NO. _____

In the
Supreme Court of the United States

MYLAN PHARMACEUTICALS INC.,

Petitioner,

v.

APOTEX INC.,

Respondent.

On Petition for Writ of Certiorari to the U.S. Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Years ago, a branded pharmaceutical company disclaimed one of two patents that underlay its brand name blood-pressure medicine in response to petitioner's Abbreviated New Drug Application ("ANDA"). Under the well-established law of this Court, that disclaimer rendered the patent a complete nullity that could not be infringed. Nonetheless, years later the respondent filed a declaratory judgment action seeking a judicial declaration of what no one did or could dispute—namely, that a generic version of the blood-pressure medicine did not infringe the disclaimed patent. Respondent's incentive for filing this action in the absence of any dispute over the question to be litigated is clear: Respondent believes that a judicial declaration of non-infringement will benefit it at petitioner's expense by effectively eliminating the period of generic exclusivity petitioner secured by filing its ANDA first. While the District Court recognized that a statutory incentive to sue was no substitute for an actual controversy, the Federal Circuit reversed in a decision that will open the doors of district courts nationwide to non-disputes over disclaimed patents.

The questions presented are:

1.) Whether Article III's case or controversy requirement can be satisfied when the suit seeks a judgment of non-infringement of a disclaimed patent.

2.) Whether Congress can create Article III jurisdiction by imposing statutory consequences that turn on obtaining a judgment of non-infringement of a disclaimed patent.

PARTIES TO THE PROCEEDING

Petitioner Mylan Pharmaceuticals Inc. was a proposed intervenor-defendant in the District Court and a movant-cross-appellant in the Court of Appeals.

Respondent Apotex Inc. was the plaintiff in the District Court and the plaintiff-appellant in the Court of Appeals.

Daiichi Sankyo, Inc., and Daiichi Sankyo Co., Ltd., were defendants in the District Court and defendants-appellees in the Court of Appeals and plan to file their own petition for certiorari arising out of the same decision.

RULE 29.6 STATEMENT

Mylan Pharmaceuticals Inc. is wholly owned by Mylan Inc., which is indirectly wholly owned by Mylan N.V., a publicly held company. Abbott Laboratories, a publicly held company, owns more than 10% of Mylan N.V.'s stock through wholly-owned subsidiaries.

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PETITION FOR WRIT OF CERTIORARI

The Federal Circuit held that federal courts have jurisdiction over actions seeking declaratory judgments of non-infringement with respect to patents that have been fully disclaimed, *i.e.*, where the patent no longer exists and there is no prospect of a judgment of infringement. That misguided expansion of Article III jurisdiction in patent cases by the Nation's patent court requires this Court's immediate review. The cardinal requirement of Article III is that the parties have an actual case or controversy—an actual, live legal dispute. A plaintiff seeking a declaration that it is not infringing the defendant's patent *when the defendant has already disclaimed the patent* does not satisfy this bedrock requirement of Article III. This Court recognized more than 80 years ago that once a patent has been disclaimed it is as if the patent never existed. Thus, once a patent is fully and irrevocably disclaimed, there can be no justiciable Article III case or controversy regarding the validity or infringement of that patent. That the Federal Circuit has nonetheless opened the doors of every district court in the Nation to suits without controversy and infringement actions without live patents is reason enough for this Court's review.

But this case also presents important issues concerning the Hatch-Waxman regime for generic pharmaceuticals and Congress' ability to create Article III jurisdiction where it does not otherwise exist. If this suit is allowed to go forward, there will be no litigation on the merits because there is no dispute on the merits: the defendant has disclaimed the only patent at issue. Plaintiff has filed suit

nonetheless in hopes of securing a judgment declaring what no one disputes, that Apotex does not, and cannot infringe, a disclaimed patent. Apotex wants that declaration concerning the patent, not because there is any dispute about the patent, but because securing the declaratory judgment potentially has certain benefits for Apotex, vis-à-vis Mylan under the Hatch-Waxman Act. In particular, a declaration of non-infringement in a suit by Apotex may have the effect of depriving Mylan of the 180 days of generic exclusivity it earned by filing the first substantially complete application with a so-called Paragraph IV certification for a generic drug. But filing this lawsuit concerning a patent about which there is no dispute simply to attempt to obtain collateral statutory benefits against a third party does not satisfy Article III. Indeed, it is a plain misuse of the Article III courts.

The Federal Circuit found Apotex's potential statutory benefits under the Hatch-Waxman Act sufficient to create Article III jurisdiction over a patent dispute in the absence of any live dispute over the patent. But Congress cannot create Article III jurisdiction by creating an incentive for someone to obtain a judgment on an issue where there is no dispute. Congress can create the incentive, but it cannot create a dispute where none exists. The Federal Circuit's contrary decision merits this Court's plenary review. But at a minimum, this Court should hold the petition pending its disposition of *Spokeo v. Robins*, No. 13-1339, which will clarify the extent to which Congress may confer Article III jurisdiction by providing a statutory benefit.

OPINIONS BELOW

The opinion of the U.S. Court of Appeals for the Federal Circuit is reported at 781 F.3d 1356 and reproduced at App. 1-31. The opinion of the Court of Appeals denying panel and en banc rehearing is reproduced at App. 32-33. The opinion of the United States District Court for the Northern District of Illinois is unreported but available at 2014 WL 114127 and reproduced at App. 34-45.

JURISDICTION

The Court of Appeals denied panel and en banc rehearing on June 8, 2015. The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Constitution art. III, §2, cl. 1 provides in pertinent part that:

> The judicial Power shall extend to all Cases, in Law and Equity, arising under th[e] … Laws of the United States ….

The Declaratory Judgment Act, 28 U.S.C. §2201, provides in pertinent part that:

> In 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.

The relevant portions of the Food, Drug, and Cosmetic Act, as modified by the Drug Price

Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, and the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, are reproduced at App. 58-61.

STATEMENT OF THE CASE

A. The Hatch-Waxman Framework

Drug approvals are governed by the federal Food, Drug, and Cosmetic Act, as modified by the Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. These laws are commonly referred to as the "Hatch-Waxman Act." Under Hatch-Waxman, a party seeking to market a brand name drug must submit a New Drug Application ("NDA") containing clinical data proving the drug's safety and efficacy. 21 U.S.C. §355(b)(1). Once approved, the NDA holder must list with the FDA each patent that covers the approved drug and "with respect to which a claim of patent infringement could reasonably be asserted if [someone else] engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §§355(b)(1)(G), (c)(2). The FDA lists these patents in a publication called the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 U.S.C. §355(j)(2)(A)(i).

Generic drugs contain the same active ingredient(s) and provide the same therapeutic benefits as brand name drugs. But before Hatch-Waxman, generic companies had to submit a full NDA—including new clinical trial data—to obtain

approval. Hatch-Waxman removed that very real barrier to entry and competition. Because two drugs with the same chemical and biological properties will be equally safe and effective, the Hatch-Waxman Act allows for generic approval where an applicant demonstrates that its proposed generic drug has the same active ingredient and is biologically equivalent to a previously approved drug. New clinical trial data are no longer required for generic approval, 21 U.S.C. §355(j), and thus the shorter application required for generics is called the Abbreviated New Drug Application ("ANDA"). Although new clinical data are not required, ANDA filers must address each of the NDA filer's patents included in the Orange Book in connection with their ANDA submission. An ANDA filer must certify that, with respect to the name-brand drug at issue: (I) no patent information has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a particular date and approval of the ANDA should be deferred until expiration; or (IV) in the opinion of the ANDA applicant, the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. 21 U.S.C. §355(j)(2)(A)(vii).

This last certification—the so-called "Paragraph IV" certification—is critical because it provides a vehicle for weeding out weak patents and expediting generic entry into the market, which benefits consumers. But filing a Paragraph IV certification is neither costless nor without risk. ANDA filers must make substantial investments to develop non-infringing but otherwise biologically equivalent versions of a brand name drug or to challenge the patents listed in the Orange Book. Moreover, merely

filing a Paragraph IV certification is deemed to be an artificial act of patent infringement which could result in costly litigation. 35 U.S.C. §271(e)(2); *see Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Indeed, where the brand company/patentee sues within 45 days of receiving notice of the certification, the FDA may not approve the ANDA until the earlier of resolution of the litigation or 30 months after notice is received. 21 U.S.C. §355(j)(5)(B)(iii).

While the first-to-file generic company assumes unique financial and litigation risks, if successful, its efforts can open the market to other generic companies. Thus, to encourage generic companies to shoulder these substantial risks, the Hatch-Waxman Act rewards the first Paragraph IV challenger with a 180-day period free from additional generic competition. 21 U.S.C. §355(j)(5)(B)(iv). This exclusivity period is expressly designed to compensate generic manufacturers for the research and development costs and litigation risks they have assumed in connection with the Paragraph IV certification. This exclusivity period begins to run when the first Paragraph IV applicant first sells its drug. 21 U.S.C. §355(j)(5)(B)(iv)(I).

The first filer's marketing exclusivity is, however, not absolute; it can be forfeited if the ANDA applicant fails to start selling its drug by certain deadlines. The first ANDA applicant can lose its exclusivity if it:

> 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 approval of the [ANDA] of

> the first applicant is made effective …; or
>
> (BB) 30 months after the date of submission of the [ANDA] 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, as to each of the patents with respect to which the first applicant submitted [a Paragraph IV certification], at least 1 of the following has occurred:
>
> (AA) … a court enters a final decision … that the patent is invalid or not infringed.
>
> (BB) … 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 information submitted under subsection (b) or (c) of this section is withdrawn by the [NDA] holder.

21 U.S.C. §355(j)(5)(D)(i)(I).

Under this "failure-to-market" trigger, the first applicant loses its exclusivity if it fails to market its product by "the later of" two dates. The first date is either 75 days after FDA approves the first applicant's ANDA or 30 months after ANDA submission,

whichever comes first. 21 U.S.C. §355(j)(5)(D)(i)(I)(aa). The second date is 75 days after the first applicant or another generic applicant whose ANDA has received "tentative approval"[1] obtains a final court decision of invalidity or non-infringement, a settlement order including such a finding, or the withdrawal of a listed patent from the Orange Book. 21 U.S.C. §355(j)(5)(D)(i)(I)(bb). Thus, exclusivity cannot be forfeited until both an event described in the (aa) subsection and an event described in the (bb) subsection occur. But once an event from both categories occurs, exclusivity may be forfeited 75 days after "the later" of the dates if the first applicant has not begun selling its product.

B. Factual Background

Daiichi Sankyo, Inc. ("Daiichi") holds the approved NDA for the blood-pressure medication Benicar® (olmesartan medoxomil). Daiichi listed two patents in the Orange Book in connection with its Benicar® NDA: U.S. Patent No. 5,616,599 ("the '599 patent"), scheduled to expire April 25, 2016, and U.S. Patent No. 6,878,703 ("the '703 patent"), scheduled to expire November 19, 2021. After studying the use of olmesartan in juvenile patients, Daiichi also earned a period of "pediatric exclusivity" that would bar FDA approval of generic applications referencing Benicar® for six months beyond the scheduled expiration date of

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[1] "Tentative approval" reflects the FDA's judgment that all scientific and procedural conditions for approval have been met, but that the application cannot be fully approved because approval is blocked by a 30-month stay, some form of marketing exclusivity, or some other barrier to approval arising from patent infringement litigation.

each patent. *See* 21 U.S.C. §355a. Absent a Paragraph IV challenge, Daiichi would thus have had a monopoly on olmesartan medoxomil until six months after the '703 patent expired, or May 19, 2022.

On April 25, 2006, Mylan filed the first substantially complete ANDA referencing Benicar®. Mylan's ANDA also contained the first Paragraph IV certifications as to both the '599 and '703 patents, meaning that Mylan intended to begin marketing its generic products more than a decade before the listed patents were scheduled to expire. As the first Paragraph IV applicant, Mylan earned the statutory 180-day exclusivity benefit. And as required by law, Mylan promptly notified Daiichi of its Paragraph IV certifications. *See Daiichi Sankyo Co. v. Mylan Pharms. Inc.*, 670 F. Supp. 2d 359, 367 (D.N.J. 2009).

Daiichi's response to Mylan's Paragraph IV certifications varied by patent. On July 11, 2006, Daiichi disclaimed the '703 patent pursuant to 35 U.S.C. §253, and informed the FDA that the '703 patent "no longer exists" and that, because the patent had been disclaimed, Daiichi could no longer bring suit based on alleged infringement of the '703 patent. App. 4. Mylan's Paragraph IV certification to the '703 patent thus accomplished precisely what Hatch-Waxman rewards: it identified weaknesses in a competition-blocking patent; caused Daiichi to abandon that patent; and thereby opened the market to competition years before the '703 patent otherwise would have allowed.

In contrast, Daiichi responded to Mylan's challenge to the '599 patent with litigation. Daiichi sued Mylan for patent infringement based on its

ANDA filing and protracted litigation followed. The District Court ultimately sided with Daiichi, and the Federal Circuit affirmed. *Daiichi Sankyo Co. v. Matrix Labs.*, 619 F.3d 1346 (Fed. Cir. 2010). As a result, Mylan's Paragraph IV certification to the '599 patent was converted to a Paragraph III certification (a certification that the patent will expire on a particular date and approval of the ANDA should be deferred until expiration), which effectively bars final FDA approval of Mylan's ANDA until the pediatric exclusivity period associated with the '599 patent expires in October 2016. Despite Mylan's failure to invalidate the '599 patent, its Paragraph IV certification nonetheless will permit generic competition to begin more than five years before it would have if the '703 patent had gone unchallenged—generic competition will commence in October 2016, when the '599 patent's period of pediatric exclusivity expires, rather than in 2022, when the '703 patent's exclusivity would have expired absent Mylan's Paragraph IV challenge.

C. Proceedings Below

Years after Daiichi's disclaimer of the '703 patent and years after litigation regarding the '599 patent had concluded, Apotex, Inc. filed its own ANDA referencing Benicar®. Apotex accepted the outcome of the '599 litigation, but nonetheless filed a Paragraph IV certification of invalidity and non-infringement regarding the disclaimed '703 patent. Apotex sent the required Paragraph IV notice letter to Daiichi and, in doing so, Apotex affirmatively acknowledged that Daiichi had disclaimed the '703 patent. CA Doc. 46 at 10. Daiichi responded by informing Apotex that it

"cannot, and does not intend to," sue Apotex for infringement of the disclaimed '703 patent. *Id.*

Apotex nonetheless filed suit seeking "a declaration of non-infringement of" the '703 patent. App. 46; *see* App. 57 (asking the District Court to "[d]eclar[e] that the claims of the '703 patent have not been infringed by the filing of Apotex's ANDA"). Apotex's complaint, like its Paragraph IV notice letter, acknowledged that "the term of every claim of the '703 patent was disclaimed," and unequivocally asserted that, as a result, "the manufacture, marketing, use, offer for sale, sale and/or importation of" generic Benicar® "will not directly infringe, induce or contribute to the infringement by others of the claims of the '703 patent." App. 55, 57. The complaint went on to assert, however, that Apotex was still entitled to a judgment of non-infringement regarding the '703 patent due to the alleged statutory consequences of such a judgment. Apotex explained that because Mylan, as the first ANDA filer, is entitled to a 180-day exclusivity period, "the FDA will be prohibited from granting final approval" of Apotex's ANDA "unless … a court enters a final decision … that the '703 patent is invalid or not infringed." App. 54 (citing 21 U.S.C. §355(j)(5)(D)(i)(I)(bb)(AA)). "As such," Apotex explained, "unless the Court first declares the '703 patent invalid, unenforceable or not infringed by Apotex's ANDA Product, Apotex will be prohibited from selling its product until 180 days after Mylan chooses to market its [product]." *Id.*

Daiichi moved to dismiss the complaint on the straightforward basis that there can be no justiciable Article III case or controversy concerning

infringement of the '703 patent because the '703 patent was disclaimed. App. 39. Mylan moved to intervene based on Apotex's effort to deprive Mylan of its statutory exclusivity period, and likewise argued that the complaint should be dismissed due to the absence of a case or controversy over the '703 patent. In opposition, Apotex asserted that it had a freestanding "statutory right to challenge the '703 patent" even though the '703 patent itself was not disputed and could not serve as the foundation of an Article III case or controversy. Dct. Doc. 42 at 2; *see id.* at 1-2 (claiming a "statutory right … to bring a declaratory judgment action and challenge Orange Book listed patents that present a barrier to timely approval of Apotex's ANDA"); Dct. Doc. 43 at 6 (Apotex has a "statutory right as a subsequent ANDA filer to create a forfeiture event"); *see also* CA Doc. 43 at 28 ("Apotex had a statutory right to file a declaratory judgment action seeking certainty that its ANDA product does not infringe the '703 patent."); *id.* at 30-31 ("Apotex should be permitted to exercise its statutory rights by challenging the Orange Book listed patent and triggering the forfeiture provisions of" Hatch-Waxman); *id.* at 32 ("Apotex is exercising its statutory rights under" Hatch-Waxman).

The District Court agreed with Daiichi and Mylan that there could be no case or controversy over the disclaimed '703 patent and dismissed Apotex's suit. "Because Daiichi disclaimed all claims associated with the '703 Patent pursuant to 35 U.S.C. §253, both Daiichi and Apotex no longer hold any meaningful interest in the now disclaimed patent." App. 42-43. "[A]ll parties acknowledge that Daiichi can never assert the '703 patent against any ANDA filer or any

entity as the patent no longer exists by virtue of Daiichi's disclaimer of all claims associated with the patent." App. 44. The District Court denied Mylan's intervention motion and motion to dismiss as moot.

The Federal Circuit reversed. The Court of Appeals began by recognizing the nature of the suit—*viz.*, that Apotex sued Daiichi "to obtain a declaratory judgment that Apotex will not infringe a patent owned but disclaimed by Daiichi if Apotex manufacturers or sells a generic drug bioequivalent to Daiichi's Benicar®." App. 1. The court expressly acknowledged that "Apotex cannot infringe the patent, because Daiichi has disclaimed it." *Id.*; *see* App. 4 ("non-infringement of the '703 patent follows as a matter of law from the fact that Daiichi has formally disclaimed it"). The court nonetheless held that even though the '703 patent was a nullity there was a justiciable Article III case or controversy concerning the patent because "[u]nder the statute that governs marketing approval of generics, Apotex has a concrete, potentially high-value stake in obtaining the judgment it seeks." App. 2. If Apotex "obtain[s] a judgment of non-infringement for its generic drug," that "judgment would enable Apotex to receive marketing approval from the" FDA "and to enter the market sooner than otherwise." *Id.*; *see* App. 20 ("a case or controversy exists here" because "Apotex can trigger forfeiture [of Mylan's 180 days of exclusivity] by obtaining the non-infringement judgment it seeks"). The Federal Circuit also reversed the District Court's denial of Mylan's motion to intervene. App. 2.

REASONS FOR GRANTING THE PETITION

The federal courts have jurisdiction over actual legal disputes, and the Federal Circuit has exclusive jurisdiction over appeals in patent disputes. But the decision below recognizes Article III jurisdiction when there is no dispute and effectively no patent. To be clear, although Apotex's lawsuit seeks a declaration that its ANDA does not infringe Daiichi's '703 patent, there is absolutely no dispute on that question. Daiichi long ago disclaimed the '703 patent, such that it does not exist and cannot be infringed by Apotex's Paragraph IV filing or anything else. Indeed, the only dispute here is on the jurisdictional questions. If this case proceeds to the merits, there will be no dispute on the merits. The absence of the kind of actual case or controversy that Article III requires could not be plainer.

The Federal Circuit's contrary conclusion is no isolated jurisdictional error. The decision here opens up every district court in the Nation to cases involving disclaimed patents, despite this Court's holding that a disclaimed patent is a nullity and despite the bedrock requirements of Article III. The fact that Apotex has a statutory incentive to obtain a judgment of non-infringement is no substitute for an actual dispute over whether the '703 patent can be or is infringed. The latter is what Article III requires and what is plainly missing here. This Court should grant plenary review to correct this glaring and consequential error concerning core Article III requirements.

But at a minimum, this Court should hold this petition pending its decision in *Spokeo v. Robins*, No. 13-1339. Congress may be able to incentivize the

litigation of actual controversies, but such a statutory incentive cannot create a case or controversy where none exists. If Congress granted Apotex a million-dollar bounty to secure a declaratory judgment concerning the infringement or validity of a disclaimed patent, the bounty would be no substitute for an actual controversy over the patent. The situation is no different here. To the extent that *Spokeo* will shed light on this question, a hold is appropriate. But the error below is both important and egregious enough to merit plenary review.

I. The Federal Circuit's Decision Opening Up Article III Courts Nationwide To Non-Disputes Over Disclaimed Patents Merits This Court's Review.

A. Holding That a Case or Controversy Exists Over a Disclaimed Patent Is Directly at Odds With This Court's Precedent.

The Federal Circuit abandoned bedrock Article III principles in finding jurisdiction in an action seeking a judgment of non-infringement of a patent where a judgment of infringement is impossible. "No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 37 (1976). "In our system of government, courts have 'no business' deciding legal disputes or expounding on law in the absence of such a case or controversy." *Already, LLC v. Nike, Inc.*, 133 S. Ct. 721, 726 (2013) (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 341 (2006)). To fall within the

limited subject matter jurisdiction of the federal courts, Article III "require[s] that the dispute be definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and admit of specific relief through a decree of a conclusive character." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (citing *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)) (quotation marks omitted).

These fundamental requirements are not altered by the fact that the suit is a declaratory judgment suit or that it concerns patent infringement. When a declaratory judgment is sought in a patent case, Article III jurisdiction turns on "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* at 127 (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)) (quotation marks omitted). And, of course, the controversy between the parties has to concern the merits of the dispute, which here concerns the infringement of the disclaimed '703 patent. The parties here dispute the jurisdictional question, but there is no controversy at all—let alone, a substantial or immediate controversy—as to the subject of Apotex's lawsuit (whether it is infringing a non-existent patent).

The Article III defect here can be expressed not just as a lack of an actual case or controversy, but as a lack of standing on Apotex's part. As with all other cases, there is no Article III controversy in a non-infringement declaratory judgment action if the

plaintiff lacks standing to seek redress against the defendant. To demonstrate standing, a party must establish that "(1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 180-81 (2000) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992)). "This triad of injury in fact, causation, and redressability constitutes the core of Article III's case-or-controversy requirement." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103-04 (1998). And ensuring that all three elements are present in every case ensures that the exercise of federal court jurisdiction is not "gratuitous." *Simon*, 426 U.S. at 38.

It is hard to imagine a more "gratuitous" exercise of federal court jurisdiction than the entertaining of an action seeking a declaration of non-infringement regarding a patent that cannot be infringed. This Court recognized more than 80 years ago that

> [D]isclaimer [of a patent] is a representation, as open as the patent itself, on which the public is entitled to rely, that the original claim is one which the patentee does not, in the language of the statute, "choose to claim or to hold by virtue of the patent." Upon the filing of the disclaimers, the original claims were withdrawn from the protection of the patent laws, and the public was entitled to manufacture and use the device originally

> claimed as freely as though it had been abandoned.

Altoona Publix Theatres v. Am. Tri-Ergon Corp., 294 U.S. 477, 492 (1935). At least prior to this case, the Federal Circuit recognized that—in light of *Altoona*—disclaiming a patent made it such that "the disclaimed claim(s) 'never existed.'" *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1299 (Fed. Cir. 2011) (quoting *Vectra Fitness, Inc. v. TNWK, Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998)); *see, e.g.*, *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996) ("A statutory disclaimer under 35 U.S.C. §253 has the effect of canceling the claims from the patent and the patent is viewed as though the disclaimed claims had never existed in the patent.").

The inexorable result of disclaiming a patent, then, is that there can be no justiciable Article III case or controversy regarding the infringement or validity of that patent. Just as the disclaiming patentee cannot bring suit alleging infringement on the disclaimed patent (something Daiichi has repeatedly acknowledged as to the disclaimed '703 patent), a party that might have infringed the patent before disclaimer cannot bring suit seeking a declaration of non-infringement. There cannot be a case or controversy over something that "never existed." *Genetics Inst.*, 655 F.3d at 1299. And in similar fashion, a disclaimed patent cannot give rise to an injury-in-fact traceable to the disclaimed patent or redressable by a judgment of non-infringement or invalidity. The disclaimed patent will be no more or less an obstacle before litigation seeking such a judgment as afterward. With or without a judicial

declaration acknowledging as much, the disclaimed patent cannot block competition.

Accordingly, the Federal Circuit's error is crystal clear. Daiichi's disclaimer of the '703 patent was complete and unequivocal: when Mylan informed Daiichi of its Paragraph IV certification regarding the '703 patent, Daiichi communicated to the FDA in no uncertain terms that it disclaimed all the claims of the '703 patent and that "[t]he effect of the disclaimer is that the 6,878,703 patent no longer exists." App. 4. Daiichi also made clear that, in the wake of its disclaimer, it could not sue anyone for infringement of the '703 patent. App. 4. When Apotex joined the fray and submitted its Paragraph IV certification, Daiichi responded by informing Apotex that it "cannot" sue Apotex for infringement of the disclaimed patent. CA Doc. 46 at 10. And both the District Court and the Court of Appeals readily acknowledged that the '703 disclaimer meant that the patent was dead. *See* App. 44 ("Daiichi can never assert the '703 patent against any ANDA filer or any entity as the patent no longer exists by virtue of Daiichi's disclaimer of all claims associated with the patent."); App. 1 ("Apotex cannot infringe the patent, because Daiichi has disclaimed it."); App. 4 ("non-infringement of the '703 patent follows as a matter of law from the fact that Daiichi has formally disclaimed it").

In light of Daiichi's disclaimer, there is no justiciable Article III case or controversy here. Apotex's suit seeks "a declaration of non-infringement of" the '703 patent. App. 46; *see* App. 57 (asking the District Court to "[d]eclar[e] that the claims of the '703 patent have not been infringed by the filing of Apotex's

ANDA"). But the '703 patent cannot be infringed. Likewise, the '703 patent cannot injure Apotex; it is a nullity. Because the '703 patent is a nullity, Apotex's injury is not traceable to the '703 patent, and a judicial judgment of non-infringement cannot redress Apotex's injuries. Apotex cannot infringe a disclaimed patent with or without a judgment of non-infringement. And the fact that Apotex may derive a statutory benefit from a judicial declaration of something no one does or can dispute may explain why Apotex filed suit, but it is no substitute for an actual controversy concerning the '703 patent. *See infra.*

B. The Need for This Court's Immediate Review Is Manifest.

The need for this Court's immediate review of the decision below is clear. At a bare minimum, the Federal Circuit has definitively held that in the Hatch-Waxman Act context, Article III allows a plaintiff to procure a declaratory judgment of non-infringement or invalidity concerning a disclaimed patent. Thus, far from an isolated jurisdictional error, the decision below orders district courts throughout the country to adjudicate disputes that lie beyond the jurisdiction of any Article III court. The decision will not only produce ultra vires litigation across the country, but also distort the carefully crafted incentive system developed by Congress in the Hatch-Waxman Act. Nor will the adverse effects of the decision below be easily cabined to the Hatch-Waxman context. It unsettles issues long thought settled, specifically the consensus that the disclaimer of a patent precludes subsequent Article III litigation concerning infringement or invalidity of the disclaimed patent.

The decision below guarantees not only litigation that exceeds the Article III limits of the federal courts, but litigation that distorts the incentives Congress intended to create in the Hatch-Waxman Act. Congress carefully crafted the incentives in the Hatch-Waxman Act to encourage generic manufacturers to challenge competition-excluding patents, with consumers ultimately benefiting from the introduction of competition into an otherwise monopolistic market. The decision below fundamentally alters those incentives in a way that jeopardizes desirable generic activity.

Mylan's Paragraph IV certification to the '703 patent accomplished precisely what Hatch-Waxman was designed to reward: it identified weaknesses in a competition blocking patent; caused Daiichi to abandon that patent; and thereby opened the market to competition years before the '703 patent otherwise would have allowed. As a result of that achievement, Hatch-Waxman rewards Mylan with a 180-day exclusivity period. The decision below provides an avenue for invalidating that statutory reward in this case and others like it in ways that neither Article III nor the policies of the statute supports. In the process, the decision below weakens the incentives to make the necessary investments to produce generic drugs. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem,* 81 N.Y.U. L. Rev. 1553, 1605 (2006) (noting the importance of the 180-day exclusivity period in incentivizing challenges of Orange Book listed patents); *Purepac Pharm. Co. v. Thompson,* 354 F.3d 877, 879 (D.C. Cir. 2004) ("In order to encourage paragraph IV challenges, thereby increasing the

availability of low-cost generic drugs ... [the first Paragraph IV ANDA filer] has the right to sell its drug without competition [from other generic entrants] for 180 days."); *Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010) ("Th[e] promise of initial marketing exclusivity is thus intended to increase competition by expediting the availability of generic equivalents.").

But while the effect of the decision below in the Hatch-Waxman context is undeniable, the consequences of the decision are not limited to that context. It has long been understood that federal courts lack jurisdiction over infringement suits and mirror image non-infringement (or invalidity) declaratory judgment actions involving disclaimed patents due to the absence of a justiciable Article III case or controversy regarding such patents. *See, e.g.*, *Merck & Co. v. Apotex, Inc.*, No. 06-5789, 2007 WL 4082616, at *5 (D.N.J. Nov. 15, 2007), *aff'd on other grounds*, 292 F. App'x 38 (Fed. Cir. 2008) ("because Merck has formally disclaimed the '735 and '443 patents, and can no longer enforce any claims as to these patents, there is no justiciable case or controversy to support jurisdiction in an action for a declaratory judgment here."); *3V, Inc. v. CIBA Specialty Chemicals Corp.*, 587 F. Supp. 2d 641, 645-46 (D. Del. 2008) (no case or controversy over disclaimed patent, despite litigant's wish to establish facts for future cases); *Belk, Inc. v. Meyer Corp.*, No. 07-168, 2008 WL 2704792, at *3-4 (W.D.N.C. July 7, 2008) (dismissing declaratory judgment claim as to a disclaimed patent); *W.L. Gore & Assocs., Inc. v. Oak Materials Grp., Inc.*, 424 F. Supp. 700, 702 (D. Del. 1976) (There is "no longer a justiciable case or

controversy before the Court with respect to the validity of any of [disclaimed] claims."); *White Mule Co. v. ATC Leasing Co.*, 540 F. Supp. 2d 869, 881 (N.D. Ohio 2008) (formal disclaimer "leaves [the court] with no 'actual controversy' to adjudicate").

The decision below unsettles this settled law and paves the way for litigants to initiate litigation over long-dead patents, at least if they can tie the patent to some other interest. For example, while courts have refused to entertain actions seeking a declaratory judgment of non-infringement regarding a disclaimed patent where the filer sought to establish relevant facts for future litigation, that interest would appear to be sufficient to litigate over the disclaimed patents under the Federal Circuit's reasoning here. The need to develop useful facts for future litigation would appear to qualify as a "concrete, potentially high-value stake" in a non-infringement judgment. App. 2.

The decision below thus leaves lower courts to guess whether or not former precedent from this Court and the Federal Circuit remains good law. As already explained, this Court held in *Altoona* that "disclaimer" means that the claims of the disclaimed patent are "withdrawn from the protection of the patent laws" and that, as a result, the "public [is] entitled to manufacture and use the device originally claimed as freely as though it had been abandoned." 294 U.S. at 492. And the Federal Circuit has applied *Altoona* to mean that, as a practical matter, a disclaimed patent "never existed." *Guinn*, 96 F.3d at 1422. Those unambiguous statements are irreconcilable with the holding below, which recognizes a case or controversy over a disclaimed patent. Thus, there is now

substantial uncertainty in an area where clarity is of the utmost import. *Cf. KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007).

This uncertainty threatens to bleed into the related context of covenants not to sue. Federal Circuit precedent has long been clear that "a covenant not to sue ... is sufficient to divest a trial court of jurisdiction over a declaratory judgment action" over non-infringement of a patent. *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999); *see, e.g.*, *Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338, 1345 (Fed. Cir. 2010). The decision below, however, calls that well-settled law into question. Disclaimer, in effect, is a universally applicable covenant not to sue; by disclaiming a patent the former patentee makes it such that the patent "never existed." *Genetics Inst.*, 655 F.3d at 1299. But if that more broadly applicable equivalent of a covenant not to sue is insufficient to eliminate a justiciable Article III case or controversy with respect to that patent, courts will be hard-pressed to explain why a more specific covenant not to sue is sufficient.

Even if the Federal Circuit limits its decision to the Hatch-Waxman Act context, it will not limit the damage. District courts nationwide will still have no choice but to entertain non-disputes about non-patents in plain contravention of both Article III and the policies of the Hatch-Waxman Act. And if the decision is limited to the Hatch-Waxman Act and its statutory incentives, that will only serve to underscore the extent to which the Federal Circuit has impermissibly allowed Congress to create Article III jurisdiction where none exists, as explained next.

II. The Federal Circuit's Decision To Allow The Statutory Consequences Of A Judgment To Serve As A Substitute For An Actual Case Or Controversy Merits This Court's Review.

The Federal Circuit missed what should have been obvious—that there can be no case or controversy in the absence of any actual dispute concerning whether Apotex was infringing the '703 patent—but only because it looked past the subject of the litigation (whether Apotex was infringing the disclaimed patent) to the statutory consequences of a judgment of non-infringement. According to the Federal Circuit, the absence of an actual dispute about infringement of the '703 patent was not dispositive because "[u]nder the statute that governs marketing approval of generics, Apotex has a concrete, potentially high-value stake in obtaining the judgment it seeks." App. at 2. If Apotex "obtain[s] a judgment of non-infringement for its generic drug," that "judgment would enable Apotex to receive marketing approval from the" FDA "and to enter the market sooner than otherwise." *Id.*; App. 20 ("a case or controversy exists here" because "Apotex can trigger forfeiture by obtaining the non-infringement judgment it seeks"). But the fact that the statute creates an incentive for the plaintiff to obtain a judgment of non-infringement is no substitute for an actual controversy over infringement, and the latter is what Article III requires. The Federal Circuit's contrary conclusion merits this Court's review.

Apotex's claim to a freestanding right to file a declaratory judgment action, and the Federal Circuit's sanctioning of such a right, is irreconcilable with both

congressional intent and Article III. *See* Dct. Doc. 42 at 2; *see id.* at 1-2 (claiming a "statutory right … to bring a declaratory judgment action and challenge Orange Book listed patents that present a barrier to timely approval of Apotex's ANDA"); Dct. Doc. 43 at 6 (Apotex has a "statutory right as a subsequent ANDA filer to create a forfeiture event"); *see also* CA Doc. 43 at 28 ("Apotex had a statutory right to file a declaratory judgment action seeking certainty that its ANDA product does not infringe the '703 patent."); *id.* at 30-31("Apotex should be permitted to exercise its statutory rights by challenging the Orange Book listed patent and triggering the forfeiture provisions of" Hatch-Waxman); *id.* at 32 ("Apotex is exercising its statutory rights under" Hatch-Waxman).

Nothing in the Hatch-Waxman Act purports to grant Apotex a right to sue in the absence of an actual controversy over the whether a patent is infringed. Nor could it. As a general matter, the statutory grant of jurisdiction over patent infringement cases under the Hatch-Waxman Act assumes that there are live patent claims at issue. Section 271(e)(2) of Title 35 specifically states that infringement exists if the purpose of an ANDA is to make, use, or sell a "drug … *claimed* in a patent or the use of which is *claimed* in a patent …." *Id.* (emphasis added). The ANDA-related infringement cause of action that Congress enacted thus provides no support for a freestanding right to obtain a judgment of non-infringement when there are no actual live patent claims at issue.

In fact, Congress expressly considered a situation analogous to this one and concluded that Article III jurisdiction would be lacking. In discussing when

there would be an Article III case or controversy with respect to a Paragraph-IV-related declaratory judgment action, Senator Kennedy—the then ranking member of the U.S. Senate Committee on Health, Education, Labor, and Pensions—remarked that it was doubtful that a case or controversy would exist where "the patent owner and brand drug company ha[d] given the generic applicant a covenant not to sue, or otherwise formally acknowledge[d] that the generic applicant's drug does not infringe." 149 Cong. Rec. S15885 (Nov. 25, 2003). That statement cannot be squared with a freestanding statutory right to a judgment of non-infringement, even in the absence of an actual dispute over infringement or indeed the absence of an actual patent, post-disclaimer.[2]

In all events, even if Congress purported to authorize Apotex to seek a declaratory judgment of non-infringement even in the absence of any dispute over infringement, that would not justify dispensing with the bedrock requirements of Article III. The Federal Circuit's contrary conclusion conflates the statutory incentive to bring a declaratory judgment action with an actual dispute over the infringement or invalidity of a patent. Congress is perfectly free to give parties a statutory incentive to bring suit, but that is no substitute for an actual controversy sufficient for an Article III court to exercise

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[2] Lest there be any doubt, the Declaratory Judgment Act itself does not create the statutory right claimed by Apotex and identified by the Court of Appeals. "The operation of the Declaratory Judgment Act is procedural only. Congress enlarged the range of remedies available in the federal courts but did not extend their jurisdiction." *Skelly Oil Co. v. Phillips Petrol. Co.*, 339 U.S. 667, 671 (1950) (citations omitted).

jurisdiction and enter a judgment of non-infringement. Here, Apotex may have ample incentives to secure such a judgment, but there is absolutely no dispute over whether Apotex infringes the disclaimed '703 patent. There is, simply put, no dispute on the merits here. Apotex may have a statutory incentive to secure an Article III judgment confirming what no one disputes, but Article III courts do not sit as issuers of valuable judgments concerning non-disputes. Indeed, what Apotex envisions and the Federal Circuit sanctioned is a plain misuse of the Article III courts.

Even if Congress has the authority to create injury-in-fact, a question this Court will decide in *Spokeo*, Congress has no authority to create an actual controversy where none exists. Daiichi's disclaimer of the '703 patent in response to Mylan's Paragraph IV certification eliminated any possibility of an infringement dispute concerning the '703 patent. No matter how great Apotex's statutory incentive to secure a judgment of non-infringement, that incentive does not create its own actual dispute over the '703 patent. If Congress provided Apotex a million-dollar bounty if it secured a judgment of non-infringement or invalidity of the '703 patent, that would not suffice to create a case or controversy concerning the disclaimed '703 patent. The result is no different for the slightly more complicated statutory incentives Apotex has to secure a judgment that may deprive Mylan of its statutorily-conferred exclusivity period. The judgment may be valuable, but it is not the product of an actual controversy concerning the '703 patent.

While this Court should grant plenary review to consider the important questions presented by this petition, at an absolute minimum, the Court should hold this petition pending the disposition of *Spokeo v. Robins*, No. 13-1339. This Court granted certiorari in *Spokeo* to decide "[w]hether Congress may confer Article III standing upon a plaintiff who suffers no concrete harm, and who therefore could not otherwise invoke the jurisdiction of a federal court," by creating a statutory right. Petition for writ of certiorari at i, *Spokeo v. Robins*, No. 13-1339 (May 1, 2014) ("*Spokeo* Cert. Pet.").

This Court held in *Raines v. Byrd*, 521 U.S. 811, 820 n.3 (1997), "that Congress cannot erase Article III's standing requirements by statutorily granting the right to sue to a plaintiff who would not otherwise have standing." Nonetheless, as the *Spokeo* petition points out, "several courts of appeals have disregarded this 'settled' principle in favor of what they perceive to be a contrary rule expressed in *Warth v. Seldin*, 422 U.S. 490, 500 (1975): 'The actual or threatened injury required by Art. III may exist solely by virtue of statutes creating legal rights.'" *Spokeo* Cert. Pet. 8; *compare David v. Alphin*, 704 F.3d 327, 338-39 (4th Cir. 2013) ("deprivation of [a] statutory right" without more is insufficient to establish standing); *Kendall v. Emps. Retirement Plan of Avon Prods.*, 561 F.3d 112, 121 (2d Cir. 2009) (same); *with Beaudry v. TeleCheck Servs., Inc.*, 579 F.3d 702, 705-07 (6th Cir. 2009) (injury to statutory right sufficient); *Murray v. GMAC Mortg. Corp.*, 434 F.3d 948, 952-53 (7th Cir. 2006) (same); *see also Spokeo* Cert. Pet. 9-12 (describing split).

The decision below goes one giant step beyond the Sixth and Seventh Circuit decisions allowing Congress to create injury-in-fact where none otherwise exists, and recognizes a congressional power to create an actual controversy where none otherwise exists. Thus, if this Court sides with the Second and Fourth Circuits in *Spokeo*, and holds that "Congress may [not] confer Article III standing upon a plaintiff who suffers no concrete harm, and who therefore could not otherwise invoke the jurisdiction of a federal court," *Spokeo* Cert. Pet. 1, then the Federal Circuit's decision must be vacated *a fortiori*. The only grounds for the Federal Circuit's recognition of Article III jurisdiction here are the statutory consequences of a judgment of non-infringement. Apart from the statutory benefits Apotex may secure as a byproduct of a judgment of non-infringement, there is plainly no dispute over the '703 patent. Apotex cannot infringe a disclaimed patent with or without a judgment of non-infringement. Thus, if Congress cannot generate Apotex's injury-in-fact by giving it a statutory incentive to sue, then there plainly is no Article III jurisdiction here. And even if this Court holds that Congress can create injury-in-fact, it would not mean that Congress could take the further step of creating an actual controversy over a disclaimed patent. The Court's decision might nonetheless shed light on the questions presented here.

CONCLUSION

The decision below opens district courts across the Nation to patent litigation despite the absence of an actual dispute or even an actual patent. That egregious and consequential error merits this Court's immediate plenary review. But, at a bare minimum, this Court should hold this petition pending the Court's resolution of *Spokeo v. Robins*, No. 13-1339.

Respectfully submitted,

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September 8, 2015

APPENDIX

TABLE OF APPENDICES

Appendix A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Nos. 2014-1282, 2014-1291

APOTEX INC.,

Plaintiff-Appellant,

v.

DAIICHI SANKYO, INC., DAIICHI SANKYO CO., LTD.,

Defendants- Appellee,

v.

MYLAN PHARMACEUTICALS INC.

Movant-Cross-Appellant.

Decided: March 31, 2015

Before TARANTO, MAYER, and CLEVENGER, *Circuit Judges.*

TARANTO, *Circuit Judge.*

Apotex, Inc. brought this action against Daiichi Sankyo Co., Ltd. and Daiichi Sankyo, Inc. (collectively, Daiichi) to obtain a declaratory judgment that Apotex will not infringe a patent owned but disclaimed by Daiichi if Apotex manufactures or sells a generic drug bioequivalent to Daiichi's Benicar®. Apotex cannot infringe the patent, because Daiichi has disclaimed it, but Apotex nevertheless claims a concrete interest in obtaining a judgment of non-infringement for its

generic drug because such a judgment would enable Apotex to receive marketing approval from the United States Food and Drug Administration and to enter the market sooner than otherwise. The district court dismissed Apotex's complaint for lack of a case or controversy. We reverse. Under the statute that governs marketing approval of generics, Apotex has a concrete, potentially high-value stake in obtaining the judgment it seeks; and Daiichi has a concrete, potentially high-value stake in denying Apotex that judgment and thereby delaying Apotex's market entry—as does Mylan Pharmaceuticals, Inc., the first applicant for approval of a generic version of Benicar®. We also reverse the district court's denial of Mylan's motion to intervene in this action.

BACKGROUND

Under the authority of the FDA's approval of its New Drug Application (NDA), 21 U.S.C. § 355(a), (c), Daiichi markets Benicar® for treating hypertension. In seeking FDA approval for Benicar®, Daiichi listed two patents in the FDA's *Approved Drug Products with Therapeutic Equivalence* Evaluations publication, or "Orange Book." *See* 21 U.S.C. § 355(b)(1) (requiring listing of patents that "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug"); 21 C.F.R. §§ 314.3, 314.53. The first, U.S. Patent No. 5,616,599, covers the active ingredient of the drug, olmesartan medoxomil. It expires on April 25, 2016, but because Daiichi provided the FDA certain data concerning the drug's effects on children, the FDA must wait six months longer—*i.e.*, until October 25, 2016—before approving a generic version

of the drug. *See* 21 U.S.C. § 355a(b)(1)(B)(i). Daiichi's second listed patent, U.S. Patent No. 6,878,703, covers methods of treatment. It expires on November 19, 2021.

At least two generic manufacturers have sought approval from the FDA to market generic olmesartan medoxomil products. All parties agree that Mylan (actually Matrix Laboratories, which is now Mylan) was the first to seek approval: it filed an Abbreviated New Drug Application (ANDA) with the FDA, under 21 U.S.C. § 355(j), in April 2006. In that application, Mylan certified under paragraph IV of § 355(j)(2)(A)(vii) that both the '599 and '703 patents were invalid or would not be infringed by Mylan's proposed drug.

In early July 2006, after receiving notice of Mylan's paragraph IV certification, Daiichi disclaimed all claims of the '703 patent. *See* 35 U.S.C. § 253. The record does not tell us why. We have no information about whether, for example, Daiichi recognized the invalidity of the patent or, even, that it never should have been listed under § 355(b)(1)'s "could reasonably be asserted" standard.

Having disclaimed the '703 patent, Daiichi sued Mylan for infringing the '599 patent, invoking the declaration of 35 U.S.C. § 271(e)(2)(A) that the submission of a paragraph IV certification constitutes an act of infringement. Only validity was disputed in the case, and after a full trial, the district court upheld the validity of the '599 patent and entered judgment of infringement against Mylan. *Daiichi Sankyo Co. v. Mylan Pharm. Inc.*, 670 F. Supp. 2d 359, 387 (D.N.J. 2009). We affirmed. *Daiichi Sankyo Co. v. Matrix*

Labs., Ltd., 619 F.3d 1346 (Fed. Cir. 2010). With the '703 patent disclaimed and the '599 patent upheld, Mylan's earliest date of market entry—the earliest effective date of any FDA approval for Mylan—is October 25, 2016, six months after the expiration date of the '599 patent.

In June 2012, four years before that date and roughly two years after the '599 litigation was over, Apotex filed its own ANDA for generic olmesartan medoxomil. Apotex included two different certifications under 21 U.S.C. § 355(j)(2)(A)(vii). One was a paragraph III certification accepting, rather than disputing, the result of the 2006–2010 litigation. That certification states that the '599 patent is valid and that Apotex's product would infringe, thereby barring an effective date of FDA approval any earlier than October 25, 2016. *See* § 355(j)(5)(B)(ii). Apotex's other certification was a paragraph IV certification stating that Apotex's product would not infringe the '703 patent.

As is undisputed here, non-infringement of the '703 patent follows as a matter of law from the fact that Daiichi has formally disclaimed it. *See Altoona Publix Theatres, Inc. v. American Tri-Ergon Corp.*, 294 U.S. 477, 492 (1935); *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996). Indeed, in its July 2006 letter asking the FDA to remove the '703 patent from the Orange Book, Daiichi stated: "The effect of the disclaimer is that the 6,878,703 patent no longer exists." J.A. 99. And in July 2012, it wrote to Apotex stating that, because of its disclaimer of the '703 patent, it "cannot . . . sue any entity . . . for infringement of that patent." J.A. 104.

Daiichi did not sue Apotex for infringing the '703 patent, and the FDA has not removed the '703 patent from the Orange Book, despite Daiichi's 2006 request. *See Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1317–18 (D.C. Cir. 2010) (patent owner's unilateral request to remove patent from Orange Book is not a sufficient basis for FDA to do so). But Apotex sued Daiichi in the United States District Court for the Northern District of Illinois under 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5), seeking a declaratory judgment that its product would not infringe the disclaimed '703 patent. Mylan moved to intervene, and both it and Daiichi moved to dismiss Apotex's complaint. Given the non-infringement consequence of the Daiichi disclaimer, the dispute in the district court was not over the merits of infringement. Rather, the dispute was over whether, precisely because non-infringement is indisputable, the district court must deny the requested declaratory judgment for lack of a case or controversy.

Apotex asserted that it has a concrete stake in securing the requested declaratory judgment because, under the governing statutory provisions, the requested judgment would allow it to enter the market earlier than it could without the judgment. Two statutory provisions are key. First: Under § 355(j)(5)(B)(iv), because Mylan was the first to file an ANDA for generic olmesartan medoxomil and has maintained a paragraph IV certification regarding the '703 patent, Mylan is presumptively entitled to a period of 180 days of exclusivity—starting whenever, after October 25, 2016, it enters the market—before facing competition from another seller of generic olmesartan medoxomil. That exclusivity period would

end no earlier than April 23, 2017. Second: Under § 355(j)(5)(D), the exclusivity period may be forfeited in certain specified circumstances. According to Apotex, a court judgment of non-infringement would cause Mylan to forfeit the exclusivity period if Mylan has not marketed its drug 75 days after appeal rights are exhausted (certiorari aside) and Apotex has obtained tentative approval for its generic product from the FDA. § 355(j)(5)(D)(i)(I)(bb)(AA). If that is correct, and the judgment comes soon enough, Apotex could enter the market substantially before April 23, 2017 (even longer before a later end of Mylan's exclusivity period if Mylan delays entry past October 25, 2016); such entry would likely transfer sales from Daiichi and Mylan to Apotex and, because of the greater competition, reduce the price Daiichi and Mylan would charge.

Daiichi and Mylan did not dispute that an earlier than-otherwise Apotex entry into the market would likely have the identified effects, to Apotex's benefit and Daiichi's and Mylan's detriment. But Daiichi argued that no controversy exists because it could not now assert the disclaimed '703 patent against Apotex. Mylan added arguments based on the fact that Apotex lacked (and lacks) a "tentative approval" from the FDA for its ANDA.[1] Specifically, Mylan argued that redress

[1] Congress has defined "tentative approval" to mean the FDA's determination that the ANDA has met the substantive requirements for obtaining generic marketing approval (by demonstrating, among other things, bioequivalence to the listed drug) but that final approval by the FDA is blocked by other barriers, such as a live patent, a 30-month stay caused by ongoing litigation, or certain exclusivity periods. § 355(j)(5)(B)(iv)(II)(dd)(AA).

of Apotex's delayed- market-entry injury is unduly speculative before tentative approval is in hand. Mylan also made an argument based on the fact that tentative approval is a necessary statutory condition for the forfeiture of Mylan's presumptive exclusivity period based on the declaratory judgment requested here. § 355(j)(5)(D). It argued that the forfeiture provision should be read to mean that, for a declaratory judgment *brought* by a second ANDA filer to cause forfeiture, the second ANDA filer must have had tentative FDA approval when it brought the declaratory judgment action. Under that interpretation, Mylan contended, the present action cannot provide Apotex forfeiture relief—even if Apotex could file an identical declaratory-judgment action as soon as it obtains tentative approval.

The district court granted Daiichi's motion. It reasoned that "both Daiichi and Apotex no longer hold any meaningful interest in the now disclaimed patent" and that the FDA's continuing to list the '703 patent in the Orange Book "does not create a case or controversy by which Apotex may seek a declaratory judgment regarding a nonexistent patent." *Apotex, Inc. v. Daiichi Sankyo, Inc.*, No. 12-CV-9295, 2014 WL 114127, at *4 (N.D. Ill. Jan. 9, 2014). The court denied Mylan's motion to intervene as moot in light of its grant of Daiichi's dismissal motion. *Id.*

Apotex appeals, and Mylan cross-appeals the denial of its motion to intervene. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review de novo a district court's dismissal of a declaratory-judgment action for lack of subject-matter

jurisdiction. *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1277 (Fed. Cir. 2014). Where, as here, no timeliness issue is present, we review denial of intervention as of right de novo. *See Stauffer v. Brooks Bros., Inc.*, 619 F.3d 1321, 1328 (Fed. Cir. 2010) (denial of intervention reviewed under regional circuit's law); *Sokaogon Chippewa Cmty. v. Babbitt*, 214 F.3d 941, 945 (7th Cir. 2000) (de novo review of denial of motion to intervene).

A

We begin by confirming Mylan's right to be a party in this case because of its obvious stake in the dispute. Rule 24(a) of the Federal Rules of Civil Procedure establishes a right to intervene when a person "claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." Mylan readily meets that standard.

In this action, Apotex seeks to cause a forfeiture of Mylan's presumed market-exclusivity period, and Mylan has a concrete monetary interest in retaining such exclusivity—six months of more sales and/or higher prices than are likely when Apotex enters the market. Although Daiichi likely benefits from the 180-day exclusivity period as well, Mylan's interest exists apart from that of Daiichi, which, as a rival of Mylan's, has its own incentives affecting decisions about how to conduct this litigation. *Keith v. Daley*, 764 F.2d 1265, 1268 (7th Cir. 1985) (interest must "belong[] to the proposed intervenor rather than to an existing party

in the suit"). Mylan's interest here is "'of such a direct and immediate character that [Mylan] will either gain or lose by the direct legal operation and effect of the judgment'" sought by *Apotex. Am. Mar. Transp., Inc. v. United States*, 870 F.2d 1559, 1561 (Fed. Cir. 1989) (emphases removed) (quoting *United States v. AT&T Co.*, 642 F.2d 1285, 1292 (D.C. Cir. 1980)). And Apotex does not defend the district court's conclusion that Mylan's interest in the case was rendered moot by the dismissal of the case, where, as here, Apotex is seeking to reverse the dismissal. Mylan has a strong, concrete interest in defending the dismissal on this appeal. Accordingly, we reverse the denial of Mylan's motion to intervene.

B

We also reverse the district court's dismissal of Apotex's complaint for lack of a case or controversy. The stakes over which the parties are vigorously fighting are concrete and substantial: the amount of revenue there will be from sales of olmesartan medoxomil, and who will get what portions of it, during a period of at least six months. We conclude that "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." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (internal quotation marks and citation omitted).

The case-or-controversy analysis, as relevant here, has borrowed from decisions on standing and ripeness. *See Sandoz*, 773 F.3d at 1277–78; *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1335–36

(Fed. Cir. 2008). "Standing under Article III of the Constitution requires that an injury be concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling." *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010). Where, as here, no further facts are needed for the requested adjudication (non-infringement is beyond dispute, given the disclaimer), ripeness depends on any harm to the plaintiff from delaying adjudication and the degree of uncertainty about whether an adjudication will be needed. *Sandoz*, 773 F.3d at 1277–78. In this case, these overlapping formulations have led the parties to focus on (1) whether Daiichi's disclaimer of the patent means that the parties lack concrete stakes in the dispute over the declaratory judgment; (2) whether the alleged harm is traceable to Daiichi; (3) whether the real-world impact is too contingent on future events—specifically, FDA tentative approval of Apotex's ANDA; and (4) whether Apotex's alleged harm would not be redressed even if Apotex receives the requested judgment because ultimate relief is independently blocked by the statutory standards for triggering forfeiture of Mylan's exclusivity period. We address those issues in turn.

1

We first reject Daiichi's contention, adopted by the district court, that Daiichi's statutory disclaimer of the '703 patent itself means that there is no adversity between it and Apotex over stakes of a concrete character. *See Hollingsworth v. Perry*, 133 S. Ct. 2652, 2662 (2013) ("To have standing, a litigant . . . must possess a 'direct stake in the outcome'

of the case.") (quoting *Arizonans for Official English v. Arizona*, 520 U.S. 43, 64 (1997)); *Warth v. Seldin*, 422 U.S. 490, 498–99 (1975). The concrete stakes over which Daiichi and Apotex are fighting are the revenues to be earned through selling olmesartan medoxomil. The patent disclaimer eliminates one, but only one, potential legal barrier to Apotex's ability to make such sales sooner rather than later. The *listing* of the patent, with its current consequence of preventing FDA approval during Mylan's presumptive exclusivity period, is another, and the parties have adverse concrete interests in the truncation or preservation of that period.

Apotex, Daiichi, and Mylan are all likely affected, though not in perfect mirror-image ways, by whether Apotex can cause the forfeiture of Mylan's exclusivity period. Until that period ends, Apotex cannot make sales, and delay of entry may have lingering adverse effects on market share. *See Teva Pharm., USA, Inc. v. FDA*, 182 F.3d 1003, 1011 n.8 (D.C. Cir. 1999) (second-filing generic manufacturers "face continued harm because of their denied access to the market . . . , harm potentially heightened because of [the first filer's] period of market exclusivity"). Once Apotex enters, Daiichi and Mylan can expect to lose sales they otherwise would have made. It is plausible, too, that entry by Apotex would produce prices noticeably lower than those Daiichi and Mylan would charge during a duopoly period (with Mylan the exclusive generic seller).[2] Daiichi and Mylan will thereby be harmed by

[2] *See* FDA, Center for Drug Evaluation and Research, *Generic Competition and Drug Prices* (last updated Mar. 1, 2010), www.fda.gov/AboutFDA/CentersOffices/Officeof

Apotex's entry (even if the lowered prices benefit consumers as much as or more than Apotex).

In these circumstances, by any common-sense measure, the parties have substantial, concrete stakes in whether Apotex secures the non-infringement judgment it seeks to advance its entry into the market. If the judgment issues, there is every likelihood that Daiichi and Mylan will lose substantial revenues, and Apotex will gain substantial revenues. This case is quite different from cases in which a case or controversy has been held missing because the plaintiffs had mere generalized or bystander interests in others' compliance with law.

Of course, other requirements for a case or controversy have to be met: most significantly, the desired advancing of FDA approval and of Apotex's market entry must not be too speculative a consequence of the requested non-infringement judgment. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992). And Daiichi and Mylan argue that the advancing of approval and entry actually cannot follow because, under the governing statutory provisions, the present Apotex lawsuit cannot strip them of what they say is their legal entitlement to hold onto the benefits of delaying

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MedicalProductsandTobacco/CDER/ucm129385.htm ("On average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer. However, the appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price.*"); Teva Pharm. USA, Inc. v. Pfizer Inc.*, 405 F.3d 990, 993 (Fed. Cir. 2005) (Gajarsa, J.) (dissenting from denial of rehearing en banc) (exclusivity period creates a "comfortable duopoly" for the NDA holder and the first ANDA filer).

Apotex's entry. We discuss those questions *infra*. But Daiichi is wrong in its threshold argument that its disclaimer of the '703 patent itself eliminates a case or controversy.

2

Daiichi is also wrong to the extent it contends that the delayed entry of Apotex at issue here is not "fairly traceable" to Daiichi. *Allen v. Wright*, 468 U.S. 737, 751 (1984). If Daiichi had not listed the '703 patent in the Orange Book in the first place, the '599 patent would be the only listed patent, and Mylan undisputedly would have no exclusivity period at present, because it lost its challenge to the '599 patent. Since 2003, the statute has expressly conditioned a first filer's eligibility for marketing exclusivity on its ability to "lawfully maintain[ ]" a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb). Where, as here, a first ANDA filer lists a patent in a paragraph IV certification and loses in litigation through a judgment that confirms infringement and rejects invalidity, that applicant may no longer lawfully maintain its paragraph IV certification.[3]

[3] FDA regulations provide that "[a]n applicant who has submitted a [paragraph IV certification] and is sued for patent infringement . . . shall amend the certification if a final judgment . . . is entered finding the patent to be infringed. In the amended certification, the applicant shall certify under paragraph [III] that the patent will expire on a specific date. Once an amendment or letter for the change has been submitted, the application will no longer be considered to be one containing a [Paragraph IV certification]." 21 C.F.R. § 314.94(a)(12)(viii)(A) (2015). The required application amendment causes the first filer to forfeit its eligibility for any market exclusivity based on that certification. 21 U.S.C. § 355(j)(5)(D)(i)(III); *see* Letter from G. Buehler, Director, Office of Generic Drugs, to ANDA Applicant

Thus, Mylan would currently not be eligible for an exclusivity period had Daiichi never listed the '703 patent. Oral Argument at 2:30–46 (Apotex), *Apotex Inc. v. Daiichi Sankyo, Inc.*, No. 2014-1282, -1291; *id.* at 16:50–17:10 (Daiichi). It is only Daiichi's original listing of that patent—which Daiichi has disclaimed—that now supports Mylan's exclusivity period, which Apotex filed this action to bring to an end.

Daiichi is therefore responsible for the current existence of Mylan's exclusivity-period rights. Importantly, by so stating, we are not asserting that such responsibility is a necessary condition for the case or controversy here. We do not decide, and do not have to decide, whether it would be enough, for a justiciable dispute, that a requested judgment of non-infringement would lead the FDA to allow a market entry that would have concrete revenue transferring effects on all parties. In this case, Daiichi's act of listing the '703 patent in the Orange Book created the entry barrier that Apotex, through a declaratory judgment, seeks to eliminate.

Relatedly, for case-or-controversy purposes, it is immaterial whether Daiichi acted contrary to the statutory standard in listing the '703 patent in the Orange Book—which we do not know, one way or the other. Daiichi is causally responsible for the current existence of the exclusivity period; Apotex seeks a judgment of non-infringement that does not depend on whether the original listing was proper; and there has

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regarding 180-day exclusivity for dorzolamide/timolol ophthalmic solution, Docket No. FDA-2008-N-0483-0017 at 5–6 (Oct. 28, 2008), *available at* www.regulations.gov (Dorzolamide/Timolol Letter).

been no suggestion that, under the statute, the forfeiture of the exclusivity period depends on the original listing's propriety. Neither the logic nor precedents controlling the Article III determination would make the entry of the requested judgment in these circumstances something other than the resolution of a case or controversy—as long as it is "likely, as opposed to merely speculative," that the consequence would be the concrete one of advancing the date of approval by the FDA and market entry by Apotex. *Lujan*, 504 U.S. at 560–61 (internal quotation marks omitted). We turn to that critical question.

3

One aspect of that question is whether, putting aside the statutory provisions governing the exclusivity period, tentative FDA approval for Apotex's proposed drug is a prerequisite for a case or controversy here. Specifically, exclusivity-period provisions aside, is the prospect of concrete relief for Apotex too uncertain to support an adjudication of the request for a non-infringement judgment until Apotex obtains tentative approval? We conclude that the answer is no.

The general principle governing the inquiry, including in situations where ultimate relief from harm depends on the action of a third party (here, the FDA's approval of the ANDA to allow marketing), is whether there is too high a degree of uncertainty about whether the judicial resolution, if in the plaintiff's favor, will matter in alleviating the harm alleged by the plaintiff. *See Lujan*, 504 U.S. at 560–61 (likely, as opposed to speculative); *Warth*, 422 U.S. at 504, 507 ("substantial probability," not "remote

possibility*"); Linda R.S. v. Richard D.*, 410 U.S. 614, 618 (1973) (not too "speculative"). That context-dependent standard has been applied to allow adjudication to remove one legal barrier to the plaintiff's obtaining the concrete alleviation of harm it seeks, notwithstanding potential independent barriers to achieving that result, as long as such other potential barriers are not unduly likely to deprive the adjudication of concrete effect. Thus, in *Arlington Heights v. Metropolitan Housing Development Corp.*, 429 U.S. 252 (1977), the Court found that a developer and a would-be resident had standing to challenge a zoning scheme that stood "as an absolute barrier to constructing the housing" the developer sought to build, stating: "If [the developer] secures the injunctive relief it seeks, that barrier will be removed." *Id.* at 261. Other barriers that might doom actual development, such as inability to obtain financing, though real, were not so certain as to bar standing to obtain removal of the barrier at issue, *id.* at 261 & n.7, because there was a "substantial probability" that the "project w[ould] materialize" if the adjudication occurred, *id.* at 264. As a result, the injuries to the developer and would-be resident were " 'likely to be redressed by a favorable decision.' " *Id.* at 262 (quoting *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 38 (1976)); *id.* at 264.

Because the likelihood of ultimate alleviation of harm involves a judgment call about a causal chain, congressional action is relevant. The Supreme Court and our court have recognized the potential significance of congressional action in "articulat[ing] chains of causation that will give rise to a case or controversy where none existed before."

Massachusetts v. EPA, 549 U.S. 497, 516 (2007); *see Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1261 (Fed. Cir. 2014). By deeming certain series of links from conduct to harm or from judgment to alleviation of harm not to be unduly speculative, Congress may "effectively creat[e] justiciability that attenuation concerns would otherwise preclude." *Sandoz*, 773 F.3d at 1281.

In the present context, the congressional judgment embodied in the "Hatch-Waxman Amendments" to the Food, Drug, and Cosmetic Act,[4] as consistently implemented in our case law, makes clear that tentative approval for Apotex is not a precondition to adjudicating the patent issue. When a generic manufacturer seeks to enter the market, the concrete stakes are the market sales upon entry. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1292 (Fed. Cir. 2008) ("exclud[ing] noninfringing generic drugs from the market . . . is a sufficient Article III injury-in-fact"). Yet Congress, in 35 U.S.C. § 271(e)(2), defined an "artificial act of infringement," *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990), that allows litigation to take place well before any product is actually placed on the market and before any FDA regulatory approval, the litigation serving to remove one barrier to such approval and marketing. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (under Hatch-Waxman, the focus of infringement

[4] Drug and Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355, 28 U.S.C. § 2201, and 35 U.S.C. §§ 156, 271, & 282).

litigation is on "what the ANDA applicant will *likely* market *if* its application is approved, an act *that has not yet occurred*") (emphases added*); cf. Amgen Inc. v. Int'l Trade Comm'n*, 565 F.3d 846, 851–52 (Fed. Cir. 2009) (noting that the Supreme Court has "stressed the congressional purpose of removing patent-based barriers to proceeding with federal regulatory approval of medical products").

Critically, the statute authorizing the litigation upon filing of an ANDA nowhere requires tentative FDA approval as a precondition: the filing of the ANDA, with a paragraph IV certification, is itself deemed an act of infringement. 35 U.S.C. § 271(e)(2); *see Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012) ("The patent statute treats such a filing as itself an act of infringement, which gives the brand an immediate right to sue."). Moreover, Congress required the ANDA filer to provide prompt notice to the relevant patent owners (and NDA holder), 21 U.S.C. § 355(j)(2)(B), and for the patent owners to bring suit within 45 days to obtain a 30-month delay in any effective date of approval for the ANDA, § 355(j)(5)(B)(iii). It is undisputed that it would be rare for tentative approval to have occurred 45 days into the ANDA process. *See also* § 355(j)(5)(D)(i)(IV) (provision triggering forfeiture based on first filer's failure to obtain tentative approval, presumptively giving first filer a full 30 months to obtain tentative approval). The statute evidently contemplates litigation well before such tentative approval.

Our decisions reflect that fact. In all of our cases involving litigation over ANDA applications, we have

never required tentative approval, including in suits brought almost immediately after the ANDA's filing. *See, e.g., Caraco*, 527 F.3d at 1295 ("*Caraco* has a complete generic drug product that has been submitted to the FDA for approval, and no additional facts are required to determine whether this drug product infringes the claims of Forest's '941 patent."); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007) (because the patent owner, upon a generic's filing of a paragraph IV certification, "would have an immediate justiciable controversy, . . .[i]t logically follows that . . . the same action should create a justiciable declaratory judgment controversy for the opposing party").[5]

Accordingly, tentative approval of an ANDA is generally not a precondition to the existence of a case or controversy concerning patents listed in the Orange Book. Moreover, that general case-or-controversy conclusion does not depend on whether the patent owner or the ANDA applicant initiates the litigation, the latter specifically authorized by Congress to bring a declaratory judgment action if the former does not sue. 21 U.S.C. § 355(j)(5)(C). For those reasons, we conclude that tentative approval is not required for the present dispute to constitute a case or controversy unless there is an additional context-specific reason tied to statutory provisions that distinguishes this

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[5] *See Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151 (Fed. Cir. 2012); *Sanofi-Aventis v. Apotex Inc.*, 659 F.3d 1171 (Fed. Cir. 2011); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358 (Fed. Cir. 2008); *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075 (Fed. Cir. 2008);

situation from those in which we have deemed tentative approval unnecessary to satisfy Article III.

4

That conclusion brings us to the objection to justiciability based on the specific statutory provisions governing forfeiture of the exclusivity period. It is undisputed here that Mylan currently has an exclusivity period available to it, based on the original listing of the now-disclaimed '703 patent and Mylan's continued maintenance of its paragraph IV certification regarding that patent. It is also undisputed that the only basis asserted for Apotex to enter earlier than the end of the exclusivity period is a forfeiture of the period under § 355(j)(5)(D)(ii)—specifically, one triggered by a "forfeiture event" defined by § 355(j)(5)(D)(i)(I)(bb)(AA). The only arguments presented to us are arguments directly about those provisions—specifically, whether they permit Apotex to trigger forfeiture by the judgment requested in this case. Daiichi and Mylan do not suggest that, were a non-infringement judgment to issue in this case, the FDA would nonetheless consider it inadequate to trigger forfeiture of Mylan's exclusivity period based on a restrictive view of the forfeiture provisions that is entitled to judicial deference. Nor do they argue that any FDA approval would come too late to advance Apotex's market entry in any event. We conclude that Apotex can trigger forfeiture by obtaining the non-infringement judgment it seeks in this case and, thus, that a case or controversy exists here.

The provisions at issue are best read with a little background and context. The provisions were added to

the statute by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108–173, § 1102, 117 Stat. 2066, 2457–60 (2003) (codified as amended at 21 U.S.C. § 355(j)).

For ANDA applications filed before the December 2003 enactment of the MMA, the statute, as this court read it, was more protective of a first ANDA filer's exclusivity period than it became under the MMA. In particular, and "[s]ignificantly, the first Paragraph IV ANDA filer [was] entitled to the 180-day exclusivity period regardless of whether it establishe[d] that the Orange Book patents [were] invalid or not infringed by the drug described in its ANDA." *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008); *see Caraco*, 527 F.3d at 1283; 21 U.S.C. § 355(j)(5)(B)(iii), (iv) (2000).[6] Moreover, the

[6] This court's Janssen decision thus ruled that exclusivity was not defeated when a patent identified in a paragraph IV certification was held valid and infringed—even though an FDA regulation required alteration of the certification to become a paragraph III certification. 21 C.F.R. § 314.94(a)(12)(viii)(A) (2003). By 2003, the FDA had been moving toward denying exclusivity, as a regulatory matter, in various circumstances where an initial paragraph IV certification lost its foundation, and the courts expressed different views on the FDA's evolving position. *See Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340 (D.N.J. 2003) (upholding the FDA's denial of exclusivity based on pre-approval expiration of patent subject to paragraph IV certification); *Mylan Pharm., Inc. v. Thompson*, 207 F. Supp. 2d 476 (N.D. W. Va. 2001) (rejecting the FDA's denial of exclusivity based on treating first filer's settlement with patent owner as effectively changing certification); Mylan *Pharm., Inc. v. Henney*, 94 F. Supp. 2d 36 (D.D.C. 2000) (rejecting the FDA's refusal to interpret its regulation to deny exclusivity based on first filer's agreement to change certification from paragraph IV to III), vacated and dismissed as moot sub nom.

pre-MMA statute contained no express requirement that the first filer lawfully maintain its paragraph IV certification, and it offered no express path for subsequent ANDA filers to eliminate a first filer's exclusivity period, *i.e.*, to trigger its forfeiture. The statute merely provided that, when a first filer had not activated its 180-day clock, a subsequent filer could do so— even where the first filer was blocked from marketing its drug by a later-expiring patent—by securing a judgment of non-infringement or invalidity. *See Janssen*, 540 F.3d at 1357; *Caraco*, 527 F.3d at 1284; 21 U.S.C. § 355(j)(5)(B)(iv) (2000). Notably, *Janssen* (like *Caraco*) was decided under the pre-MMA scheme, *see* 540 F.3d at 1357 n.2, and it was under that scheme that *Janssen* concluded that the second filer's "inability to promptly launch its generic" product "because of [the first filer's] 180-day exclusivity period is not a cognizable Article III controversy, but a result envisioned by the Hatch-Waxman Act." *Id.* at 1361.

Section 1102 of the MMA altered the exclusivity scheme in two fundamental ways. First: It expressly conditioned the first filer's eligibility for exclusivity on its "lawfully maintain[ing]" a paragraph IV certification, § 355(j)(5)(B)(iv)(II)(bb). As already described, a first filer may not lawfully maintain an initial paragraph IV certification as to which it lost a litigation challenge regarding infringement and

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Pharmachemie B.V. v. Barr Labs., Inc., 276 F.3d 627 (D.C. Cir. 2002); *Mova Pharm Corp. v. Shalala*, 140 F.3d 1060, 1071 (D.C. Cir. 1998) (noting the FDA's view that exclusivity is not lost upon certification change after adjudication of validity and infringement).

validity. *See supra* p. 12 & n.3. In other words, the exclusivity period is no longer guaranteed just for the effort of challenging a patent (its scope or its validity), as *Janssen* had said of the pre-2003 statute. Losing in the challenge eliminates the patent from the group of patents that can support an exclusivity period.

Second: The MMA added to the statute an elaborate new forfeiture provision that declares that "[t]he 180-day exclusivity period described in [§ 355(j)(5)(B)(iv)] shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant." § 355(j)(5)(D)(ii). The provision defines "forfeiture event," § 355(j)(5)(D)(i), and one group of such events is the first filer's "failure to market" "by the later of" two dates. § 355(j)(5)(D)(i)(I). One of those dates is specified in (aa): the *earlier* of 75 days after the first filer's effective date for approval or 30 months after the first filer submitted its application. § 355(j)(5)(D)(i)(I)(aa). In the present case, because Mylan filed in April 2006, the 30-month date arrived in October 2008. The second of the "later of" dates is specified in (bb), which is what is at issue here:[7]

> (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, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification

[7] No one here disputes that the "later of" language applies only if one of the (bb)-specified events occurs, *i.e.*, that the arrival of one of the (aa)-specified dates is not itself enough if no (bb) event has occurred. *See also Teva v. Sebelius*, 595 F.3d at 1316–17.

qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), *at least 1 of the following has occurred*:

> (AA) In an infringement action brought against that applicant with respect to the patent or *in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision* from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken *that the patent is invalid or not infringed.*
>
> (BB) In an infringement action or a declaratory judgment action described in subitem (AA), 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 information submitted under subsection (b) or (c) of this section [§ 355] is withdrawn by the holder of the application approved under subsection (b) of this section [the NDA].

§ 355(j)(5)(D)(i)(I)(bb) (emphases added).

The first step in applying that provision to the present case is to note that, although Mylan (the "first applicant") initially made a paragraph IV certification for both the '599 and '703 patents, the '599 certification is no longer "lawfully maintained," because Mylan lost its litigation over that patent. As a result, the only lawfully maintained certification involves the '703 patent, and the (bb) standards must be applied only to that patent. As to that patent, then,

(bb)(AA) specifies that Mylan forfeits its exclusivity period if it has not entered the market by the following date: with respect to Apotex, a second-filing applicant, "which other applicant has received tentative approval," 75 days after what we may, for convenience, call the "non-infringement finality date"—more precisely, when the appeal time ends without an appeal after the district court enters a non-infringement judgment, *see* 28 U.S.C. § 2107(a) (30-day period); Fed. R. App. P. 4, or when this court enters its judgment affirming the non-infringement judgment if there has been an appeal.

This provision, which separates the tentative approval phrase from its specification of certain forfeiture-triggering dates, including the non-infringement finality date of (AA), admits of a simple reading. There are two requirements for forfeiture: a court must have entered a final decision of non-infringement that is no longer appealable (certiorari aside), and the second (or later) filer must have received tentative approval. The first filer forfeits its exclusivity if it has not entered 75 days after those two requirements are satisfied. Under that reading, Apotex can trigger forfeiture in this case by obtaining the judgment it seeks here and by obtaining tentative approval, if it does both early enough in relation to Mylan's market entry.

Mylan argues for a different interpretation of the statute—that the second filer (the "other applicant" in (bb)) must have tentative approval before it *initiates* the declaratory-judgment action. Mylan Br. 5, 21–22. Mylan contends that the text of (bb) and (AA) taken together unambiguously mandates that tentative

approval is a prerequisite for entry into court if the action is ultimately to have a forfeiture effect. We reject that reading of the provision.

The statutory text does not compel Mylan's interpretation. The provision's language, standing alone, leaves ambiguous the time at which the "received tentative approval" requirement must be met—at the institution of the declaratory-judgment action or at some later time. We must therefore look to the statutory context and policy. That analysis points convincingly against Mylan's view.

The textual contrast with another relevant provision added to the statute by the MMA, namely, § 355(j)(5)(C)—under which Apotex filed its declaratory-judgment action—confirms the facial ambiguity of the (bb)(AA) language at issue and reinforces our interpretation that tentative approval is not required at the outset of the action. Section 355(j)(5)(C) imposes clear preconditions on an ANDA filer's *bringing* of a declaratory-judgment action against the patent owner: "No action may be brought under [the Declaratory Judgment Act] . . . *unless*" the patent owner declines to sue the ANDA applicant 45 days after it gives notice of filing a paragraph IV certification. *Id.* (emphasis added); *see* 35 U.S.C. § 271(e)(5). No such initiation-focused mandatory language is found in the forfeiture provision at issue here. The contrast is significant.

Indeed, it would be surprising to find an entry-into-court prerequisite in the forfeiture provision, given how the forfeiture provision is plainly intended to operate. The only role to be played by the declaratory-judgment action referred to

in § 355(j)(5)(D)(i)(I)(bb)(AA) is a role played at the *end* of the action—a "final decision" in the defined sense of completing as-of-right appeals—namely, forfeiture no earlier than 75 days after that event. The provision does not give the mere filing of the action any effect. It makes no sense, where not compelled by the text or context, to give the provision an interpretation extraneous to its evident function.

Moreover, Mylan's view that tentative approval is required for a second filer to be "that applicant" under (AA) would, for all we can tell, have to apply even when, as (AA) expressly contemplates, the patent owner brings "an infringement action . . . against that applicant." For reasons we have noted, such as preventing immediate approval of an ANDA and triggering a 30-month delay in the effectiveness of any approval, § 355(j)(5)(B)(iii), it is commonplace and expected that the patent owner will bring an infringement action under 35 U.S.C. § 271(e)(2) within 45 days of receiving notice of the ANDA, well before any tentative approval. It appears that, under Mylan's "that applicant" view, such a suit, even when the second filer wins, would fall outside the (AA) provision at issue here and thus not have any forfeiture effect. Mylan has not shown us why that result is a sensible one. Indeed, in that instance, where the second filer has been responsible for winning a contested invalidity or non-infringement ruling, it would be the second filer that conferred the public benefit that Mylan has touted before us: clearing the particular patent from the field of potential competition.

Not only does it make no sense to read the forfeiture provision as requiring tentative approval at

the outset of the second filer's declaratory-judgment action. It makes good sense to read the provision as providing for forfeiture simply when there has been no entry 75 days after the non-infringement finality date and the date of tentative approval. That reading serves the evident congressional policy of triggering forfeiture when a second filer is ready to launch. *See* 149 Cong. Rec. 31,200 (2003) (statement of Sen. Schumer) ("If it forfeits, then the exclusivity is lost and any other generic applicant that is ready to be approved and go to market can go.").

Tentative approval is required before a second filer can actually trigger forfeiture, because exclusivity should not be lost unless the second filer is on the verge of having an approved product to deliver the benefits of competition. It would be arbitrary, in terms of the discernible policy, to require tentative approval earlier. Thus, for this case, the purpose of requiring tentative approval has nothing to do with Apotex's approval status at the time it brought the declaratory-judgment action, and it has everything to do with its approval status when forfeiture is triggered. Our interpretation—the 75-day clock for Mylan starts to run when Apotex has both tentative approval and a no-longer appealable judgment of non-infringement—fits the concrete function of the provision, whereas Mylan's does not.

Mylan argues that its view is required by the statutory policy underlying the exclusivity period. But its argument is too detached from the particulars of the statute. The exclusivity period, § 355(j)(5)(B)(iv), rests on a balancing of interests: encouraging early entry by generics into the market by providing a

reward to first filers (substantially higher prices for a time and a first-mover advantage, *see Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 n.6 (D.C. Cir. 1998)), but only up to a point (as that reward creates higher prices for consumers, *see Teva*, 595 F.3d at 1318). There is no a priori right balance. We must look to what Congress enacted—specifically, the MMA provisions that reset the statutory balance. *See Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005) ("Because the balance struck between these competing goals is quintessentially a matter for legislative judgment, the court must attend closely to the terms in which the Congress expressed that judgment."). Here, as we have explained, when Mylan lost its case regarding the '599 patent, it lost its right to invoke that patent to support an exclusivity period. And there is no evident "policy" supporting maintenance of that period based on the '703 patent once (it is 75 days after) Apotex secures a no-longer-appealable judgment of noninfringement, no matter how quick and easy the litigation, and has tentative approval, whenever that occurs.

The decision by the D.C. Circuit in *Teva v. Sebelius* is not contrary to our interpretation of "tentative approval" and its role in (bb)(AA). 595 F.3d at 1317–18. That case addressed whether an NDA holder's unilateral request to the FDA to delist a patent, if granted by the FDA, could terminate a first filer's eligibility for exclusivity under subparagraph (CC) of § 355(j)(5)(D)(i)(I)(bb)—without any judicial involvement, and indeed without a disclaimer of the patent. 595 F.3d at 1315. The court read the language of (CC), which provides for forfeiture upon the "withdrawal" of an Orange Book listing by the NDA

holder, as of a piece with subparagraphs (AA) and (BB), which specify judicial actions as prerequisites for the causing of a "failure to market" forfeiture. *Id.* at 1317–18. So read, the *Teva* court held, (CC) did not authorize forfeiture of the exclusivity period by unilateral action of the NDA holder (even with FDA ratification) without judicial involvement. In the present case, in contrast, the forfeiture Apotex seeks to produce is not to be effected by Daiichi's unilateral action but by a court judgment.

The *Teva* rationale does not carry over to curtail the forfeiture effects prescribed by (AA) and (BB), which require judicial involvement and which were not invoked as forfeiture bases in *Teva*. The D.C. Circuit in *Teva* did not say that forfeiture is rendered unavailable, even with judicial involvement, just because the NDA holder/patent owner has agreed to non-infringement. Indeed, (BB) expressly provides for forfeiture based on a "settlement order or consent decree" signed by a court where the judgment includes a non-infringement or invalidity finding. As a statutory matter, the judicial role is key in distinguishing two situations, both of which may involve an NDA holder/patent owner that has given up on one of its patents.

CONCLUSION

For the foregoing reasons, we hold that Apotex has alleged facts supporting the conclusion "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." *MedImmune*, 549 U.S. at 127 (internal quotation marks and citation omitted). We reverse the

judgment of the district court dismissing the case, as well as the denial of Mylan's motion to intervene.

REVERSED

Appendix B

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Nos. 2014-1282, -1291

APOTEX INC.,

Plaintiff-Appellant,

v.

DAIICHI SANKYO, INC., DAIICHI SANKYO CO., LTD.,

Defendants- Appellee,

v.

MYLAN PHARMACEUTICALS INC.

Movant-Cross-Appellant.

Filed: June 8, 2015

ORDER

Before PROST, Chief Judge, NEWMAN, MAYER, LOURIE, CLEVENGER, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN and Hughes, Circuit Judges.*

PER CURIAM

Cross-Appellant Mylan Pharmaceuticals Inc. filed a combined petition for panel rehearing and rehearing en banc. Appellees Daiichi Sankyo, Inc., and Daiichi

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* Circuit Judges Mayer and Clevenger participated only in the decision on the petition for panel rehearing.

Sankyo Co., Ltd. also filed a combined petition for panel rehearing and rehearing en banc. Both petitions were referred to the panel that heard the appeal, and thereafter the petitions for rehearing en banc were referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petitions for panel rehearing are denied.

(2) The petitions for rehearing en banc are denied. The mandate of the court will issue on June 15, 2015.

June 8, 2015
Date

FOR THE COURT

/s/Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court

Appendix C

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

No. 1:12-cv-9295

APOTEX INC.,

Plaintiff,

v.

DAIICHI SANKYO, INC., DAIICHI SANKYO CO., LTD.,

Defendants.

Filed: January 9, 2014

MEMORANDUM OPINION AND ORDER

The defendants Daiichi Sankyo Co. Ltd. and Daiichi Sankyo, Inc. (collectively "Daiichi") listed United States Patents Nos. 6,878,703 (the "'703 Patent") and 5,616,599 (the "'599 Patent") in connection with their new drug Benicar, consisting of olmesartan medoxomil. Daiichi Sankyo, Co., Ltd. is a Japanese pharmaceutical company and the parent company to Daiichi Sankyo., Inc. This case involves Plaintiff Apotex, Inc.'s ("Apotex") efforts to obtain the Food and Drug Administration's ("FDA") approval to market a generic version of Daiichi's Benicar drug. Apotex seeks a declaratory judgment of noninfringement of the '703 Patent. Pursuant to Fed. R. Civ. P. 12(b)(1), Daiichi moves to dismiss Apotex's

amended complaint for lack of subject matter jurisdiction. For the following reasons, Daiichi's motion to dismiss is granted in its entirety.

Background

I. *Statutory Framework*

The Hatch-Waxman Act (the "Act") governs the FDA's approval process for prescription drugs. The Act was created to "'strike a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.'" *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008) (citing *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002)). Pursuant to the Act, brand-name (or "pioneering") pharmaceutical companies seeking to market new, previously unapproved drugs are required to file a New Drug Application ("NDA") with the FDA. *Seattle Children's Hosp. v. Akorn, Inc.*, No. 10-CV-5118, 2011 U.S. Dist. LEXIS 145998 at *2 (N.D. Ill. Dec. 20, 2011); *see also* 21 U.S.C. § 355(a), (b). As part of the NDA process, a pioneering drug company must submit information regarding the new drug's safety and efficacy obtained from clinical trials. 21 U.S.C. § 355(b)(1). The pioneering drug company must also provide the FDA with information including "all patents covering its drug or the methods of using the drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.'" *Caraco Pharm. Labs.*, 527 F.3d at 1282 (citing 21 U.S.C. § 355 (b)(1), (c)(2)). The FDA lists these patents

provided by the drug company in a publication called the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 USC § 355(j)(2)(A)(i). Drugs approved by the FDA are known as "listed drugs." *Id.*

To encourage the development of generic versions of listed drugs, the Hatch-Waxman Act provides for an expedited and far cheaper approval process for generic versions of patented drugs to enter the market. This process is known as the "Abbreviated New Drug Application" ("ANDA"). *Caraco Pharm. Labs.*, 527 F.3d at 1282. Under the ANDA process, generic drug companies are not required to conduct their own independent clinical trials to prove the safety and efficacy of their drugs. 21 U.S.C. § 355(j)(2)(A)(iv). Instead generic drug companies can rely on the research of a pioneering pharmaceutical company so long as the generic drug company demonstrates that its generic drug product is the "bioequivalent" to a NDA listed drug. *Id.* An ANDA applicant must also submit one of four certifications addressing each of the patents listed in the Orange Book that cover the relevant listed drug. 21 U.S.C. §355(j)(2)(A)(vii). Specifically the ANDA filer must certify that either: (I) no patent information has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a particular date and approval of the ANDA should be deferred until expiration; or (IV) in the opinion of the ANDA applicant, the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. *Seattle Children's Hosp.*, 2011 U.S. Dist. LEXIS 145998 at *3. A certification that an Orange-Book-listed patent is invalid or not infringed is commonly known as a "Paragraph IV" certification.

Where an ANDA contains a Paragraph IV certification, the timing of approval depends on two events: (i) whether the holder of the listed patent brings an infringement suit within 45 days of receiving notice of the ANDA filing, and (ii) whether the company seeking approval was the first to file an ANDA with a Paragraph IV certification to the listed patent. *Id*. at *4; *see also* 21 USC 355(j)(5)(B)(iii).

The Hatch-Waxman Act provides that the mere act of filing a Paragraph IV ANDA for a listed drug constitutes an act of patent infringement. *Caraco Pharm. Labs.*, 527 F.3d at 1283. If a patentee or NDA holder does not bring suit within 45 days of receiving notice of a Paragraph IV certification filing, the FDA will approve the ANDA immediately. If the pioneering drug company does bring suit within 45 days, the FDA may not approve the ANDA for 30 months, unless a court decides that the patent(s)-in-suit are invalid or not infringed. *Seattle Children's Hosp*., 2011 U.S. Dist. LEXIS 145998 at *4. Where a generic company is the first to file an ANDA Paragraph IV certification for a listed patent, the Hatch-Waxman Act grants that company a 180-day period of generic marketing exclusivity during which time the FDA will not approve a later filed Paragraph IV ANDA based on the same NDA. In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") which amended the Hatch-Waxman provisions governing the commencement of the 180-day exclusivity period. *Id.* at *5. After the enactment of the MMA, the exclusivity period can only be triggered by the first-filer's commercial marketing of its generic drug product. However, under the MMA, there is now a forfeiture provision. The first-filer of a

Paragraph IV ANDA may forfeit its exclusivity period if a subsequent ANDA filer obtains a final judgment of invalidity or noninfringement. *Id.*

II. *Factual Background*

Daiichi holds an approved NDA for Benicar, a drug used for the treatment of high blood pressure. As part of the process for filing its Benicar NDA, Daiichi listed Patents '599 and '703 in the FDA's Orange Book in connection with its NDA No. 21-286. The first ANDA applicant to file a Paragraph IV certification for Daiichi's '599 and '703 patents was Mylan Laboratories, Ltd. ("Mylan").[1] Accordingly, Mylan is entitled to 180 days of market exclusivity regardless of whether it established that the Orange Book patents were invalid or not. *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008) (noting that "[a]ll that is required for the first Paragraph IV ANDA filer to receive the 180-day exclusivity period is that it submits a substantially complete ANDA that contains a Paragraph IV Certification"). The start of the 180- day exclusivity period can only be triggered by Mylan's marketing of its generic drug. 21 U.S.C. § 355(j)(5)(B)(iv). If however, a subsequent filer obtains a final judgment of invalidity or noninfringement, Mylan must begin marketing within 75 days or forfeit its exclusivity period. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA); *see also Seattle Children's Hosp.*, 2011 U.S. Dist. LEXIS 145998 at *5-6.

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[1] Mylan is presently not a party in this case. Mylan has moved to intervene and has filed its own motion to dismiss should this Court grant its motion to intervene.

After Mylan filed its Paragraph IV ANDA regarding both Patents '703 and '599, Daiichi sued Mylan on July 31, 2006 for infringement of the '599 patent in a district court in New Jersey. Prior to suing Mylan regarding the '599 patent, Daiichi statutorily disclaimed every claim of the '703 patent pursuant to 35 U.S.C. § 253. Eventually the district court found that the '599 patent was valid and that Mylan infringed the '599 patent. Mylan never brought a declaratory judgment action regarding the disclaimed '703 patent. In the instant case, Apotex seeks a final judgment of invalidity or noninfringement regarding the '703 patent in the hopes of compelling Mylan to begin marketing within 75 days or forfeiting its exclusivity period. Daiichi moves to dismiss Apotex's complaint for lack of subject matter jurisdiction. Daiichi argues that there is no case or controversy here because the '703 patent was disclaimed. Apotex argues that despite Daiichi's disclaimer, the '703 patent continues to exclude competition in the market because it remains listed in the FDA's Orange Book.

Legal Standard

Pursuant to Fed. R. Civ. P. 12(b)(1), a court must dismiss any action for which it lacks subject matter jurisdiction. Rule 12(b)(1) motions are premised on either facial or factual attacks on jurisdiction. *Simonian v. Oreck Corp.*, No. 10 C 1224, 2010 U.S. Dist. LEXIS 86832, at *3-4 (N.D. Ill. Aug. 23, 2010). If the defendant makes a factual attack on the plaintiff's assertion of subject matter jurisdiction, it is proper for the court to look beyond the jurisdictional allegations in the complaint and to view whatever evidence has been submitted in response to the motion. *Id.* The

plaintiff must then put forth "competent proof" that the court has subject matter jurisdiction. *NLFC, Inc. v. Devcom Mid-America, Inc.*, 45 F.3d 231, 237 (7th Cir. 1995). Federal courts have subject matter jurisdiction over declaratory judgment actions brought by Paragraph IV ANDA filers to establish noninfringement or invalidity of Orange-Book-listed patents to the extent that they present an Article III case or controversy. *Caraco Pharm. Labs.*, 527 F.3d at 1285; *see also* 31 U.S.C. § 271(e)(5). To determine whether a declaratory judgment action satisfies the Article III case or controversy requirement, the court must inquire as to "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (U.S. 2007). "[A]n action is justiciable under Article III only where (1) the plaintiff has standing, *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992), (2) the issues presented are ripe for judicial review, *Abbott Labs. v. Gardner*, 387 U.S. 136, 149, 87 S. Ct. 1507, 18 L. Ed. 2d 681 (1967), and (3) the case is not rendered moot at any stage of the litigation, *United States Parole Comm'n. v. Geraghty*, 445 U.S. 388, 397, 100 S. Ct. 1202, 63 L. Ed. 2d 479 (1980)." *Caraco Pharm. Labs.*, 527 F.3d at 1291; *see also Seattle Children's Hosp.*, 2011 U.S. Dist. LEXIS 145998, at *13.

In order to have standing, a party must demonstrate: (1) an alleged injury in fact, a harm suffered by the plaintiff that is concrete and actual or imminent; (2) causation, a fairly traceable connection

between the plaintiff's injury and the complained-of conduct of the defendant; and (3) redressability, a likelihood that the requested relief will redress the alleged injury. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008). "The Federal Circuit has recognized, in the context of the Hatch-Waxman Act, that the creation of 'an independent barrier to the drug market' by a brand drug company 'that deprives [the generic company] of an economic opportunity to compete' satisfies the injury-in-fact and causation requirements of Article III standing." *Seattle Children's Hosp. v. Akorn, Inc.*, No. 10-CV-5118, 2011 U.S. Dist. LEXIS 145998, at *15 (N.D. Ill. Dec. 20, 2011) (citing *Caraco*, 527 F.3d at 1285 and *Prasco*, 537 F.3d at 1339).

Discussion

Daiichi moves to dismiss Apotex's complaint arguing that there can be no justiciable dispute concerning a disclaimed patent. Apotex concedes that the '703 patent is no longer enforceable, but argues that it continues to exclude competition in the market and continues to have preclusive effect. (Apotex Resp. at 1 and 5). Apotex argues that because a judgment has never been entered stating that the '703 patent is invalid, the '703 patent prevents it from selling its competing generic version of the Benicar drug until the end of Mylan's 180 day exclusivity period.

The Federal Circuit has recognized that prior to the "2003 [MMA] amendments, 'NDA holders employed several methods of delaying the early resolution of patent disputes.'" *Dey Pharma, LP v. Sunovion Pharms., Inc.*, 677 F.3d 1158, 1160 (Fed. Cir. 2012) (citing *Janssen Pharmaceutica, N.V. v. Apotex*,

Inc., 540 F.3d 1353, 1357 (Fed. Cir. 2008). In some cases where NDA patent holders listed multiple patents in the FDA's Orange Book, NDA holders developed a strategy where they would initiate suit on only one of the patents after receiving notice of a Paragraph IV ANDA filing. This would entitle the NDA holder to a 30-month stay before FDA approval of the generic drug. Moreover, even if the one patent sued on was found invalid or not infringed by the generic drug, the ANDA filer would still run the risk of infringing on the other patents implicated, but not sued on by the NDA holder. "To address this problem Congress specified that an ANDA filer who is not sued within 45 days could bring a declaratory judgment action under 28 U.S.C. § 2201 against the NDA holder." *Dey Pharma*, 677 F.3d at 1160-1161 (citing 21 U.S.C. § 355(j)(5)(C)). These amendments also protect subsequent ANDA filers' interest in the early resolution of patent rights due to the 180-day exclusivity period afforded successful first ANDA filers. "If the first ANDA filer 'parked' its 180-day exclusivity under an agreement with the brand-name company, a subsequent ANDA filer could independently trigger the first filer's exclusivity period through a declaratory judgment action leading to a final judgment of invalidity or noninfringement, thereby accelerating the second ANDA filer's ability to market its drug." *Dey Pharma*, 677 F.3d at 1160-1161.

Here, Patent '703 does not create an independent barrier that deprives Apotex of an economic opportunity to compete. Because Daiichi disclaimed all claims associated with the '703 Patent pursuant to 35 U.S.C. § 253, both Daiichi and Apotex no longer hold any meaningful interest in the now disclaimed

patent. "Disclaiming particular claims under § 253 'effectively eliminate[s] those claims from the original patent.'" *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1299 (Fed. Cir. 2011) (*citing Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998)). "In other words, upon entry of a disclaimer under § 253, we treat the patent as though the disclaimed claim(s) had 'never existed.'" *Genetics Inst.*, 655 F.3d at 1299; *see also Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996). Apotex concedes that the '703 patent was statutorily disclaimed and does not dispute the effects of such a disclaimer. Nevertheless, Apotex argues that this Court must still decide whether its generic drug infringes on the non-existent '703 patent because the patent remains listed in the Orange Book. Daiichi, however, requested that the FDA delist the '703 Patent on July 11, 2006. It is unclear why the FDA has yet to actually remove the patent from the Orange Book.

Apotex relies on *Caraco Pharm. Labs.*, 527 F.3d 1278, to support its argument that there is jurisdiction where a first ANDA filer has not begun its exclusivity period and a subsequent ANDA filer seeks a declaratory judgment of noninfringement to eliminate an independent barrier to regulatory approval. *Caraco*, however, is distinguishable from the case at hand by the important fact that the patent at issue in that case was never disclaimed. The Federal Circuit held that by preventing the FDA from approving ANDAs of generic drug manufacturers, the NDA holder was effectively excluding *Caraco* from offering what it claimed to be a non-infringing generic drug. Unlike *Caraco*, there is no such exclusion in the

instant case. Daiichi is not preventing the FDA from approving Apotex's ANDA through any delay tactics or strategies similar to the NDA holder's covenant not to sue in *Caraco*. Moreover, all parties acknowledge that Daiichi can never assert the '703 patent against any ANDA filer or any entity as the patent no longer exists by virtue of Daiichi's disclaimer of all claims associated with the patent. The mere fact that the FDA has failed for some reason to delist Patent '703, despite Daiichi's request, does not create a case or controversy by which Apotex may seek a declaratory judgment regarding a nonexistent patent. Daiichi disclaimed Patent '703 and properly requested that the Orange Book be updated to reflect Daiichi's disclaimer. Although in *Seattle Children's Hosp*., 2011 U.S. Dist. LEXIS 145998, the court held that notwithstanding an NDA holders unilateral covenant not to sue, a case or controversy continued to exist between the parties because of the continued listing of the patent in the FDA's Orange Book; in that case, again, the listed patent was never disclaimed. Accordingly, in that case, the patent actually served as an independent barrier to the approval of the defendant's ANDA. Here, the '703 patent continues to be listed, by no error on Daiichi's part, even though the patent was disclaimed. This is insufficient to meet the case and controversy standing requirements under Article III.

Conclusion

For the foregoing reasons, Daiichi's motion to dismiss is granted in its entirety. Given this Court's ruling granting Daiichi's motion to dismiss, non-party Mylan's motions are moot.

IT IS SO ORDERED. /s/Sharon Johnson Coleman

Date: January 9, 2014

Sharon Johnson Coleman
United States
District Judge

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

No. 12-cv-09295

APOTEX INC.,

Plaintiff,

v.

DAIICHI SANKYO, INC., DAIICHI SANKYO CO., LTD.,

Defendants.

Filed: February 12, 2013

AMENDED COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Apotex Inc. ("Apotex"), through counsel, hereby brings its Amended Complaint for Declaratory Judgment against Daiichi Sankyo, Inc. and Daiichi Sankyo Co., Ltd. (collectively "Daiichi"), and alleges as follows:

INTRODUCTION

1. This is a declaratory judgment action seeking a declaration of non-infringement of United States Patent No. 6,878,703 ("the '703 patent") to enable Apotex to bring its generic olmesartan medoxomil tablets in dosages of 5 mg, 20 mg, or 40 mg to market at the earliest possible date under the applicable statutory and FDA regulatory provisions and to allow

the public to enjoy the benefits of generic competition for these products.

THE PARTIES

2. Apotex Inc. is a Canadian corporation having its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

3. On information and belief, Daiichi Sankyo, Inc. is a Delaware corporation with its principal place of business at Two Hilton Court, Parsippany, New Jersey 07054 and has a registered agent for service of process in Illinois, National Registered Agents Inc., located at 200 West Adams Street, Chicago, Illinois 60606.

4. On information and belief, Daiichi Sankyo Co., Ltd. was formed as the result of a merger between Daiichi Pharmaceutical Co., Ltd. and Sankyo Co., Ltd.

5. On information and belief, Daiichi Sankyo Co., Ltd., is a Japanese corporation having its principal place of business at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan.

6. On information and belief, Daiichi Sankyo Co., Ltd is the parent company of Daiichi Sankyo, Inc. and Daiichi Sankyo, Inc. operates as the U.S. headquarters of Daiichi Sankyo, Co., Ltd.

JURISDICTION AND VENUE

7. This Complaint arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984 (codified as

amended at 21 U.S.C. § 355)) (hereinafter "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 17 Stat. 2066 (2003) ("hereinafter "MMA"), based upon an actual controversy between the parties to declare that Apotex is free, upon approval by the FDA, to manufacture, use, market, sell, offer to sell, and/or import its proposed Apotex's ANDA Product as described in the ANDA upon the expiration of the '599 patent and any applicable pediatric exclusivity.

8. This Court has original jurisdiction over the subject matter of these claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Upon information and belief, Daiichi Sankyo Inc. is the U.S. subsidiary of Daiichi Sankyo Co. Ltd. that sells pharmaceutical products manufactured by Daiichi Sankyo Co. Ltd. in the U.S. and in this judicial district, and "forms the nucleus" of Daiichi Sankyo Co. Ltd.'s U.S. Operations. *See* website of Daiichi Sankyo Co., Ltd. attached hereto as **Exhibit A.**

10. This Court has personal jurisdiction over Daiichi Sankyo Inc. because it has designated an agent in this district for service of process. On information and belief, Daiichi Sankyo also has a regular and established regional sales office in the Chicago area and employs sales agents in Chicago to sell its pharmaceutical products in the Northern District of Illinois. *See* website of Daiichi Sankyo, Inc., attached as **Exhibit B.**

11. This Court has personal jurisdiction over Daiichi Sankyo Inc. and Daiichi Sankyo Co., Ltd. at least because of their continuous and systematic

contacts with the state of Illinois, including conducting of substantial and regular business therein through marketing and sales of pharmaceutical products in Illinois including but not limited to the olmesartan medoxomil products.

12. This Court has personal jurisdiction over Daiichi Sankyo Inc. because Daiichi Sankyo Inc., upon information and belief, directly or indirectly markets and sells pharmaceutical products throughout the United States and in this judicial district. Upon information and belief, Daiichi Sankyo Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a destination of Daiichi Sankyo Inc.'s pharmaceutical products. Upon information and belief Daiichi Sankyo Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction.

13. This court has personal jurisdiction over Daiichi Sankyo Co., Ltd. because, upon information and belief, Daiichi Sankyo Co., Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products and directly, or through its wholly-owned subsidiaries, manufactures, markets and sells pharmaceutical drug products throughout the United States and in this judicial district. Upon information and belief, Daiichi Sankyo Co., Ltd has previously submitted to the jurisdiction of this Court and has further availed itself of this Court by filing suit in this jurisdiction.

14. Venue is proper in this District under 28 U.S.C. §§ 1391 (b), (c), 1400 (b) and/or 21 U.S.C. §355.

PATENT IN SUIT

15. On its face the '703 patent entitled "Pharmaceutical Composition" indicates it was issued by the United States Patent and Trademark Office on April 12, 2005. A copy of the '703 patent is attached as **Exhibit C**.

16. According to the records at the United States Patent and Trademark Office, Sankyo Company, Limited is the assignee of the '703 patent.

17. On information and belief, Daiichi Sankyo Co., Ltd. was the successor in interest to the '703 patent after the merger between Daiichi Pharmaceutical Co., Ltd. and Sankyo Co., Ltd.

18. On July 11, 2006, the term of every claim of the '703 patent was disclaimed. *See* Disclaimer, dated 7/11/06, attached hereto as **Exhibit D**.

19. On April 12, 2009, the '703 patent expired for failure to pay maintenance fees. *See* United States Patent and Trademark Record, attached hereto as **Exhibit E**.

BACKGROUND

20. In December 2003, Congress passed the Medicare Modernization Act of 2003 ("MMA"). Title XI of that Act entitled "Access to Affordable Pharmaceuticals," which included a provision allowing an ANDA applicant to bring a declaratory judgment action for invalidity or non-infringement of an Orange Book listed patent if the NDA holder does not sue within 45 days of receiving notice of a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(C).

21. The MMA also added forfeiture provisions for the 180-day exclusivity to which a first generic ANDA

filer might otherwise be entitled pursuant to the Hatch Waxman Act. 21 U.S.C. §355 (j)(5)(D). The forfeiture provision at issue here requires, *inter alia*, the entry of a judgment of non-infringement, unenforceability or invalidity with respect to the patents against which a first ANDA filer has filed a Paragraph IV certification, regardless of whether those patents are asserted against subsequent ANDA filers. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

22. Upon information and belief, Daiichi Sankyo Inc. is the current holder of approved New Drug Application ("NDA") No. 21-286 for Benicar® tablets containing olmesartan medoxomil 5 mg, 20 mg, and 40 mg tablets.

23. Daiichi identified the '703 patent along with United States Patent No. 5,616,599 ("the '599 patent") to the Food and Drug Administration ("FDA") for listing in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"), as patents to which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" products containing olmesartan medoxomil 5 mg, 20 mg, and 40 mg tablets ("olmesartan medoxomil products").

24. The '599 and '703 patents remain listed in the Orange Book with respect to NDA No. 21-286 and Daiichi maintains and continues to represent to the public that the '703 patent claims the drug approved in NDA 21-286 or a method of using that drug, and that a claim of patent infringement could reasonably be asserted against any unlicensed ANDA applicant who attempts to market a generic version of the drug

prior to the delisting of the '703 patent. The FDA Orange Book also lists a six month pediatric exclusivity for the '599 patent, which upon information and belief will prevent ANDA filers from obtaining final FDA marketing approval for its generic olmesartin medoxomil product until six months after the expiration of the '599 patent.

25. According to Orange Book listings, Benicar®, or treatments using Benicar® are claimed in the '703 patent.

26. Apotex has submitted an Abbreviated New Drug Application ("ANDA") 204089 for a proposed drug product containing 5 mg, 20 mg, or 40 mg olmesartan medoxomil ("Apotex ANDA Product"). Apotex's ANDA seeks FDA approval for the commercial manufacture, use, importation, offer for sale and sale of generic olmesartan medoxomil 5 mg, 20 mg, and 40 mg tablets.

27. Apotex filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") certifying that the '703 patent will not be infringed by the manufacture, use, or sale of the Apotex's ANDA Product.

28. In accordance with 35 U.S.C. §§355(j)(2)(B) and 21 C.F.R. § 314.95, Apotex, on or about June 12, 2012, served Daiichi with a Notice Letter informing Daiichi of Apotex's ANDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of the Apotex's ANDA Product before the expiration of the '703 patent. Apotex's Notice Letter included a Paragraph IV certification, that the '703 patent would not be infringed by the manufacture, use, or sale of Apotex's ANDA Product

because the '703 patent expired in 2009 and the term of every claim had been disclaimed in 2007.

29. Apotex desires to bring its generic olmesartan medoxomil tablets in dosages of 5 mg, 20 mg, or 40 mg to market and to allow the public to enjoy the benefits of generic competition for these products at the earliest possible date under the applicable statutory and FDA regulatory provisions.

30. On information and belief, the earliest possible date that Apotex can obtain final FDA marketing approval for its ANDA Product is upon the expiration of the '599 patent and any applicable pediatric exclusivity. However, unless more than 75 days before the expiration of the '599 patent and any applicable pediatric exclusivity, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the '703 patent is invalid or not infringed, Apotex will not be able begin marketing its ANDA Product upon the expiration of the '599 patent and any applicable pediatric exclusivity.

31. Upon information and belief, Matrix Laboratories Limited ("Matrix"), now Mylan Laboratories Limited ("Mylan"), was the first generic ANDA applicant to have filed a Paragraph IV certification against both the '599 and '703 patents with respect to olmesartan medoxomil tablets 5 mg, 20 mg, and 40 mg, challenging, *inter alia*, the validity of both patents. Daiichi filed suit against Matrix in the District of New Jersey for patent infringement, alleging that Matrix infringed the '599 patent, but on information and belief did not assert the '703 patent against Matrix in that lawsuit. Matrix failed in its

Paragraph IV challenge to the validity of the '599 patent, and in 2010, the Federal Circuit affirmed the validity of the '599 patent in *Daiichi Sankyo Co. v. Matrix Labs.*, 619 F.3d 1346 (Fed. Cir. 2010).

32. Because Matrix failed in its attempt to have the '599 patent held invalid, Matrix's Paragraph IV certification with respect to that patent converted to a Paragraph III certification, which requires Mylan to wait until the expiration of the '599 patent and any applicable pediatric exclusivity before it can market its generic olmesartan products.

33. On information and belief, despite Matrix's failure to invalidate the '599 patent, Mylan retains a 180-day first generic applicant exclusivity by virtue of Matrix's Paragraph IV certification against the '703 patent. As such, the FDA will be prohibited from granting final approval to Apotex to market its olmesartan medoxomil tablets 5 mg, 20 mg, and 40 mg upon the expiration of the '599 patent and any applicable pediatric exclusivity, unless more than 75 days before the expiration of the '599 patent and any applicable pediatric exclusivity, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the '703 patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA). As such, unless the Court first declares the '703 patent invalid, unenforceable or not infringed by Apotex's ANDA Product, Apotex will be prohibited from selling its product until 180 days after Mylan chooses to market its olmesartan medoxomil tablets 5 mg, 20 mg, and 40 mg generic product, thereby injuring Apotex by depriving it of sales revenue for that period of time and

injuring the public by depriving the public of the benefit of the generic competition that would otherwise be provided by Apotex's ANDA product.

34. On information and belief, no court has entered the "final decision" identified in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) with respect to the '703 patent. Upon information and belief, no court has entered a final decision from which an appeal has been or can be taken that the '703 patent is invalid or not infringed.

35. On information and belief, no court has signed a "settlement order or consent decree" identified in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB) that enters final judgment which includes a finding that the '703 patent is invalid or not infringed.

COUNT 1

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '703 PATENT

36. Apotex repeats and realleges each of the allegations in paragraphs 1-35 as if fully set forth herein.

37. Because the '703 patent has expired for failure to pay maintenance fees and every claim was disclaimed, the manufacture, marketing, use, offer for sale, sale and/or importation of the product that is the subject of Apotex's ANDA No. 204089 will not directly infringe, induce or contribute to the infringement by others of the claims of the '703 patent, nor are the claims of the '703 patent being infringed by the filing of Apotex's ANDA 204089.

38. There is a substantial and continuing controversy between Daiichi and Apotex and a

declaration of rights is both necessary and appropriate to establish that Apotex does not infringe any valid or enforceable claim of the '703 patent and allow it to bring its ANDA product to market upon the expiration of the '599 patent and any applicable pediatric exclusivity.

39. But for Daiichi's decision to list the '703 patent in the Orange Book, FDA approval of Apotex's ANDA would not have been independently delayed by that patent. Apotex is being injured by Daiichi's actions of requesting the FDA to list the '703 patent in the FDA Orange Book and continuing said listing in the FDA Orange Book.

40. Apotex's injury can be redressed by the requested relief: a declaratory judgment of noninfringement would trigger first applicant Mylan's exclusivity period, which otherwise will block final FDA marketing approval of Apotex's ANDA even after the expiration of the '599 patent and any applicable pediatric exclusivity. If Apotex is blocked by Mylan's first applicant exclusivity, Apotex will be monetarily harmed, as it will lose sales of its ANDA product by virtue of not being able to enter the market at the earliest possible date under the applicable statutory and FDA regulatory provisions, and be deprived of an economic opportunity to compete in the market for olmesartan medoxomil 5 mg, 20 mg, and 40 mg tablets.

PRAYER FOR RELIEF

WHEREFORE, Apotex respectfully requests the Court to enter judgment as follows:

A. Declaring that the claims of the '703 patent have not been infringed by the filing of Apotex's ANDA 204089;

B. Declaring that the manufacture, marketing, use, offer for sale, sale and/or importation of the products that are the subject of Apotex's ANDA 204089 have not infringed, do not infringe, and would not, if marketed, infringe or induce or contribute to the infringement by others of any claims of the '703 patent;

C. Declaring that the Food & Drug Administration may approve Apotex's Abbreviated New Drug Application (No. 204089) concerning olmesartan medoxomil 5 mg, 20 mg, and 40 mg tablets whenever that application is otherwise in condition for approval, without awaiting any further order, judgment, or decree of this Court; that the judgment entered in this case is a judgment reflecting a decision that the patent in suit is not infringed pursuant to 21 U.S.C. § 355 (j)(5)(B)(iii)(I)(aa); and that the thirty-month period referred to in 21 U.S.C. § 355(j)(5)(B)(iii) and any other marketing exclusivity periods to which Plaintiffs might otherwise be entitled (including any pediatric exclusivity) with respect to the '703 patent are shortened to expire upon the date of entry of judgment in this case;

D. Awarding Apotex its costs, expenses and reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

E. Awarding Apotex such other relief that the Court deems just and proper under the circumstances.

Respectfully submitted,

HUSCH BLACKWELL LLP

21 U.S.C. §355(j) EXCERPTS

(iv) 180-day exclusivity period

(I) Effectiveness of application

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) Definitions

In this paragraph:

(aa) 180-day exclusivity period

The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant

As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a

certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application

As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval

(AA) In general

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(D) Forfeiture of 180-day exclusivity period

(i) Definition of forfeiture event

In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(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 approval of the application of the first applicant is made effective under subparagraph (B)(iii); 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, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action

brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), 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 information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.