

NOTE

TEVA V. EISAI: WHAT'S THE REAL "CONTROVERSY"?

*Grace Wang**

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INTRODUCTION

Ever since the passage of the Hatch-Waxman Act in 1984, Congress has struggled to establish the appropriate balance of power between brand name pharmaceutical companies and generic drug manufacturers. In an effort to make generic drugs more affordable and accessible to the public,

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the Hatch-Waxman Act changed patent infringement litigation at the point of generic drug entry in the pharmaceutical marketplace.¹ This scheme represented the first time Congress directed the U.S. Food & Drug Administration (“FDA”) to consider patents for a brand name drug in timing the approval of a generic version of that drug. The Hatch-Waxman framework not only facilitates generic drug entry once valid patents expire but also allows generic manufacturers to challenge drug patents before launching their own products, thereby providing some measure of risk management.² It also creates incentives for generic manufacturers to challenge these patents as early as possible with a 180-day period of market exclusivity.³ Through these incentives, Congress deliberately instituted a system that would allow parties to adjudicate patent issues before generic market entry.

Since 1984, both brand name and generic manufacturers have devised innovative strategies to exploit the system, resulting in a number of unintended consequences. Efforts have been made to capitalize on the Congressionally-designed reward of 180 days of “generic exclusivity” for the first entrant to challenge the patent(s) on a drug. In practice, generic exclusivity has sometimes lasted far longer than the half-year Congress contemplated because companies have found ways to delay the “trigger” events that start the 180-day meter running. For example, if a first-filer chose not to enter the market immediately,⁴ and the patent holder did not sue, then the approval of subsequent-filers’ ANDAs could be delayed indefinitely. Declaratory judgments could potentially solve this problem by allowing a subsequent filer to unilaterally trigger the start of the generic exclusivity period.

Congress responded by making a number of changes to the Hatch-Waxman Act in 2003, including new provisions to facilitate declaratory judgment actions by generic manufacturers seeking to challenge the validity of drug patents.⁵ By allowing a generic manufacturer to file a declaratory judgment action before the potentially infringing product becomes commercially available, the Hatch-Waxman Act authorizes courts to issue what

1. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, tit. I, 98 Stat. 1585, amended the Federal Food, Drug, and Cosmetic Act § 505 (codified as amended at 21 U.S.C. § 355). *See infra* Background.

2. The Food and Drug Administration (FDA) defers generic approval during the term(s) of the patent(s) covering the brand name drug unless the sponsor of the generic product challenges patent validity and infringement. Instead of waiting until the generic manufacturer has started marketing its drug and becomes liable for damages, the statute allows the brand name manufacturer or patent owner to sue for infringement when a generic manufacturer submits an application to the FDA for approval that challenges those patents. *See infra* Background.

3. *See infra* Background.

4. First-filers may voluntarily delay market entry as a result of manufacturing difficulties or an agreement with the brand name manufacturer to delay entry.

5. *See infra* Background.

appear to be advisory opinions. Meanwhile, following the Supreme Court's decision in *MedImmune, Inc. v. Genentech, Inc.*,⁶ the Court of Appeals for the Federal Circuit ("Federal Circuit") broadened its view on the scope of standing for generic manufacturers in declaratory judgment actions.⁷ These recent reforms have allowed subsequent generic manufacturers to circumvent the first-filer's delays. At the same time, however, these reforms reduce the Act's incentive for first-filers to bring prompt patent challenges by promoting disputes over their priority.

This Note examines the changing role of declaratory judgment actions in challenging patents upon generic entry and evaluates alternative regulatory schemes to the FDA's current system of patent enforcement in the drug approval setting. Part I reviews the Federal Circuit's recent decisions regarding generic drug entry, focusing on how the courts justify declaratory judgments in the current system and when a "controversy" exists to create Article III jurisdiction. Part II examines the complex system of regulating generic drug entry and how attempts to stop the exploitation of loopholes have resulted in a patchwork of regulation by various parties. It challenges the current regulatory scheme with alternative regulatory mechanisms of discretion by courts, litigation by subsequent-filers, legislative changes by Congress, and antitrust policing by the FTC. Part III hypothesizes that a likely increase in litigation will force courts to become more active in the regulation of patent rights in relation to generic drug entry, especially in light of the recently liberalized standing requirements, and draws attention to the competing goals of the Hatch-Waxman Act that courts must remember to balance.

BACKGROUND

In a series of recent cases, the Federal Circuit has liberalized the availability of declaratory judgment actions involving generic drug entry. In order to understand these cases, it is necessary to provide a bit of background on the relevant statutory provisions. Congress first codified the current system in the Hatch-Waxman Act (also known as the Drug Price Competition and Patent Term Restoration Act of 1984). This statute created the framework for controlling the approval of generic drugs with a notification and certification system that heavily relies on the "Approved Drug Products with Therapeutic Equivalence Evaluations," a publication commonly known as

6. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

7. Before *MedImmune*, the Federal Circuit's jurisprudence on declaratory judgments in pharmaceutical patent litigation at the point of generic drug entry stood out against the backdrop of otherwise settled declaratory judgment decisions. After the 2003 amendments, the court's strict requirements were also out of line with Congressional policy, so the Supreme Court made its stance clear in *MedImmune* that jurisdiction requirements should be liberalized. These recent Federal Circuit cases may not have been necessary except to clear up the Federal Circuit's previous anomalous jurisprudence. See *infra* Part I.

the “Orange Book.”⁸ When filing a New Drug Application (“NDA”), an applicant must include every relevant patent that the applicant could reasonably assert to protect the innovator drug⁹ for which the applicant is seeking approval.¹⁰ The NDA applicant must also file any subsequent, post-NDA patents that issue.¹¹ Once the NDA is approved, the FDA publishes the innovator drug as a “Reference Listed Drug” (“RLD”) with a list of all relevant patents in the Orange Book.¹²

When a generic manufacturer wishes to enter the market, it may submit an Abbreviated New Drug Application (“ANDA”). Instead of conducting its own time-consuming and expensive clinical studies, a generic manufacturer filing an ANDA may rely on an RLD’s safety and efficacy studies so long as the applicant can show the generic drug to be “bioequivalent” to the RLD.¹³ Often, the drug described in the ANDA may infringe the patents that cover the RLD. The Hatch-Waxman Act addresses this by requiring the generic manufacturer to file a “Paragraph IV certification,” where the generic manufacturer guarantees that either: (1) the ANDA product does not infringe any of the RLD’s listed patents; or (2) the RLD’s patents are invalid.¹⁴ Paragraph IV certifications drive ANDA litigation; once each owner of the patent and the NDA holder have been notified of the Paragraph IV certification, each has standing to sue the generic manufacturer for patent infringement based

8. See 21 U.S.C. § 355(j)(2)(A) (2010); FOOD & DRUG ADMIN., ELECTRONIC ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2011), <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> [hereinafter ORANGE BOOK]. The generic drug information in the Orange Book is updated daily to reflect new approvals.

9. The “innovator” drug is usually a “brand name” drug.

10. 21 U.S.C. § 355(b)(1). According to the FDA, the following patents *must* be filed: patents that claim the active ingredient(s), including those claiming polymorphs, metabolites, and intermediates; patents that claim the drug formulation or composition, including intermediates or novel products of product-by-process patents; and patents claiming one or more methods of use for which approval is being sought. If there are no relevant patents, the New Drug Application (NDA) applicant must note that. 21 C.F.R. § 314.53(c)–(d) (2011); see also FOOD & DRUG ADMIN., PATENT INFORMATION SUBMITTED WITH THE FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT, FORM 3542A (2010), *available at* <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048352.pdf> [hereinafter FDA FORM 3542A]; ORANGE BOOK, *supra* note 8, at Preface.

11. 21 U.S.C. § 355(c)(2); 21 C.F.R. § 314.53(d)(3); FDA FORM 3542A.

12. 21 C.F.R. § 314.53(e); ORANGE BOOK, *supra* note 8, at § 1.4.

13. Bioequivalence is a complicated term that is defined in section 505(j)(8) of the Hatch-Waxman Act. See 21 U.S.C. § 355(j)(8)(B). See also 21 C.F.R. § 320.24 for methods used to define bioequivalence. A pioneer or innovator drug is also called the “Reference Listed Drug” (RLD) for Orange Book purposes. ORANGE BOOK, *supra* note 8, at § 1.4. The Hatch-Waxman Act refers to it as the “listed drug.” See 21 U.S.C. § 355(j)(2)(A)(i).

14. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The “ANDA product” is the drug described in the Abbreviated New Drug Application (ANDA). ANDAs can alternatively include a Paragraph I certification “that such patent information has not been filed”; a Paragraph II certification “that such patent has expired”; or a Paragraph III certification “of the date on which such patent will expire.” *Id.* § 355(j)(2)(A)(vii)(I)–(III).

on the description of its ANDA product.¹⁵ If the patent owner or NDA holder does not sue within forty-five days of receiving notice, the FDA can approve the ANDA immediately.¹⁶ However, if the patent owner or NDA holder does sue the generic manufacturer within forty-five days, the FDA automatically stays approval of the ANDA for thirty months (the “30-month stay”).¹⁷

In 2003, Congress changed the playing field with Title XI, the “Access to Affordable Pharmaceuticals” subtitle of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”).¹⁸ These amendments to the Hatch-Waxman Act affected the rights of manufacturers who filed ANDAs containing Paragraph IV certifications after December 8, 2003.¹⁹ The MMA amendments created a cause of action permitting ANDA filers to seek declaratory judgments if they provided notice and neither the NDA holder nor patent owner sued for infringement within the statutory forty-five day window.²⁰ This codified courts’ subject matter jurisdiction over declaratory judgments by ANDA filers “to the extent consistent with the Constitution.”²¹

15. See *id.* § 355(j)(2)(B). The “NDA holder” is the brand name manufacturer who “holds” an approved NDA for the RLD.

16. *Id.* § 355(j)(5)(B)(iii) (2006). The NDA holder can still assert its patents (including any not listed in the Orange Book) and sue for patent infringement later, but it loses a very significant portion of the market once the generic drug is launched.

17. *Id.* § 355(j)(5)(B)(iii). The FDA will not approve the ANDA until the patent expires, a court finds noninfringement or invalidity, or the end of the thirty-month stay, whichever of the three is earliest. See, e.g., *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000), in which the FDA granted a thirty-month stay when a generic manufacturer filed a Paragraph IV certification of noninfringement, and the NDA holder sued. The district court’s decision of summary judgment of noninfringement was affirmed by the Federal Circuit.

18. Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, §§ 1101–02, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355(j)).

19. The FDA noted in its Guidance Document that the collusive agreement forfeiture provision (21 U.S.C. § 355(j)(5)(D)(i)(V)) would apply to all ANDAs filed after December 2003 even if the first ANDA with a Paragraph IV certification was filed before December 2003. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: LISTED DRUGS, 30-MONTH STAYS, AND APPROVAL OF ANDAs AND 505(B)(2) APPLICATIONS UNDER HATCH-WAXMAN, AS AMENDED BY THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003 12 (2004), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072887.pdf>.

20. See 21 U.S.C. § 355(j)(5)(C)(i)(I). If the patent owner and NDA holder do not sue within these forty-five days, they do not relinquish their cause of action. They can still sue the generic manufacturer for patent infringement when the generic drug product enters the market.

21. See 35 U.S.C. § 271(e)(5); see also *infra* Part I. Congress enacted this legislation prior to *MedImmune*, but the Supreme Court appears to have confirmed that the Constitution should be less of a constraint than the Federal Circuit seemed to believe. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126–36 (2007). In light of the *MedImmune* decision, these amendments are much more likely to be upheld if challenged.

The FDA grants a 180-day exclusivity period to the first generic manufacturer that files a Paragraph IV certification to a patent listed for an RLD, the “first-filer.”²² A generic manufacturer that files or certifies later based on the same NDA is dubbed a “subsequent-filer.” The FDA delays final approval of a subsequent-filer’s ANDA until the first-filer’s exclusivity period ends.²³ The exclusivity period begins when the first-filer engages in its first commercial marketing (the “commercial marketing trigger”).²⁴ For ANDAs filed pre-MMA, a court judgment finding the patent invalid or not infringed can also trigger the start of the generic exclusivity period (the “court judgment trigger”).²⁵ The purpose of this exclusivity period is to incentivize ANDA filers to challenge the validity of or to design around the listed patents as early as possible,²⁶ clearing the path for subsequent generic manufacturers to enter the market.²⁷

Another consideration in ANDA litigation comes from the tendency for multiple patents to be listed in the Orange Book for a single RLD, with differing expiration dates for each patent. In ANDA litigation, these patents are often distinguished as “earlier-expiring patents” (“EEPs”) or “later-expiring patents” (“LEPs”). This distinction is important because ANDA approval is restricted by the term of *any* valid, listed patent. The NDA holder can

22. See 21 U.S.C. § 355(j)(5)(B)(iii)–(iv) (2006). This exclusivity period results in a much larger market share for the first-filer. The generic exclusivity period does not extend past the expiration of the relevant patent(s).

23. See *id.* § 355(j)(5)(B)(iv).

24. See *id.* Triggering the generic exclusivity period by a first commercial marketing was clarified in the MMA amendments to include marketing of authorized generics. An “authorized generic” is a licensed version of the RLD. See 157 CONG. REC. S797 (daily ed. Feb. 16, 2011) (introducing the Fair Prescription Drug Competition Act, S. 373, 112th Cong. (1st Sess. 2011)). While the NDA holder can market or license the right to make an authorized generic, the FDA will not approve any ANDA, and so other generic manufacturers cannot enter the market. 21 U.S.C. § 355(j)(5)(B)(iv).

25. The MMA amendments replaced the court judgment trigger with forfeiture provisions to create situations in which the first-filer would lose its exclusivity period. See *id.* § 355(j)(5)(D)(i)(I)–(VI). These new provisions only apply to ANDAs with Paragraph IV certifications filed after the effective date of the MMA, in December 2003. See *id.* § 355(j)(5)(B)(iv)(II). The court judgment trigger is no longer explicit in the exclusivity period provision, but it is an important element in the cases following *MedImmune*. See *id.*; *infra* note 41.

26. A generic manufacturer cannot file an ANDA for a certain number of years after an NDA is approved. See *id.* § 355(c)(3)(E).

27. The MMA amendments added six forfeiture provisions, including one that rescinds a first-filer’s exclusivity period if it fails to go to market within seventy-five days or enters into an agreement with the NDA holder that the Federal Trade Commission (FTC) finds anticompetitive. See *id.* § 355(j)(5)(D)(i)(I), (V). This language was added in response to reverse payment settlements, in which a brand manufacturer would make a deal with the first-filer generic to delay market entry by “parking” its exclusivity period, thus delaying the market entry of subsequent-filing generics as well. See 149 CONG. REC. 15,884 (2003). Notably, once a first-filer has forfeited its exclusivity period, the exclusivity period does not “roll over” to a subsequent filer; the exclusivity is forfeited completely, instead of inherited by the second-to-file generic manufacturer. 21 U.S.C. § 355(j)(5)(D)(i)(VI)(iii)(II).

choose to sue on only one of several patents—usually the EEP—to trigger the 30-month stay. Different ANDA filers may challenge different patents; thus, a subsequent-filer can challenge a patent that the first-filer did not challenge. As a result, before the MMA amendments, multiple ANDA filers could share the generic exclusivity period because there could be more than one “first” Paragraph IV certification for an RLD.²⁸ The setup of this complex regulatory scheme in the multi-billion-dollar pharmaceutical industry gave rise to the ANDA litigation that explores the courts’ interpretation of the relevant Hatch-Waxman provisions.

I. “CONTROVERSY” IN DECLARATORY JUDGMENT ACTIONS

A. *The MedImmune Change*

The Supreme Court recently liberalized the jurisdictional requirements²⁹ for potential defendants in patent infringement suits to bring declaratory judgment actions, overturning a long line of Federal Circuit patent cases.³⁰ In *MedImmune, Inc. v. Genentech, Inc.*,³¹ the Supreme Court reversed a Federal

28. The MMA amendments attached the exclusivity period to the first-filer(s) for the *product*, whereas previously it attached to the individual *patent*. This was directed to the shared “patent-by-patent” exclusivity policies of the FDA that resulted in the confusion in *Teva v. Eisai* about whether Ranbaxy, Teva, or both had exclusivity periods. See *infra* I.C. The exclusivity period could be triggered by any commercial marketing, and the FDA would approve any eligible “first-filer” ANDAs during the exclusivity. See Letter from Gary Buehler, Dir., Office of Generic Drugs, Food & Drug Admin. Ctr. for Drug Evaluation & Research, to Andrx Pharm., Inc. (Nov. 16, 2001), available at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm120609.htm>; Letter from Gary Buehler, Dir., Office of Generic Drugs, Food & Drug Admin. Ctr. for Drug Evaluation & Research, to Apotex Corp. (July 30, 2003), available at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm120608.htm>. Now shared exclusivity exists on a “first applicant” basis if the ANDA filers file “first” on the same day. See 21 U.S.C. § 355(j)(5)(B)(iv) (2000); 149 CONG. REC. 15,884 (2003); Letter from Gary Buehler, Dir., Office of Generic Drugs, Food & Drug Admin. Ctr. for Drug Evaluation & Research, to Applicant (Sept. 11, 2009), available at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM182134.pdf>.

29. Article III of the Constitution limits the jurisdiction of federal courts to “cases” and “controversies,” and the Declaratory Judgment Act created a prospective cause of action limited to cases of “actual controversy.” U.S. CONST. art. III, § 2; 28 U.S.C. § 2201(a) (2010).

30. The Federal Circuit had previously applied a narrow reading of this requirement in order to limit standing, requiring that the declaratory judgment plaintiff have “reasonable apprehension” of the patent holder bringing an infringement suit. See, e.g., *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005) (rejecting Teva’s argument that it had reasonable apprehension of *imminent* suit simply because the NDA holder had listed patents in the Orange Book); *BP Chem. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993) (“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 plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.”).

31. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 118–19 (2007).

Circuit decision that the plaintiff in a declaratory judgment action lacked standing. MedImmune had a licensing agreement with Genentech, who held patents and patent applications that covered MedImmune's product. Both the district court and Federal Circuit had dismissed MedImmune's declaratory judgment action, finding that MedImmune did not present a "controversy" because a patent holder presumably had no reason to sue its licensee.³² The Supreme Court held that the Federal Circuit's "apprehension of suit" test to determine standing conflicted with Supreme Court precedent.³³ The Court explained that a dispute satisfies the constitutional requirement when "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."³⁴ The Supreme Court's holding overturned the Federal Circuit's restrictive approach for determining whether a party had standing to file a declaratory judgment action against a patent holder. As a result, the decision expanded the range of plaintiffs who could challenge a patent's validity, enforceability, or scope. Though the MMA amendments themselves were not at issue in *MedImmune*, the Court appeared to confirm the constitutional authority of Congress to create the MMA's declaratory judgment cause of action.

Yet, *MedImmune* may be distinguishable from normal ANDA litigation because it did not examine infringement based on Paragraph IV certifications, but rather literal patent infringement outside of the drug approval process. In *MedImmune*, Genentech licensed MedImmune to sell a drug covered by, among other things, a pending patent application.³⁵ When the patent issued, Genentech sent a letter stating that the drug was covered by the new patent.³⁶ MedImmune then sought a declaratory judgment that

32. The Federal Circuit previously held that a patent licensee in good standing could not establish Article III jurisdiction as to the validity, enforceability, or scope of the patent. *See Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1381 (Fed. Cir. 2004) (finding that "unless materially breached," a license agreement "obliterated any reasonable apprehension of a lawsuit"). A patent holder would not have any reason to sue a licensee because the licensee has been granted rights by the patent holder to make, use, or sell what is covered by the patent. However, if the licensee fails to pay royalties or otherwise follow the licensing agreement, or infringes other patents not included in the license, then the patent holder could sue. *Id.*

33. Congress also addressed the Federal Circuit's "reasonable apprehension" test when discussing the MMA amendments. *See* 149 CONG. REC. 15, 752–55 (2003) (noting that "to the extent consistent with the Constitution" language in 35 U.S.C. § 271(e)(5) was meant to allow courts to use a "reasonable apprehension" test so long as they found it within constitutional bounds, but the test was more narrow than what is required by Article III or the Declaratory Judgment Act, and the focus of the standing inquiry should be "whether the would-be patent challenger has been reasonably and actually deterred from undertaking a profitable enterprise").

34. *MedImmune*, 549 U.S. at 127 (quoting *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)) (emphasis added).

35. *Id.* at 121.

36. *Id.*

Genentech's patent was invalid.³⁷ Thus, the drug product in *MedImmune* was already on the market, and the dispute stemmed from continued royalty payments.³⁸ In contrast, ANDA filers bring declaratory judgments *prior* to market entry, which is only possible because Congress created an artificial infringement cause of action when an ANDA is filed.³⁹ As a result, cases about generic drug entry address more hypothetical issues, and court decisions in this arena seem much like advisory opinions. By explicitly adding a cause of action to the MMA amendments, it seems clear that Congress wanted courts to have jurisdiction over this matter. Nevertheless, the Supreme Court may be unwilling to relax jurisdictional requirements to this degree.⁴⁰

Furthermore, *MedImmune* did not address the potential deprivation of a third party's rights. In ANDA litigation, actions brought by subsequent-filers can affect a first-filer's exclusivity period. Nonetheless, the basic message in *MedImmune* directed courts to reconsider standing in declaratory judgment actions, and the Federal Circuit responded.

B. Federal Circuit Cases After *MedImmune*

In response to the MMA amendments and the Supreme Court's opinion in *MedImmune*, the Federal Circuit in subsequent cases liberalized its rules for allowing ANDA plaintiffs to challenge patents in declaratory judgment actions.⁴¹ Instead of using the ANDA statutory provisions as a special reason to *deny* standing, the Federal Circuit used the provisions as a special reason to *recognize* it.⁴² The court explored the repercussions of declaratory judgment actions in the Hatch-Waxman scheme in this recent series of cases involving subsequent-filers, who were not the first generic manufacturers to

37. *Id.* at 121–22.

38. A licensee like *MedImmune* would have chosen to continue paying royalties because courts may issue treble damages if the infringement is found to be willful, which can be shown by continued infringing actions after notice of the patent. *See* 35 U.S.C. § 284 (2000); *see also* *Underwater Devices Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380 (Fed. Cir. 1983), *overruled by In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007). In contrast, no commercial product is at issue in ANDA litigation since the litigation is prior to market entry, so no money damages are at stake.

39. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I) (2010); *supra* text accompanying note 20.

40. The Supreme Court still emphasized the impropriety of advisory opinions in *MedImmune* by noting that a declaratory judgment that satisfies standing requirements could be “distinguished from an opinion advising what the law would be upon a hypothetical state of facts.” *MedImmune*, 549 U.S. at 127–28.

41. *See, e.g.*, *Teva Pharm. USA, Inc. v. Eisai Co. Ltd.*, 620 F.3d 1341 (Fed. Cir. 2010); *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007). Although the MMA changes technically did not apply in cases like these where the first ANDA with Paragraph IV certification was filed before December 2003, the Supreme Court certainly mentioned the legislation and discussed the changes to the system in *MedImmune*.

42. *See supra* note 41 and accompanying text.

challenge a patent on a given brand name drug.⁴³ In all of these cases, the first-filers included Paragraph IV certifications to all of the patents listed—both EEPs and LEPs—for the RLDs. Upon receiving notice, the NDA holders (the brand name manufacturers) sued the generic manufacturers for infringing the EEPs but did not assert any LEPs. This classic NDA holder's strategy allowed them to assert a patent to trigger the 30-month stay, while still protecting the other patents from potentially being invalidated. Through *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, and *Teva Pharmaceutical USA, Inc. v. Eisai Company Ltd.*, the Federal Circuit elaborated on the range of circumstances under which it would grant standing for subsequent-filers to challenge the patents that provide generic exclusivity.

While both first-filers and subsequent-filers stand to benefit from judicial determinations of patent invalidity that allow them to obtain final approval of their ANDAs, thus expediting their entry into the pharmaceutical marketplace, only first-filers have the added incentive of securing 180-day generic exclusivity.⁴⁴ For subsequent-filers, the generic exclusivity period is an additional barrier that delays final approval of ANDAs by the FDA. In practice, the entry barrier may last far longer than 180 days if competitors are able to delay the events which trigger the exclusivity period. Therefore, subsequent-filers stand to benefit from an early start to the exclusivity period, as they can enter the market sooner. Before the 2003 amendments, if the first-filer (1) chose not to enter the market immediately upon approval of its ANDA, whether from manufacturing difficulties or because of an agreement with the NDA holder; and (2) was not sued by the patent holder, the subsequent-filers would be held in limbo indefinitely.⁴⁵ With neither of the two trigger events to start the 180-day period, the period would never come to an end, and subsequent-filers could never get their products approved. If, however, a subsequent-filer could bring its own declaratory judgment action, a favorable court judgment would trigger the start of the first-filer's exclusivity period.

This potential delay of exclusivity formed the context of this series of recent Federal Circuit cases. In several different situations, the court considered whether a subsequent-filer had standing to sue an NDA holder for listing a patent in the Orange Book. Shortly after the *MedImmune* decision, the Federal Circuit issued an opinion in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*⁴⁶ Teva, the first generic manufacturer to file Paragraph IV certifications to all five patents listed in the Orange Book for

43. *Eisai*, 620 F.3d 1341; *Caraco*, 527 F.3d 1278; *Janssen Pharmaceutica*, 540 F.3d 1353; *Novartis*, 482 F.3d 1330.

44. See 21 U.S.C. § 355(j)(5)(B)(iv) (2010).

45. See *supra* text accompanying notes 24–25 (referring to the “commercial marketing trigger” and the “court judgment trigger”).

46. *Novartis*, 482 F.3d at 1330.

the RLD, sought a declaratory judgment against the remaining four patents, after the NDA holder, Novartis, only asserted the EEP.⁴⁷ The Federal Circuit reversed the district court's dismissal of the declaratory judgment and rejected the "reasonable apprehension of imminent suit" test that it had followed for years.⁴⁸ Instead, the *Novartis* court adopted *MedImmune's* "all the circumstances" standard for determining whether a justiciable controversy for declaratory judgment actions exists. The court concluded that when an NDA holder chooses not to assert all its patents in an infringement suit at generic entry, the ANDA filer is still under the "threat of litigation" and subject to "legal uncertainty," because the NDA holder can choose to sue on the other patents at any time.⁴⁹ Accordingly, by listing its patents in the Orange Book and filing suit based on the Paragraph IV certification, the NDA holder directly caused an injury to Teva, the ANDA applicant.⁵⁰ Therefore, the court found that a justiciable controversy existed for *all* of the listed patents to which the ANDA filer had made a Paragraph IV certification, not just those on which the NDA holder had elected to sue.⁵¹ While the case was brought by a first-filer seeking a declaratory judgment action,⁵² *Novartis* exemplifies the start of the Federal Circuit's liberalization of declaratory judgment actions in the generic drug entry context.

The Federal Circuit revisited the issue in *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*⁵³ *Caraco* focused on a subsequent-filer's ability to bring a declaratory judgment action against an NDA holder.⁵⁴ The NDA holder, Forest Labs, listed two patents for the

47. Novartis could put Teva in a difficult position. Even if Teva prevailed in the infringement suit or waited until the earlier-expiring patent (EEP) expired, entering the market would put Teva at risk of patent infringement liability because the later-expiring patents (LEPs) could still be enforced. The district court, applying the Federal Circuit's former "apprehension of suit" test, dismissed Teva's declaratory judgment action for lack of jurisdiction. *Id.* at 1339–40.

48. *Id.* at 1339, 1346. Instead of analyzing jurisdiction as whether Teva had "reasonable apprehension" of being sued by Novartis, the court stated that "[a]n Article III controversy is found where a plaintiff has demonstrated an injury-in-fact caused by the defendant that can be redressed by the court." *Id.* at 1340 (citing *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83 (1998)). Using language from declaratory judgment cases outside the ANDA litigation context highlighted the changes in how the court discussed standing and justified those changes.

49. *Id.* at 1345; see 21 U.S.C. § 355(j)(5)(C)(i)(I).

50. *Novartis*, 483 F.3d at 1345.

51. *Id.* at 1344.

52. Because Teva was a first-filer, its concern was "at-risk launch" rather than delay from generic exclusivity. Launching "at risk" means the generic manufacturer knows it may be liable for patent infringement but chooses to enter the market anyway. If a generic manufacturer loses the infringement suit, a court may award treble damages for willful infringement. See *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 121–22 (2007).

53. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008).

54. The ANDA in question was submitted by Caraco, a generic manufacturer, and contained Paragraph IV certifications to two patents, an EEP and a LEP. Another generic manufacturer, Ivax, had filed Paragraph IV certifications to the patents first, and thus had the generic exclusivity period. Forest, the NDA holder, had sued Ivax for infringing the EEP and

RLD.⁵⁵ Forest sued the subsequent-filer, Caraco, solely for infringement of the EEP.⁵⁶ After the decision in *Novartis* was issued, Forest unilaterally granted Caraco an irrevocable covenant not to sue for infringement of the LEP.⁵⁷ Nonetheless, Caraco brought a declaratory judgment action against Forest for noninfringement of the LEP because it was prevented from marketing the drug based on a previous generic filer's ANDA application.⁵⁸

The district judge dismissed the action for lack of Article III jurisdiction, finding that there was “no threat of lawsuit” because of the covenant not to sue.⁵⁹ The Federal Circuit reversed and held that preventing Caraco from going to market with a noninfringing drug created a justiciable controversy.⁶⁰ Caraco's injury-in-fact was a “restraint on the free exploitation of non-infringing goods”⁶¹—that is, the improperly delayed approval of its ANDA and the resulting deprivation of an economic opportunity to compete.⁶² The *Caraco* panel found that, under all the circumstances, neither the Hatch-Waxman Act nor the FDA framework alone was responsible for Caraco's injury; the improper use of the system created standing.⁶³ The LEP as

won, surviving a challenge to the patent's validity and obtaining a court finding of infringement by Ivax's ANDA product. As a result, Ivax could not obtain approval to enter the market and begin its exclusivity period (via the commercial marketing trigger) until the EEP expired or was found invalid by another court judgment. However, a subsequent-filer like Caraco could challenge both the EEP and LEP and use the court judgment trigger to start the first-filer's exclusivity period. *See id.* at 1286, 1296.

55. *Caraco*, 527 F.3d at 1286.

56. *Id.* at 1288.

57. *Id.* at 1289.

58. *Id.* at 1288.

59. *Id.* at 1289–90.

60. *Id.* at 1291. The court found that following *Novartis*, the Article III controversy still existed “in the context of the Hatch-Waxman framework.” *Id.* at 1292. The FDA cannot grant final approval to another ANDA until the first-filer's exclusivity has run, even if the subsequent-filer's ANDA product would not infringe the patents. *Id.* Therefore, the subsequent-filer would need a way to trigger the exclusivity period without “apprehension” of being sued for infringement. *Id.* Thus, “proving a reasonable apprehension of suit is only one of many ways a patentee can satisfy the Supreme Court's more general all-the-circumstances test to establish that an action presents a justiciable Article III controversy.” *Id.* at 1291.

61. *Id.* at 1291 (citing *Red Wing Shoe Co. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1360 (Fed. Cir. 1998)).

62. *Id.* at 1291–92. The Hatch-Waxman scheme created this artificial infringement where a commercial product has not yet been released so there is no possibility of damages. *Id.* at 1283. In this special context, the court found that the injury should be a lack of opportunity to compete in the marketplace and should be traceable to the NDA holder. *Id.* at 1292.

63. Because Forest listed the LEP in the Orange Book, a generic manufacturer could file a Paragraph IV certification and obtain an exclusivity period. This would delay the final approval of any subsequent ANDAs (including Caraco's) for the same RLD. Without NDA holders listing patents as valid and covering the RLD, the statute “would not independently delay Caraco's ANDA from being approved by the FDA.” *Id.* at 1292. Even if Forest's action “could only exclude Caraco from the drug market in the context of the Hatch-Waxman framework,” Caraco's injury was no less “concrete, actual, or imminent.” *Id.* (citing *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102–03 (1998)). When a first-filer's exclusivity based on a properly listed patent is the source of delay, no injury should be found because

listed in the Orange Book created “an independent barrier to the drug market,” so Caraco’s injury was “fairly traceable” to Forest.⁶⁴ The injury was redressable because a favorable declaratory judgment for Caraco (i.e., that the LEP was not infringed) would “clear the path to FDA approval that Forest’s actions would otherwise deny Caraco”⁶⁵ by triggering the first-filer’s exclusivity period.⁶⁶ The court further held that the covenant not to sue did not make the action moot because the listing of the LEP and the resulting FDA enforcement of the generic exclusivity period, *not* the threat of suit, delayed Caraco’s market entry. A covenant not to sue “does not affect the FDA’s authority to approve the ANDA” in the Hatch-Waxman framework.⁶⁷ As such, the only way to resolve the controversy would be to determine whether the drug in Caraco’s ANDA infringed the LEP.

By going through the standard factors for standing and applying them specifically in an ANDA case, the Federal Circuit appeared to be rationalizing the switch to allow standing in declaratory judgment actions. The *Caraco* panel found that allowing a subsequent-filer to initiate a declaratory judgment in these circumstances was “consistent with the basic purpose of the Declaratory Judgment Act.”⁶⁸ The court did not want to permit “a restricted patent to justify much wider claims of infringement”⁶⁹ through the FDA’s enforcement of the Hatch-Waxman procedure without subjecting the patent to a “court determination of its scope.”⁷⁰ The court also found that a declaratory judgment action would be consistent with the “basic goal of the

that delay comes from the intended operation of the Hatch-Waxman Act. When an NDA holder lists patents improperly, the unintended downstream effect delays subsequent generic entry, so a justiciable injury (and standing) exists.

64. *Id.* at 1293.

65. *Id.* See *supra* Background for the forfeiture provisions added by the MMA.

66. Caraco would still have to obtain a finding of invalidity or noninfringement on the EEP, which was already subject to ongoing litigation. However, without standing for a declaratory judgment action, even if Caraco prevailed in the EEP litigation, it would not obtain final FDA approval and enter the market until the first-filer’s generic exclusivity period, created by the LEP, had run. The court found that the action was ripe because dismissing Caraco’s action would have “the ‘immediate and substantial impact’ of forestalling Caraco’s ability to activate [the first-filer]’s exclusivity period through the court-judgment trigger.” *Caraco*, 527 F.3d at 1295 (quoting 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000)). “Whether an action is ‘ripe’ requires an evaluation of ‘both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.’” *Id.* at 1294–95 (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)). The court reasoned that “additional factual development would not advance the district court’s ability to decide” the declaratory judgment action since the submitted ANDA would provide the information necessary to determine noninfringement. *Id.* at 1295.

67. *Id.* at 1296.

68. *Id.* at 1293.

69. *Id.* at 1293–94 (citing EDWIN MONTEFIORE BORCHARD, DECLARATORY JUDGMENTS 803–04 (2d ed. 1941)).

70. *Id.* at 1294. The majority also noted in a previous footnote that if Forest had agreed to a consent decree finding non-infringement of the LEP, the “controversy” would apparently have been resolved. *Id.* at 1293 n.11.

Hatch-Waxman Act, which is to balance the need for pharmaceutical innovation with the need for generic drug competition.”⁷¹

The opinion in *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*,⁷² delineates the other end of the standing spectrum. The Federal Circuit panel found that the district court correctly dismissed a subsequent-filer’s declaratory judgment counterclaims against the NDA holder for lack of Article III jurisdiction where the subsequent-filer had stipulated to the validity of the patent at issue. As in *Caraco*, the NDA holder, Janssen, asserted only the EEP against a subsequent-filer, Apotex, and granted a covenant not to sue on the LEPs. However, unlike the declaratory judgment plaintiff in *Caraco*, Apotex stipulated to the validity of the EEP listed for the RLD.⁷³ The district court held that Apotex created its own block to approval, so the “controversy” no longer existed between the subsequent-filer and the NDA holder.

On appeal, Apotex presented several different injuries on which to base its “controversy,” including the inability to promptly launch upon expiration of the EEP and infinite delay of approval for its noninfringing product.⁷⁴ For the “prompt launch” injury, Apotex argued that it currently would not be able to enter the market until 181 days after the EEP expired because of the first-filer’s generic exclusivity period.⁷⁵ However, the *Janssen* court found that “the harm that created a justiciable Article III controversy in *Caraco*” was the subsequent-filer’s delayed market entry by a noninfringed patent, which “ceased to exist” in this case because of Apotex’s stipulation to infringement.⁷⁶ The harm that continued to exist—Apotex’s “inability to

71. *Id.* at 1294 (citing *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002)).

72. *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008). The first to file an ANDA containing a Paragraph IV certification was Teva, but Teva filed Paragraph IV certifications only to the LEPs and a Paragraph III certification to the EEP. As in *Caraco*, the first Paragraph IV ANDA was filed before the 2003 MMA amendments, so the forfeiture provisions did not apply. Janssen did not sue Teva for infringement of either LEP, so Teva not only obtained first-filer 180-day exclusivity, but was also able to start marketing as soon as the EEP expired.

73. *Id.* at 1358.

74. *Id.* at 1359 (“Specifically, Apotex argues that (1) it is unable to promptly launch its generic risperidone product and compete in the market immediately upon the expiration of the ‘663 patent; (2) its approval of its noninfringing generic risperidone product is being indefinitely delayed; and (3) its affiliates, suppliers, and downstream customers face patent uncertainty because Janssen’s covenant-not-to-sue does not cover them.”). As for the “infinite delay” argument, the court found that there needed to be “a basis to conclude” that the first-filer would, or was likely to, delay in entering the market; without this, the alleged harm was “too speculative.” *Id.* at 1363 (citing *Caraco*, 527 F.3d at 1296 n.14). The court also noted that Apotex would have to show this possibility of infinite delay between “the filing of the counterclaims” and “the final judgment,” not during oral arguments on appeal. The panel held that “a possible delay in the future of a first Paragraph IV ANDA filer in launching its generic product does not give rise to declaratory judgment jurisdiction.” *Id.* at 1363.

75. *Id.* at 1359–60. Since the first-filer’s exclusivity period is based on its Paragraph IV certifications to the LEPs, a court’s judgment of noninfringement or invalidity of only the LEPs would suffice to trigger the start of the generic exclusivity period.

76. *Id.* at 1360.

launch immediately upon the expiration of the [EEP]”—was “not sufficient to give rise to declaratory judgment jurisdiction.”⁷⁷ Here, the first-filer, Teva, could not trigger its exclusivity period with the “commercial marketing trigger”⁷⁸ until the EEP expired because it filed a Paragraph III certification, which certifies that the patent is valid and the generic cannot obtain FDA approval and enter the market until that patent expires. Therefore, Teva’s “statutorily entitled” exclusivity was the actual cause of Apotex’s “inability to promptly launch,” which was a result “envisioned by the Hatch-Waxman Act.”⁷⁹ Apotex sought to trigger the exclusivity period immediately, instead of waiting for the commercial marketing trigger, so Teva would effectively lose its generic exclusivity. The *Janssen* court distinguished *Caraco*, because the *Caraco* subsequent-filer sought to trigger the first-filer’s exclusivity period “at a time when [the first-filer] could obtain FDA approval and then launch its product;” i.e., if *Caraco* obtained a favorable judgment, the first-filer could start its exclusivity by marketing sooner, and *Caraco* would get its approval sooner.⁸⁰ This was not the case in *Janssen* because Apotex was not able to obtain approval and launch until the EEP expired due to its stipulation.

Furthermore, in a non-precedential opinion,⁸¹ the Federal Circuit recognized that once a first-filer’s exclusivity period has been triggered, any potential controversy is rendered moot. The only remaining delay would be “the balance of the [first-filer]’s 180-day exclusivity period,” which is part of the Hatch-Waxman framework.⁸² The court also noted that while a judgment “may have *triggered* [the first-filer]’s 180-day exclusivity period, nothing in the statute provides that such a judgment can *eliminate* [the first-filer]’s exclusivity period.”⁸³

C. The Controversy Over Aricept

On October 6, 2010, the Federal Circuit further clarified its views on declaratory judgments in ANDA litigation with its opinion in *Teva Pharmaceuticals USA, Inc. v. Eisai Co.*⁸⁴ The case revolved around

77. *Id.*

78. *See supra* text accompanying note 24.

79. *Id.* at 1361. The court stressed the importance of the exclusivity period and the Hatch-Waxman balance in finding that Apotex’s injury did not present a justiciable “controversy.” *Id.* (citing C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1605 (2006)); *Purepac Pharm. Co. v. TorPharm, Inc.*, 354 F.3d 877, 879 (D.C. Cir. 2004)). By the generic exclusivity provision, Congress intended for *some* situations when otherwise permissible generic entry would be delayed. *See* 21 U.S.C. 355(j)(5)(b)(iv) (providing an “exclusivity” period in which the FDA will not grant final approval to other ANDAs).

80. *Janssen*, 540 F.3d at 1361 (emphasis removed).

81. *Merck & Co. v. Apotex*, No. 2007-1362 (Fed. Cir. July 16, 2008).

82. *Id.* at 7.

83. *Id.*

84. *Teva Pharm. USA, Inc. v. Eisai Co.*, 620 F.3d 1341 (Fed. Cir. 2010).

Aricept,⁸⁵ a drug mainly used to treat Alzheimer's disease. Aricept generates global sales of approximately three billion dollars a year, with about two billion dollars per year from U.S. sales.⁸⁶ A generic version is expected to take in \$200 million or more in its first six months on the market,⁸⁷ and Aricept's U.S.-based revenue is expected to drop by sixty percent.⁸⁸ It is no exaggeration to say that millions of dollars were at stake in this case.

In 1996, Eisai received FDA approval for Aricept, manufactured as tablets with the active ingredient of donepezil hydrochloride.⁸⁹ Eisai listed five patents—one EEP and four LEPs—in the Orange Book.⁹⁰ Ranbaxy filed an ANDA with a Paragraph III certification to the EEP and Paragraph IV certifications to the LEPs.⁹¹ Ranbaxy was the first to file Paragraph IV certifications to the LEPs, so it obtained a generic exclusivity period based on the LEPs.⁹² Eisai did not sue Ranbaxy, so the FDA granted tentative approval to Ranbaxy's ANDA, to become final approval at the expiration of the EEP.⁹³

Teva filed an ANDA with Paragraph IV certifications to all of the patents.⁹⁴ As a result, Teva was a subsequent-filer to the LEPs, but a first-filer to the EEP.⁹⁵ Teva filed a second ANDA for donepezil in a different form

85. Aricept is a registered trademark of Eisai Company.

86. Press Release, Ranbaxy Laboratories, Ltd., Ranbaxy Launches Donepezil 5 MG and 10 MG Tablets to U.S. Healthcare System (Nov. 30, 2010), available at <http://www.ranbaxyusa.com/newsdisp301210.aspx>. Aricept represents about forty percent of the overall revenue of Japan's fourth-largest drug company, the Eisai Company. EISAI CO., LTD., ANNUAL REPORT 43–69 (2011), available at <http://www.eisai.com/pdf/eannual/epdf2011an.pdf>. In comparison, Lipitor alone brought in \$10.7 billion in 2010 and \$11.4 billion in 2009. PFIZER INC., 2010 FINANCIAL REPORT 25 (2011), available at <http://www.pfizer.com/files/annualreport/2010/financial/financial2010.pdf>. To put all these numbers in perspective, *Total Unaudited and Audited Global Pharmaceutical Market 2003–2010*, IMS HEALTH, available at http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/_Total_Market_2003-2010 (last visited Dec. 12, 2011).

87. *Ranbaxy to Launch Low-Cost Alzheimer Drug in US Soon*, THE ECON. TIMES OF INDIA (Nov. 28, 2010), <http://economictimes.indiatimes.com/features/sunday-et/dataline-india/Ranbaxy-to-launch-low-cost-Alzheimer-drug-in-US-soon/articleshow/7003214.cms>. Generics make up 75% of dispensed prescriptions in the U.S. Jonathan D. Rockoff, *Prescription-Drug Sales Rise 5.1%*, WALL ST. J., Apr. 2, 2010, at B4.

88. *Eisai says Aricept's U.S. Sales to More than Halve*, REUTERS (Mar. 4, 2010), <http://www.reuters.com/article/idUSTOE62306Z20100304>.

89. *Orange Book Detail Record Search for Aricept*, FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=020690&TABLE1=OB_Rx (last visited Nov. 16, 2011).

90. *Teva Pharm. USA, Inc. v. Eisai Co.*, 620 F.3d 1341 (Fed. Cir. 2010).

91. *Id.* at 1344.

92. *Id.*

93. *Orange Book Detail Record Search for Donepezil Hydrochloride*, FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=076786&TABLE1=OB_Rx (last visited Nov. 16, 2011).

94. *Eisai*, 620 F.3d at 1344.

95. The FDA potentially could have awarded Teva a shared exclusivity period under the FDA's previous patent-based approach, but the FDA later found that shared exclusivity did not apply in this case, so Ranbaxy had the only generic exclusivity period. See Letter

with Paragraph IV certifications to all patents, but the FDA requested the application be filed through a subsidiary, Gate Pharmaceuticals.⁹⁶ Under the Gate ANDA, the actual ANDA underlying the dispute in *Eisai*, Teva is a subsequent-filer with respect to both the EEP and LEPs.

In the same vein as *Novartis*, *Caraco*, and *Janssen*, the *Eisai* court addressed the issue of whether a district court had Article III jurisdiction over a declaratory judgment action brought by a subsequent ANDA filer against the NDA holder. The court found jurisdiction where the injury was an inability to enter the market due to a first-filer's generic exclusivity period created by improperly listed patents.

The NDA holder, Eisai, sued the subsequent-filer, Teva, for infringement of the EEP and triggered the statutory 30-month stay. In return, Teva sought a declaratory judgment that its ANDA product did not infringe the LEPs.⁹⁷ Eisai filed statutory disclaimers for two of the LEPs and offered Teva a covenant not to sue on the remaining two.⁹⁸ The district court found that it did not have jurisdiction for lack of controversy, and, even if it did have jurisdiction, would decline to exercise it.⁹⁹ The Federal Circuit reversed and held that a subsequent-filer has a "legally cognizable interest in when the first-filer's exclusivity period begins." Therefore, when an NDA holder lists its patents in the Orange Book, it causes an injury-in-fact sufficient to create "controversy" for Article III jurisdiction.¹⁰⁰ Eisai would not be able to assert any of the LEPs against Teva because of the disclaimers and covenant, but the Federal Circuit decided that generic drug entry would still be improperly delayed. Because an ANDA filer must include certifications to *all* patents listed for the RLD, the fact that those unenforceable patents remained listed in the Orange Book would provide generic exclusivity periods for first-filers and defer FDA approval of any subsequently-filed ANDAs.¹⁰¹

Teva presented an "infinite delay" argument, claiming that its injury was traceable to Eisai because Eisai listed the LEPs in the Orange Book, which provided the first-filer, Ranbaxy, with a generic exclusivity period.¹⁰²

from Keith Webber, Deputy Dir., Office of Pharm. Sci., to Ranbaxy Inc. (Nov. 26, 2010), available http://www.accessdata.fda.gov/drugsatfda_docs/apletter/2010/076786s000ltr.pdf (finding Ranbaxy held the sole 180-day exclusivity period).

96. *Eisai*, 620 F.3d at 1344.

97. *Id.* at 1343.

98. *See* 35 U.S.C. § 253 (2007); 37 C.F.R. § 1.321 (1997). By statute, a patent owner may disclaim patent claims in order to avoid invalidation of an entire patent, or a patent owner may disclaim the remainder of the patent term. A covenant not to sue is an agreement not to bring suit against that party for patent infringement. It is unclear why Eisai treated the patents differently, but essentially Eisai could not assert any of the LEPs against Teva.

99. *Eisai*, 620 F.3d at 1344.

100. *Id.*

101. *Id.* at 1345.

102. *Id.* at 1343. This exclusivity period was deferring final approval of Teva's ANDA, and Ranbaxy was likely to delay entry into the market because of its regulatory troubles. The FDA

Like the first-filer in *Janssen*, Ranbaxy could not enter the market until the expiration of the EEP because of its Paragraph III certification.¹⁰³ Therefore, its exclusivity could not be triggered any earlier than the expiration of the EEP unless a court ruled that the LEPs were invalid or not infringed.¹⁰⁴ Teva, like the subsequent-filer in *Janssen*, was seeking to trigger the first-filer's exclusivity period before the first-filer could even begin marketing its product. The *Eisai* court found the critical distinction to be that the subsequent-filer in *Janssen* had stipulated to the validity, infringement, and enforceability of the EEP. Therefore, the EEP in *Janssen* was no longer a disputed factor deferring generic entry, and the earliest the FDA could approve *any* ANDA would be upon expiration of the EEP. In contrast, the first-filer in *Caraco* had filed a Paragraph IV certification to the EEP and lost the litigation challenging the EEP, but the first-filer *would* have been able to market its drug if the EEP was declared invalid in another suit.¹⁰⁵ In both *Caraco* and *Eisai*, the EEP was the subject of pending litigation between the NDA holder and the subsequent-filer. If a court found the EEP to be invalid, not infringed, or unenforceable, then the exclusivity period of the first-filer could potentially be triggered and begin to run *before* the expiration of the EEP.

In response to the comparison with *Caraco* and *Janssen*, *Eisai* argued that the preliminary injunction in the pending EEP litigation meant that Teva could not enter the market until the EEP expired. Even though Teva stipulated to infringement of the EEP and agreed that the injunction would be enforced until the expiration of the EEP, the court found that the preliminary

sent warning letters about problems with manufacturing practices at certain facilities in India and issued an Import Alert for drugs from those facilities. See Press Release, Food & Drug Admin., FDA Issues Warning Letters to Ranbaxy Laboratories Ltd., and an Import Alert for Drugs from Two Ranbaxy Plants in India (Sept. 16, 2008), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116949.htm>. Apotex argued that the warnings indicated that the FDA would not grant final approval to Ranbaxy upon expiration of the EEP. A few months later, the FDA also suspended review of applications containing data from a specific facility, based on findings of falsified data and test results for approved and pending drug applications. See Press Release, Food & Drug Admin., FDA Takes New Regulatory Action Against Ranbaxy's Paonta Sahib Plant in India (Feb. 25, 2009), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149532.htm>. However, Ranbaxy was able to circumvent these issues by manufacturing drugs at other facilities. Mohit Bhalla & Khomba Singh, *Daiichi to Leverage Ranbaxy Abroad*, THE ECON. TIMES OF INDIA (Nov. 11, 2009), <http://economictimes.indiatimes.com/articleshow/5217703.cms> (discussing drug production to other facilities).

103. See *supra* note 14 and accompanying text.

104. See *Eisai*, 620 F.3d at 1348 n.4. Ranbaxy filed its ANDA before the MMA amendments became effective in December, so it could only start its exclusivity period via commercial marketing or court judgment triggers. *Id.* at 1344 & n.2.

105. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1287 (Fed. Cir. 2008). In *Caraco*, the first-filer (who had exclusivity based on an unasserted LEP) had lost the EEP litigation and was barred by a court decision from marketing until the EEP expired, so if a court judgment declared the EEP invalid, the first-filer could obtain approval and enter the market. *Id.*

injunction issued by the district court did not factor into whether Teva's injury was imminent, because jurisdiction is determined at the outset of the appeal.¹⁰⁶ In a world post-*eBay v. MercExchange*, injunctions are much more difficult to obtain in patent cases than they previously were.¹⁰⁷ However, the *Eisai* court chose to disregard the district court's findings as merely "preliminary" and not a "final determination" on the patent.¹⁰⁸ As a result, the court could justify its decision that a controversy existed and found imminent harm for the purposes of standing.

D. Additional District Court Analyses

Two pre-*Eisai* district court decisions allowing declaratory judgment actions to proceed present additional considerations for declaratory judgments brought by subsequent-filers. Like the Federal Circuit cases, the NDA holder in both of these cases did not assert all of its listed patents when suing the subsequent-filer for infringement.¹⁰⁹ As a result, these subsequent-filers also had potential injuries the courts could address.

In *Dey, L.P. v. Sepracor, Inc.*,¹¹⁰ the district court focused on whether the subsequent-filer would be able to enter the market before the first-filer

106. *Eisai*, 620 F.3d at 1348 n.4. The *Janssen* court recognized that "[j]urisdiction over a declaratory judgment action must be present 'at all stages of review, not merely at the time the complaint is filed.'" *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1360 (Fed. Cir. 2008) (quoting *Steffel v. Thompson*, 415 U.S. 452, 459 n.10 (1974)). The court also found that "inability to launch its generic product immediately upon the expiration of [an EEP] is not sufficient to give rise to declaratory judgment jurisdiction." *Id.*

107. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). In *eBay*, the Supreme Court criticized the Federal Circuit's practice of routinely granting injunctions in patent infringement cases and held that courts had to analyze the traditional equitable factors even in these types of cases. *Id.* at 392.

108. *Eisai*, 620 F.3d at 1348. One of the traditional factors in evaluating preliminary injunctions is reasonable likelihood of success on the merits, so the district court already found that *Eisai* was likely to succeed in its patent infringement suit as Teva stipulated to infringement. *Teva Pharm. USA, Inc. v. Eisai Co.*, No. 08-2344, slip. op. at 4 (D.N.J. Sept. 9, 2009). Teva would likely be unable to enter the market until the LEPs expired, so challenging the EEP would in fact be pointless.

109. Unlike the Federal Circuit cases *Caraco*, *Janssen*, and *Eisai*, however, the first-filer in these cases had settled with the NDA holder and agreed to delay its entry into the market, with the result of deferring other generic drug entry.

110. *Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355 (D. Del. 2009). The NDA holder listed six patents in the Orange Book and sued the subsequent-filer for infringement of five patents, leaving one unasserted. *Id.* at 358. The subsequent-filer sought a declaratory judgment that its ANDA product would not infringe the unasserted LEP, even though the NDA holder had offered a covenant not to sue for the LEP. *Id.* By holding the LEP in reserve and not asserting it, the NDA holder was not risking a court finding of invalidity. *Id.* at 357-59. If the subsequent-filer succeeded in the patent litigation and invalidated the asserted EEPs, it would still be unable to enter the market until the LEP expired and the first-filer's exclusivity period had run. *Id.* at 360-61 (discussing *Janssen*).

could,¹¹¹ rather than examining whether the subsequent-filer had an “infinite delay” issue.¹¹² The court found that a declaratory judgment action might allow the subsequent-filer to trigger the first-filer’s exclusivity period before the first-filer could go to market. Doctrinally, this case addresses issues somewhere in between *Caraco* and *Janssen*.¹¹³ The district court distinguished *Janssen* because the subsequent-filer in this case had not “precluded itself from going to market prior to the [first-filer]” or otherwise stipulated “to be on equal footing” with the first-filer.¹¹⁴ Therefore, the case presented a justiciable controversy.

In *Pfizer Inc. v. Apotex Inc.*,¹¹⁵ the district court found that the subsequent-filer could counterclaim for a declaratory judgment even if it had filed a Paragraph III certification. Therefore, even if successful in challenging the other patents, the subsequent-filer could not begin obtaining FDA approval and enter the market immediately. In *Pfizer*, the subsequent-filer had filed a Paragraph III certification to the EEP, so the alleged harm—the dilatory effects of an agreement between the NDA holder and first-filer¹¹⁶—would not take place until the EEP expired. Despite this, the district court found that because the agreement between the first-filer and NDA holder was in place when the subsequent-filer filed its counterclaims,¹¹⁷ there was likely an imminent injury-in-fact and the case was ripe.

111. *Id.* The NDA holder and first-filer had entered into a settlement agreement in which the generic manufacturer could enter the market with a royalty-bearing license before three of the six listed patents expired. *Id.* at 359, 361.

112. The first ANDA with a Paragraph IV certification in this case was filed after the effective date of the MMA amendments, so the forfeiture provisions would apply and there would be no “infinite delay” issue. *Id.* at 357–58.

113. *Id.* at 361. If the subsequent-filer could challenge the LEP, and successfully challenged all of the EEPs, the first-filer’s exclusivity period would be triggered and start running immediately. *Id.* at 361–62. The first-filer, bound by its settlement agreement, would not be able to start marketing until the agreed-upon time in 2012, by which time the 180-day period would have already run. *Id.* at 362. The first-filer would thus lose its generic exclusivity. *Id.*

114. *Id.* at 362. In *Janssen*, the first-filer had filed a Paragraph III certification to the EEP. The subsequent-filer stipulated to infringement of the EEP, so it could not obtain FDA approval until the EEP expired (or was found invalid)—the same practical effect as a Paragraph III certification. *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1360 (Fed. Cir. 2008).

115. *Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921 (N.D. Ill. 2010). The NDA holder had six patents listed in the Orange Book. *Id.* at 925. The subsequent-filer’s ANDA included Paragraph IV certifications to the LEPs and a Paragraph III certification to the EEP. *Id.* at 926. The NDA holder only sued the subsequent-filer for infringement of two of the LEPs. *Id.* at 925. The subsequent-filer counterclaimed for declaratory judgment of noninfringement and invalidity for the three unasserted LEPs. *Id.* at 926.

116. *Id.* The NDA holder and first-filer entered into a settlement agreement to delay the first-filer’s market entry until 2011. Without a forfeiture provision or court judgment invalidating the LEPs, the first-filer could defer the approval of any other ANDAs. *Id.*

117. *Id.* This case highlights the court’s focus on technicalities over equities. The technical issues of timing control whether jurisdiction is found. The question of whether a

Following the Federal Circuit's decision in *Eisai*, the courts will probably focus less on the constitutional restraint of "controversy" and more on whether the subsequent-filer can obtain approval and enter the market with a favorable outcome in the declaratory judgment action, regardless of the effects on the first-filer's exclusivity period. It also seems likely that courts will take a rather expansive view of what is "imminent" harm, since neither covenants not to sue nor statutory disclaimers sufficed to dismiss declaratory judgment actions. Both of these favor plaintiffs in declaratory judgment actions and therefore would allow and encourage subsequent ANDA filers to challenge more patents and seek to trigger generic exclusivity sooner.

Furthermore, although these cases formally concern the constitutional right to immediate adjudication of rights, the courts can and probably will limit this controversy analysis to the ANDA litigation arena. The question of whether declaratory judgment actions allowed by Congress pose a case or controversy was settled long ago.¹¹⁸ *MedImmune* may simply have been the Supreme Court's way of confirming Congress's constitutional authority to create the cause of action for declaratory judgments by generic manufacturers.

II: WHO SHOULD REGULATE THE ORANGE BOOK?

The Federal Circuit may be liberalizing the standing requirement for declaratory judgment actions in response to the problems with the current regulation system for generic entry. This section will argue that some other forms of regulation are necessary due to the uninvolved and mechanical approach that the FDA takes in regulating which patents are listed in the Orange Book, which in turn controls the timing of generic approval and entry. Possible forms of regulation include: (1) self-regulation by NDA holders; (2) declaratory judgment actions to invalidate patents brought by subsequent filers and issued by courts; (3) citizen petitions filed by various competitors; (4) legislative amendments by Congress; and (5) antitrust investigations by the FTC.

A. Current FDA Regulation of the Orange Book

When a patent owner lists a patent in the Orange Book, the FDA provides regulatory enforcement of patent rights, even if its actions have the effect of enforcing invalid patents or extending the scope of the patent to

subsequent-filer should be able to trigger a first-filer's exclusivity period (and, in essence, appropriate that generic exclusivity) is a secondary consideration.

118. See *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937) ("In providing remedies and defining procedure in relation to cases and controversies in the constitutional sense the Congress is acting within its delegated power over the jurisdiction of the federal courts which the Congress is authorized to establish.").

include noninfringing products.¹¹⁹ For example, without a Paragraph IV certification to challenge the listed patents, the FDA will simply refuse to approve any ANDAs until the listed patents for the RLD have expired.¹²⁰ The FDA does not consider the patent's validity or whether it really covers the approved drug.¹²¹ Moreover, once the generic manufacturer files the Paragraph IV certification, the NDA holder then has forty-five days to file an infringement suit and trigger the automatic 30-month stay that prevents the FDA from approving the ANDA.¹²² This automatic stay does not require the NDA holder to meet the requirements for obtaining an injunction.¹²³

The FDA only edits the Orange Book to remove ("delist") a patent in response to an NDA holder's request,¹²⁴ even if the drug can no longer be marketed.¹²⁵ Even if an ANDA filer believes a patent is improperly listed, it must include a certification to the patent.¹²⁶ The FDA's regulations permit

119. See *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004); *infra* note 139.

120. 21 U.S.C. § 355(j)(5)(B).

121. See *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1349 (Fed. Cir. 2003) ("[T]he [Hatch-Waxman] Act does not require [the FDA] to police the listing process by analyzing whether the patents listed by NDA applicants actually claim the subject drugs or applicable methods of using those drugs."); 59 Fed. Reg. 50, 343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims."); ORANGE BOOK, *supra* note 8, at § 1.12 ("Applicant holders are requested to inform the FDA Orange Book Staff (OBS) of any changes or corrections.").

122. See *supra* note 17 and accompanying text.

123. See *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1378 n.6 (Fed. Cir. 2002) (quoting Terry G. Mahn, *Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process*, 54 FOOD DRUG L.J. 245, 250 (1999)) ("[L]isting gives 'the patentee/NDA holder almost automatic injunctive relief for even marginal infringement claims.'"); see also *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) (applying to patent litigation these requirements: a reasonable likelihood of success on the merits, irreparable harm without an injunction, balance of hardships tipping in its favor, and considerations of the public interest).

124. 21 C.F.R. § 314.53(f) (2010) ("Unless the application holder withdraws or amends its patent information in response to FDA's request, the agency will not change the patent information in the list.").

125. See ORANGE BOOK, *supra* note 8, at Preface, Introduction ("Every product on the List is subject at all times to regulatory action. From time to time, approved products may be found in violation of one or more provisions of the Act. In such circumstances, the Agency will commence appropriate enforcement action to correct the violation, if necessary, by securing removal of the product from the market by voluntary recall, seizure, or other enforcement actions. *Such regulatory actions are, however, independent of the inclusion of a product on the List.* The main criterion for inclusion of a product is that it has an application with an effective approval that has not been withdrawn for safety or efficacy reasons. FDA believes that retention of a violative product on the List will not have any significant adverse health consequences, because other legal mechanisms are available to the Agency to prevent the product's actual marketing. FDA may however, change a product's therapeutic equivalence rating if the circumstances giving rise to the violation change or otherwise call into question the data upon which the Agency's assessment of whether a product meets the criteria for therapeutic equivalence was made.") (emphasis added).

126. 21 C.F.R. § 314.53(f).

any person to write to the agency to dispute the listing of a patent by calling into question “the accuracy or relevance of patent information submitted” or claiming that “an applicant has failed to submit required patent information.”¹²⁷ However, the FDA will *not* change the listings unless the NDA holder affirmatively requests the change.

B. *The Role of NDA Holders*

NDA holders are the least likely to efficiently and effectively regulate the Orange Book under the current system. The FDA mechanically applies the rules to preserve an NDA holder’s market exclusivity, without any consideration of the patent’s validity or scope—a fact that NDA holders have learned to exploit. In practice, NDA holders have commonly listed as many patents as possible in order to cover as many variations of a drug as possible.¹²⁸ For example, in *Teva v. Eisai*,¹²⁹ Eisai, the NDA holder, listed four patents that it later decided not to enforce; Eisai statutorily disclaimed two patents and offered a covenant not to sue on the two nondisclaimed patents.¹³⁰ However, all of these patents remained listed in the Orange Book and continued to serve as an obstacle for generic drug entry. As *Eisai* shows, such a scenario has been quite advantageous to NDA holders, since they do not have to defend their decision to list the patents to the FDA.¹³¹

The Hatch-Waxman framework also relieves NDA holders of the burden to monitor competitors who may be developing generic drugs that potentially infringe on the listed patents. When a generic manufacturer files an ANDA with a Paragraph IV certification, the generic manufacturer must notify the NDA holder and patent owner of the possible infringing product.¹³² Without the need for a more proactive role, it seems that NDA holders stand to benefit from keeping the status quo.

C. *The Role of the Courts*

If courts consistently choose to exercise jurisdiction over declaratory judgment actions claiming injuries caused by Orange Book listings, NDA holders could be forced to more effectively self-regulate. With an increase in

127. *Id.*

128. See FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 5, 70–71 (2002), <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>; see also 148 CONG. REC. S7635–37 (daily ed. July 31, 2002) (listing examples of tangential patents listed in the Orange Book and noting that “drug manufacturers go to extraordinary lengths to insure that the FDA list any un-expired patent covering a profitable brand-name drug”).

129. *Teva Pharm. USA, Inc. v. Eisai Co.*, 620 F.3d 1341 (Fed. Cir. 2010).

130. *Id.* at 1345.

131. The requirement for listing patents is only whether the RLD falls within the scope of the patent’s claims. See *Biovail Corp., Int’l v. Andrx Pharm., Inc.*, 239 F.3d 1297, 1301 (Fed. Cir. 2001). As a result, listed patents often cover more than just the RLD.

132. 21 U.S.C. § 355(j)(2)(B).

declaratory judgment actions from subsequent-filers eager to trigger exclusivity periods, NDA holders will more frequently participate in costly litigation and their patents will be subject to more challenges. If they continue to lose declaratory judgment actions, NDA holders may start spending time and effort pruning the Orange Book listings rather than merely awaiting possible court judgments and injunctions.

In addition, while courts may not be able to directly order the FDA to delist a patent,¹³³ the D.C. Circuit has required the FDA to relist patents that an NDA holder has requested to be delisted.¹³⁴ The court found that ordering the removal of a Paragraph IV certification in an ANDA unlawfully deprived the first-filer of its exclusivity period.¹³⁵ The FDA argued that its policy—delisting a patent when an NDA holder has requested it and has not filed a lawsuit against an ANDA holder who has filed a Paragraph IV certification to the patent—allows the NDA holder to remove a barrier to ANDA approval if the drug is not relevant. This policy also allows the FDA to retain its ministerial role rather than being forced into a role of interpreting patent listings.¹³⁶ Finding for the generics, the D.C. Circuit supported its ruling by noting that the removal requirement took away the Act's intended incentive for challenging the patent.¹³⁷ If this reasoning is followed, the courts could have a limited role in ensuring that NDA holders do not strategically delist patents to eliminate a first-filer's exclusivity period.

133. The FDA will only remove a patent listed in the Orange Book in response to an NDA holder's request. 21 C.F.R. § 314.53(f) (2011). To get around this, a court can enter an injunction ordering the NDA holder to request that the FDA delist a patent. *See Abbott Labs. v. Novopharm Ltd.*, 104 F.3d 1305, 1309 (Fed. Cir. 1997) (requiring the NDA holder to submit a request to the FDA to remove an expired patent).

134. *See Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006). NDA holders have tried to strategically delist patents so that a first-filer forfeits its generic exclusivity period. *See, e.g.*, Letter from Gary Buehler, Dir., Office of Generic Drugs, Food & Drug Admin. Ctr. for Drug Evaluation & Research, to William A. Rakoczy, Rakoczy, Molino, Mazzochi & Siwik, LLP, (May 7, 2008), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2007-N-0445-0026> (finding that delisting a patent triggers the seventy-five-day clock for "failure to market" forfeiture event under 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb) unless the delisting is as a result of a counterclaim by an ANDA applicant); Letter from Gary Buehler, Dir., Office of Generic Drugs, Food & Drug Admin. Ctr. for Drug Evaluation & Research, to ANDA Applicant (Oct. 28, 2008), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2008-N-0483-0017> (finding a first-filer forfeited exclusivity for failing to maintain its Paragraph IV certification).

135. *Ranbaxy*, 469 F.3d at 126; *see also* 21 C.F.R. § 314.94(a)(12)(viii)(B) (requiring ANDA filers to amend the application if a patent is delisted). This court's decision seems to be more in line with the view that the generic exclusivity period is a "right" not merely an "incentive."

136. *Ranbaxy*, 469 F.3d at 123, 125.

137. *Id.* at 126; *see Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010) (holding that MMA forfeiture provisions not meant to allow brand manufacturers to "unilaterally vitiate a generic's exclusivity").

D. *The Role of ANDA Filers*

The MMA amendments permit generic manufacturers to bring counterclaims ordering the NDA holder to “correct or delete” patent information if the patent claimed neither the approved drug nor an approved method of use.¹³⁸ The Federal Circuit has construed this statutory language to constrain the scope of relief to correcting or deleting an incorrect patent number or expiration date, but not a use code.¹³⁹ Even if the listed use code is beyond the scope of the patent claims, the Federal Circuit will deem a patent properly listed in the Orange Book so long as it claims any one of the approved uses. The statute also expressly states that the provision does not create an independent cause of action; a generic manufacturer can only seek correction or deletion as a counterclaim in a patent infringement suit.¹⁴⁰ However, one district court has held that the generic manufacturer can ask for that relief in a declaratory judgment action as part of the district court’s inherent power of giving effect to its judgment.¹⁴¹ Even though *Teva v. Eisai*

138. 21 U.S.C. § 355(j)(5)(D)(ii)(2010). Before the 2003 MMA amendments, a generic drug manufacturer did not have a cause of action to seek to delist a patent in the Orange Book; it had to seek relief under the Administrative Procedure Act. *See* Administrative Procedure Act, 5 U.S.C. §§ 702–06 (1999); *Andrx v. Biovail Corp.*, 276 F.3d 1368, 1378–80 (Fed. Cir. 2002); *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1332–33 (Fed. Cir. 2001) (holding that declaratory judgment action by the generic manufacturer to challenge listing in Orange Book was an improper private action as an attempt to enforce the Federal Food, Drug, and Cosmetic Act and not a proper defense to infringement suit). A district court could, however, order a patentee to request that the FDA delist its expired patent in order to effectuate a judgment. *See Abbott Labs.*, 104 F.3d at 1309 (requiring the NDA holder to submit a request to the FDA to remove an expired patent).

139. *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1364–66 (Fed. Cir. 2010). FDA regulations require NDA holders to submit a “use code narrative” that describes a method of using the drug. *See* 21 C.F.R. § 314.53 (2010); FDA FORM 3542A, *supra* note 10; FOOD & DRUG ADMIN., PATENT INFORMATION SUBMITTED WITH THE FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT, FORM 3542 (2010), *available at* <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048345.pdf>. The FDA assigns a “use code” based on this narrative and uses the description provided to determine whether a generic manufacturer is seeking approval for a patented use of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(viii). However, without a way to correct a use code, generic manufacturers cannot force the FDA to recognize when it enforces a patent beyond its proper scope.

140. There was significant concern that creating a private cause of action might result in generics abusing this and harassing brands. *See* 148 CONG. REC. S7,644 (daily ed. July 31, 2002); 148 CONG. REC. S7345 (daily ed. July 25, 2002); Letter Carl B. Feldbaum, President, Biotechnology Indus. Ass’n, to Senator Edward Kennedy (July 15, 2002), *available at* <http://www.bio.org/advocacy/letters/letter-sen-ted-kennedy>. This was addressed by the language that generics would not obtain civil and monetary penalties, only delisting of patents. *See* 148 CONG. REC. S7641 (daily ed. July 31, 2002) (including a letter from the President and CEO of General Motors).

141. 21 U.S.C. § 355(j)(5)(D)(ii)(II); *Apotex, Inc. v. Cephalon, Inc.*, No. 06-2768, 2010 WL 678104, at *6 (E.D. Pa. Feb. 23, 2010) (citing *Mylan Pharm.*, 268 F.3d at 1333). *But see* 148 CONG. REC. S7645 (daily ed. July 31, 2002) (proposing that the cause of action be limited to counterclaims, not “as an original and separate action,” in order to curb litigation that would not necessarily advance the goal of “making generics available to consumers more quickly”). The purpose of adding this cause of action was stated as to “help to reduce both

may lead to more declaratory judgments and thus increase the availability of this remedy, the limited changes that a generic manufacturer could effect make it impractical to leave regulation of the Orange Book to the ANDA filers.¹⁴²

E. *The Use of Citizen Petitions*

Generic manufacturers have also used citizen petitions¹⁴³ as an attempt to circumvent delays to generic drug entry. Brand name manufacturers and first-filers may also use citizen petitions as a tool to delay generic entry. Brand name manufacturers have filed citizen petitions requesting, among other things, additional bioequivalence or safety studies from generic manufacturers, additional patent certifications to post-NDA patents, and classification of the NDA as a different dosage form.¹⁴⁴ Examples of these petitions in the Aricept controversy include the citizen petition filed by Ranbaxy to challenge Teva's shared exclusivity period¹⁴⁵ and the Apotex and Eisai citizen petitions to revoke final approval of Teva's ANDA.¹⁴⁶ This was previously an easy delay tactic because the FDA was not allowed to review an ANDA until the petition was resolved. However, Congress passed the FDA Amendments Act ("FDAA") in 2007,¹⁴⁷ which requires the FDA to continue the ANDA approval process during the petition review period and to

the cost of prescription drugs and the cost of prescription drug litigation," which may very well be derailed by declaratory judgment actions increasing the amount and costs of litigation. *See* 148 CONG. REC. S7648 (daily ed. July 31, 2002).

142. On a side note, one generic manufacturer attempted to effectuate regulation of listings through false marking litigation, arguing that Eisai is "advertising" its disclaimed patents in the Orange Book by including them in the Aricept listing. *See* Complaint, Pharm. Techs., LLC v. Eisai, Inc., No. 11-cv-00665 (D. Ariz. Apr. 5, 2011).

143. A citizen petition is a request that an administrative agency take or refrain from some administrative action, including issuing, amending, or revoking a regulation or order. 21 C.F.R. § 10.30 (2011). The FDA's response to a citizen petition is considered the agency's official position. *See* 21 C.F.R. § 10.45(d) (2011).

144. *See* GENERIC DRUG ENTRY, *supra* note 128.

145. *See* Letter from Janet Woodcock, Dir., Food & Drug Admin., Ctr. for Drug Evaluation & Research, to Shashank Upadhye, Vice President, Global Intellectual Prop., and David M. Fox, Hogan Lovells US LLP (Nov. 26, 2010), *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-2010-P-0430-0015> (showing that Ranbaxy was the first-filer).

146. *See* Letter from David M. Fox to Div. of Dockets Mgmt., Food & Drug Admin. (Aug. 12, 2010), *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-2010-P-0430-0001>; Letter from Janet Woodcock, Director, Ctr. for Drug Evaluation & Research, to Shashank Upadhye, Vice President, Global Intellectual Prop., and David M. Fox, *supra* note 145; Letter from Shashank Upadhye, Vice President, Global Head of Intellectual Prop., Apotex Inc., to Dockets Mgmt. Branch, Office of Generic Drugs, Food & Drug Admin. (July 14, 2009), *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-2009-P-0326-0001> (showing that Apotex was a subsequent-filer and Eisai was the NDA holder).

147. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007).

take final action on the petition within six months.¹⁴⁸ Congress also directed the FDA to deny citizen petitions if they were “submitted with the primary purpose of delaying the approval of an applicant” and do not facially raise “valid scientific or regulatory issues.”¹⁴⁹ Nonetheless, citizen petitions are still used to challenge exclusivity periods¹⁵⁰ and to potentially extend exclusivity¹⁵¹ based on patents in the Orange Book.

F. *The Role of Congress*

Further congressional modifications to the Hatch-Waxman Act concerning Orange Book listings seem unlikely in the near future. Even if Congress does address the issue and put a different statutory framework in place, the FDA may lack the resources or capacity to better monitor and update the Orange Book.¹⁵² Instead, the recent discussions in Congress relating to drug regulation have debated the anticompetitive effects of NDA holders settling with first-filers to delay triggering their exclusivity periods and the FTC’s possible role in the regulation of those agreements.¹⁵³ There has also been

148. See *id.* § 914 (codified as amended at 21 U.S.C. § 355(q)(1)(F) (2010)).

149. 21 U.S.C. § 355(q)(1)(E)(2010).

150. See Letter from William A. Rakoczy and Lara E. FitzSimmons, Counsel for Lupin Ltd., to Division of Dockets Mgmt., Food & Drug Admin. (Oct. 18, 2010), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2010-P-0549-0001> (asking that the first-filer’s exclusivity be revoked and awarded to the subsequent-filer because the first-filer’s ANDA was not “substantially complete” when filed or “lawfully maintain[ed]” because it had a Paragraph IV certification to the EEP and a Paragraph III certification to an LEP).

151. See Letter from Robert F. Green, Counsel to Lupin Atlantis Holdings, S.A., to Div. of Documents Mgmt., Food & Drug Admin. (Oct. 22, 2010), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2010-P-0561-0001> (asking that accepted ANDAs claiming dosage forms different from the RLD be rescinded and required to submit new certifications, thus requiring new notice letter and restarting the 30-month stay).

152. See 148 CONG. REC. 6024 (2002) (attempting to amend 21 U.S.C. § 321 to require the FDA to “publish . . . only information that is qualified patent information” and “consult with” the USPTO); 147 CONG. REC. 3918–21 (2001) (discussing the proposed Brown-Emerson Amendment to direct FDA’s funding toward regulation of Orange Book listings, with opposition noting that the FDA does not have the statutory authority to evaluate the validity of patents).

153. See Preserve Access to Affordable Generics Act, S. 27, 112th Cong. (1st Sess. 2011), available at <http://thomas.loc.gov/cgi-bin/bdquery/z?d112:s.00027:>. In previous sessions of Congress, the former was raised under the same title as: S. 369, 111th Cong. (1st Sess. 2009); S. 316, 110th Cong. (1st Sess. 2007); S. 3582, 109th Cong. (2d Sess. 2006); and H.R. 1432, 110th Cong. (1st Sess. 2007). A similar bill was previously raised as Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (1st Sess. 2009) and H.R. 1902, 110th Cong. (1st Sess. 2007). Congressmen in favor of the bill attempted to include it in the Supplemental Appropriations Act (War Funding Bill), H.R. 4899, 111th Cong. (2d Sess. 2010), but the Senate dropped the provision. 156 CONG. REC. 5379, 5358, 5404–05 (daily ed. Jul. 1, 2010); <http://www.gpo.gov/fdsys/pkg/BILLS-111hr4899enr/pdf/BILLS-111hr4899enr.pdf>. They also attempted and failed to pass it in the Fiscal Year 2011 Financial Services and General Government Appropriations Bill, also known as S. 3677, 111th Cong. (2d Sess. 2010), available at <http://thomas.loc.gov/cgi-bin/bdquery/z?d111:s.03677:>. Several Congress members expressed their concerns that these changes would give the FTC too much power and would go

some debate about whether authorized generics should be banned during the generic exclusivity period, but Congress has not acted to close that loophole in the patent laws.¹⁵⁴ In short, Congress has apparently decided to leave the current regulatory system in place as is.

G. *The Role of the FTC*

The FTC has attempted to regulate the Orange Book with little success so far. Because listings allow NDA holders to trigger 30-month stays or otherwise delay the entry of generics into the market, the FTC believes that improper listings extend the legal monopoly of a patent beyond its intended term. In support of its view, the FTC has filed amicus briefs¹⁵⁵ and lawsuits,¹⁵⁶ testified before Congress,¹⁵⁷ commented on the FDA's procedures,¹⁵⁸ investigated listings and issued complaints¹⁵⁹ and consent orders,¹⁶⁰ released reports,¹⁶¹ and submitted citizen petitions.¹⁶² Despite this effort, several courts have already disagreed

against the goals of the Hatch-Waxman Act by discouraging generic manufacturers from challenging patents. 156 CONG. REC. H5386 (daily ed. Jul. 1, 2010). The bill has been revived, but unless those concerns are addressed it most likely will not get passed. *See Preserve Access to Affordable Generics Act*, S. 27, 112th Cong. (2011).

154. *See Fair Prescription Drug Competition Act*, S. 373, 112th Cong. (1st Sess. 2011); H.R. 741, 112th Cong. (1st Sess. 2011); H.R. 573, 111th Cong. (1st Sess. 2009); S. 438, 110th Cong. (1st Sess. 2007); H.R. 806, 110th Cong. (1st Sess. 2007); *see also supra* note 24.

155. *See Brief for Federal Trade Commission as Amicus Curiae*, Am. Bioscience, Inc. v. Bristol-Myers Squibb Co. (C.D. Cal. Sept. 7, 2000) (No. CV-00-08577), *available at* <http://www.ftc.gov/os/2000/09/amicusbrief.pdf>; Memorandum of Law of Amicus Curiae, *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (No. 1410), *available at* <http://www.ftc.gov/ogc/briefs/buspirone.pdf>.

156. *See Fed. Trade Comm'n v. Cephalon*, 551 F. Supp. 2d 21 (D.D.C. 2008); *In re Androgel Antitrust Litig.* (No. II), 687 F. Supp. 2d 1371 (N.D. Ga. 2010).

157. *See, e.g., Examining Issues Related to Competition in the Pharmaceutical Marketplace: A Review of the FTC Report, Generic Drug Entry Prior to Patent Expiration: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 107th Cong. (2002) (statement of Timothy J. Muris, Chairman, Federal Trade Commission), *available at* <http://www.ftc.gov/os/2002/10/generic testimony021009.pdf>.

158. *See Applications for FDA Approval to Market a New Drug*, Food & Drug Admin. Docket No. 02N-0417 (Dec. 23, 2002) (comments of the Fed. Trade Comm'n), *available at* <http://www.ftc.gov/be/v030002.pdf>; *180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications*, Food & Drug Admin. Docket No. 85N-0214 (Nov. 4, 1999) (comments of the Bureau of Competition & of Policy Planning of the Fed. Trade Comm'n), *available at* <http://www.ftc.gov/be/v990016.shtm>.

159. *See, e.g., Complaint*, Bristol-Myers Squibb Co., 135 F.T.C. 444 (2003) (No. C-4076), *available at* <http://www.ftc.gov/os/2003/04/bristolmyerssquibbcmp.pdf>.

160. *See, e.g., Biovail Corp.*, 134 F.T.C. 407 (2002) (consent order), *available at* <http://www.ftc.gov/os/2002/04/biovaildecision.htm>.

161. *See Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, FEDERAL TRADE COMMISSION (Jan. 2010), <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>.

162. *See Competition in the Technology Marketplace: Amicus Briefs and Other Advocacy*, FED. TRADE COMM'N (Aug. 19, 2010), <http://www.ftc.gov/bc/tech/property/advocacy.htm> (noting that in May 2001 the FTC submitted a citizen petition to the FDA seeking guidance on Orange Book patent listings).

with the FTC, finding that settlements between brand name manufacturers and generic manufacturers, along with settlements between competing generic manufacturers, would not be per se illegal so long as they do not attempt to go beyond the exclusionary restrictions provided to patent holders.¹⁶³ Furthermore, although the MMA amendments require filing these settlement agreements with the Assistant Attorney General and the FTC, the Savings Clause notes that “any filing under this subtitle [shall not] constitute or create a presumption of any violation of any competition laws.”¹⁶⁴ The Supreme Court declined to weigh in on this issue, denying certiorari in a recent case from the Second Circuit that asked whether such a settlement agreement is per se lawful under the Sherman Act.¹⁶⁵

H. *So Who Should Regulate?*

Unfortunately, the status quo reveals no single, effective source of regulation. Without changes from Congress, it would appear that NDA holders continue to hold significant power in controlling the patent listings in the Orange Book under the Hatch-Waxman Act today. However, the liberalization of declaratory judgment standing provides the courts, in conjunction with subsequent-filers, a much more practical role in influencing that regulation. Declaratory judgment actions may focus on collusion between brand name manufacturers and first-filers, yet they may also effect better control of the listings that time the entry of generic drugs. So long as the courts keep in mind the goals of the Hatch-Waxman Act in deciding whether to exercise jurisdiction over the declaratory judgment actions brought by subsequent-filers, this combination of ANDA filers and judicial discretion may help tie up some of the loose ends left by Congress.

III. *EISAI*'S POTENTIAL EFFECTS ON ANDA LITIGATION

In the recent Federal Circuit opinions in *Caraco*, *Janssen*, and *Eisai*, the court noted that the cases before it would be analyzed differently under the new MMA forfeiture provisions.¹⁶⁶ Perhaps the court viewed the amendments as a cue that Congress expected the legislative expansion of declaratory judgment jurisdiction to address the issue of delays from generic exclusivity. The

163. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056 (11th Cir. 2005). *But see In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908–09 (6th Cir. 2003) (holding that a similarly structured noncompete agreement is “per se illegal”).

164. Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, §§ 1112(a)(1), 1117.

165. *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1606 (2011).

166. The first Paragraph IV certifications in those cases were filed *before* December 2003, so the MMA amendments did not apply. See *supra* Background.

Federal Circuit's decision in *Eisai* establishes a subsequent-filer's ability to survive a motion to dismiss based on Article III requirements in a declaratory judgment action.¹⁶⁷ As a result, the number of suits brought by subsequent-filers is quite likely to increase, providing the courts with a more practical role in influencing NDA-holders' self-regulation of the Orange Book. If NDA holders observe subsequent-filers prevailing in these actions, they may become more reluctant to list questionable patents. The effect of the increase in litigation on the marketplace and its players, however, is unclear, and courts will have to make a number of policy decisions when choosing to exercise jurisdiction over these cases. These Federal Circuit cases formally concerned whether a case or controversy existed, but the court was also conscious of the equities of allowing declaratory judgment actions to proceed, when those actions could generate final court judgments that take away the statutorily-provided generic exclusivity period from the first-filers.¹⁶⁸ Courts should still consider the purpose of the Hatch-Waxman Act: to encourage generic manufacturers to be aggressive in challenging patents for the public good while recognizing the need to protect and reward innovation in the pharmaceutical field.¹⁶⁹

The liberalization of standing for generic manufacturers may have a number of positive consequences. By allowing generic manufacturers to challenge patents, the courts provide shorter timelines for ascertaining the legal rights of the parties.¹⁷⁰ The increased certainty that results from a declaratory judgment of invalidity or noninfringement will encourage generic companies to expend resources in order to enter the market sooner.¹⁷¹ Another benefit of liberalizing standing is a reduction in the number of "scarecrow" patents listed in the Orange Book to delay generic entry.¹⁷² Allowing more declaratory judgment

167. See Courtenay Brinckerhoff, *The Federal Circuit Solidifies the Future for Subsequent ANDA Litigation*, PHARMAPATENTS (Oct. 12, 2010), <http://www.pharmapatentsblog.com/federal-circuit-decisions/the-federal-circuit-solidifies-the-future-for-subsequent-anda-litigation>.

168. The Federal Circuit in *Eisai* found that the district court had erred in dismissing the case because it based its decision on its apparently incorrect belief that it lacked subject matter jurisdiction, but the Federal Circuit's decision still left the exercise of jurisdiction over these declaratory judgments to the discretion of the district courts. *Teva Pharm. USA, Inc. v. Eisai Co.*, 620 F.3d 1341, 1349 (Fed. Cir. 2010).

169. See, e.g., *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1294 (Fed. Cir. 2008) (citing *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002)).

170. See 149 CONG. REC. S15,885 (daily ed. Nov. 25, 2003) ("The declaratory judgment provisions in [the MMA] are intended to encourage such early resolution of patent disputes.").

171. Cf. *Apotex Inc. v. Forest Labs., Inc.*, Case No. 2:11-cv-10129-AJT-MKM (E.D. Mich. Jan. 10, 2011) (filed) (subsequent-filer seeking to trigger exclusivity because its "right to market a non-infringing generic product without the risk of catastrophic infringement damages" is "impaired" by "legal uncertainty"); *Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921, 932 (N.D. Ill. 2010) (citing 149 CONG. REC. S15,885 (daily ed. Nov. 25, 2003)).

172. See *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1336 n.2 (Fed. Cir. 2007) (quoting *Arrowhead Indus. Water, Inc. v. Ecolochem*, 846 F.2d 731, 735 (Fed. Cir. 1988)). The phrase analogizes patents to scarecrows that NDA holders have listed in the Orange Book to "scare off" generic competitors who do not wish to be subjected to

actions by generic manufacturers may also speed up time-to-market for affordable generics, resulting in more savings both to consumers and the government.

The MMA amendments included a provision that generic exclusivity would not “roll over,” which Congress obviously intended to speed up the entry of generics into the market.¹⁷³ This statutory clarification may push other generic manufacturers to more actively regulate the patents listed in the Orange Book through litigation. Soon after the *Eisai* decision, a generic manufacturer filed a complaint to obtain a declaratory judgment against a disclaimed patent to create a forfeiture event.¹⁷⁴ If a subsequent-filer challenges patents in order to eliminate a first-filer’s exclusivity period¹⁷⁵ and convinces the court to order the NDA holder to delist its patent,¹⁷⁶ this creates an interesting dynamic: since all of the first-filer’s competitors stand to benefit from a declaratory judgment that results in forfeiture of the exclusivity period, subsequent-filers might possibly join forces for this kind of litigation.

On the other hand, setting precedent that is very likely to lead to an increase in litigation has its downsides. The federal courts currently have heavy caseloads, and adding more declaratory judgment actions would only further overload the courts. Additionally, there is often concurrent litigation on other patents between the same parties,¹⁷⁷ which may already be determinative of whether the ANDA filer can enter the market any earlier.¹⁷⁸

potential patent infringement litigation even if a court would eventually find the patents invalid or unenforceable.

173. A “second-to-file” ANDA does not inherit exclusivity if a first-filer forfeits it, so the market would be open to all generics sooner. *See* 21 U.S.C. § 355(j)(5)(D)(i)(VI)(iii)(II) (2010).

174. *See* Complaint, *Par Pharm., Inc. v. UCB, Inc.*, No. 11-cv-02010-MSG (E.D. Pa. Mar. 23, 2011); Complaint, *Impax Labs., Inc. v. Pfizer Inc.*, No. 10-cv-06554(DMC-JAD) (D.N.J. Dec. 16, 2010); Complaint, *Sandoz Inc. v. Boehringer Ingelheim Int’l GmbH*, 3:10-cv-00437-UATC-MCR (M.D. Fla. May 19, 2010). A “forfeiture event” is an event that triggers the forfeiture of the generic exclusivity period. By creating the forfeiture event, other generic manufacturers can obtain FDA approval, and the disclaimed patent that is still listed in the Orange Book is no longer a block to generic entry.

175. *See* *Pfizer Inc. v. Apotex Inc.*, 726 F.Supp.2d 921, 926 (N.D. Ill. 2010); *Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355, 361–62 (D. Del. 2009).

176. The MMA amendments created a counterclaim cause of action to delist patents from the Orange Book. 21 U.S.C. § 355(j)(5)(C)(ii).

177. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008); and *Teva Pharm. USA, Inc. v. Eisai Co., Ltd.*, 620 F.3d 1341 (Fed. Cir. 2010), exemplify this very likely possibility—the parties were already involved in infringement suits for the EEPs when the subsequent-filers attempted to initiate declaratory judgment actions for the LEPs.

178. For example, if an EEP is found to be valid, infringed, and enforceable, then the declaratory judgment action on unasserted LEPs is rendered moot. In his dissent in *Caraco*, Senior Judge Friedman argued that declaratory judgments are “[i]n most instances [sought] to protect [the alleged infringer] from a subsequent judicial determination that has a significant adverse financial impact upon the infringer.” *Caraco*, 527 F.3d at 1298 (Friedman, J., dissenting). However, in that case, *Caraco* was seeking a declaratory judgment to trigger the first-filer’s exclusivity period so that its own entry into the market could be hastened. Judge Friedman found that *Caraco*’s argument was “highly speculative and conjectural,”

Furthermore, permitting subsequent-filers to trigger first-filers' exclusivity periods before they can start marketing would seem to cheapen the incentive to file first.¹⁷⁹ Subsequent-filers are obviously motivated to eliminate the first-filer's generic exclusivity so they can enter the market sooner. While courts can encourage first-filers to be more aggressive in challenging patents, entirely depriving first-filers of the generic exclusivity period may contravene the goals of the Hatch-Waxman Act.

Liberalizing declaratory judgments may also be an attempt to push ANDA filers toward filing more Paragraph IV certifications.¹⁸⁰ This may speed up generic entry by weeding out scarecrow patents sooner, but it would do so at the very steep cost of discouraging investments by innovators in pioneer drug research and development.¹⁸¹ NDA holders will also be much more determined to hold onto and litigate any exclusivity they can with the "patent cliff" rapidly approaching.¹⁸² If the courts could keep the purpose of the generic exclusivity period in mind when deciding these

"involve[d] uncertain legal issues that have not yet been resolved," and "assume[d] that [Caraco] [would] prevail in its non-infringement claim—an uncertain assumption at best." *Id.* at 1298.

179. On the other hand, the generic exclusivity period may not have been the best incentive to encourage faster generic drug entry. In *Eisai*, 620 F.3d 1353, Teva spent the resources to litigate and challenge the patents even with no chance of obtaining the exclusivity via the Gate ANDA. *See supra* notes 94–96 and accompanying text.

180. If first-filers fail to "clear the brush" for other generics to enter the market, allowing subsequent-filers to expropriate the generic exclusivity period could spur first-filers to be more aggressive in challenging patents. However, pushing more Paragraph IV certifications may result in more frivolous arguments being made when challenging patents. *See Yamanoichi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347–48 (Fed. Cir. 2000); *Glaxo Grp. Ltd. v. Apotex, Inc.*, 268 F. Supp. 2d 1013, 1033 (N.D. Ill. 2003); *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 264 F. Supp. 2d 753, 759 (S.D. Ind. 2003).

181. *See* 153 CONG. REC. S1352 (daily ed. Jan. 30, 2007) (statement of Sen. Leahy) (noting that the declaratory judgments were intended to be an additional incentive for generic manufacturers to challenge patents); 149 CONG. REC. S8190 (daily ed. Jun. 19, 2003) (statement of Sen. McCain) (recognizing that bolstering generic entry may be seen as impeding the "tremendous investments" of the drug industry); *Id.* at S8193 (statement of Sen. Judd Gregg) (elaborating on the need to support the drug industry's "innovation side" as balanced with public's need for accessible generic drugs).

182. The "patent cliff" is the short, upcoming timeframe in which key patents covering top-selling brand name drugs will expire, so sales will plummet as generic drug competitors take over the market. *See* Ben Hirschler, *Drugmakers Face \$140 bln Patent "Cliff"*, REUTERS (May 1, 2007), <http://www.reuters.com/article/idUSL0112153120070502>; Sara Houlton, *Pharma Refocuses on the Patent Cliff*, CHEMISTRY WORLD (Jan. 2009), <http://www.rsc.org/chemistryworld/Issues/2009/January/PharmaRefocusesOnThePatentCliff.asp>. *But see* Stewart Lyman, *The Myth of the "Patent Cliff"*, XCONOMY (Nov. 29, 2010), <http://www.xconomy.com/national/2010/11/29/the-myth-of-the-patent-cliff>.

actions,¹⁸³ they could align their analyses of justiciability with the goals of the Hatch-Waxman Act.¹⁸⁴

Furthermore, while Congress intended to create an incentive for generic manufacturers to challenge listed patents with the 180-day exclusivity period—either by questioning a patent’s validity or by designing around a narrow one—generic manufacturers have viewed the exclusivity period as a right, not a reward.¹⁸⁵ As a result, generic manufacturers have designed settlements, commonly known as “reverse payment” or “pay-for-delay” agreements, where they trade their “right” to enter the market under their ANDA for large sums of money from the brand name manufacturer. The brand manufacturers obviously benefit from the extra time as the sole provider of the drug. The FTC keenly opposes this entitled attitude, especially in light of what it considers to be anticompetitive behavior;¹⁸⁶ when first-filers use their “right” to delay their own entry and create a bottleneck that delays the entry of other generics, this improperly extends the statutory exclusivity.¹⁸⁷ Some recent district court opinions¹⁸⁸ appear to support the FTC’s interpretation by allowing declaratory judgments by subsequent-filers that may very well eliminate the “right” of a first-filer, especially when it appears to the court

183. It may make sense for first-filers to intervene in these declaratory judgment actions if courts view generic exclusivity as a “right.” Then first-filers have a legal interest in the decisions.

184. One commonly understood goal of the Hatch-Waxman Act, particularly from the MMA provision explicitly authorizing declaratory judgments, is providing legal certainty but not prematurely advising parties. *See supra* notes 170–171. Another such goal is maintaining the careful balance between protecting innovator drug research and development and facilitating generic drug approval. *See supra* note 169.

185. According to the FTC, generic manufacturers see the exclusivity as a “right” that “cannot be divested even when that eligibility is based on an erroneously listed patent”; the FTC noted that exclusivity is not guaranteed, so it is merely an “incentive.” *See* Letter from Donald S. Clark, Secretary, Fed. Trade Comm’n, to Div. of Dockets Mgmt., Food & Drug Admin. (April 5, 2005), available at <http://www.ftc.gov/os/2005/04/0504071trivaxpharm.pdf>. The FDA avoided the semantics and stated, “Exclusivity has been recognized as an incentive and reward for challenging a patent, but . . . it is not an entitlement that vests with the submission of a paragraph IV certification.” Letter from Stephen K. Galson, Dir., Food & Drug Admin. Ctr. for Drug Evaluation & Research, to Monte R. Browder, Intellectual Prop. Counsel, Ivax Pharm., Inc., to Kate C. Beardsley and Carmen M. Shepard (Oct. 24, 2005).

186. *See* Letter from Donald S. Clark, Secretary, Fed. Trade Comm’n, to Div. of Dockets Mgmt., Food & Drug Admin., *supra* note 185 (stating that the generic manufacturer had a “flawed view” of the exclusivity as “a right awarded to a [first-filer], rather than an incentive to challenge weak patents and design products that avoid infringing narrow ones.”); *see also supra* notes 135, 155–162 and accompanying text.

187. Even with the MMA forfeiture provisions, first-filers can still delay subsequent-filers’ ANDAs by waiting seventy-five days before entering the market. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I) (2010).

188. *See* Pfizer Inc. v. Apotex Inc., 726 F. Supp. 2d 921 (N.D. Ill. 2010); Dey, L.P. v. Sepracor, Inc., 595 F. Supp. 2d 355 (D. Del. 2009).

that the first-filer is using its generic exclusivity in a manner inconsistent with the purpose of the “incentive.”¹⁸⁹

If courts tend toward finding for declaratory judgment plaintiffs, the entry of generic drugs in the market may speed up and therefore more rapidly reduce the cost of drugs to the public. On the other hand, if the courts favor NDA-holding defendants, these declaratory judgment proceedings may fortify the patents against further attack. The courts need to keep the goals of the Hatch-Waxman Act in mind in deciding which way to tilt the balance: in favor of protecting drug innovation or in favor of speeding up generic drug accessibility.

CONCLUSION

The Federal Circuit’s decision in *Teva v. Eisai* will likely have consequences beyond simply establishing that subsequent-filers have standing to file declaratory judgment actions to trigger a first-filer’s exclusivity period. Increased litigation involving subsequent-filers and analyzing generic exclusivity based on the Orange Book listings will probably cause a shift in power to courts. This could have an overall positive effect so long as the courts, when deciding whether to allow an action to proceed, remember the Hatch-Waxman Act’s goal of balancing the incentives for both brand name manufacturers and generic manufacturers. There may be other opportunities for courts if parties raise issues that are more amenable to considering that balance. Escalated litigation may also encourage NDA holders to more effectively monitor which patents are listed or stay listed in the Orange Book, which could speed up generic drug entry in a legitimate way. In the near future, the courts will likely be the main force to effect change in the regulation of generic drug entry and deal with the new dynamics among brand name manufacturers, first-filers, and subsequent-filers. So long as the courts maintain their focus on the balancing goals of the Hatch-Waxman Act, their regulation may best serve all of the interests involved.

189. Using the “right” to delay entry for monetary gain in these pay-for-delay settlements could be seen as antithetical to the purpose of the “incentive” of speeding up generic entry. See *Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921, 932 (N.D. Ill. 2010); *Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355, 357 (D. Del. 2009).