent owner in which a court does not enter a final judgment of invalidity or non-infringement (i.e., without a forfeiture event under subpart (bb) occurring), and that subsequent applicants would be unable to initiate a forfeiture with a declaratory judgment action. This inability to force a forfeiture of 180-day exclusivity could result in delays in the approval of otherwise approvable ANDAs owned by applicants that would market their generic drugs if they could but obtain approval. This potential scenario is not one for which the statute currently provides a remedy.[471]

5. *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*

In 2010, the Second Circuit had the opportunity to revisit the issue of the legality of reverse-payment settlement agreements in *Arkansas Carpenters Health and Welfare Fund v.*

---

[469] *See* 21 U.S.C. § 505(j)(5)(D)(i)(I)(bb)(BB).

[470] FDA, *Letter to Marc A. Goshko*, RE: Docket No. 2007N-0389, ANDA 77-165: Granisetron Hydrochloride Injection (Jan. 17, 2008), at 6.

[471] *Id.* at 5 n.6.

Bayer AG.[472] This case concerned Bayer AG's brand-name drug Cipro, which is "the most prescribed antibiotic in the world."[473] Barr Laboratories, Inc. filed an ANDA with a Paragraph IV certification to a patent of Cipro. Bayer sued Barr for patent infringement, and two weeks before the start of the trial, Bayer and Barr entered into a reverse-payment settlement agreement. Bayer agreed to pay Barr approximately $398 million, and Barr agreed to concede to the validity of the patent and refrain from marketing a generic version of Cipro until the expiration of the patent.[474] In its analysis, the panel of the Second Circuit felt bound to apply the law as stated in the *In re Tamoxifen* case[475] and held that the reverse-payment settlement agreement did not violate the Sherman Act.[476] However, the court added several paragraphs at the end of its opinion that explained "why this case might be appropriate for reexamination by our full Court."[477] First, the panel noted that the United States believes that the *Tamoxifen* standard does not contain the appropriate level of antitrust inquiry. Second, the court stated that since the Second Circuit decided the *Tamoxifen* case, there has been an increase in the number of reverse-payment settlement agreements.[478] Third, the court noted that after *Tamoxifen* was decided, Senator Hatch – a principal drafter of the Hatch-Waxman Act – stated, "I can tell you that I find these type[s] of reverse payment collusive agreements appalling."[479] The court thus urged the plaintiffs to petition for a rehearing en banc.

---

[472] 604 F.3d 98 (2d Cir. 2010).

[473] *Id.* at 100.

[474] *Id.* at 102.

[475] 466 F.3d 187 (2d Cir. 2006).

[476] *Id.* at 106.

[477] *Id.* at 108.

[478] *Id.* at 109.

[479] *Id.* (quoting 148 Cong. Rec. S7565 (July 30, 2002)).

The Second Circuit denied the plaintiffs' petition for a rehearing en banc. In dissent, Judge Pooler, a member of the original panel, expressed her discontent with patent settlement agreements, stating that "such settlements serve no obvious redeeming purpose."[480] Furthermore, she stated, "This type of settlement, once unheard of, has become increasingly common. This Court has played a significant role in encouraging this unfortunate practice."[481] The plaintiffs filed a petition for a writ of certiorari on December 6, 2010. Several prominent *amici* briefs were filed in support of the petition for writ of certiorari. For instance, a group of thirty-two state attorneys general urged the Supreme Court to hear the case, arguing that these reverse-payment settlement agreements drive up drug prices for both the states' citizens and the states themselves.[482] Additionally, a group of eighty law professors filed a brief urging the Supreme Court to take the case. However, the Supreme Court denied the petition for writ of certiorari on March 7, 2011.[483]

The Supreme Court might not have granted the writ due to a lack of a circuit split, as three of the four courts of appeals to address the matter have held that reverse-payment settlement agreements are not *per se* illegal. It appears likely that the FTC will continue to file suits in different district courts to try to create a circuit split for resolution by the Supreme Court. As one FTC employee stated, "As long as there are still circuits to bring cases in, we're out there trying to do that."[484] Or, the Supreme Court might not have taken the case given that the issue of

---

[480] *Ark. Carpenters Health and Welfare Fund*, 625 F.3d 779, 780 (2d Cir. 2010).

[481] *Id.* at 780.

[482] Brief of the States of California, Arizona, et al. as Amici Curiae Supporting Petitioners, Louisiana Wholesale Drug Co., Inc. v. Bayer AG, No. 10-762, 2011 WL 96299.

[483] Louisiana Wholesale Drug Co., Inc. v. Bayer AG, 79 USLW 3370 (U.S. Mar. 07, 2011) (No. 10-762).

[484] *See Official Says FTC Still Seeks to Bring Case on Reverse Payments to End Circuit Split*, BNA PHARM. L. & INDUS. REP. (Oct. 8, 2010).

reverse-payment settlement agreements "is [currently] a hot topic in the halls of Congress."[485] Given that the FTC, the United States, the federal courts, members of Congress, scholars, and drug companies have diverging views on the anticompetitive consequences of reverse-payment settlement agreements, a legislative or judicial resolution of the issue seems necessary. The potential for legislative reform in this area will be discussed in Part VI.

F. Authorized Generic Drugs

Both the 2003 MMA and FDA final rule failed to address the issue of authorized generic drugs ("authorized generics") and the concern over these drugs' anticompetitive consequences. When an NDA holder's pioneer drug is about to lose its market exclusivity and patent protections, the NDA holder may try to maintain some of its market share by competing with the new generic competitors that are about to enter the market. The innovator drug company has two basic options in entering the generic drug market: either the innovator company itself (usually through a subsidiary) can manufacture, market, and sell a generic version of the pioneer drug under its own NDA, or the innovator company can license a generic drug company to market a generic version of the pioneer drug. These types of generic drugs that enter the market are referred to as authorized generics.

One commentator explains that "instead of being manufactured and marketed by a generic drug firm pursuant to FDA's approval of an ANDA, authorized generics are

[485] Kurt R. Karst, *Psych! Second Circuit Denies Rehearing Petition in CIPRO Patent Settlement Litigation after Panel Invites Petition*, FDA LAW BLOG (Sept. 9, 2010 12:20PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/09/psych-second-circuit-denies-rehearing-petition-in-cipro-patent-settlement-litigation-after-panel-inv.html.

manufactured by, or under a licensing agreement with, the approved NDA holder for the brand-name drug."[486] FDA defines an authorized generic drug as the following:

> [T]he Agency defines the term . . . as any marketing by an NDA holder or authorized by an NDA holder, including through a third-party distributor, of the drug product approved under the NDA in a manner equivalent to the marketing practices of holders of an approved ANDA for that drug. For example, an NDA holder might change the product's label . . . or market the product through commercial channels routinely used by generics.[487]

Authorized generics are not listed in the Orange Book, but are identical to the substance of the pioneer drug.[488] Pursuant to the FDA Amendments Act of 2007 ("FDAA"), on July 28, 2009, FDA promulgated a final rule requiring that pioneer drug companies submit information to FDA on the sale of their authorized generics.[489]

A 2006 FDA study determined the effect of generic drug entry on pioneer drug prices.[490] When the first generic drug competitor enters the market, the pioneer drug price only decreases by about five percent. However, when the sixth generic drug competitor enters the market, there is about a seventy-five percent decrease in the pioneer drug price.[491] So, when the NDA holder is about to lose patent protection of its pioneer drug, it makes economic sense for the NDA holder to enter the generic drug market as soon as possible, before the substantial decrease in drug prices with the entry of multiple generic drug competitors.

---

[486] Jeffrey N. Wasserstein & Kurt R. Karst, *New Law Reins in "Authorized Generics" Despite Generic Industry Court Losses, But Leaves Several Ambiguities*, 11 REG. AFFAIRS FOCUS 8 (2006), *available at* http://www.hpm.com/pdf/AUTHORIZED%20GENERICS_1.PDF.

[487] FDA, *Letter to Stuart A. Williams (Mylan Pharmaceuticals) and James N. Czaban (Heller Ehrman)*, RE: Docket Nos. 2004P-0075/CP1 & 2004P-0261/CP1 (July 2, 2004), at 2 n.2, *available at* http://www.fda.gov/ohrms/DOCKETS/dailys/04/july04/070704/04p-0075-pdn0001.pdf.

[488] *Id.*

[489] 74 Fed. Reg. 37,163 (2009).

[490] *See supra* notes 103-104 and accompanying text.

[491] *Id.*

The main debate over authorized generics arises when an authorized generic is marketed during a first generic applicant's 180-day exclusivity. Under the MMA, a first generic applicant that submits to FDA a substantially complete ANDA with a Paragraph IV certification to a patent of the pioneer drug is eligible for a period of 180 days of market exclusivity. [492] During this 180-day period, FDA is prohibited from approving any other ANDAs for the listed drug.[493] However, the MMA does not explicitly prohibit the marketing of a generic version of a pioneer drug under the pioneer drug company's NDA. One scholar notes that the market entry of an authorized generic during a first generic applicant's 180-day exclusivity "substantially reduces the value of this period of market exclusivity."[494] Many generic drug companies have petitioned FDA and sued in court to stop the marketing of authorized generics during the period of 180-day market exclusivity. This next section explores the views of the federal courts, FTC, FDA, members of Congress, and Hatch-Waxman scholars on this new pressing issue of authorized generics.

1. The Position of FDA and the Courts

In 2004, Mylan Pharmaceuticals Inc. and Teva Pharmaceuticals USA, Inc., both generic drug manufacturers, submitted citizen petitions to FDA, requesting that FDA prohibit the marketing and distribution of authorized generic drugs until after the companies' respective periods of 180-day market exclusivity had expired.[495] The companies argued that, based on both the statutory provisions and policy of the Hatch-Waxman Act, FDA should delay the marketing of authorized generics until after a generic applicant's valuable 180-day exclusivity period. FDA

[492] *See* 21 U.S.C. § 355(j)(5)(B)(iv).

[493] *See* 21 U.S.C. § 355(j)(5)(B)(iv).

[494] HUTT, MERRILL & GROSSMAN, *supra* note 16, at 767.

[495] *See* Citizen Petition of Mylan Pharmaceuticals, Inc., Docket No. 2004P-0074 (Feb. 18, 2004); Citizen Petition of Teva Pharmaceuticals USA, Inc., Docket No. 2004P-0261 (June 9, 2004).

denied both citizen petitions. In its July 2, 2004 decision letter, FDA first stated that because an authorized generic is marketed under the FDA-approved NDA, simply at a lower price and under a different name, an authorized generic does not need FDA approval prior to being marketed.[496] Then, FDA proceeded to reject the petitioners' arguments based on both law and policy grounds. FDA stated that "[n]ot only does FDA lack authority to justify delaying the marketing of authorized generics solely to protect 180-day exclusivity, the Agency does not believe their marketing should be delayed in this manner, as this marketing appears to promote competition in the pharmaceutical marketplace."[497]

FDA concluded that the entry of an authorized generic onto the market during a generic company's 180-day exclusivity would increase competition and drive down prices of generic drugs for consumers, thus fulfilling one of the objectives of the Hatch-Waxman Act.[498] FDA did not find any long-term anticompetitive consequences from allowing authorized generics onto the market during periods of 180-day exclusivity, as neither petitioner proffered evidence that "competition from authorized generics has the effect of destroying the intended benefit of the 180-day exclusivity and, thereby, the incentive to challenge patents."[499] FDA concluded with the strong declaration that "[t]he marketing of authorized generics during the 180-day exclusivity period is a long-standing, pro-competitive practice, permissible under the Act."[500]

---

[496] FDA, *Letter to Stuart A. Williams (Mylan Pharmaceuticals) and James N. Czaban (Heller Ehrman)*, *supra* note 487, at 2 ("Because removing the brand name or changing the channel of distribution is unlikely to pose any threats to public health, FDA has made clear that applicants generally need not submit any pre-approval notification to the Agency for these changes.").

[497] *Id.*

[498] *Id.* at 12.

[499] *Id.* at 13.

[500] *Id.*

Both Teva and Mylan filed complaints against FDA in federal district court, asking the courts to order that FDA prevent the marketing of authorized generics during the generic companies' 180-day exclusivity. The district courts affirmed FDA's decisions.[501] The generic companies appealed, but both courts of appeals affirmed the district courts' decisions.[502] For instance, in *Teva Pharmaceutical Industries Ltd v. Crawford*,[503] the D.C. Circuit upheld FDA's ruling in its decision letter under *Chevron* step one. The court concluded that the 180-day exclusivity provision of the Hatch-Waxman Act[504] does not prohibit an NDA holder from marketing an authorized generic during a generic company's 180-day exclusivity period.[505]

2. The Position of Generic Drug Companies and Other Scholars

In its response to the Mylan and Teva citizen petitions, FDA clearly made known its position on authorized generics: (1) the Hatch-Waxman Act does not prohibit the marketing of authorized generics during a generic company's 180-day exclusivity; and (2) the entry of authorized generic drugs increases competition, thus achieving one of the goals of the Hatch-Waxman Act. FDA's first position regarding the mandate of the Hatch-Waxman Act has been upheld by the federal courts and is "undoubtedly correct."[506]

However, much controversy remains regarding FDA's second proposition that authorized generics have clear pro-competitive consequences by increasing competition in the generic drug market and thus driving down consumer prices. While this short-term analysis may

---

[501] *See* Teva Pharm. Indus. v. FDA, 355 F. Supp. 2d 111 (D.D.C. 2004); Mylan Pharm., Inc. v. FDA, Civ. No. 1:04cv174 (N.D. W. Va. Aug. 30, 2004).

[502] Mylan Pharm., Inc. v. FDA, 454 F.3d 270 (4th Cir. 2006); Teva Pharm. Indus., Ltd. v. Crawford, 410 F.3d 51 (D.C. Cir. 2005).

[503] 410 F.3d 51 (D.C. Cir. 2005).

[504] *See* 21 U.S.C. § 355(j)(5)(B)(iv).

[505] *Teva*, 410 F.3d at 55.

[506] *See* Avery, *supra* note 3, at 196.

be correct, generic drug companies and many scholars believe that the entry of authorized generics during generic companies' periods of 180-day exclusivity may have great anticompetitive consequences in the long term. The entry of an authorized generic during the 180-day exclusivity period greatly cuts into the generic company's profit during this period. Many scholars argue that this decreased profitability during the 180-day exclusivity period will lead to less generic ANDA applicants challenging patents through Paragraph IV certifications. One antitrust attorney reasoned that if generic companies are not certain that they can recoup their high patent litigation costs through the bounty of 180-day exclusivity, many generic companies will be less willing to challenge patents prior to expiration.[507] As a result, some scholars conclude that "in the long run, consumers will be harmed because an expectation of competition from authorized generics will significantly decrease the incentives of generic manufacturers to pursue entry prior to patent expiration."[508]

One example of an authorized generic drug's entry onto the market during a generic company's 180-day exclusivity period is illustrative. In 2003, FDA found that Apotex was eligible for 180-day exclusivity for its generic version of the anti-depressant drug Paxil.[509] The pioneer drug company, GlaxoSmithKline, licensed Par Pharmaceutical to market an authorized generic of Paxil during Apotex's 180-day exclusivity. Apotex had estimated sales of $575 million during its period of 180-day market exclusivity; however, with the entry of the authorized generic, its actual sales were less than half of what it expected – only between $150

[507] David A. Balto, *We'll Sell Generics Too: Innovator Drug Makers Are Gaming the Regulatory System and Harming Competition*, 39 LEGAL TIMES 12 (Mar. 20, 2006).

[508] Bourke & Danberg, *supra* note 86, at 983.

[509] John R. Thomas, *Authorized Generic Pharmaceuticals: Effects on Innovation*, CONGRESSIONAL RESEARCH SERVICE (Jan. 29, 2010), at 8.

million and $200 million.[510] Apotex asserted in a filing to FDA "that the authorized generic crippled Apotex's 180-day exclusivity."[511]

There still exists much debate regarding the pro-competitive and anticompetitive consequences of authorized generic entry. Pharmaceutical Research and Manufacturers of America ("PhRMA") hired IMS Consulting to conduct a study on authorized generics and in 2006, IMS released a study that found that authorized generics benefit consumers.[512] Shortly thereafter, Generic Pharmaceutical Association ("GPha") performed its own statistical analysis of the IMS study and found that the entry of authorized generics onto the market did not have the effect of lowering consumer prices and discouraged generic companies from challenging patents prior to expiration.[513]

3. Legislative Action

After generic companies like Teva and Mylan Pharmaceuticals lost their claims against authorized generics under the Hatch-Waxman Act, generic companies challenged the way authorized generics were considered under the Medicaid Drug Rebate Program.[514] Under the program, drug manufacturers must pay rebates to state Medicaid programs for "covered outpatient drugs." The rebate is calculated based on the difference between the drug's Average Manufacturer Price (AMP) and the drug's best price.[515] The statute treats authorized generics as

---

[510] *Id.*

[511] *Id.*

[512] *See* IMS CONSULTING, REPORT TO PHRMA: ASSESSMENT OF AUTHORIZED GENERICS IN THE U.S. (2006); *see also* Bourke & Danberg, *supra* note 86, at 986 – 87.

[513] *See* Bourke & Danberg, *supra* note 86, at 987.

[514] *See* Medicaid Drug Rebate Statute, 42 U.S.C. § 1396r-8; Wasserstein & Karst, *supra* note 486.

[515] Wasserstein & Karst, *supra* note 486.

pioneer drugs, as they are manufactured and sold under the innovator companies' NDAs.[516] However, the Centers for Medicare & Medicaid Services ("CMS") "has historically acquiesced to the practice of drug manufacturers excluding authorized generics from the best price" of the pioneer drug.[517] Thus, by excluding authorized generics from the brand-name drug's best price, innovator companies were able to pay lower rebates under the Medicaid program. The Generic Pharmaceutical Association petitioned CMS to include the authorized generic price in an innovator drug's best price for purposes of calculating the rebates.[518]

Congress resolved this issue when it enacted the Deficit Reduction Act of 2005 ("DRA"),[519] signed into law by President Bush on February 8, 2006. The DRA amended the Medicaid Drug Rebate Statute to provide that the price of an authorized generic is now included in the calculation of a brand-name drug's best price. As a result of this revision, innovator companies that sell or license the marketing of authorized generics will have to pay higher rebates to state Medicaid programs. One commentator explained that under the DRA, "generic manufacturers got much of what they were demanding," and the DRA "will negatively affect the continued viability of authorized generic arrangements."[520] Although this may constitute a success for generic companies against authorized generics in the Medicaid rebate context, the debate over authorized generic competition still persists in the Hatch-Waxman context.

4. The FTC Study

Given the controversy over whether authorized generics have pro-competitive or anticompetitive consequences, and in response to several requests from concerned members of

[516] *See* Medicaid Drug Rebate Statute, 42 U.S.C. § 1396r-8(k)(7)(A).

[517] *See* Wasserstein & Karst, *supra* note 486.

[518] *Id.*

[519] Pub. L. No. 109-171, 120 Stat. 4 (2006).

[520] Wasserstein & Karst, *supra* note 486.

Congress,[521] in April 2006 the FTC published a notice of its intent to conduct a study to examine both the short-term and long-term competitive effects of authorized generic drug entry.[522] The FTC released an Interim Report in June 2009.[523] The Interim Report only includes data and analysis of the short-term effects of authorized generic drug competition and does not assess the long-term effects of authorized generic drug entry.[524] With respect to the short-term effects, the FTC concluded that "our initial analysis suggests that consumers benefit and the healthcare system saves money during the 180-day exclusivity period when an [authorized generic] enters the market, due to the greater discounting that accompanies the added competition provided by the [authorized generic]."[525] The study also found that authorized generic entry during a generic company's 180-day exclusivity cut the generic company's profits by fifty percent.[526] The FTC will examine the long-term incentive effects on generic companies in its final report.[527] The debate over authorized generics still continues today, but the FTC's issuance of the final report could lead to a legislative solution to the problem.

---

[521] Senators Grassley, Leahy, and Rockefeller, and Representative Waxman asked the FTC to conduct a study on the competitive effects of authorized generic competition in the pharmaceutical marketplace. *See* FTC, AUTHORIZED GENERICS: AN INTERIM REPORT 1 (June 2009), *available at* http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf.

[522] *See* FTC, Notice of Authorized Generic Drug Study, 71 Fed. Reg. 16,779 (Apr. 4, 2006); *see also Hearing of the Senate Special Committee on Aging*, 109th Cong. (July 20, 2006) (statement of Jon Leibowitz, Commissioner of the FTC) ("In the short run, the entry of an authorized generic may benefit consumers by creating additional competition that lowers prices. Critics assert, however, that in the long term consumers will be harmed because competition from authorized generics – and the significantly lower profits that result – will decrease the incentives of generic firms to pursue entry, especially for non-blockbuster drugs. At the Commission, we are undertaking a study to examine the competitive effects of authorized generics.").

[523] FTC, AUTHORIZED GENERICS: AN INTERIM REPORT (June 2009), *available at* http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf.

[524] *Id.* at Executive Summary, 1.

[525] *Id.* at 2.

[526] *Id.* at Ch. 2, 1.

[527] *Id.* at Ch. 1, 16.

VI. Avenues for Future Reform

As illustrated in Part V of this paper, the MMA left unresolved several important issues under the Hatch-Waxman scheme and through the addition of new statutory provisions, the MMA also led to the unintended consequence of new Hatch-Waxman interpretive issues. Relying on the findings and analysis in Part V, this Part of the paper discusses several avenues of potential reform of the Hatch-Waxman scheme to settle these outstanding issues. Particularly, this Part will briefly discuss possibilities of legislative reform in the areas of authorized generics, patent settlement agreements, the 180-day exclusivity provision, and the failure to market forfeiture provision.

A. Authorized Generics

One Hatch-Waxman scholar noted that "[i]f authorized generics are to be prohibited or restricted, it is a change that Congress will likely have to make."[528] This commentator is undeniably correct. Under FDA's interpretation, which was affirmed by the federal courts, the Hatch-Waxman Act does not prohibit the marketing of authorized generics during a generic company's 180-day exclusivity. Additionally, FDA has taken the position that authorized generics have pro-competitive consequences and that therefore NDA holders should be free to market these authorized generics for the benefit of consumers. The federal courts have agreed with the FDA's policy regarding authorized generics. Therefore, if any reform of the way authorized generics are treated under the Hatch-Waxman Act occurs, it will be through Congress. As illustrated by the passage of the DRA, which mandates that authorized generic prices be included in a brand-name drug's best price for the purpose of calculating rebates under the Medicaid Drug Rebate Program, Congress has intervened in the area of authorized generics.

[528] Bourke & Danberg, *supra* note 86, at 987.

One commentator noted that with the enactment of the DRA, "generic manufacturers got much of what they were demanding" with respect to the treatment of authorized generics under the Medicaid Drug Rebate Program. Thus, this may be a good indicator that generic drug manufacturers have the political clout to persuade Congress to pass a law revising how Hatch-Waxman treats authorized generics, particularly regarding the issue of authorized generic competition during generic companies' 180-day exclusivity period.

The prospect of legislative reform with respect to authorized generics has already been initiated. On February 16, 2011, Senator John Rockefeller introduced Senate bill S. 373, entitled the "Fair Prescription Drug Competition Act."[529] On the same day, Representative Jo Ann Emerson introduced a similar bill – H.R. 741 – in the House.[530] Senator Rockefeller and Representative Emerson had introduced similar bills in the 110th Congress, but no action was taken on the bills.[531] Both of the current bills would amend the Hatch-Waxman Act to add new section 21 U.S.C. § 355(w), entitled the "Prohibition of Authorized Generic Drugs."[532] This provision would prohibit NDA holders, directly or indirectly, from marketing authorized generics from the time they receive notice of an ANDA applicant's Paragraph IV certification to a patent of the listed drug until the expiration or forfeiture of the generic applicant's 180-day

[529] LIBRARY OF CONGRESS, BILL SUMMARY & STATUS, 112TH CONGRESS (2011 – 2012), S. 373, http://thomas.loc.gov/cgi-bin/bdquery/z?d112:S.373:.

[530] LIBRARY OF CONGRESS, BILL SUMMARY & STATUS, 112TH CONGRESS (2011 – 2012), H.R. 741, http://thomas.loc.gov/cgi-bin/bdquery/z?d112:HR00741:.

[531] In 2007, Senator John Rockefeller introduced bill S. 438 and Representative Jo Ann Emerson introduced bill H.R. 806 that would prohibit the marketing of authorized generic drugs during a generic company's 180-day exclusivity period. See LIBRARY OF CONGRESS, BILL SUMMARY & STATUS, 110TH CONGRESS (2007 – 2008), H.R. 806, http://thomas.loc.gov/cgi-bin/bdquery/z?d110:HR00806:@@@D&summ2=m&.

[532] LIBRARY OF CONGRESS, BILL TEXT, 112TH CONGRESS (2011 – 2012), S. 373, http://thomas.loc.gov/cgi-bin/query/z?c112:S.373:.

exclusivity.[533] Senator Rockefeller stated that "the 180-day exclusivity incentive to launch a patent challenge is being widely undermined by authorized generics," and the passage of the bill would "revitalize and protect the true intent of the 180-day marketing exclusivity period created in the Hatch-Waxman Act."[534] Furthermore, the Senator declared, "Our legislation eliminates one of the most prominent loopholes that brand name drug companies use to limit consumer access to lower-cost generic drugs."[535] The loophole the Senator is referring to is the 180-day exclusivity provision, which only prevents FDA from approving other ANDAs during a generic company's 180-day exclusivity period and not drugs marketed under the NDA for the listed drug.

Until the FTC issues its final report, it is hard to determine the appropriateness of the proposed legislative reform. In order to make an informed judgment, legislators need to have an understanding of both the short-term and long-term consequences of authorized generic competition. As illustrated in Part IV, the FTC Report issued in 2002 regarding the thirty-month stay and 180-day exclusivity provisions of the Hatch-Waxman Act had a profound influence on the drafters of the MMA. The final FTC Report on authorized generics will probably have a similar effect – depending on the results, either urging legislators to pass the bill or persuading legislators to defeat the bill.

---

[533] *Id.*

[534] *See* Kurt R. Karst, *Legislation to Ban Authorized Generics During 180-Day Exclusivity Period Makes a Comeback in Congress*, FDA LAW BLOG (Feb. 21, 2011 1:04 PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/02/legislation-to-ban-authorized-generics-during-180-day-exclusivity-period-makes-a-comeback-in-congres.html.

[535] *Bills Introduced in Senate, House Seek to Prohibit Authorized Generics*, BNA PHARM. L. & INDUS. REP. (Fed. 25, 2011).

B. Patent Settlement Agreements

FTC Commissioner Jon Leibowitz stated in a 2006 congressional hearing, "From our perspective, we'll continue to be vigilant in looking for ways to challenge anticompetitive settlements, and I hope the Supreme Court will eventually weigh in on this problem. A legislative approach, however, could provide a swifter and more comprehensive solution."[536] Indeed, some members of Congress have been working on a legislative solution to the problem of reverse-payment settlement agreements in the past several years. In June 2006, Senator Kohl introduced bill S. 3582, entitled the "Preserve Access to Affordable Generics Act," in the Senate.[537] This bill would have amended section 5 of the FTC Act so that it would be an unfair method of competition for any company to enter into a patent settlement agreement in which the ANDA filer received anything of value and the ANDA filer agreed not to research, manufacture, or sell the ANDA product for any period of time.[538] However, the bill was never acted upon in the Senate.

In January 2010, the FTC issued a study on patent settlement agreements titled PAY FOR DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS.[539] In this study, the FTC found that reverse-payment settlement agreements significantly delayed generic competition – on average, for seventeen months longer than settlement agreements that did not

---

[536] *See Hearing of the Senate Special Committee on Aging*, 109th Cong. (July 20, 2006) (statement of Jon Leibowitz, Commissioner of the FTC).

[537] LIBRARY OF CONGRESS, BILL SUMMARY & STATUS, 109TH CONGRESS (2005 – 2006), S. 3582, http://thomas.loc.gov/cgi-bin/bdquery/z?d109:s.03582:.

[538] LIBRARY OF CONGRESS, BILL TEXT, 109TH CONGRESS (2005 – 2006), S. 3582, http://thomas.loc.gov/cgi-bin/query/z?c109:S.3582:.

[539] FTC, PAY FOR DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (Jan. 2010), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

include reverse payments.[540] The FTC then calculated that this delay in generic competition will cost American consumers approximately $3.5 billion a year in drug costs.[541] Due to these findings, the FTC recommended that Congress pass legislation, although the FTC did not recommend anything in particular about the substance of this legislation. The FTC concluded that "a legislative solution offers the quickest and clearest way to deter these agreements and obtain the benefits of generic competition for consumers."[542]

On January 25, 2011, Senator Kohl introduced bill S. 27 in the Senate.[543] The bill, amending the FTC Act, creates a presumption of illegality for any patent settlement agreement in which the ANDA filer receives anything of value and the ANDA filer agrees to limit or forgo research, development, manufacturing, or sales of the ANDA product for any period of time.[544] The presumption of illegality will be rebutted if the parties to the agreement "demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement."[545] The bill gives the FTC the authority to initiate a proceeding against the parties to such an agreement in order to enforce the bill's provisions. As one commentator noted, bill S. 27 would "effectively ban patent settlement agreements."[546] President Obama supports this ban on reverse-payment settlement agreements,

---

[540] *Id.* at 2.

[541] *Id.*

[542] *Id.* at 6.

[543] LIBRARY OF CONGRESS, BILL SUMMARY & STATUS, 112TH CONGRESS (2010 – 2011), S. 27, http://thomas.loc.gov/cgi-bin/bdquery/z?d112:s.00027:.

[544] LIBRARY OF CONGRESS, BILL TEXT, 112TH CONGRESS (2010 – 2011), S. 27, http://thomas.loc.gov/cgi-bin/query/F?c112:1:./temp/~c112tNT1NP:e3580:.

[545] *Id.*

[546] Kurt R. Karst, *Supreme Court Shuts Another Door on Patent Settlement Agreement Antitrust Challenge – Denies Certiorari in CIPRO Case*, FDA LAW BLOG (Mar. 7, 2011 1:45PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/03/supreme-court-shuts-another-door-on-patent-settlement-agreement-antitrust-challenge-denies-certiorat.html.

as the President's Budget for FY 2012 "would give the [FTC] the authority to prohibit pay-for-delay agreements in order to facilitate access to lower-cost generics," which would lead to savings of $8.7 billion between 2012 and 2021.[547] Whether this support for a ban on reverse-settlement payments will result in legislation is uncertain at this time.

C. 180-Day Exclusivity Provision

Many scholars believe that the 180-day exclusivity provision of the Hatch-Waxman Act, even as reformed by the MMA, is flawed. One commentator noted that "the 180-day exclusivity period is not serving its purpose of eliminating weak patents. True, it is encouraging lots of *challenges* to those patents. But it is encouraging the challengers to accept compensation to drop those challenges, rather than taking them to judgment and benefiting the rest of the world."[548] Senator Hatch noted the problems with the "first-to-file" regime prior to the passage of the MMA. For instance, during a legislative hearing, he stated that he believed that the first-filer regime gave an unjustified advantage to the first Paragraph IV ANDA applicant. Additionally, he believed that the first-filer regime provided the wrong incentives, as it encouraged generic applicants to challenge patents, whether or not their claims were meritorious. Because of these concerns, Senator Hatch stated that "I am a proponent of what I call a successful challenger system. . . . [I]t appears to me that the 180-day marketing exclusivity provisions in the pending legislation contain perverse incentives that may result in unfortunate, if

[547] Kurt R. Karst, *The President's FY 2012 Budget Would Create New User Fees, Ban Patent Settlements, and Reduce BPCIA Reference Product Exclusivity*, FDA LAW BLOG (Feb. 15, 2011 10:05 AM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/02/the-presidents-fy-2012-budget-would-create-new-user-fees-ban-patent-settlements-and-reduce-bpcia-ref.html.

[548] C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, ANTITRUST L.J. (forthcoming in 2011), at 2 – 3.

unintended, consequences."[549] Before the passage of the MMA, FDA interpreted the 180-day exclusivity provision to have a "successful defense" requirement. However, this interpretation was rejected by the D.C. Circuit[550] and subsequently not adopted by Congress, as Congress failed to include this requirement in the MMA.

Recently, several scholars have advocated for reform similar to the "successful defense" requirement. For instance, Professors C. Scott Hemphill and Mark Lemley offer an earned exclusivity proposal: "first-filing generic drug companies should be entitled to 180 days of exclusivity only if they successfully defeat the patent owner, for example by invalidating the patent or by proving that they did not infringe the patent."[551] Thus, if the generic company loses the patent infringement case or enters into a settlement agreement with the innovator company, the generic company loses its 180-day exclusivity. Though similar to FDA's "successful defense" requirement, this proposal is broader in that if an innovator company does not sue the ANDA applicant for infringement, the generic company is still eligible for 180-day exclusivity.[552] This proposal could be implemented by amending the Hatch-Waxman Act.

D. Failure to Market Forfeiture Provision

Many commentators have expressed a concern that the failure to market forfeiture provision currently does not achieve its intended goal of preventing the parking of 180-day exclusivity and increasing generic drug competition. As explained in section V.E, FDA has recognized a loophole in the second prong of the failure to market forfeiture provision relating to

---

[549] Examining the Senate and House Versions Hearing, *supra* note 216, at 2 – 3 (statement of Senator Orrin G. Hatch).

[550] Mova Pharmaceuticals, Corp. v. Shalala, 955 F. Supp. 128, 130 (D.D.C. 1997), *aff'd* 140 F.3d 1060 (D.C. Cir. 1998).

[551] Hemphill & Lemley, *supra* note 548, at 3 – 4.

[552] *Id.* at 4.

patent settlement agreements. Generic and innovator drug companies have evaded triggering the second date of the failure to market forfeiture provision by entering into an agreement that does not include a finding that the patent is invalid or not infringed.[553] Therefore, the generic company maintains its 180-day exclusivity and the generic and innovator companies benefit from the delayed entry of generic competition. Given the statutory language of the failure to market provision, there does not appear to be an administrative fix, whereby FDA could interpret the statute so that it would cover patent settlement agreements that did not find the patent to be invalid or not infringed. One commentator noted that "Congress clearly needs to return to this area to correct the flawed forfeiture provisions."[554]

E. Innovation

All of the discussion and analysis regarding the post-MMA controversies in Part V and the areas of possible reform in Part VI have primarily dealt with the goal of increasing generic competition in the pharmaceutical market. However, it is important not to lose sight of the other important goal of the Hatch-Waxman Act – encouraging innovation. The MMA did not amend the patent term extension provisions of the original Hatch-Waxman Act to increase the length of patent term restoration. During the legislative hearings and debates, an important theme that ran throughout the statements of various members of Congress, regulators, and others was that the balance struck between competition and innovation achieved by the original Hatch-Waxman Act must be maintained.[555] However, one scholar stated that "their words in this regard

---

[553] *See* Avery, *supra* note 3, at 200 ("[T]hese flawed provisions are easily avoided by drafting settlement agreements that contain no finding of patent invalidity or noninfringement.").

[554] *Id.*

[555] For instance, during the June 2003 Senate Judiciary Committee Hearing, the Chief Counsel of FDA stated that the "main goal . . . in this area is to promote innovation, while also promoting rapid access to low-cost, safe and effective generic drugs." 2003 Hearing, *supra* note 1, at 6 (statement of Daniel E. Troy, Chief Counsel, FDA). Additionally, during the Senate debate,

seemed to be spoken without any actual analysis of whether the reforms, together with other changes in the pharmaceutical industry, might dampen innovative incentives for innovative companies."[556] The scholar predicted that, although the MMA's reform of the Hatch-Waxman Act might lead to greater generic competition, the MMA "could depress the rate of pharmaceutical innovation."[557]

In 2006, the Congressional Budget Office ("CBO") released a study entitled RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY.[558] The study reported that pharmaceutical companies' spending on research and development ("R&D") has increased threefold to sixfold over the past twenty-five years. In 1984, pharmaceutical companies spent approximately $6 billion on R&D, and in 2004, pharmaceutical companies spent approximately $39 billion on R&D.[559] However, the study found that the "[c]ontinued growth in R&D spending has appeared to have little effect on the pace at which new drugs are developed. . . . As a result, the average R&D cost per new drug has grown significantly."[560] The CBO study revealed the extraordinary cost and length of time it took to develop a new NCE drug. The study stated that the time from development to marketing of a new NCE drug is about twelve years at a cost of about $800 million.[561]

Senator Frist remarked, "The Hatch-Waxman law has almost 20 years of balance, and now is the time to go back and readjust and make sure that balance is well situated going forward." 149 Cong. Rec. S8197.

[556] Derzko, *supra* note 19, at 251.

[557] *Id.* "[T]he continued downward pressure on the prices of innovative pharmaceuticals will lead to fewer resources for drug development, which may further dampen the pharmaceutical innovation drought that is already being experienced." *Id.* at 265.

[558] CBO, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (Oct. 2006), *available at* http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf.

[559] *Id.* at 7.

[560] *Id.* at 11.

[561] *Id.* at 20 – 21.

These findings of increasing R&D costs and decreasing production of innovative drugs indicate that "at some point, Congress must reconsider the compromise made in the 1984 Act and find a new mechanism for assuring adequate market protection for NCE NDA drugs that will provide sufficient incentive for investment in research and development."[562] One scholar recommended that one avenue might be to increase the length of patent protection or market exclusivity[563] so that the innovator companies could adequately earn back their R&D costs.[564] Or, Congress could revise the original patent term extension provisions, increasing the length of the patent term extension. Although this issue has not been extensively debated in Congress, it is an issue that must be considered in the future in order to maintain the original Hatch-Waxman balance.

VII. Conclusion

On February 8, 2011, the Congressional Research Service ("CRS") released a report entitled THE HATCH-WAXMAN ACT: A QUARTER CENTURY LATER.[565] The report concludes that the Hatch-Waxman Act has been a success. At the time of the original Act's passage in 1984, only approximately thirty-five percent of brand-name blockbuster drugs had generic counterparts, while today, virtually all brand-name blockbuster drugs have generic

[562] HUTT, MERRILL & GROSSMAN, *supra* note 16, at 764.

[563] However, a recent study published in THE NEW ENGLAND JOURNAL OF MEDICINE found that several laws granting market exclusivity (such as the Orphan Drug Act), which aim to increase drug innovation, "have led to higher drug costs and misuse of exclusivity periods." *Laws Granting Market Exclusivity Lead to Higher Drug Costs, Misuse, Analysis Says*, BNA PHARM. L. & REP. (Nov. 12, 2010).

[564] *See* Derzko, *supra* note 19, at 253.

[565] WENDY H. SCHACHT & JOHN R. THOMAS, THE HATCH-WAXMAN ACT: A QUARTER CENTURY LATER, CONGRESSIONAL RESEARCH SERVICE (2011).

counterparts. However, the report states that "concerns still remain whether or not the balance achieved by the Act remains appropriate 25 years later."[566]

The background, discussion, and analysis of this paper are in line with the findings of the CRS report. The Hatch-Waxman Act of 1984 greatly increased generic competition, but at the same time, both innovator and generic competitors engaged in "gaming" several provisions of the Act for their own profit. In 2003, FDA issued a final rule and Congress passed the MMA to close the loopholes that had become apparent in the years after the Hatch-Waxman Act's passage. Although the final rule and statutory amendments definitively resolved the controversies regarding patent listing and thirty-month stays, the addition of new provisions to the Hatch-Waxman Act has led to unintended consequences and new controversies since 2003. For instance, much debate and controversy has surrounded the interpretation of the failure to market forfeiture provision and the patent delisting counterclaim provision, which have generated substantial litigation between innovator and generic drug companies. Additionally, under the declaratory judgment action provision, courts are still grappling with what suffices as a controversy under Article III for generic companies' declaratory judgment actions. Further, two of the main issues being debated in Congress are the legality of reverse-payment settlement agreements and the legality of authorized generic competition.

There are several possible legislative reforms pending relating to several of the controversies mentioned above, although it is hard to predict whether there will be enough political will to enact these reforms. Moreover, it is difficult to predict whether these additional reforms, if enacted, will achieve their intended goals and maintain the ideal balance between innovation and competition. It is important to note the 2003 statement of Daniel Troy, Chief

[566] *Id.* The report specifically mentions the current issues of reverse-payment settlement agreements and authorized generics. *Id.*

Counsel of FDA, regarding the inevitability of unintended consequences when amending the Hatch-Waxman Act: "But I am not smart enough, and the 20 people sitting around the room aren't smart enough and far-sighted enough, despite all of our expertise and experience, to see every single situation that could be gamed."[567] If Congress chooses to revise the Hatch-Waxman Act, there is no doubt that these provisions will be carefully thought out and drafted just as the MMA provisions were. However, similar to the MMA provisions, it is likely that unintended consequences will result, leading to future controversy. Given the complexity of the Hatch-Waxman Act, the enormous sums of money involved in Hatch-Waxman issues, and the hiring of creative lawyers, Hatch-Waxman controversies are likely to extend well into the future. Regulators and policymakers face a daunting task in both maintaining the balance between innovation and competition struck by the original Hatch-Waxman Act and preventing the unintended consequences from legislative or administrative reform.

[567] 2003 Hearing, *supra* note 1, at 15 (statement of Daniel E. Troy, Chief Counsel, FDA).