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THE ROADBLOCK FOR GENERIC DRUGS: DECLARATORY JUDGMENT JURISDICTION FOR LATER GENERIC CHALLENGERS

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The Hatch-Waxman Act allows generic drug manufacturers to market a generic equivalent of a pharmaceutical company's patented drug prior to the patent's expiration by bringing Paragraph IV challenges against the patent holder. To encourage generic manufacturers to make these challenges, the Hatch-Waxman Act grants the first generic challenger ("first-filer") for a particular drug a 180-day period of marketing exclusivity during which the Food and Drug Administration ("FDA") will not approve applications from later generic challengers ("later-filers"). However, the first-filer almost always enters into reverse-payment settlement agreements with the pharmaceutical patent holder, where the patent holder agrees to pay the generic challenger to postpone entering the market. These settlement agreements act as roadblocks for later-filers.

One of the only ways for a later-filer to overcome such a roadblock is to bring a declaratory judgment action against the pharmaceutical patent holder. Early decisions by the Federal Circuit, however, suggested that later-filers could not bring declaratory judgment actions because they failed to satisfy the Constitution's Article III "case or controversy" requirement.

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This Article analyzes current case law regarding declaratory judgment jurisdiction for later-filers, provides strategies that both patent holders and generic challengers should consider before bringing suit, and proposes several ways to balance the competing interests of the Hatch-Waxman Act.

I. INTRODUCTION

Pharmaceutical innovations have transformed health care in the United States. Consumers have turned to a variety of drug therapies to help prevent, control, and treat their many ailments, spending a total of $320 billion on prescription drugs in 2011.[1] Eighty percent of these prescriptions were for generic drugs, which are generally more affordable than brand-name drugs.[2] However, the declining use of brand-name drugs has arguably reduced the incentive for innovators to create new drugs.[3] The annual number of new drugs approved for marketing has declined from a peak of fifty-three in 1996 to only thirty-nine in 2012.[4] Over the last

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[1] *See The Use of Medicines in the United States: Review of 2011*, IMS INST. FOR HEALTH INFO. (Apr. 2012), http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf.

[2] *Id.*

[3] *See* Henry G. Grabowski et al., *Evolving Brand-Name and Generic Drug Competition May Warrant A Revision Of The Hatch-Waxman Act*, 30 HEALTH AFF. 2157 (2011), *available at* http://content.healthaffairs.org/content/30/11/2157.full.html.

[4] *See* Matthew Arnold, *FDA BLA Approvals Rose in 2009 While NMEs Stumbled*, MED. MKTG. & MEDIA (Dec. 31, 2009), http://www.mmm-online.com/fda-bla-approvals-rose-in-2009-while-nmes-stumbled/article/160496/; Matthew Avery, *Personalized Medicine and Rescuing "Unsafe" Drugs with Pharmacogenomics: A Regulatory Perspective*, 65 FOOD & DRUG L.J. 37, 38 (2010); *Pills Get Smart: Potential Encapsulated*, ECONOMIST (Jan. 14, 2010), *available at* http://www.economist.com/businessfinance/displayStory.cfm?story_id=15276730; Anna Edney & Catherine Larkin, *Drug Approvals Reach 15-Year High on Smoother FDA Reviews*, BLOOMBERG (Jan. 2, 2013, 12:00 AM), http://www.bloomberg.com/news/2013-01-02/drug-approvals-reach-15-year-high-on-smoother-fda-reviews.html. However, the thirty-nine new drug approvals in 2012 was a dramatic increase from the FDA's historical practice; from 2001 to 2010, the FDA averaged just under twenty-three new drug approvals each year. *See* FOOD & DRUG ADMIN., *Summary of NDA Approvals and Receipts, 1938 to the Present*

decade, revenue generated by the introduction of new drugs has failed to counterbalance the loss of sales revenue caused by generic drug competition.[5] This competition is becoming more intense—generic companies continue to file hundreds of applications each year to market generic versions of brand-name drugs, with 853 such applications filed in 2011 alone.[6] Compounding this problem is a rapidly approaching "patent cliff," when numerous pharmaceutical products are expected to lose patent protection.[7] In 2011, for example, brand-name drug spending declined by $14.9 billion due to expired patents.[8] In the past three years, more than seventy drugs have gone off patent.[9] By the year 2016, nine of the top fifteen best-selling drugs in the world will lose patent protection.[10]

(Jan. 18, 2013), http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SummaryofNDAApprovalsReceipts1938tothepresent/default.htm.

[5] Grabowski et al., *supra* note 3, at 2160.

[6] *See* Dave McCleary, *eCTD ANDA Submission Statistics*, CUSTOPHARM BLOG (Oct. 7, 2011), http://www.custopharm.com/blog/bid/73873/eCTD-ANDA-Submission-Statistics; *see also* Kwadwo Awuah, *GPhA 2011: Regulatory Recommendations for ANDAs*, FDA (Oct. 4, 2011), http:// www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM292651.pdf.

[7] *See* Christopher K. Hepp, *Big Pharma Gearing up to Face the Patent Cliff*, PHILLY.COM (Nov. 12, 2010), http://www.philly.com/inquirer/business/107412428.html; *More Than 1,000 Drug Patents Expiring During the Next Two Years: PharmaLive Special Reports*, UBM CANON (Dec. 3, 2010), http://www.mddionline.com/blog/devicetalk/more-1000-drug-patents-expiring-during-next-two-years-pharmalive-special-reports.

[8] *See* IMS INST. FOR HEALTH INFO., *supra* note 1.

[9] *See* DAVID COLLINS & TROY SMITH, STRATEGY IN THE TWENTY FIRST CENTURY PHARMACEUTICAL INDUSTRY: MERCK & CO. AND PFIZER INC. 5 (HARV. BUS. SCH. rev. 2007) (2006), *available at* http://magus9653.files.wordpress.com/2008/11/harvard-business-review-strategy-in-the.pdf. One group reported that nine of the top ten best-selling drugs in the world will lose patent protection by 2014. *See* Hepp, *supra* note 7.

[10] *See* Tom Randall, *Drugmakers Poised to Report Biggest Drop Since 2006 on Record Patent Loss*, BLOOMBERG (Apr. 15, 2011, 10:13 AM), http://www.bloomberg.com/news/2011-04-15/drugmakers-poised-to-report-biggest-drop-since-2006-on-record-patent-loss.html.

Under the Hatch-Waxman Act, competitors seeking to market a generic version of a previously approved pharmaceutical product must file and receive approval of an Abbreviated New Drug Application ("ANDA").[11] By filing an ANDA, a competitor need only demonstrate that its product is bioequivalent to a brand-name drug, rather than conduct clinical trials on the efficacy or safety of its products.[12] If the competitor also files a "Paragraph IV Certification," asserting that each of the patents for the pharmaceutical product is invalid and/or not infringed by the competitor's product, then the competitor receives a 180-day period of market exclusivity during which the FDA may not approve ANDAs subsequently filed by other generic manufacturers who filed Paragraph IV certifications for the same patent.[13] The 180-day exclusivity period typically allows the first ANDA filer to capture 80% to 90% of the market, often within months of entering the marketplace.[14]

In response to this intense generic competition, pharmaceutical patent holders have used a variety of controversial means to extend their patent-granted monopoly, many of which have been criticized by both academics and the government.[15] For example, pharmaceutical

[11] *See* 21 U.S.C. § 355(a) (2006) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug."); 21 U.S.C. §§ 355(j)(1)–355(j)(5)(A) (2006) ("Any person may file with the Secretary an abbreviated application for the approval of a new drug . . . [and] the Secretary shall approve or disapprove the application.").

[12] *See* Grabowski et al., *supra* note 3, at 2157.

[13] 21 U.S.C. § 355(j)(5)(B)(iv)(II)(a).

[14] For example, the generic form of Prozac (fluoxetine) claimed approximately 65% of the market within a month of generic entry, 80% by the end of the first generic competitor's 180-day exclusivity period, and leveled out at almost 90% after a year of generic competition. *See* Benjamin G. Druss et al., *Listening to Generic Prozac: Winners, Losers, and Sideliners*, 23 HEALTH AFF. 210, 214 (2004), *available at* http://content.healthaffairs.org/content/23/5/210.full.

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

patent holders almost always enter into reverse-payment settlements with the first generic drug manufacturer to file an ANDA.[16] A reverse-payment settlement is when the patent holder agrees to make cash payments to the generic challenger in exchange for the generic challenger agreeing to delay the launch of its generic product.[17] By carefully crafting these settlements, the patent holder and the first ANDA filer are able to take advantage of certain provisions of the Hatch-Waxman Act to create a roadblock based on the first-filer's 180-day exclusivity period, which prevents other generic companies from entering the market.[18]

One of the only ways for later-filers to overcome such a roadblock is to bring a declaratory judgment action against the pharmaceutical patent holder to obtain a judgment that its patents are invalid or not infringed. Early decisions by the Federal Circuit, however, suggested that these later-filers could not bring declaratory judgment actions because the later-filers could not satisfy the Constitution's Article III "case or controversy" requirement, which authorizes a federal court to exercise jurisdiction over a case only when there is an actual controversy between the parties before the court.[19]

Recent Federal Circuit decisions have helped clear the path for later-filers to bring declaratory judgment actions against

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omitted); Matthew Avery, Note, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 179–83 (2008).

[16] *See* Avery, *supra* note 15, at 192–93.

[17] *See, e.g.*, FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013) ("Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a 'reverse payment' settlement agreement."). Commentators refer to such settlements as "reverse payments" because they involve payments from the plaintiff to the defendant—i.e., from the patentee to the generic manufacturer. *See* James C. Burling, *Hatch-Waxman Patent Settlements: The Battle for a Benchmark*, 20 ANTITRUST 41, 41 (2006).

[18] *See* Avery, *supra* note 15, at 191–93.

[19] *Id.* at 187 n.111.

pharmaceutical patent holders. In two bookend decisions, *Caraco v. Forest*[20] and *Janssen v. Apotex*,[21] the Federal Circuit stipulated that a later-filer may bring a declaratory judgment action so long as the first ANDA filer's 180-day exclusivity period is the only bar to the later-filer's ability to enter the marketplace.[22] Based on the *Caraco* and *Janssen* decisions, district courts are now allowing later-filers to bring declaratory judgment actions in order to force first-filers to forfeit their 180-day exclusivity periods. Generally, courts allow these actions to progress so long as the later-filer: (1) has filed Paragraph IV certifications against every patent listed in the FDA's *Orange Book*[23] for the challenged brand-name drug, and; (2) has not independently stipulated to the validity of any of these patents.

This Article reviews how declaratory judgment jurisdiction for generic challengers has evolved over time, provides strategies for both patent holders and later ANDA filers, and proposes modifying the current regulatory regime to resolve problems with declaratory judgment jurisdiction for later ANDA filers. Part II of this Article provides a brief overview of the Hatch-Waxman Act and the Paragraph IV certification process. Part III discusses how the Federal Circuit has reconciled the Constitution's Article III "case or controversy" requirement with declaratory judgment actions, allowing first ANDA filers to bring such actions against brand-name drug manufacturers. Part IV reviews Federal Circuit decisions that have provided the framework for determining whether later ANDA filers may bring these declaratory judgment actions. Part V discusses recent district court decisions that have followed this framework in determining declaratory judgment jurisdiction for later ANDA filers. Part VI provides strategies that both patent holders and later ANDA filers should consider before bringing suit. Finally, Part VII proposes modifying the current

[20] 527 F.3d 1278 (Fed. Cir. 2008).
[21] 540 F.3d 1353 (Fed. Cir. 2008).
[22] *Janssen*, 540 F.3d at 1361; *Caraco*, 527 F.3d at 1293–94.
[23] The *Orange Book* lists drugs "approved on the basis of safety and effectiveness by the [FDA]." FOOD & DRUG ADMIN., *Approved Drugs with Therapeutic Equivalence Evaluations* (*Orange Book*) (Apr. 12, 2013), http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm.

regulatory regime to resolve problems with declaratory judgment jurisdiction by: (1) expressly granting declaratory judgment jurisdiction to later ANDA filers; (2) reforming use of the 180-day exclusivity period; or (3) making it easier for generic challengers to get blocking patents delisted from the *Orange Book*.[24]

II. FDA REGULATION OF GENERIC DRUGS

A. *The Hatch-Waxman Act and Paragraph IV Certifications*

The marketing of generic drugs is regulated in part by the Hatch-Waxman Act.[25] Under Hatch-Waxman, before a generic drug manufacturer can enter the market, it must seek FDA approval by filing an ANDA.[26] A pharmaceutical company must list all patents that claim its brand-name drug in the FDA's so-called *Orange Book*.[27] As part of the ANDA, the generic applicant is required to make one of the following certifications regarding *each* patent listed in the *Orange Book* that claims the drug it seeks to copy: (I) that the drug is not patented or that patent information has not been filed; (II) that the patent has expired; (III) that the generic drug will not enter the market until the patent expires; or

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[24] It is beyond the scope of this Article to analyze whether later generic challengers can use *inter partes* review as an alternative to a declaratory judgment action for triggering forfeiture of a first-filer's 180-day exclusivity period. Because *inter partes* review is still a new process, it is unclear whether patent nullification by the Patent Trial and Appeals Board in an *inter partes* review proceeding would qualify to trigger forfeiture. *See* Kurt R. Karst, Inter Partes *Review and Forfeiture of 180-Day Generic Drug Exclusivity*, FDA LAW BLOG (Feb. 28, 2013, 12:31 PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2013/02/inter-partes-review-and-forfeiture-of-180-day-generic-drug-exclusivity.html.

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

[26] *See* H.R. REP. NO. 98-857, pt. 1, at 16 (1984).

[27] *See* 21 U.S.C. § 355(b)(1) (2006). The *Orange Book* is the common name for the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is published monthly. OFFICE OF GENERIC DRUGS, FOOD & DRUG ADMIN., APPROVED DRUG PROD. WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2008) [hereinafter *Orange Book*], *available at* http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

(IV) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the application is submitted.[28] These are called Paragraph I, II, III, and IV certifications, respectively.

By making a Paragraph IV certification, a generic manufacturer can seek FDA approval to market a generic equivalent of a pioneer's patented drug before the patent term has expired.[29] Subsection 271(e) of the Patent Act, however, provides that making a Paragraph IV certification alone is an act of patent infringement.[30] Consequently, the mere filing of an ANDA with a Paragraph IV certification allows the pioneer to sue the generic challenger for infringing its patents listed in the *Orange Book*.

As an incentive for generic drug manufacturers to risk ANDA litigation, the Hatch-Waxman Act provides a 180-day exclusivity period to the first generic manufacturer to file an ANDA containing a Paragraph IV certification for a particular drug.[31] The FDA is forbidden from approving later-filed ANDAs for the same drug until 180 days after the first-filer begins commercially marketing a generic equivalent of the drug.[32] This 180-day period is not triggered until the first-filer enters the marketplace.[33] Using this provision to their advantage, pharmaceutical patent holders often enter into so-called reverse-payment settlements where the

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

[29] Consequently, patent challenges pursuant to Paragraph IV are a frequently deployed mechanism for the early introduction of generic competition. *See* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 10 (2002) (reporting challenges involving 130 drugs between 1984 and 2000); *Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act": Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 113, 117 (2003) (statement of Timothy Muris, Chairman, Federal Trade Commission) (noting challenges involving more than eighty drugs between January 2001 and June 2003).

[30] 35 U.S.C. § 271(e)(2)(A) (2012) ("It shall be an act of infringement to submit . . . an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . .").

[31] 21 U.S.C. § 355(j)(5)(B)(iv) (2012) (providing that until the 180-day exclusivity period has run, the FDA may not approve any successive ANDA applications on the same patent).

[32] *See id.*

[33] *See id.* at (I).

pharmaceutical patent holder pays the first-filer and the first-filer agrees to delay marketing its generic equivalent until a later date (often until right before the patent expires).[34] If the first-filer never enters the market under reverse payment settlements, the 180-day exclusivity period is not triggered; generic entry, therefore, becomes bottlenecked because the FDA cannot approve later-filed ANDAs.[35] One of the only ways this roadblock can be broken is if the first-filer forfeits the 180-day exclusivity.[36] Furthermore, one of the few ways for a later-filer to cause forfeiture by the first-filer is by securing a Federal Circuit holding that the pioneer's patent is either invalid or not infringed.[37]

When later-filers bring Paragraph IV ANDA challenges, pharmaceutical patent holders often choose not to sue the later-filers for patent infringement, thereby avoiding a possible finding of invalidity or non-infringement. In response, later-filers have brought declaratory judgment actions to obtain a judgment that the patents at issue are invalid or have not been infringed.[38]

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[34] *See* Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L.J. 51, 74 (2003); Avery, *supra* note 15, at 181. The Supreme Court recently held that reverse-payment settlement agreements may be antitrust violations subject to a "rule of reason" analysis. Fed. Trade Comm'n v. Actavis, No. 12-416, slip op. at 3, 13 (S. Ct. June 17, 2013). The Court rejected both the traditional scope-of-the patent test, which made most reverse-payment settlement agreements presumptively lawful, and the FTC's proposal to make such settlements presumptively unlawful. *Id.* at 13. Instead, the Court took the middle ground and held that courts reviewing such agreements should apply the rule-of-reason analysis but left it to the lower courts to figure out what types of settlements would actually be antitrust violations. *Id.* at 13–14.

[35] *See* Soehnge, *supra* note 34, at 74; Avery, *supra* note 15, at 181.

[36] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (effective Dec. 8, 2003) (codified as amended in scattered sections of 21 and 42 U.S.C.) [hereinafter Medicare Modernization Act or "MMA"]; Avery, *supra* note 15, at 185.

[37] *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (2012); Avery, *supra* note 15, at 191–92.

[38] *See, e.g.*, 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).

B. *The Roadblock of the Failure-to-Market Forfeiture Provision*

Because the FDA cannot approve any later-filed ANDAs until the exclusivity period expires, reverse-payment settlements effectively create a barrier that stops all generic manufacturers from bringing a generic version of the drug to market until the brand-name company's patent expires. However, the Hatch-Waxman Act provides that the exclusivity period is forfeited if the first applicant does not enter the market in a timely manner.[39] The forfeiture provisions state that the first-filer's 180-day exclusivity is lost if, among other things, there is a "failure to market" event.[40] The Act defines "failure to market" as follows:

> (I) FAILURE TO MARKET. The first applicant fails to market the drug by the *later of*--
>
> (aa) the *earlier of* the date that is--
>
> (AA) 75 days after the date on which the [application of the first applicant is approved]; or
>
> (BB) 30 months after the date of submission of the application of the first applicant; *or*
>
> (bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is *75 days after* the date as of which . . . *at least 1 of the following has occurred*:
>
> (AA) In an infringement action . . . or in a declaratory judgment action . . . [the Federal Circuit finds on appeal] that the patent is invalid or not infringed.
>
> (BB) In an infringement action or a declaratory judgment action . . . a court signs a settlement order or consent decree that enters a final judgment that *includes a finding that the patent is invalid or not infringed*.
>
> (CC) [The patent holder delists the patent from the *Orange Book*].[41]

But this "failure to market" provision is almost never triggered because all elements of the complicated "earlier of"/"later of" provisions are not satisfied by the typical reverse-payment settlement. In order to trigger a failure to market forfeiture, an event in both subparts (aa) and (bb) must occur.[42] However, the

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[39] *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa)(AA).
[40] *Id.* § 355(j)(5)(D)(i)–(ii).
[41] *Id.* § 355(j)(5)(D)(i)(I) (emphasis added).
[42] Avery, *supra* note 15, at 192.

typical reverse-payment settlement is crafted to ensure that an event in subpart (bb) never occurs.[43] More specifically, these settlements do not include a finding that the pioneer's patent is invalid or not infringed, as required by event (bb)(BB).[44] Consequently, the only practical way a later-filing applicant can trigger the failure-to-market provision is by satisfying event (bb)(AA), that is, by bringing a declaratory judgment action against the patent holder to demonstrate that each of the pioneer's patents for a given drug is invalid or not infringed.[45]

III. DECLARATORY JUDGMENT ACTIONS AND THE ARTICLE III CASE-OR-CONTROVERSY REQUIREMENT

A. *Declaratory Judgment Actions Generally*

Article III of the Constitution limits the jurisdiction of federal courts to "cases" and "controversies."[46] Under the Case or Controversy Clause, a court may only render an opinion when there is a party before the court who has suffered actual injury that is traceable to the defendant, and where the injury can be redressed by the court.[47] In the case of declaratory judgment actions, where a party is merely asking the court to state the legal effect of *proposed* conduct, the court may only issue an opinion when a specific, concrete controversy exists between the parties. This is codified in the Declaratory Judgment Act ("Act"), which provides that:

> [i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.[48]

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[43] *See id.* at 191.

[44] *See id.* at 192.

[45] Note that the (bb)(AA) event is only triggered if the generic challenger can show that *all* of the patents listed in its Paragraph IV certification are either invalid or not infringed.

[46] U.S. CONST. art. III, § 2, cl. 1.

[47] *See* Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992).

[48] 28 U.S.C. § 2201(a) (2012).

In *Aetna Life Insurance Co. v. Haworth*,[49] the Supreme Court held that for there to be an "actual controversy" under the Act, the case must: (1) be "appropriate for judicial determination" in the constitutional sense; (2) be "definite and concrete, touching the legal relations of parties having adverse legal interests;" and (3) have "real and substantial controversy admitting of specific relief through a decree of a conclusive character."[50] In other words, the Court held that federal courts may issue a declaratory judgment if the plaintiff shows that the defendant caused an actual or imminent injury that can be resolved by a favorable decision by the court.

B. *The Federal Circuit's Application of the Case-or-Controversy Requirement*

Despite the Supreme Court's ruling in *Aetna*, the Federal Circuit historically applied a reasonable-apprehension-of-suit test to determine whether or not a plaintiff presented a case or controversy in declaratory judgment actions.[51] The reasonable-apprehension-of-suit test required: (1) that the patent holder made an explicit threat or took some other action that created a reasonable apprehension that it would sue the declaratory judgment plaintiff; and (2) that the declaratory judgment plaintiff is currently acting in an manner that could constitute infringement, or intends to conduct such activity and has taken concrete steps towards conducting such activity.[52] Under this test, the Federal Circuit did not allow declaratory judgment actions by plaintiffs who had been

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[49] 300 U.S. 227 (1937).

[50] *Id.* at 240–41 (citations omitted) ("Where there is such a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged, the judicial function may be appropriately exercised although the adjudication of the rights of the litigants may not require the award of process or the payment of damages.").

[51] *See* Teva Pharm. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1332 (Fed. Cir. 2005), *abrogated by* MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007). Note, however, that in *Aetna* the Court gave the lower courts discretion in deciding whether they will claim jurisdiction over a particular case, even when an "actual controversy" is deemed to exist.

[52] *See id.* (citing Gen-Probe, Inc. v. Vysis, Inc., 359 F.3d 1376, 1380 (Fed. Cir. 2004)).

granted covenants not to sue or were not immediately threatened with suit.

In *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*,[53] the Federal Circuit held that Teva could not bring a declaratory judgment action challenging Pfizer's patent because it failed to meet the "case or controversy" requirement under the reasonable-apprehension-of-suit test.[54] Pfizer held the '518 and the '699 patents, which covered the drug Zoloft (sertraline hydrochloride).[55] In 1999, Ivax Pharmaceuticals filed the first ANDA seeking to manufacture a generic version of Zoloft.[56] Ivax's ANDA contained a Paragraph IV certification for the '699 patent, stating that patent was invalid or not infringed by Ivax's product.[57] However, Ivax only made a Paragraph III certification with respect to the '518 patent, stating that it would not market a generic version of Zoloft until after the expiration of the '518 patent.[58] Pfizer responded to the Paragraph IV certification by suing Ivax for infringing the '699 patent.[59] Eventually, Pfizer entered into a reverse-payment settlement with Ivax, where it agreed to pay Ivax a royalty, and in return, Ivax agreed not to enter the market with its generic version of Zoloft until the '518 patent expired in June 2006.[60] Because Ivax was the first ANDA filer for Zoloft, it was entitled to a 180-day generic market exclusivity period.[61] Furthermore, because Ivax agreed in the settlement not to launch its generic drug until the '518 patent expired, other generic challengers would be barred from marketing their generic versions of Zoloft until at least six months after the expiry of the '518 patent.[62]

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[53] 395 F.3d 1324 (Fed. Cir. 2005), *abrogated by* MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007).

[54] *Id.* at 1338.

[55] *Id.* at 1326, 1329.

[56] *Id.* at 1330.

[57] *Id.*

[58] *Id.*

[59] *Id.*

[60] *Id.*

[61] *Id.* ("As the first-filer of an ANDA for the generic version of Zoloft®, Ivax is entitled, under 21 U.S.C. § 355(j)(5)(B)(iv), to a 180-day generic market exclusivity period.").

[62] *Id.*

Three years after Ivax filed the first ANDA challenging Zoloft, Teva filed a similar ANDA seeking approval to manufacture its own version of Zoloft.[63] Teva also made a Paragraph III certification against the '518 patent and a Paragraph IV certification against the '699 patent.[64] Rather than suing Teva for filing a Paragraph IV certification, Pfizer chose to ignore Teva's challenge.[65] Because of Ivax's 180-day exclusivity period, the FDA was barred from approving Teva's later-filed ANDA until the exclusivity period expired.[66] Because of the reverse-payment settlement between Ivax and Pfizer, the exclusivity period would not run until six months after the June 2006 expiry date of the '518 patent.[67] In order to break this roadblock, Teva filed a declaratory judgment action against Pfizer seeking a determination that the '699 patent was either invalid or not infringed.[68] Pfizer moved to dismiss the action on the grounds that there was no actual controversy.[69]

Both the trial court and the appellate court applied the reasonable-apprehension-of-suit test and held that Teva did not have standing to bring the declaratory judgment action because there was no actual controversy with Pfizer.[70] Although Teva actually infringed the '699 patent with its Paragraph IV certification, thus satisfying the second prong of the reasonable-apprehension-of-suit test, Teva failed to satisfy the first prong of the test because Pfizer had not taken actions indicating that it would sue Teva for infringing the '699 patent.[71] Thus, the Federal Circuit dismissed Teva's suit for lack of subject matter jurisdiction, holding that Teva had failed to establish that an actual controversy existed with Pfizer.[72]

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[63] *Id.*
[64] *Id.* at 1326.
[65] *Id.* at 1330.
[66] *Id.* at 1334.
[67] *Id.* at 1330.
[68] *Id.* at 1327.
[69] *Id.* at 1330.
[70] *Id.* at 1332.
[71] *Id.* at 1334.
[72] *Id.* at 1338.

In *MedImmune, Inc. v. Genentech, Inc.*,[73] the Supreme Court lowered the requirements for meeting the Article III "case or controversy" requirement and explicitly criticized the Federal Circuit's use of the reasonable-apprehension-of-suit test.[74] In this case, MedImmune brought a declaratory judgment action challenging the validity of a patent that it had already licensed.[75] MedImmune had previously agreed to the license agreement under threat of suit, but believed the patent to be invalid or not infringed.[76] Rather than simply refusing to pay the license agreement and face legal action, MedImmune agreed to pay the license but brought a declaratory judgment action challenging Genentech's patent.[77] Applying the two-prong test from *Teva v. Pfizer*, the District Court and the Federal Circuit dismissed MedImmune's suit, holding that MedImmune failed the case-or-controversy requirement because, at the time of suit, the license agreement eliminated any reasonable apprehension that Genentech would sue for infringement.[78]

On appeal, the Supreme Court rejected the Federal Circuit's two-prong test and re-affirmed that the Declaratory Judgment Act's "actual controversy" requirement is the same as Article III's "case or controversy" requirement.[79] Thus, a case or controversy exists in declaratory judgment actions 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."[80]

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[73] 549 U.S. 118 (2007).

[74] *Id.* at 132 n.11 ("Even if *Altvater* could be distinguished as an 'injunction' case, it would still contradict the Federal Circuit's 'reasonable apprehension of suit' test (or, in its evolved form, the 'reasonable apprehension of *imminent* suit' test, *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1333 (2005)).").

[75] *Id.* at 121–22.

[76] *Id.*

[77] *Id.* at 122.

[78] *Id.* Essentially, the Federal Circuit required that the plaintiff break the license agreement before bringing a declaratory judgment action. *Id.*

[79] *Id.* at 127–28, 132 n.11.

[80] *Id.* at 126 (citations omitted).

Under the "all circumstances test," the Court reasoned that although MedImmune's payment of the royalties eliminated the risk that the licensor would sue, it did not eliminate MedImmune's Article III jurisdiction because of the coercive nature of the licensor's demand; the Declaratory Judgment Act was designed to ameliorate such situations.[81] Therefore, the Court held that MedImmune was not required to breach the license agreement before seeking a declaratory judgment that the patent was invalid, unenforceable, or not infringed.[82]

C. *First ANDA Filers Generally Have Standing in Declaratory Judgment Actions*

Initially, the Federal Circuit held that all ANDA applicants—both first-filers and later-filers—failed to satisfy the Constitution's Article III "case or controversy" requirement.[83] However, after the Supreme Court's 2007 decision in *MedImmune v. Genentech*, the Federal Circuit revised its position.

In *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*,[84] the Federal Circuit found that its prior decisions conflicted with *MedImmune* and held that a first ANDA filer could bring a declaratory judgment action against the patent holder, even though the filer recited multiple patents in a single ANDA and was later sued by the patent holder on only one of those patents.[85] Novartis listed five patents in the FDA's *Orange Book*.[86] Teva was the first ANDA applicant to certify under Paragraph IV that its drug either did not infringe any of Novartis's five patents or that Novartis's

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[81] *Id.* at 129, 131.

[82] *Id.* at 137.

[83] *See* Teva Pharm. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1334 (Fed. Cir. 2005). The Federal Circuit's decision in *Teva* was surprising considering Congress explicitly granted ANDA applicants declaratory judgment jurisdiction. *See* 21 U.S.C. § 355(j)(5)(C)(i) (2013); 35 U.S.C. § 271(e)(5) (2010).

[84] 482 F.3d 1330 (Fed. Cir. 2007).

[85] *Id.* at 1334, 1346 (holding that the first ANDA filer could bring a declaratory judgment action against the patent holder where the patent holder responded to a Paragraph IV ANDA by only suing the first-filer for infringing one of five patents listed in the *Orange Book*).

[86] *Id.* at 1334.

patents were invalid.[87] Within forty-five days of receiving notice of Teva's Paragraph IV certification, Novartis sued Teva for infringing its '937 patent but not the other four patents.[88] In response, Teva brought an action against Novartis seeking a declaration that its drug did not infringe Novartis's remaining four method patents.[89] The district court dismissed Teva's declaratory judgment action for lack of subject matter jurisdiction on grounds that Teva had no reasonable apprehension of suit on the remaining four patents, but the Federal Circuit reversed its decision.[90] Applying the Supreme Court's "all circumstances" test from *MedImmune*, the Federal Circuit held that although Novartis neither filed suit nor threatened to sue Teva on the method patents, Novartis created an actual controversy by suing Teva for infringement of the '937 patent while retaining the right to sue Teva under the remaining patents.[91] The court did note, however, that:

> [T]he only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand name drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.[92]

IV. DECLARATORY JUDGMENT JURISDICTION FOR LATER ANDA FILERS

Teva v. Novartis made it clear that the first Paragraph IV ANDA filer essentially can always bring a declaratory judgment

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[87] *Id.* at 1334–35.
[88] *Id.* at 1335.
[89] *Id.*
[90] *Id.*
[91] *Id.* at 1340–41. The court found that the following circumstances, taken as a whole, were sufficient to create an actual controversy and establish declaratory judgment jurisdiction: (1) Novartis listed its patents in the *Orange Book*; (2) Teva submitted an ANDA certifying that it did not infringe Novartis' patents or that the patents were invalid; (3) statutory provisions permitted an ANDA applicant to file declaratory judgment action to obtain patent certainty in federal court; (4) Novartis sued Teva for infringement of the '937 patent; and (5) Novartis created the possibility of future litigation by retaining the right to sue Teva under the remaining patents. *Id.*
[92] *Id.* at 1343.

action against the pioneer, although the court's dicta suggests that jurisdiction can be defeated by simply granting a covenant not to sue to the generic challenger.[93] Whether courts have jurisdiction to hear declaratory judgment actions brought by later-filers, however, is still in dispute. Subsequent decisions by the Federal Circuit suggest that declaratory judgment actions brought by later-filing ANDA applicants may still fail the "case or controversy" requirement, effectively eliminating the only pathway for later-filers to break the exclusivity roadblock created by the first-filer's reverse-payment settlement.[94] In other cases, however, the Federal Circuit has allowed later-filers to bring declaratory judgment actions against pharmaceutical patent holders. These cases, which are discussed herein, show that it is not at all clear if and when later-filers can bring such actions.

A. Caraco v. Forest*: Blocking Patents Create Sufficient "Case or Controversy"*

In *Caraco*, the Federal Circuit held that an Article III controversy existed even though the patent holder had granted the later ANDA filer a covenant not to sue because the patent holder's mere listing of patents in the *Orange Book* created an injury-in-fact that prevented the later-filer from entering the marketplace.[95] Forest Laboratories held the '712 and '941 patents, which were listed in the *Orange Book* as covering Lexapro (escitalopram), a drug used to treat depression.[96] Ivax Pharmaceuticals filed the first ANDA application for Lexapro, which included Paragraph IV

[93] See *supra* notes 84–92 and accompanying text.

[94] *See* Janssen Pharm. v. Apotex, Inc., 540 F.3d 1353 (Fed. Cir. 2008); Merck & Co. v. Apotex, Inc., 287 F. App'x 884 (Fed. Cir. 2008).

[95] Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1292 (Fed. Cir. 2008) (stating that under the "all circumstances" test set forth in *MedImmune*, the defendant's mere listing of the patents in the *Orange Book* was the but-for causation of the plaintiff's inability to enter the marketplace and thus sufficient to create an Article III case or controversy). Because the first ANDA filer in *Caraco* had filed its Paragraph IV certifications before the amendments to the Hatch-Waxman Act set forth in the Medicare Modernization Act (MMA) took effect, the MMA amendments to the 180-day triggers were inapplicable to this case. *Id.* at 1283–84 n.2.

[96] *Id.* at 1286.

certifications against both patents.[97] Therefore, it was entitled to 180 days of generic marketing exclusivity, which could be triggered by marketing its drug or by a judgment that both the '712 and '941 patents were invalid or not infringed.[98] Forest sued Ivax for infringement of only the '712 patent and won.[99] However, Forest did not sue Ivax for infringing the '941 patent, likely in order to insulate itself from a possible invalidity/non-infringement judgment.[100] As a result, Ivax failed to obtain a court judgment that both the '712 and '941 patents were invalid or not infringed, which was needed to trigger its 180-day exclusivity period.[101] Ivax was thus excluded from entering the marketplace until the '712 patent expired in 2012.[102]

Subsequently, Caraco Pharmaceutical Labs filed a Paragraph IV ANDA challenging both the '712 and '941 patents.[103] However, Forest sued Caraco for infringement of only the '712 patent,[104] which expired in 2012.[105] Caraco then brought a declaratory judgment action against Forest seeking a judgment of non-infringement with respect to the '941 patent, which would not expire until 2023.[106] Because Ivax still held the 180-day exclusivity period, the FDA could not approve Caraco's ANDA until after the exclusivity period ran or was forfeited. Thus, Caraco needed to trigger the failure to market forfeiture event by getting a court decision that the '941 patent was either invalid or not infringed. In an apparent attempt to avoid this, Forest granted Caraco a unilateral covenant not to sue on the '941 patent.[107] Forest then

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[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] *Id.* The '941 patent was not set to expire until 2023. *Id.*
[101] *Id.* at 1286–87.
[102] *Id.* at 1287.
[103] *Id.* at 1288. Forest probably chose to assert only the earlier-expiring '712 patent because, even if the '712 patent was found invalid or not infringed by the court, the ANDA filer would still not be able to safely enter the market without risking patent infringement until the expiry of the '941 patent in 2023.
[104] *Id.*
[105] *Id.* at 1287.
[106] *Id.* at 1288.
[107] *Id.* at 1289.

moved to dismiss the declaratory judgment action on the grounds that, because of the covenant not to sue, Caraco had no fear of suit and therefore lacked a case or controversy.[108] The Federal Circuit disagreed, stating that although Caraco had no reasonable apprehension of suit as a result of the covenant not to sue, Caraco had alleged a cognizable injury in fact—the inability to enter the marketplace.[109]

In determining that Caraco had standing, the Federal Circuit stated that there were three requirements: (1) "there must be alleged (and ultimately proved) an 'injury in fact'—a harm suffered by the plaintiff that is 'concrete' and actual or imminent, not 'conjectural' or 'hypothetical;' " (2) "there must be causation—a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant;" and (3) "there must be redressability—a likelihood that the requested relief will redress the alleged injury."[110] The court ultimately concluded that there was an injury-in-fact because Caraco was being restrained from selling its generic version of Lexapro.[111] Even though Forest had granted Caraco a covenant not to sue on the '941 patent, Caraco was still prevented from entering the marketplace due to the FDA's inability to approve its ANDA.[112] The court further stated that this injury was caused by Forest because it was directly traceable to its listing of the '941 patent in the *Orange Book*.[113] Finally, the court held that Caraco's injury-in-fact was redressable by a declaratory

[108] *Id.* at 1288.

[109] *Id.* at 1291.

[110] *Id.* (quoting Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 102–03 (1998)).

[111] *Id.* at 1292 (alterations in original) (internal quotation marks omitted) (quoting Red Wing Shoe Co. v. Hockerson-Halberstadt, Inc., 148 F.3d 1355, 1360 (Fed. Cir. 1998)). Specifically, the court stated that "[i]f [the applicant] is correct that its generic drug does not infringe [the patent holder's] [asserted] patent, then it has a right to enter the generic drug market, and its exclusion from the generic drug market by [the patent holder's] actions is a sufficient Article III injury-in-fact." *Id.*

[112] *Id.*

[113] *Id.* at 1292–93 ("Forest's listing of the '712 and '941 patents in the Orange-Book effectively denies Caraco an economic opportunity to enter the marketplace unless Caraco can obtain a judgment that both those patents are invalid or not infringed by its generic drug.").

judgment that the ’941 patent was not infringed, which would cause Ivax to forfeit its exclusivity period and allow the FDA to approve Caraco’s drug for marketing.[114] Thus, the court held that Caraco had presented an Article III case or controversy and allowed the declaratory judgment action to proceed.[115]

B. Janssen v. Apotex*: The 180-day Exclusivity Bottleneck is Not a Sufficient Injury*

In *Janssen*, the Federal Circuit found that an Article III case or controversy did not exist between a patent holder and a later-filer where the later-filer had stipulated to the validity, enforceability, and infringement of one of the patents listed in the *Orange Book*.[116] Janssen Pharmaceuticals listed three patents in the *Orange Book* as covering its drug Risperdal (risperidone), which is used to treat schizophrenia and bipolar mania.[117] In 2002, Teva Pharmaceuticals, the first generic challenger, filed an ANDA with a Paragraph IV certification directed to just two of the patents, the ’425 and ’587

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[114] *Id.* at 1293 (“A favorable judgment in this case would clear the path to FDA approval that Forest’s actions would otherwise deny Caraco—namely, using the court-judgment trigger of [§ 355] to activate [the first ANDA filer’s] exclusivity period.”). The Court also held that the patent holder’s grant of a covenant not to sue did not render the declaratory judgment action moot because the covenant not to sue did not alleviate the harm of not being able to enter the generic drug market. *Id.* at 1297.

[115] *Id.* at 1297. Eventually, the parties stipulated to an order dismissing the case. Stipulation and Order, No. 2:09-CV-10274 (E.D. Mich. Oct. 7, 2009).

[116] Janssen Pharm., N.V. v. Apotex, Inc., 540 F.3d 1353, 1361 (Fed. Cir. 2008); *see also* Merck & Co., Inc. v. Apotex, Inc., 287 F. App’x 884, 885–88 (Fed. Cir. 2008) (indicating that Apotex filed an ANDA seeking FDA approval of a generic version of Fosamax). In response to a declaratory judgment action by Apotex, Merck granted Apotex a covenant not to sue for infringement and moved to dismiss all claims and counterclaims for lack of Article III jurisdiction. *Id.* The district court granted Merck’s motion, however, on appeal the Federal Circuit dismissed the case as moot. *Id.* While the appeal was pending, the first ANDA filer triggered its 180-day exclusivity period by marketing its generic version of Fosamax. *Id.* Consequently, a declaratory judgment would no longer allow Apotex to market its drug any sooner. *Id.*

[117] *Janssen*, 540 F.3d at 1357; *see also About RISPERDAL CONSTA (risperidone)*, JANSSEN PHARM., http://www.risperdalconsta.com/about-risperdal-consta (last updated May 8, 2013, 5:41 PM).

patents.[118] As for the third patent, the '663 patent, the ANDA included a Paragraph III certification stating that Teva would not launch its generic drug until the patent expired in June 2008.[119] Thus, Teva's 180-day exclusivity period could not begin until after the '663 patent expired in June 2008.

In 2006, Apotex subsequently filed an ANDA with Paragraph IV certifications against all three patents in an attempt to trigger forfeiture of Teva's exclusivity period.[120] In response, Janssen sued Apotex for infringing only the '663 patent.[121] Apotex filed a counterclaim seeking a declaratory judgment of non-infringement with respect to the '425 and '587 patents because the FDA could not approve its drug for marketing unless all three patents were found invalid or not infringed.[122] In an apparent attempt to avoid litigating the '425 and '587 patents, Janssen then unilaterally granted Apotex a covenant not to sue with respect to these two patents.[123] After this covenant was granted, Apotex stipulated that the '663 patent was valid, enforceable, and infringed because it had agreed to be bound by the result of a separate litigation.[124]

Janssen moved to dismiss the declaratory judgment action on the grounds that there was no Article III case or controversy.[125] Apotex contested this and argued that an Article III case or controversy existed for three reasons. First, Apotex argued that it

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[118] *Janssen*, 540 F.3d at 1358. The first ANDA applicant filed a Paragraph III declaration to the '663 patent because that patent had previously been found valid and enforceable by the Federal Circuit in previous litigation. *Id.*

[119] *Id.* The '663 patent expired in December 2007, but the effective expiration date of the '663 patent was in June 2008 because the FDA granted an additional six months of pediatric exclusivity. *Id.* at 1357.

[120] *Id.* at 1358. Apotex's ANDA initially contained Paragraph IV certifications on only the '425 and '587 patents, but later amended its ANDA to include a Paragraph IV certification on the'663 patent in January 2006. *Id.*

[121] *Id.*

[122] *Id.*

[123] *Id.*

[124] *Id.* Although Apotex was not a party, it had agreed to be bound by the result of another case before the Federal Circuit regarding the infringement, validity, and enforceability of the '663 patent. *Id.* (citing Janssen Pharm., N.V. v. Mylan Pharm., Inc., 456 F. Supp. 2d 644, 671 (D.N.J. 2006), *aff'd*, 223 F. App'x 999 (Fed. Cir. 2007)).

[125] *Id.* at 1359.

could not promptly launch its generic drug once the '663 patent expired, but the Federal Circuit found that Apotex's injury of not being able to enter the marketplace was not directly traceable to Janssen's actions or redressable by the declaratory judgment action.[126] Instead, Apotex's injury arose from the first ANDA applicant's 180-day exclusivity period.[127] According to the court, "Apotex's inability to promptly launch its generic risperidone product because of [the first applicant's] 180-day exclusivity period is not a cognizable Article III controversy, but a result envisioned by the Hatch-Waxman Act."[128] Even if Apotex were to prevail on its declaratory judgment action, it would still be prevented from entering the marketplace until the expiration of the '663 patent because Apotex previously stipulated to its validity and enforceability.[129] Second, Apotex argued that the first ANDA filer could indefinitely delay approval of Apotex's generic drug by not marketing its drug.[130] However, the court found this alleged harm was too speculative because there was no evidence that the first ANDA filer would actually delay marketing of its generic drug.[131] Finally, Apotex argued that the covenant not to sue did not protect its affiliates, suppliers, and downstream customers, but the court found that the covenant not to sue contained language that expressly covered all suppliers and affiliates involved in the manufacturing process and all customers.[132] Having rejected all of Apotex's arguments, the court held that this later ANDA filer did not satisfy the case or controversy requirement.[133]

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[126] *Id.* at 1359–60.
[127] *Id.* at 1360.
[128] *Id.* at 1361.
[129] *Id.* The Court noted that if Apotex had not stipulated to the validity of the '663 patent then the *Caraco* decision would have been controlling and Apotex would have been able to bring the declaratory judgment actions. *Id*.
[130] *Id.* at 1362.
[131] *Id.* at 1363.
[132] *Id.*
[133] *Id.* at 1363–64.

C. Teva v. Eisai*: Covenants Not to Sue Do Not Remove Article III "Case or Controversy"*

In *Caraco v. Forest* and *Janssen v. Apotex*, the Federal Circuit set forth the framework for determining when the Article III "case or controversy" requirement was satisfied. This framework was reaffirmed in the now moot *Teva v. Eisai* decision.[134] In *Teva*, the Federal Circuit reaffirmed the holdings of *Caraco* and *Janssen*, finding that a later-filing ANDA applicant satisfied the case-or-controversy requirement even though the patentee had granted covenants not to sue to the generic challenger and secured a preliminary injunction to bar it from entering the market.[135] Subsequently, the Supreme Court vacated the case as moot, but *Teva* may still provide guidance on how the Federal Circuit will decide challenges to declaratory judgment jurisdiction in the future.[136]

Eisai manufactured the brand-name drug Aricept (donepezil hydrochloride), which is used to treat Alzheimer's disease.[137] The *Orange Book* listed five patents as covering Aricept: the '321, '760, '841, '864, and '911 patents.[138] In 2003, Ranbaxy filed the first ANDA for a generic form of Aricept.[139] Ranbaxy's ANDA contained a Paragraph III certification for the '841 patent, thereby agreeing not to market its generic drug until after the '841 patent expired in November 2010.[140] The ANDA also contained Paragraph IV certifications for the remaining four patents.[141] Because Ranbaxy was the first Paragraph IV ANDA filer, it secured the 180-day exclusivity period, which would begin, at the earliest,

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[134] Teva Pharm. USA, Inc., v. Eisai Med. Research, Inc., 620 F.3d 1341 (Fed. Cir. 2010).

[135] *Id.* at 1347.

[136] Even though it was vacated as moot, *Teva* serves as a valuable tool for understanding the Federal Circuit's thinking in harmonizing the rules set forth in *Caraco* and *Janssen*.

[137] *Teva*, 620 F.3d at 1343.

[138] *Id.*

[139] *Id.* at 1344.

[140] *Id.*

[141] *Id.*

when it entered the market after the expiry of the '841 patent.[142]

In 2005 and 2007, Teva filed two separate ANDAs with Paragraph IV certifications against all five of the Eisai's *Orange Book*-listed patents for Aricept.[143] Eisai responded by suing Teva only for infringing its '841 patent, and the district court awarded Eisai a preliminary injunction that prevented Teva from marketing any drug covered by the '841 patent.[144] Nevertheless, Teva filed a declaratory judgment action for non-infringement with respect to the remaining four patents.[145] Because Ranbaxy's exclusivity period was blocking the FDA from approving Teva's later-filed ANDA, Teva sought to trigger the failure-to-market forfeiture event by obtaining a declaratory judgment that the remaining four patents were either invalid or not infringed.[146] In order to avoid this, Eisai moved to dismiss for lack of jurisdiction, asserting that Teva failed to satisfy the case-or-controversy requirement.[147] Eisai subsequently granted Teva a covenant not to sue covering the '911 and '760 patents.[148] Eisai had previously filed statutory disclaimers for the other two patents, the '321 and '864 patents, in 2006 and 2007 respectively.[149] The statutory disclaimers effectively cancelled the patent claims, preventing them from being reissued or enforced, but did not remove the patents from the *Orange Book*.[150]

The Federal Circuit held that Teva had satisfied the case-or-controversy requirement, notwithstanding Eisai's preliminary

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[142] *Id.*

[143] *Id.*

[144] *Id.* at 1345. A separate litigation dealing with just the '841 patent was pending while this case covering the remaining four patents was being heard. *See* Eisai Co. v. Teva Pharm. USA, Inc., No. 05-5727/07-5489, 2008 WL 1722098, at *13 (D.N.J. Mar. 28, 2008). In the litigation over the '841 patent, the parties agreed that the preliminary injunction would remain in effect until the '841 patent expired in November 2010. *Teva*, 620 F.3d at 1348 n.4.

[145] *Teva*, 620 F.3d at 1345.

[146] *Id.*

[147] *Id.*

[148] *Id.*

[149] *Id.*

[150] *Id.* (quoting Guinn v. Kopf, 96 F.3d 1419, 1422 (Fed. Cir. 1996)) ("A statutory disclaimer has the effect of cancelling the patent claims, meaning they cannot be reissued or subsequently enforced.").

injunction, statutory disclaimers, and covenants not to sue.[151] The court reasoned that here, like in *Caraco*, the very listing of the patents in the *Orange Book* prevented Teva from entering the marketplace.[152] In contrast to *Janssen*, here the preliminary injunction against Teva was not a final judgment and would not necessarily prevent Teva from entering the marketplace before the expiration of the '841 patent unless it matured into a permanent injunction.[153] The court also held that the disclaimers and covenants not to sue did not eliminate Teva's case or controversy because all four patents remained listed in the *Orange Book*, creating a "but-for" scenario, where but for the *Orange Book* listings, Teva would be able to launch its generic product.[154] Because Teva suffered an injury that could not be redressed without a court judgment of invalidity or non-infringement the court held that Teva had satisfied the case-or-controversy requirement.[155]

Eisai filed a petition for writ of certiorari with the Supreme Court.[156] The Court granted the petition, but vacated the case as moot when Ranbaxy, the first ANDA applicant, entered the

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[151] *Id.* at 1347.

[152] *Id.* at 1347 n.3.

[153] *Id.* at 1347–48. The court was careful to note the difference between the preliminary injunction in this case and the stipulation of validity in *Janssen*. *Id.* at 1348 ("Thus, unlike the generic drug company in *Janssen* which stipulated to the validity, enforceability and infringement of an *Orange Book* patent, there was no equivalent final judgment regarding the '841 patent.").

[154] *Id.* at 1347. The court explained that, because the preliminary injunction from the concurrent litigation dealing with the '841 patent would be lifted if Teva prevailed in that case, only the listing of the remaining four patents in the *Orange Book* prevented Teva's product launch. *Id.* at 1348. The court also noted that, although the parties had agreed that the preliminary injunction would remain in effect until the '841 patent expired on November 25, 2010, this did not change its analysis because: (1) it did not affect jurisdiction at the beginning of this appeal; and (2) the stipulation would only be relevant until the '841 patent expired. *Id.* at 1348 n.4. The remaining four patents would still bar Teva from obtaining FDA approval earlier, and the first-filer's 180-day exclusivity period would run after the '841 patent's expiration date. *Id.*

[155] *Id.* at 1347–48.

[156] Petition for Writ of Certiorari, Eisai Co., Ltd. v. Teva Pharm. USA, Inc., 131 S. Ct. 2991 (2011) (No. 10-1070).

marketplace, triggering its 180-day exclusivity period.[157] Consequently, while the Federal Circuit's *Teva* decision cannot be cited with authority, it may still serve as a useful guide for how the court would decide future jurisdiction conflicts.

D. Dey v. Sunovion*: The Possibility That the First ANDA Filer Will Not Market Its Generic Drug Creates a "Case or Controversy"*

In *Dey v. Sunovion*,[158] the Federal Circuit affirmed a district court's conclusion that it had jurisdiction over a later ANDA filer's declaratory judgment action.[159] Sunovion Pharmaceuticals manufactured the brand-name drug Xopenex (levalbuterol), which is used to treat asthma and other lung problems.[160] The *Orange Book* listed three patents as covering Xopenex: the '755, '994, and '289 patents.[161] In June 2005, Breath Pharmaceuticals filed the first ANDA application for Xopenex, which included Paragraph IV certifications against all three of Sunovion's patents, thus entitling Breath to a 180-day exclusivity period.[162] Sunovion sued Breath for infringing all three patents, but they eventually entered into a settlement agreement where Breath agreed not to launch its generic version of Xopenex until August 2012, which was a little over six months before the March 2013 expiry date of the '755 patent.[163] Assuming Breath launched its generic version of Xopenex on time, its 180-day exclusivity period would end at approximately the same time the '755 patent expired.[164]

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[157] Eisai Co., Ltd. v. Teva Pharm. USA, Inc., 131 S. Ct. 2991 (2011) (mem.) (vacating and remanding the case to the Federal Circuit with instructions to dismiss the case as moot).

[158] 677 F.3d 1158 (Fed. Cir. 2012).

[159] Dey Pharma, LP v. Sunovion Pharm. Inc., 677 F.3d 1158, 1159 (Fed. Cir. 2012).

[160] *Id.* at 1161; *see* XOPENEXHFA (2012), http://www.xopenex.com/ (last visited Sept. 20, 2013).

[161] *Dey*, 677 F.3d at 1161.

[162] *Id.*

[163] *Id.*

[164] The '994 and '289 patents had expiry dates in August 2013 and March 2021, respectively. *Id.* Yet, for some reason, Sunovion agreed to allow Breath to launch its generic product in August 2012, after the expiration of the '755

In July 2005, Dey filed an ANDA with Paragraph IV certifications against all three of the *Orange Book*-listed patents for Xopenex.[165] Sunovion sued Dey for infringing the '755 and '994 patents but not the '289 patent, which would not expire until March 2021.[166] However, without a judgment of invalidity or non-infringement for the '289 patent, Breath's exclusivity period blocked the FDA from approving Dey's later-filed ANDA. In order to remove the roadblock caused by Breath's exclusivity period, Dey needed to obtain a judgment of invalidity or non-infringement against all three *Orange Book*-listed patents, which would cause Breath to forfeit the 180-day exclusivity period. Thus, in an attempt to trigger forfeiture and obtain FDA approval, Dey brought a declaratory judgment action against Sunovion.[167] Sunovion responded by granting Dey a unilateral covenant not to sue on the '289 patent and moved to dismiss the declaratory judgment action for lack of subject matter jurisdiction.[168] However, the district court held that a covenant not to sue did not eliminate the court's declaratory judgment jurisdiction.[169] In a likely attempt to avoid having its patent invalidated, Sunovion stipulated that Dey's generic product would not infringe the '289 patent, which the district court entered as a final judgment.[170] Sunovion then appealed, challenging the court's jurisdiction.[171]

Sunovion's first argument on appeal was that jurisdiction was improper because a declaratory judgment would not redress Dey's

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patent. *Id.* The reason for this strategy is not at all clear. It is possible that Sunovion did not want to risk litigating the '994 and '289 patents because it did not want to risk having a court find the patents invalid and/or non-infringed. This strategy would ensure that these later-expiring patents would be available to deter future generic challengers, or at least force them to launch at-risk. Presumably, Breath must have threatened to litigate the '994 and '289 patents, thus forcing Sunovion to use the earlier-expiring '755 patent as the basis for negotiating a generic-entry date.

[165] *Id.*
[166] *Id.*
[167] *Id.*
[168] *Id.*
[169] *Id.*
[170] *Id.*
[171] *Id.* at 1162.

injury.[172] Even if the action over the '289 patent was successful, Dey still needed to succeed in the separate infringement litigation over the '755 and '994 patents to enter the market.[173] Second, Sunovion argued that the case was essentially moot because the separate ligation over the '755 and '994 patents would not result in a final judgment prior to August 2012, at which time Breath could launch its generic product, triggering the 180-day exclusivity period before it could be forfeited.[174]

However, the Federal Circuit rejected both of Sunovion's arguments and affirmed the district court's jurisdiction to hear the declaratory judgment action.[175] In reaching its conclusion, the court relied on its prior decision in *Caraco*, where the patent holder also sued the later ANDA filer for infringing all but one of its *Orange Book*-listed patents, and the later ANDA filer brought a declaratory judgment action over the last-expiring *Orange Book* patent because only a judgment of invalidity or infringement with respect to all patents could trigger the first ANDA filer's exclusivity period.[176] Like the later ANDA filer in *Caraco*, Dey was being excluded from selling an allegedly non-infringing product, an injury that was traceable to the patent holder and redressable by a declaratory judgment that the last-expiring patent was not infringed.[177] The court also noted that this case was distinguishable from its prior decision in *Janssen v. Apotex*, where the court held that the second ANDA filer failed to satisfy the case-or-controversy requirement because the later-filer had stipulated to the validity of one of the *Orange-Book*-listed patents, and thus success in the declaratory judgment action would still be

[172] *Id.* at 1163.

[173] *Id.* Recall that in order to trigger the failure-to-market forfeiture provision, Dey would still need to succeed in showing that all three *Orange Book*-listed patents were invalid or not infringed. *See* discussion *supra* Part II.B.

[174] *Dey*, 677 F.3d at 1164. Furthermore, once Breath launched its drug, there would no longer be a case or controversy because it would have triggered its exclusivity period, enabling Dey and other generics to launch their generic drugs after 180 days. *Id.*

[175] *Id.*

[176] *Id.* at 1163.

[177] *Id.*

insufficient to trigger a forfeiture event.[178] Consequently, the court concluded in this case that simply eliminating Sunovion's '289 patent was sufficient for declaratory judgment jurisdiction because litigation was pending that could eliminate the other barriers.[179]

As for Sunovion's second argument, the court concluded that the possibility that Breath might launch its product before the litigation was resolved was not sufficient to defeat jurisdiction.[180] The court reasoned that a case or controversy persisted because there was still a possibility that Breath would not market its drug, which would prevent Dey, or other generics, from entering the market until the '289 patent expired in 2021.[181] Sunovion argued that the mere possibility that Breath might delay its generic launch was not sufficient to satisfy the case-or-controversy requirement.[182] However, Sunovion conceded during oral arguments that the case would not be rendered moot until Breath actually launched its product.[183] Consequently, the court held that the district court properly held jurisdiction over Dey's declaratory judgment action and affirmed the lower court's judgment of non-infringement.[184]

V. APPLYING THE FEDERAL CIRCUIT'S RULINGS TO DECLARATORY JUDGMENT ACTIONS

A. *Overview of the Federal Circuit's Holdings*

As seen in the Federal Circuit decisions discussed above, a later ANDA filer generally has standing to bring declaratory judgment actions against the patent holder so long as the only thing preventing the later-filer from entering the market is the first-filer's 180-day exclusivity period.[185] For example, in *Caraco*, *Teva*, and *Dey* the only bar to the later ANDA filer's entry into the marketplace was the existence of a 180-day exclusivity period, so

[178] *Id.* at 1162–63.
[179] *Id.* at 1164.
[180] *Id.* at 1164–65.
[181] *Id.*
[182] *Id.* at 1165.
[183] *Id.* at 1166.
[184] *Id.*
[185] *See supra* Part IV.A–D.

the court held that the later ANDA filer could bring a declaratory judgment action in an attempt to trigger that 180-day period.[186] However, once this 180-day exclusivity period has been triggered by the first ANDA filer, a later ANDA filer can no longer satisfy the case-or-controversy requirement because a declaratory judgment action will not quicken the later ANDA filer's entry into the market.[187] Furthermore, if there are any blocking patents or other barriers to market entry besides the first-filer's 180-day exclusivity period, then the later ANDA filer will likely not have standing.[188] For example, in *Janssen*, the court reasoned that the later ANDA filer was prevented from entering the marketplace because the later-filer had already stipulated that one of the *Orange Book*-listed patents was valid, which meant that triggering the first-filer's 180-day exclusivity period would still not allow the later-filer to enter the market before the expiration of the stipulated patent.[189] Thus, the ability of a later ANDA filer to bring declaratory judgment actions against an *Orange Book*-listed patent turns on whether or not the later ANDA filer would be barred from entering the marketplace independent of the first-filer's 180-day exclusivity period.

In the wake of the Federal Circuit's decisions in *Caraco*, *Janssen*, and *Teva*, district courts have largely followed the above analysis.[190] The district court decisions discussed below confirm that a later ANDA filer generally has jurisdiction to bring

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[186] *See* Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1293 (Fed. Cir. 2008); Teva Pharm. USA, Inc. v. Eisai Co., 620 F.3d 1341, 1348 (Fed. Cir. 2010), *vacated as moot*, 131 S. Ct. 2991 (2011).

[187] *See* Merck & Co. v. Apotex, Inc., 287 F. App'x 884, 888 (Fed. Cir. 2008).

[188] *See Caraco*, 527 F.3d at 1293; Janssen Pharm., N.V. v. Apotex, Inc., 540 F.3d 1353, 1361 (Fed. Cir. 2008).

[189] *Janssen*, 540 F.3d at 1361.

[190] With the exception of *Dey* and *Apotex*, discussed *infra* Part IV, most court cases have settled on technicalities rather than on the merits of the cases. *See, e.g.*, Medeva Pharma Suisse A.G. v. Par Pharm., Inc., 774 F. Supp. 2d 691, 696–97 (D.N.J. 2011) (stating that the court would follow the rules set forth in *Caraco* and *Janssen*, but dismissing the case because the first ANDA filer had given up their 180-day exclusivity); *Merck*, 287 F. App'x at 888 (dismissing the case as moot because the case was decided one week before the patents in question expired).

declaratory judgment actions against the patent holder so long as the later ANDA filer has not independently prevented itself from entering the market. In *Seattle Children's Hospital v. Akorn*,[191] the court held that the later ANDA filer could bring a declaratory judgment action in attempt to trigger the 180-day exclusivity period because the later-filer had not stipulated to the validity of any *Orange Book* patents.[192] In contrast, the later-filers in both *Apotex v. Eisai*[193] and *Laboratories, Inc. v. Pfizer, Inc.*[194] had expressly recognized the validity of an *Orange Book* patent by filing a Paragraph III certification or by filing a stipulation of validity or infringement.[195] Thus, neither applicant had standing to bring a declaratory judgment action.[196]

B. Seattle Children's Hospital v. Akorn

In *Seattle Children's Hospital v. Akorn*, the district court held that an actual controversy existed because a judgment would remove the potential for an *Orange Book*-listed patent to exclude the later-filer from the market.[197] Novartis Pharmaceuticals listed the '269 patent in the *Orange Book* as covering Tobi (tobramycin inhalation solution), an inhaled antibiotic for treating cystic fibrosis symptoms.[198] In 2009, Teva Pharmaceuticals filed the first ANDA with a Paragraph IV certification against the '269 patent to market a generic version of the drug, and therefore was entitled to a 180-day exclusivity period.[199]

Akorn subsequently filed an ANDA with a Paragraph IV certification for the '269 patent and notified Novartis in July 2010.[200] In response, Novartis sued Akorn for infringement but

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[191] No. 10-CV-5118, 2011 WL 6378838 (N.D. Ill. Dec. 20, 2011).
[192] *See id.* at *6.
[193] No. 1:09CV477, 2010 WL 3420470 (M.D.N.C. Aug. 27, 2010).
[194] No. 10-CV-06554, 2011 WL 4594824 (D.N.J. Sept. 30, 2011).
[195] *See Impax*, 2011 WL 4594824, at *7; *Apotex*, 2010 WL 3420470, at *11.
[196] *See Impax*, 2011 WL 4594824, at *7; *Apotex*, 2010 WL 3420470, at *11.
[197] *Seattle Children's Hosp.*, 2011 WL 6378838, at *6, *10.
[198] *Id*. at *2; *see also About TOBI*, NOVARTIS PHARM. CORP., http://www.tobitime.com/info/about-tobi/About-TOBI.jsp?usertrack.filter_applied=true&NovaId=4029462082237159967 (last visited Sept. 6, 2013).
[199] *Akorn*, 2011 WL 6378838, at *3 n.2.
[200] *Id.*

later granted Akorn a covenant not to sue on the '269 patent in June 2011.[201] Novartis then filed a motion to dismiss for lack of subject matter jurisdiction, arguing the covenant not to sue mooted the controversy between the parties.[202] Because litigation was still pending between Novartis and Teva, the 180-day exclusivity period had not yet been triggered or forfeited, which prevented the FDA from approving Akorn's ANDA.[203] Akorn responded by bringing a declaratory judgment action against Novartis seeking a finding of invalidity or non-infringement against the '269 patent, which, if successful, would cause Teva to forfeit its exclusivity period.[204]

Following *Caraco* and *Janssen*, the court concluded that there was an actual controversy notwithstanding the covenant not to sue because Akorn's alleged injury was fairly traceable to Novartis.[205] While a successful declaratory judgment action would not directly result in approval of Akorn's ANDA because the first-filer could hypothetically begin commercialization early, the court reasoned that this alone did not preclude jurisdiction.[206] If Novartis had not listed the '269 patent in the *Orange Book*, then FDA approval of Akorn's generic drug would not have been independently delayed because Akorn had not stipulated to the validity, infringement, or enforceability of any patents.[207] Furthermore, a favorable judgment would eliminate the *potential* for the '269 patent to exclude Akorn from the drug market.[208] Thus, the court held that there was a case or controversy and granted Akorn's motion to amend its answer to include the declaratory judgment claim for non-infringement.[209]

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[201] *Id.*
[202] *Id.* at *3.
[203] *Id.* at *3 n.2.
[204] *Id.* at *3.
[205] *Id.* at *6.
[206] *Id.*
[207] *Id.*
[208] *Id.*
[209] *Id.* at *10.

C. Apotex v. Eisai

In *Apotex v. Eisai*, the district court followed the reasoning in *Janssen* and held that a later ANDA filer did not have standing to bring a declaratory judgment action when it failed to make Paragraph IV certifications against all the pioneer's unexpired *Orange Book*-listed patents.[210] Eisai manufactures the brand-name drug Aricept (donepezil hydrochloride), which is used to treat symptoms of Alzheimer's disease.[211] The *Orange Book* lists five patents as covering Aricept: the '321, '760, '841, '864, and '911 patents.[212] Both Ranbaxy and Teva filed ANDAs for Aricept and shared the 180-day exclusivity period. Ranbaxy's ANDA, filed in August 2003, included a Paragraph III certification for the '841 patent, which would expire in November 2010, and Paragraph IV certifications for the remaining four patents.[213] Teva's ANDA, filed in October 2005, included Paragraph IV certifications for all five *Orange Book*-listed patents.[214] Because Teva was the first to file an ANDA with a Paragraph IV certification challenging the '841 patent, Teva was eligible to share Ranbaxy's 180-day exclusivity period.[215]

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[210] Apotex v. Eisai, No. 1:09CV477, 2010 WL 3420470, at *11 (M.D.N.C. Aug. 27, 2010).

[211] *Id.* at *3.

[212] *Id.*

[213] *Id.* Eisai chose not to sue Ranbaxy for infringing its patents. *Id.* Consequently, Ranbaxy would be able to enter market as soon as the '841 patent expired in November 2010, which would trigger the start of its exclusivity period. *Id.* However, in September 2008, the FDA sent Ranbaxy a warning letter, alleging regulatory noncompliance, which could affect its FDA approval. *Id.*

[214] *Id.* at *4. Teva's ANDA originally contained the same certifications as Ranbaxy's ANDA, but Teva later amended its ANDA in October 2006 to include Paragraph IV certifications against all five of Eisai's *Orange Book*-listed patents. *Id.* Eisai sued Teva for infringing the '841 patent, but not the remaining four patents. *Id.* At the time of the litigation between Eisai and Apotex, the suit between Eisai and Teva was still pending, but Eisai had been awarded a preliminary injunction that prevented Teva from marketing its generic until the '841 patent expired in November 2010. *Id.*

[215] *Id.* Note that before the Medicare Modernization Act of 2003, exclusivity was granted on a patent-by-patent basis, such that later ANDA filers could share exclusivity if they were the first to file an ANDA with a Paragraph IV

In July 2007, Apotex filed an ANDA with a Paragraph III certification against the '841 patent and Paragraph IV certifications against the remaining four patents.[216] Rather than suing Apotex, Eisai unilaterally granted Apotex a covenant not to sue with respect to the '760 and '911 patents and filed statutory disclaimers with respect to the '321 and '864 patents.[217] Apotex, however, was still blocked from entering the market by Ranbaxy and Teva's exclusivity periods.[218] Thus, in an attempt to cause Ranbaxy and Teva to forfeit the exclusivity period, Apotex filed a declaratory judgment action in July 2009 asserting that it did not infringe the '321, '760, '864, and '911 patents.[219]

Because Apotex expressly recognized the validity of the '841 patent by filing a Paragraph III certification, the court held that the Paragraph III certification was analogous to the stipulation of validity in *Janssen*.[220] As a result, even if Apotex were to prevail in their declaratory judgment action, it would still be prevented from entering the marketplace until after the '841 patent expired.[221] Therefore, the court held that Apotex failed to satisfy the Article III case-or-controversy requirement and lacked standing to bring the declaratory judgment action.[222]

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certification for a particular *Orange Book*-listed patent. However, the MMA amended the Hatch-Waxman Act so that exclusivity is now granted on a drug-by-drug (or NDA-by-NDA) basis, such that the first ANDA filer with a Paragraph IV certification against any *Orange Book*-listed patent now receives the 180-day exclusivity period. Shared exclusivity will only happen if multiple generics file ANDAs on the same day. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended in scattered sections of 21 and 42 U.S.C.).

[216] *Apotex*, 2010 WL 3420470, at *4.

[217] *Id.* The statutory disclaimers for the '321 and '864 patents were filed in 2006 and 2007, respectively, prior to the filing of Apotex's ANDA. *Id.*

[218] *Id.* at *7.

[219] *Id.* at *4.

[220] *Id.* at *10. The court stated that the filing of a Paragraph III certification in effect recognizes the validity and enforceability of the patent. *Id.* at *11 n.4.

[221] *Id.* at *11. This case essentially came to the same conclusion as *Janssen*, holding that for a later ANDA filer to have standing, the 180-day exclusivity period must be the only bar to entering the marketplace.

[222] *Id.*

D. Impax Laboratories v. Pfizer

In *Impax Laboratories, Inc. v. Pfizer, Inc.*,[223] the district court held, similarly to *Apotex v. Eisai*, that a later ANDA filer failed to satisfy the case-or-controversy requirement because the later ANDA filer had stipulated to be bound by a final court decision of patent invalidity or non-infringement.[224] Pfizer manufactures the drug Detrol LA (tolerodine tartrate extended-release capsules), which is used to treat symptoms related to an overactive bladder.[225] In the *Orange Book*, Pfizer listed four patents as covering Detrol LA: the '600, '162, '295, and '217 patent.[226] Teva filed the first ANDA application with Paragraph IV certifications against all four of Pfizer's patents and became eligible for a 180-day exclusivity period.[227] Pfizer sued Teva for infringing only the '600 patent, and this litigation was still pending when the *Impax* case arose.[228]

In December 2007, Impax filed an ANDA with Paragraph IV certifications against all four of Pfizer's *Orange Book* patents.[229] Pfizer sued Impax for infringing three of its patents, but not the fourth patent—the '217 patent.[230] The lawsuit was consolidated with the Pfizer's infringement suit against Teva, and all parties agreed and stipulated to be bound by a final judgment regarding the validity or non-infringement of the '600 patent.[231] However, the FDA could not approve Impax's ANDA unless Teva's exclusivity period ran or was forfeited. To cause Teva to forfeit its

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[223] No. 10-CV-06554, 2011 WL 4594824.

[224] Impax Laboratories, Inc. v. Pfizer, Inc., No. 10-CV-06554, 2011 WL 4594824, at *7 (D.N.J. Sept. 30, 2011) (granting motion to dismiss for lack of declaratory judgment jurisdiction); *see also* Kurt R. Karst, *New Jersey District Court Says ANDA Approval Delay and Patent Uncertainty Are Insufficient to Support DJ Jurisdiction in Generic DETROL LA Litigation*, FDA LAW BLOG (Nov. 10, 2011, 7:16 PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/11/new-jersey-district-court-says-anda-approval-delay-and-patent-uncertainty-are-insufficient-to-suppor.html.

[225] *Impax*, 2011 WL 4594824, at *2.

[226] *Id.*

[227] *Id.*

[228] *Id.* at *3.

[229] *Id.* at *2.

[230] *Id.* at *3.

[231] *Id.*

exclusivity period, Impax needed a court judgment that all four of Pfizer's patents were invalid or not infringed. Thus, Impax filed an action against Pfizer in December 2010, seeking a declaration that it did not infringe the '217 patent.[232] In response, Pfizer granted Impax a covenant not to sue with respect to the '217 patent and filed a motion to dismiss the case for lack of subject matter jurisdiction.[233]

The court granted Pfizer's motion to dismiss because here, like in *Janssen*, Impax had stipulated to be bound by any decision regarding the validity or non-infringement of the '600 patent.[234] Although Impax claimed that it was injured because it could not promptly launch its generic drug and was subject to patent uncertainty absent a declaratory judgment, the court held that these injuries were not directly traceable to the '217 patent or redressable by the declaratory judgment action because a final judgment finding that the '600 patent was valid had been entered.[235] Thus, the court held that Impax had not presented an Article III case or controversy.[236]

VI. STRATEGIES FOR PATENT HOLDERS AND LATER ANDA FILERS

The Federal Circuit and district court opinions discussed above show that later ANDA filers can bring declaratory judgment actions to trigger the first ANDA filer's 180-day exclusivity period and quicken market entry of their drugs. However, it is not always clear when declaratory judgment jurisdiction is available. The following discusses strategies that both patent holders and later ANDA filers should consider before bringing suit.

A. *ANDAs with Both Paragraph III and Paragraph IV Certifications*

An ANDA application must include a certification for each

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[232] *Id.*
[233] *Id.*
[234] *Id.* at *7.
[235] *Id.* at *5.
[236] *Id.* at *7.

Orange Book-listed patent covering that drug the applicant seeks to copy.[237] An applicant can either make a Paragraph III certification, stating that their generic drug will not enter the market until the patent expires, or a Paragraph IV certification, stating that the patent is invalid or will not be infringed by their generic drug.[238]

If an ANDA application from a later-filer includes any Paragraph III certifications, this will likely preclude them from bringing a declaratory judgment action against a patent holder to trigger a first ANDA filer's 180-day exclusivity period. The Federal Circuit's holdings make it clear that a later ANDA filer will likely not have standing to bring a declaratory judgment action if there are any blocking patents or other barriers to market entry. In the case where a later-filer is making a Paragraph III certification stating that they will not enter the market until a particular patent expires, that patent will likely be considered a blocking patent that defeats declaratory judgment jurisdiction.

For example, in *Apotex v. Eisai*, a later ANDA applicant filed Paragraph IV certifications for all but one patent listed in the *Orange Book* and a Paragraph III certification for the remaining patent.[239] The district court held that the later ANDA filer could not bring a declaratory judgment action against the patent holder because the Paragraph III certification was analogous to the stipulation of validity in *Janssen*.[240] Later ANDA filers who anticipate filing a declaratory judgment action in the future should file Paragraph IV certifications to all of the *Orange Book* patents that cover a given drug.

If, for some reason, the later-filer wishes to file an ANDA containing a Paragraph III certification, the applicant should ensure that any patent it makes such a certification against has an expiration date that precedes the earliest generic entry date of the

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[237] *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV) (2012); *see also supra* Part I.

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

[239] Apotex, Inc. v. Eisai, Inc., No. 1:09CV477, 2010 WL 3420470, at *9 (M.D.N.C. Aug. 27, 2010).

[240] *Id.* The court stated that the filing of a Paragraph III certification in effect recognizes the validity and enforceability of the patent. *Id.* at *11 n.4.

first-filer.[241] This means that, in general, later-filers should only make Paragraph III certifications against the earliest expiring *Orange Book*-listed patents covering a particular drug. Any Paragraph III patent having an expiration date after the first-filer's expected generic entry date will act as a blocking patent for declaratory judgment jurisdiction purposes.

For example, suppose the NDA-holder listed two patents in the *Orange Book*, and the first-filer has entered into a reverse-payment settlement with the NDA-holder where it agrees not to enter the market until both patents expire. This means later-filers will not be able to enter the market until at least six months after the patents expire and the first-filer has expended its 180-day exclusivity period. If the later ANDA filer makes a Paragraph III certification against the later-expiring patent and a Paragraph IV certification against the earlier-expiring patent, then the later ANDA filer will not be able to market its drug until the later date, even if it obtains a judgment that the earlier-expiring patent is invalid or not infringed. In this case, the later-expiring patent will act as a blocking patent and defeat declaratory judgment jurisdiction, as in *Janssen*.[242] However, if the later ANDA filer makes a Paragraph III certification against the earlier-expiring patent and a Paragraph IV certification against the later-expiring patent, then the applicant would theoretically be able to enter the market on the earlier date, assuming that it can cause the first-filer to forfeit its 180-day exclusivity period. Thus, filing a Paragraph III certification against the earlier-expiring patent prevents it from being used as a blocking patent that would defeat declaratory judgment jurisdiction.

Likewise, a patent holder will want to avoid litigating its later-expiring patents and instead assert its earlier-expiring patents. Even if the earliest expiring patent is held invalid or not infringed, any later-expiring patents will still be available to deter generic

[241] Or before the anticipated entry date of the 180-day-exclusivity-period holder if that is not the first-filer.

[242] Janssen Pharm., N.V. v. Apotex, Inc., 540 F.3d 1353 (Fed. Cir. 2008).

challengers, forcing the generic challengers to either bring a declaratory judgment action or launch at risk.[243]

B. *Asserting Fewer than All Patents in Response to a Paragraph IV ANDA*

When a later-filed ANDA application includes Paragraph IV certifications against all of the unexpired *Orange Book*-listed patents covering a drug, the patent holder has the option of suing the generic challenger for infringing all, some, or even none of the listed patents. While the Hatch-Waxman Act gives the patentee the right to sue the generic challenger in response to a Paragraph IV ANDA, patentees often choose not to sue later-filers in order to avoid litigating a particular patent. Because the failure-to-market forfeiture provision requires a finding of invalidity or non-infringement with respect to *all* patents with Paragraph IV certifications by the first ANDA filer, all the pioneer needs to do to prevent this forfeiture event from occurring is to keep at least one patent out of litigation.

Failing to sue a later ANDA filer for infringing an *Orange Book*-listed patent, however, is not sufficient to defeat declaratory judgment jurisdiction. The patent holder may be able to delay final resolution of all its patents by not asserting some of them, but it cannot stop the generic challenger from seeking a final resolution by doing so. At best, the patent holder can force the ANDA filer to litigate the unasserted patents in a separate declaratory judgment action. The Federal Circuit's decisions in *Dey* and *Caraco* make it clear that a generic challenger can bring a declaratory judgment action against these unasserted patents as long as there is a way for the generic challenger to obtain a finding of invalidity or non-infringement for all the remaining *Orange Book*-listed patents. For example, in *Dey*, the Federal Circuit held that even though the later ANDA applicant still needed to succeed in the separate

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

infringement litigation over two other *Orange Book*-listed patents to enter the market, the later ANDA filer could file declaratory action to eliminate an unasserted patent because litigation was pending that could eliminate the other patents.[244] Thus, absent other factors, declaratory judgment jurisdiction is not precluded merely because the patent holder has chosen not to assert all of its patents. But if the NDA holder can get at least one blocking patent—i.e., a patent that cannot be challenged for some reason—then later-filers will be precluded from bring declaratory judgment actions against any unasserted patents.

C. *Unilateral Covenants Not to Sue*

After the Supreme Court reaffirmed the "all circumstances test" in *MedImmune*, patent holders began granting unilateral covenants not to sue on unasserted patents listed in the *Orange Book* in an attempt to eliminate any possible case or controversy. However, the Federal Circuit's precedent makes it clear that a unilateral covenant not to sue will not defeat declaratory judgment jurisdiction. For example, in *Caraco*, the Federal Circuit held that a covenant not to sue did not eliminate the controversy between the parties because the patent holder's mere listing of patents in the *Orange Book* prevented the later ANDA filer from entering the marketplace, which created an injury-in-fact that was redressable by a declaratory judgment.[245] Thus, patent holders should be aware that a unilateral covenant not to sue alone is not sufficient to defeat a later-filer's ability to bring a declaratory judgment action.

However, if there is at least one blocking patent, a unilateral covenant not to sue from the patent holder should always be sufficient to terminate a declaratory judgment action by a later ANDA filer. Interestingly, outside of the Hatch-Waxman context a unilateral covenant not to sue will almost always be sufficient to moot a patent infringement case, including declaratory judgment actions, so long as the covenant covers past, present, and future

[244] Dey Pharma, LP v. Sunovion Pharm. Inc., 677 F.3d 1158, 1163–64 (Fed. Cir. 2012).

[245] Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1292 (Fed. Cir. 2008).

actions.[246] Such a covenant will generally eliminate any actual injury, and thus eliminate any case or controversy necessary to establish Article III standing.[247] Furthermore, in a recent trademark case, the Supreme Court held that a covenant not to sue granted by the trademark holder was sufficient to moot a counterclaim challenging the validity of its trademark.[248] As discussed above, the reason that a covenant not to sue alone is not sufficient to defeat declaratory judgment jurisdiction for generic challengers is because, under Hatch-Waxman's complex statutory scheme, the mere existence of the patent may cause harm to the generic because its listing in the *Orange Book* can prevent the challenger from entering the market. But if the later generic challenger cannot enter the market even if it prevails in the declaratory judgment action, then a covenant not to sue should defeat the action for the same reasons as it would outside of the Hatch-Waxman context.

VII. FIXING THE ROADBLOCK TO GENERIC DRUGS

The inability of generic drug manufacturers to bring declaratory judgment actions has led to situations where the first ANDA filer's 180-day exclusivity period keeps generic drugs off the market indefinitely. To solve these problems, this Article proposes the following solutions.

A. *Expanding Declaratory Judgment Jurisdiction*

Patent holders have used a variety of controversial means to effectively extend their patent-granted monopoly.[249] By entering into reverse-payment settlements with the first ANDA filer, patent holders have been able to block other generic companies from entering the market using the first ANDA filer's exclusivity

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[246] *See, e.g.*, Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054 (Fed. Cir. 1995).

[247] *See id.*

[248] *See* Already LLC v. Nike, Inc., 133 S. Ct. 721, 724 (2013) (finding that Already's counterclaim challenging the validity of Nike's trademark was mooted after Nike withdrew its claim of trademark infringement with prejudice and granted a covenant not to sue to Already).

[249] *See* Avery, *supra* note 15, at 192–93.

period.[250] One of the only ways for a later-filer to overcome such a roadblock is by bringing a declaratory judgment action against the patent holder, but whether courts have jurisdiction to hear declaratory judgment actions brought by later ANDA filers is still not clear. The current regulatory regime should be modified to resolve problems with declaratory judgment jurisdiction by expressly granting jurisdiction to later ANDA filers.

The Federal Circuit has already indicated that later ANDA applicants may bring declaratory judgment actions against patent holders to trigger a first ANDA filer's exclusivity period. Furthermore, Congress has stated:

> In . . . these . . . circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the *Orange Book* with respect to the drug immediately upon the expiration of the 45-day period. We believe there can be a case or controversy sufficient for courts to hear these cases merely because the patents at issue have been listed in the FDA *Orange Book*, and because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes. The declaratory judgment provisions in this bill are intended to encourage such early resolution of patent disputes.[251]

Yet, later ANDA filers have been precluded from bringing declaratory judgments in certain contexts. Congress could clear the path for later ANDA filers to bring declaratory judgment actions by changing the Hatch-Waxman Act to expressly grant declaratory judgment jurisdiction to later ANDA filers. By encouraging early resolution of these patent disputes, generic manufacturers will be able to bring their drugs to the market sooner.

B. *Reforming the 180-day Exclusivity Period*

Under the Hatch-Waxman Act, only the first ANDA applicant to file a Paragraph IV certification for a particular drug is eligible for the 180-day exclusivity period.[252] The purpose of the exclusivity period is to encourage generic manufacturers to

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[250] *See id.*

[251] 149 CONG. REC. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of U.S. Senate Committee on Health, Education, Labor, and Pensions).

[252] *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2012).

challenge a brand-name drug company's patents, but many first-filers enter into reverse payment settlements, retaining the 180-day exclusivity period and blocking their competitors from entering the market.[253]

This problem of penalizing later-filers could be fixed by creating "rolling exclusivity."[254] The Hatch-Waxman Act should be revised so that if the first Paragraph IV challenger settles and does not enter the market, the 180-day exclusivity would instead be granted to the next challenger.[255] Granting the exclusivity period to the first *successful* generic challenger would eliminate the roadblock to generic entry and deter reverse payment settlements because it would be less feasible for the patent holder to enter such settlements with multiple generic challengers.[256] Awarding the exclusivity period only to the first generic manufacturer to succeed at trial aligns with the purpose of the exclusivity period, which is to encourage generic drug manufacturers to challenge weak patents. It also increases the chances that generic companies will introduce low-cost drugs to the market earlier. Additionally, implementing a rolling exclusivity award has the potential to protect pharmaceutical patent holders from frivolous lawsuits by generic manufacturers who are merely hoping for a quick settlement, and encourages generic manufacturers to bring suit only when they have relatively strong claims.

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[253] *See id.*

[254] Avery, *supra* note 15, at 194.

[255] *See* Ashlee B. Mehl, Note, *The Hatch-Waxman Act and Market Exclusivity for Generic Drug Manufacturers: An Entitlement or an Incentive?*, 81 CHI.-KENT. L. REV. 649, 674 (2006); *cf.* C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 986 (2011) (proposing the first-entry exclusivity where Congress grants exclusivity not to the first ANDA filer, but to the first generic to successfully enter the market). Note that if the first-filer proceeds to trial and loses, it must amend its Paragraph IV certification to a Paragraph III certification, which may trigger a forfeiture event. *See* 21 U.S.C. § 355(j)(5)(D)(i)(III) (stating that the first ANDA filer forfeits its exclusivity period if it "amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period").

[256] *See* Avery, *supra* note 15, at 194.

C. *Expediting Orange Book Patent Delistings*

A generic manufacturer that is sued for patent infringement in response to a Paragraph IV ANDA filing may bring a counterclaim to delist the patent from the *Orange Book*.[257] If the pioneer's patent is found either to not cover the listed drug or to cover only an invalid method of using the listed drug, the pioneer can be forced to withdraw the patent listing from the *Orange Book*, allowing the generic challenger to amend its application to a Paragraph I certification and thereby avoid litigation. Additionally, delisting a patent from the *Orange Book* is a forfeiture event, which would force a first-filing applicant with an approved ANDA to enter the market within seventy-five days in order to avoid forfeiting its exclusivity period.[258]

Currently, ANDA filers have the right to assert a delisting counterclaim if the patentee has already sued the ANDA filer for infringement.[259] This right should be expanded so that generic challengers can bring declaratory judgment actions to force NDA holders to delist improperly listed patents from the *Orange Book*. In cases where the patentee has chosen not to assert its patents or disclaimed them, there would arguably be no harm to the patentee and the public would greatly benefit because it would allow low-cost generic drugs to reach the market sooner.[260] In cases where there are other patents and there is an actual dispute between the

[257] *See* 21 U.S.C. § 355(j)(5)(C)(ii) ("If an owner of the patent . . . brings a patent infringement action against the [ANDA] applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder . . . on the ground that the patent does not claim either - (aa) the drug for which the application was approved; or (bb) an approved method of using the drug."). Note that this is not an independent cause of action and can only be raised as a counterclaim.

[258] *See id.* § 355(j)(5)(D)(i)(I)(bb)(CC) (stating that the exclusivity period is forfeited 75 days after "[t]he patent information submitted under subsection (b) or (c) is withdrawn by the [ANDA] holder").

[259] *See id.*

[260] A patentee may file a statutory disclaimer with the USPTO to relinquish some or all of the rights associated with a particular patent. *See* 37 C.F.R. § 1.321 (2013) ("A patentee owning the whole or any sectional interest in a patent may disclaim any complete claim or claims in a patent.").

parties, it would help facilitate the early resolution of patent disputes between generic and brand-name drug manufacturers.

Alternatively, patent holders should be required to remove unasserted or disclaimed patents from the *Orange Book*. Because the FDA serves only a ministerial role when listing patents in the *Orange Book*, the FDA will only delist patents if the patent holder requests that it do so.[261] As a result, unasserted or disclaimed patents can block generic drugs from reaching the market even though those patents cannot be enforced. For example, in *Teva v. Eisai* the Federal Circuit noted that because Eisai's disclaimed patents still were listed in the *Orange Book*, FDA approval of Teva's ANDA was delayed until the first-filer's exclusivity period expired.[262] Requiring removal of unasserted or disclaimed patents from the *Orange Book* would avoid such situations. Patent holders are arguably not harmed because they have either chosen not to exercise their rights or have already forfeited them, and generic manufacturers would be able to enter the market more quickly.

VIII. CONCLUSION

Later-filing ANDA applicants are almost always blocked from entering the market by the exclusivity period of the first-filers who often delay their own market entry because of reverse payment settlements with the brand-name drug manufacturers. One of the only ways for a later-filer to enter the market is by bringing a declaratory judgment action against the brand-name company. Determining when these later-filers have jurisdiction to bring such actions, however, is complicated. The Federal Circuit's decisions indicate that a later-filer will generally have standing to bring a declaratory judgment action against the brand-name company so long as the later-filer is not otherwise prevented from entering the marketplace. If the later-filer has made Paragraph IV certifications against all unexpired *Orange Book*-listed patents covering a drug, then the later-filer should be able to bring a declaratory judgment

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[261] *See* aaiPharma Inc. v. Thompson, 296 F.3d 227, 241 (4th Cir. 2002); 21 C.F.R. § 314.53(f) (2011).

[262] Teva Pharm. USA, Inc. v. Eisai Co., 620 F.3d 1341, 1348 n.3 (Fed. Cir. 2010), *vacated as moot*, 131 S. Ct. 2991 (2011).

action. However, if there are any blocking patents, such as those covered by stipulations of validity or Paragraph III certifications, then declaratory judgment jurisdiction can likely be defeated.

In order to prevent the first-filer's exclusivity period from being used as a roadblock to generic drugs, Congress should expressly grant declaratory judgment jurisdiction to later challengers or, alternatively, reform the Hatch-Waxman Act so that the exclusivity period rolls over to the first successful generic challenger. Furthermore, Congress should allow generic challengers to bring declaratory judgment actions to delist improperly listed patents from the *Orange Book*, which would cause forfeiture of the exclusivity period and allow later generic challengers to enter the market. All of these solutions would further Hatch-Waxman's goal of facilitating the market entry of generic drugs, while still preserving the rights of pharmaceutical patent holders.