No.

In the Supreme Court of the United States

DAIICHI SANKYO, INC., AND DAIICHI SANKYO CO., LTD.,
PETITIONERS

v.

APOTEX, INC.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether an action seeking a declaration that a patent would not be infringed presents a justiciable case or controversy under Article III of the Constitution where the patent at issue was previously disclaimed and thus cannot be enforced.

CORPORATE DISCLOSURE STATEMENT

Petitioner Daiichi Sankyo, Inc., is an indirect subsidiary of petitioner Daiichi Sankyo Co., Ltd., a publicly held company. Daiichi Sankyo Co., Ltd., has no parent corporation, and no publicly held company owns 10% or more of its stock.

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Daiichi Sankyo, Inc., and Daiichi Sankyo Co., Ltd., respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-29a) is reported at 781 F.3d 1356. The memorandum opinion and order of the district court granting petitioners' motion to dismiss (App., *infra*, 32a-42a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on March 31, 2015. Petitioners' petition for rehearing was denied on June 8, 2015 (App., *infra*, 30a-31a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant provisions of the Drug Price Competition and Patent Term 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 in the appendix to this petition (App., *infra*, 43a-72a).

STATEMENT

This petition presents the important question whether, under Article III of the Constitution, a party may invoke the jurisdiction of the federal courts to obtain a declaration that a patent would not be infringed where the patent was previously disclaimed and thus cannot be enforced. The plaintiff in this case, a generic drug manufacturer, brought a declaratory-judgment action against a brand-name drug manufacturer, seeking a declaration that a patent the brand-name manufacturer had previously disclaimed would not be infringed by a generic version of the brand-name manufacturer's drug. The generic manufacturer did not bring suit because it was concerned that the brand-name manufacturer would sue it for infringement of the disclaimed patent; indeed, the brand-name manufacturer had specifically confirmed it could not and would not bring suit. Instead, the generic manufacturer brought suit in order to set in motion a chain of events that might cause *another* generic manufacturer to forfeit its statutory right to a 180-day period of market exclusivity for its generic version of the drug.

Article III of the Constitution does not permit a party to seek a declaration of non-infringement of a patent that cannot be enforced—and, in fact, is treated as if it had never existed. That is because, as a result of the disclaimer of the patent, there are no legal rights in the patent and thus no dispute between the parties for an Article III court to resolve. Because the Federal Circuit erred in permitting this action to proceed, the petition for a writ of certiorari should be granted.

A. Background

1. The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) seeks to balance the need for incentives to develop new drugs with the desire to facilitate the availability of lower-priced generic drugs. The Hatch-Waxman Act allows a generic drug manufacturer to "piggy-back on the * * * approval efforts" of a brand-name manufacturer by permitting it to obtain expedited approval from the Food and Drug Administration (FDA) for a generic version of the drug without a lengthy and costly drug development process. *FTC* v. *Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013). Whereas a brand-name manufacturer must file a full-fledged new drug application (NDA), involving costly and time-intensive clinical trials and testing, a generic manufacturer may obtain expedited approval by filing an abbreviated new drug application (ANDA), in which it need only show that its proposed generic drug is bioequivalent to the brand-name version. 21 U.S.C. 355(j)(2).

While the Hatch-Waxman Act lowered regulatory barriers to entry for generic drug manufacturers, it also created an "important new mechanism" for the resolution of patent disputes before FDA grants approval for the generic drug. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676-677 (1990). The Hatch-Waxman Act re-

quires brand-name drug manufacturers to report to FDA all patents that "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of [an approved] drug." 21 U.S.C. 355(b)(1). FDA publicly lists those patents in a database called Approved Drug Products with Therapeutic Equivalence Evaluations—colloquially known as the "Orange Book." *Caraco Pharmaceutical Laboratories, Inc.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).

A generic drug manufacturer that files an ANDA is required to certify (1) that no patent listed in the Orange Book covers the generic drug it seeks to market; (2) that any such patent has expired; (3) that any such patent will expire before the manufacturer markets the generic drug; or (4) that any such patent is invalid or would not be infringed by the generic drug. 21 U.S.C. 355(j)(2)(A)(vii)(I)-(IV). The latter two certifications are known as "paragraph III" and "paragraph IV" certifications, respectively.

The Hatch-Waxman Act treats the submission of an ANDA with a paragraph IV certification as an act of patent infringement. 35 U.S.C. 271(e)(2)(A). Upon receipt of notification of a paragraph IV filing, the patentee must file a patent-infringement action against the generic drug manufacturer within 45 days in order to stay FDA's approval of the generic drug. 21 U.S.C. 355(j)(5)(B)(iii). If the patentee does not sue, the generic manufacturer may "obtain patent certainty" by filing an action of its own seeking a declaration that the patent is invalid or would not be infringed. 21 U.S.C. 355(j)(5)(C).

Of particular relevance here, the Hatch-Waxman Act provides an incentive for generic drug manufacturers to challenge listed patents, potentially enabling generic drugs to reach the market more quickly. The first generic manufacturer to file an ANDA that makes (and

maintains) a paragraph IV certification is entitled to a 180-day period of market exclusivity for its generic version against those of other generic manufacturers, as long as the patent remains listed in the Orange Book. 21 U.S.C. 355(j)(5)(B)(iv). As this Court has recognized, that exclusivity period is a powerful incentive that can be worth hundreds of millions of dollars. See *Actavis*, 133 S. Ct. at 2229.

At the same time, a first-filing generic drug manufacturer's right to exclusivity is not absolute: the manufacturer may forfeit that right as a result of a number of "forfeiture event[s]," including a "[f]ailure to market." 21 U.S.C. 355(j)(5)(D)(i). A failure to market may occur when a later-filing generic manufacturer obtains a judgment of invalidity or non-infringement for each patent against which the first-filing generic manufacturer lawfully maintains a paragraph IV certification. 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(AA). In that event, once the judgment has become final and the later-filing generic manufacturer has obtained tentative approval for its ANDA, the first-filing generic manufacturer must enter the market within 75 days or forfeit its exclusivity. *Ibid.* A first-filing generic manufacturer thus cannot delay its competitors' market entry by "parking" its ANDA and not using it.

2. Petitioners are the patentee and NDA holder for Benicar®, which is used for the treatment of high blood pressure. Consistent with their statutory obligation, petitioners initially reported to FDA two patents related to Benicar: U.S. Patent No. 5,616,599 (the '599 patent) and U.S. Patent No. 6,878,703 (the '703 patent). FDA thereafter listed both patents in the Orange Book. App., *infra*, 2a-3a.

In 2006, Mylan Pharmaceuticals filed the first ANDA for a generic version of Benicar. Mylan included para-

graph IV certifications with respect to both the '599 and '703 patents. Petitioners sued Mylan for infringement of the '599 patent. Petitioners prevailed on both validity and infringement, and the decision was affirmed on appeal. See *Daiichi Sankyo Co.* v. *Mylan Pharmaceuticals Inc.*, 670 F. Supp. 2d 359 (D.N.J. 2009), aff'd, 619 F.3d 1346 (Fed. Cir. 2010), cert. denied, 562 U.S. 1286 (2011). Because petitioners prevailed, Mylan converted its paragraph IV certification against the '599 patent into a paragraph III certification. As matters currently stand, therefore, Mylan (along with any other prospective generic drug manufacturers) is barred from entering the market with a generic version of Benicar before petitioners' patent rights expire on October 25, 2016. App., *infra*, 3a-4a.

While petitioners asserted the '599 patent against Mylan in the wake of Mylan's ANDA filing, they disclaimed the '703 patent. See 35 U.S.C. 253. The result of the disclaimer is that the '703 patent cannot be enforced and is treated as if it never existed. See *ibid.*; *Altoona Publix Theatres* v. *American Tri-Ergon Corp.*, 294 U.S. 477, 492 (1935); *Genetics Institute, LLC* v. *Novartis Vaccines Diagnostic, Inc.*, 655 F.3d 1291, 1299 (Fed. Cir. 2011). Consistent with their disclaimer, petitioners requested that FDA delist the '703 patent from the Orange Book. Notwithstanding petitioners' request, however, FDA continues to list the '703 patent in the Orange Book. As a result, Mylan maintains its paragraph IV certification with respect to the '703 patent, even though it no longer does so with respect to the '599 patent. That certification entitles Mylan to a 180-day exclusivity period beginning on the date it first markets its ANDA product—which, because the '599 patent is valid and infringed, can be no earlier than October 25, 2016. App., *infra*, 3a-4a.

3. In 2012—over six years after Mylan filed the first ANDA for a generic version of Benicar—respondent filed an ANDA of its own. Respondent did not include a paragraph IV certification with respect to the '599 patent; instead, respondent submitted a paragraph III certification, thus conceding both that the '599 patent was valid and that it would be infringed by respondent's ANDA product. As a result, respondent acknowledged that it cannot enter the market with its ANDA product before petitioners' rights under the '599 patent expire on October 25, 2016. App., *infra*, 4a.

Respondent, however, did include a paragraph IV certification with respect to the '703 patent. In response, petitioners stated that they had disclaimed the '703 patent and therefore could not, and would not, assert it against respondent. Petitioners did not sue respondent for infringement of the '703 patent. As of the time of the decision below—and, to the best of petitioners' knowledge, to the present day—respondent has not received tentative approval from FDA for its ANDA. App., *infra*, 4a-6a.

B. Procedural History

1. On November 20, 2012, respondent sued petitioners in the United States District Court for the Northern District of Illinois, seeking a declaration that its ANDA product would not infringe the '703 patent. By respondent's own admission, the sole purpose of its suit was to eliminate Mylan's 180-day exclusivity period. Under respondent's theory, once respondent obtained tentative approval for its ANDA, a judgment of non-infringement would trigger the 75-day period in which Mylan must enter the market or forfeit its exclusivity. Because the '599 patent prevents Mylan from entering the market until October 25, 2016, respondent's strategy, if successful,

would force Mylan to forfeit the exclusivity it received as the first to challenge the '703 patent. App., *infra*, 4a-6a.

2. Petitioners moved to dismiss the complaint for lack of subject-matter jurisdiction, arguing that, because the '703 patent had been disclaimed and thus could not be enforced, there was no legal adversity between the parties and no case or controversy under Article III of the Constitution.

The district court granted petitioners' motion to dismiss. App., *infra*, 32a-42a. The court reasoned that the '703 patent "does not create an independent barrier that deprives [respondent] of an economic opportunity to compete." *Id.* at 40a. The court noted that "[respondent] concedes that the '703 patent was statutorily disclaimed and does not dispute the effects of such a disclaimer": namely, that the patent is treated "as though [it] had never existed." *Ibid.* (citation omitted). The court further noted that "all parties acknowledge that [petitioners] can never assert the '703 patent against any ANDA filer or any entity * * * by virtue of [petitioners'] disclaimer." *Id.* at 41a. For those reasons, the court explained, "both [petitioners] and [respondent] no longer hold any meaningful interest in the now disclaimed patent." *Id.* at 40a. The court added that "[t]he mere fact that the FDA has failed for some reason to delist [the '703 patent], despite [petitioners'] request, does not create a case or controversy by which [respondent] may seek a declaratory judgment regarding a nonexistent patent." *Id.* at 41a. Accordingly, the court concluded that respondent's action failed to satisfy Article III's case-or-controversy requirement. *Id.* at 42a.

3. The court of appeals reversed. App., *infra*, 1a-29a. It held that a case or controversy existed because "[respondent] has a concrete, potentially high-value stake in obtaining the judgment it seeks" and "[petition-

ers] ha[ve] a concrete, potentially high-value stake in denying [respondent] that judgment." *Id.* at 2a.

At the outset, the court of appeals correctly acknowledged that adversity between the parties was a necessary prerequisite for an Article III case or controversy. App., *infra*, 9a. The court also recognized that, by virtue of petitioners' disclaimer, they could not enforce the '703 patent. *Id.* at 10a. The court nevertheless concluded that the requisite adversity arose from "[t]he *listing* of the patent, with its current consequence of preventing FDA approval during Mylan's presumptive exclusivity period." *Ibid.* According to the court, "the parties have adverse concrete interests in the truncation or preservation of that period": specifically, their financial stakes in "the revenues to be earned through selling" their respective versions of Benicar. *Ibid.* "[B]y any common-sense measure," the court concluded, "the parties have substantial, concrete stakes in whether [respondent] secures the non-infringement judgment it seeks"—even if, as the court recognized, "non-infringement is indisputable." *Id.* at 5a, 11a. Based on those economic interests alone, the court found the requisite adversity. *Id.* at 10a-12a.

The court of appeals rejected petitioners' related argument that respondent's claimed injury was not traceable to any challenged action by petitioners because FDA, not petitioners, was responsible for the continued listing of the '703 patent in the Orange Book. App., *infra*, 12a. The court reasoned that, because petitioners had *originally* triggered the listing of the '703 patent, they were "causally responsible for the current existence of the exclusivity period." *Id.* at 14a. Similarly, the court rejected the argument that, because respondent had not yet received tentative approval from FDA for its ANDA, it was too speculative that respondent's claimed injury would be redressed by a declaratory judgment in its fa-

vor. *Ibid.* The court reasoned that "the prospect of concrete relief for [respondent]" was not "too uncertain to support an adjudication of the request for a non-infringement judgment." *Ibid.*[1]

4. The court of appeals subsequently denied petitioners' petition for rehearing without recorded dissent. App., *infra*, 30a-31a.[2]

REASONS FOR GRANTING THE PETITION

In the decision under review, the Federal Circuit held that a federal court may adjudicate an action seeking a declaration of non-infringement of a patent that was previously disclaimed, and that all parties agree cannot be enforced. Put another way, the Federal Circuit determined that a declaratory-judgment action concerning a dispute that can never be litigated presents a case or controversy under Article III of the Constitution. The Federal Circuit's holding is, to say the least, counterintuitive. And it cannot be reconciled with decisions of this Court limiting Article III jurisdiction to cases or controversies between parties that are not simply ad-

[1] Mylan moved to intervene in the district court, but the district court denied its motion. App., *infra*, 42a. As a result, Mylan was not a party to the judgment entered by the district court and was not an appellee before the court of appeals. Mylan cross-appealed the district court's denial of its motion to intervene, and, in a separate part of its opinion, the court of appeals reversed that denial. *Id.* at 7a-8a.

[2] After the court of appeals' decision in this case, respondent filed a second declaratory-judgment action concerning Benicar HCT®, another of petitioners' products. See *Apotex, Inc.* v. *Daiichi Sankyo, Inc.*, Civ. No. 15-3695 (N.D. Ill. filed Apr. 27, 2015). Because Benicar HCT contains the same active ingredient as Benicar, the Orange Book lists the '599 and '703 patents in conjunction with both drugs. Petitioners have moved to dismiss that action, raising the same jurisdictional objection presented here.

verse to each other, but have adverse *legal* interests. If the Federal Circuit's decision is left undisturbed, it will provide a blueprint for the demolition of important limits on the jurisdiction of the federal courts. This Court should grant review and reverse the Federal Circuit's deeply flawed decision.

A. The Court of Appeals' Decision Conflicts With This Court's Decisions Concerning The Limits On Article III Jurisdiction

1. It is a familiar principle that Article III of the Constitution confines federal jurisdiction to actual "Cases" and "Controversies." That principle constitutes a "fundamental limit[] on federal judicial power in our system of government." *Allen* v. *Wright*, 468 U.S. 737, 750 (1984). And it serves to ensure that federal courts entertain only disputes that are presented in an adversary context—and thus that "the federal courts will not intrude into areas committed to the other branches of government." *Flast* v. *Cohen*, 392 U.S. 83, 95 (1968).

A dispute presents a justiciable case or controversy where it "[is] definite and concrete, touching the legal relations of parties having adverse legal interests." *North Carolina* v. *Rice*, 404 U.S. 244, 246 (1971) (per curiam) (citation omitted). Conversely, "the oldest and most consistent thread in the federal law of justiciability" is that "the federal courts will not give advisory opinions," *Flast*, 392 U.S. at 96 (citation omitted), and thus "may not * * * give opinion[s] advising what the law would be upon a hypothetical state of facts," *Chafin* v. *Chafin*, 133 S. Ct. 1017, 1023 (2013) (internal quotation marks and citation omitted).

The foregoing requirements are "no less strict under the Declaratory Judgment Act." *Altvater* v. *Freeman*, 319 U.S. 359, 363 (1943). In particular, those require-

ments "are not satisfied merely because a party requests a court of the United States to declare its legal rights." *Valley Forge Christian College* v. *Americans United for Separation of Church and State*, 454 U.S. 464, 471 (1982). Instead, a declaratory-judgment action presents a justiciable case or controversy only where it concerns a dispute that is "real and substantial and admi[ts] of specific relief through a decree of conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 127 (2007) (internal quotation marks and citation omitted).

Accordingly, a declaratory-judgment action must concern a "specific live grievance," *Lewis* v. *Continental Bank Corp.*, 494 U.S. 472, 479 (1990) (citation omitted), and not merely a "collateral legal issue" that may "govern[] certain aspects of [a] pending or future suit[]," *Calderon* v. *Ashmus*, 523 U.S. 740, 747 (1998). And a declaratory-judgment action may not serve as the "medium for securing an advisory opinion in a controversy which has not arisen." *Coffman* v. *Breeze Corps.*, 323 U.S. 316, 324 (1945).

2. The holding of the decision below—that this case constitutes a justiciable case or controversy under Article III even though the patent at issue was previously disclaimed—cannot be reconciled with this Court's decisions concerning the case-or-controversy requirement. Precisely because the patent was disclaimed, petitioners cannot bring a patent-infringement action against respondent. As a result, petitioners and respondent have no "adverse legal interests" with respect to the patent-infringement question presented by this action, *MedImmune*, 549 U.S. at 127 (citation omitted); all parties agree that respondent necessarily cannot infringe a patent that is treated as if it had never existed. By holding that re-

spondent's action nevertheless presented a justiciable controversy, the Federal Circuit permitted respondent to use the declaratory-judgment process not to resolve a "specific live grievance" between the parties concerning patent infringement, *Golden* v. *Zwickler*, 394 U.S. 103, 110 (1969), but rather to obtain a judgment where "a controversy * * * has not arisen" (and will never arise), *Coffman*, 323 U.S. at 324.

This Court's recent analysis in *Already, LLC* v. *Nike, Inc.*, 133 S. Ct. 721 (2013), is instructive. In that case, Nike filed suit in federal court against Already, alleging infringement of one of Nike's trademarks. *Id.* at 725. Already filed a counterclaim, alleging that the trademark was invalid. *Ibid.* Nike subsequently issued a broad covenant not to enforce its trademark against Already, then moved to dismiss the entire case with prejudice on the ground that the covenant "had extinguished the case or controversy." *Ibid.* Over Already's opposition, the district court dismissed Already's counterclaim on that basis, and the court of appeals and this Court affirmed. *Id.* at 725-726, 733.

This Court began its analysis by noting that, "[i]n our system of government, courts have no business deciding legal disputes or expounding on law in the absence of * * * a case or controversy." *Already*, 133 S. Ct. at 726 (internal quotation marks and citation omitted). The Court proceeded to hold that, in light of Nike's covenant, the case no longer presented a case or controversy and was accordingly moot. *Id.* at 732. In so holding, the Court explained that "[a] case becomes moot—and therefore no longer a 'Case' or 'Controversy' for purposes of Article III"—when, *inter alia*, "the dispute is no longer embedded in any actual controversy about the plaintiffs' particular legal rights." *Id.* at 726-727 (internal quotation marks and citation omitted). The Court

explained that "Already's only legally cognizable injury—the fact that Nike took steps to enforce its trademark—is now gone and, given the breadth of the covenant, cannot reasonably be expected to recur." *Id.* at 732. In the absence of any "live controversy" between the parties, the Court concluded, Already's invalidity counterclaim was "clearly moot." *Ibid.*

Here, as in *Already*, there is no "live controversy" between the parties. Respondent seeks a declaration that its ANDA product would not infringe the '703 patent. See p. 7, *supra*. As in *Already*, however, respondent faces no risk that petitioners will ever "[take] steps to enforce" the '703 patent against it. 133 S. Ct. at 732. Indeed, the certainty that petitioners will not attempt to enforce the '703 patent is even greater here than it was with regard to the trademark in *Already*. Petitioners have not simply issued a covenant not to sue respondent on the '703 patent; they have disclaimed the patent as a matter of law. Petitioners thus could not enforce the '703 patent against *anyone*, let alone respondent. And because the Declaratory Judgment Act does not enlarge the jurisdiction of federal courts, there can be no case or controversy here in the absence of any possible "threatened action" by petitioners. *Medtronic, Inc.* v. *Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 848 (2014).

To the extent that respondent asserts any injury here, the injury arises not from the threat of enforcement of the '703 patent against it, but rather from FDA's *listing* of the patent—the maintenance of which is not within petitioners' control.[3] Indeed, respondent's tactics

[3] Petitioners cannot delist the patent, notwithstanding their request to FDA, because FDA is not required to comply with a patentee's request. See *Teva Pharmaceuticals USA, Inc.* v. *Sebelius*, 595 F.3d 1303, 1317-1318 (D.C. Cir. 2010).

demonstrate the lack of a controversy here: the legal tool respondent seeks to use (a declaratory-judgment action) is entirely incongruent with the outcome it desires (forfeiture of Mylan's 180-day exclusivity period). While respondent is purportedly seeking a judgment of non-infringement, it has not (and will not) ask a federal court to perform the tasks traditionally required for such a judgment: namely, to construe the claims in the '703 patent or to compare those claims to its ANDA product. And while the Hatch-Waxman Act sanctions declaratory-judgment actions to "obtain patent certainty," 21 U.S.C. 355(j)(5)(C), respondent already has unconditional certainty that it will not be liable for infringement of the '703 patent.

In short, the Federal Circuit's decision permits respondent to force petitioners into federal court based on a legal nullity in order to obtain relief against FDA and Mylan. Such a situation is far afield from those contemplated by this Court's case-or-controversy jurisprudence. Because the only "legally cognizable injury" respondent faces from petitioners "is now gone," *Already*, 133 S. Ct. at 732—and, indeed, was already long gone at the time respondent filed suit—this case plainly does not present a justiciable case or controversy under this Court's precedent.[4]

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[4] For the reasons discussed above, the question presented in this case is best understood in terms of justiciability generally, rather than standing or mootness. The doctrine of standing relates to whether the *plaintiff* is the "proper party to request an adjudication of a particular issue and not whether the issue itself is justiciable," *Flast*, 392 U.S. at 100, and the doctrine of mootness relates to whether a dispute *no longer* presents a proper case or controversy based on developments occurring after "the case has been brought," *Friends of the Earth, Inc.* v. *Laidlaw Environmental Services*, 528 U.S. 167, 191 (2000). Of course, all of these doctrines originate

3. In the decision under review, the Federal Circuit recognized that, by virtue of their disclaimer, petitioners could not enforce the '703 patent against respondent. App., *infra*, 10a. But the lower court nevertheless held that the action was justiciable because "the parties have substantial, concrete stakes in whether [respondent] secures the non-infringement judgment it seeks." *Id.* at 11a. Specifically, the Federal Circuit explained that "[t]he concrete stakes over which [petitioners] and [respondent] are fighting are the revenues to be earned through selling" their respective versions of Benicar. *Id.* at 10a. Because a declaratory judgment of non-infringement of the '703 patent might eliminate a barrier to respondent's market entry, and because respondent's entry would redound to its financial benefit (and potentially to petitioners' detriment), the Federal Circuit concluded that the action was justiciable. *Id.* at 10a-12a.

Under this Court's decisions, the Federal Circuit's reasoning is flatly incorrect. In *Already*, in an attempt to "save the case from mootness," Already advanced an "alternative theor[y] of Article III injur[y]." 133 S. Ct. at 729. It contended that, "so long as Nike remains free to assert its trademark, investors will be apprehensive about investing in Already," with the result that the "mere existence [of the trademark] hampers its ability to attract capital." *Id.* at 729-730. In support of that argument, Already presented affidavits from prospective investors stating that they would "consider investing in

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"from the same Article III limitation," and, as a practical matter, the "issues * * * 'boil down to the same question'" here. *Susan B. Anthony List* v. *Driehaus*, 134 S. Ct. 2334, 2341 n.5 (2014) (quoting *MedImmune*, 549 U.S. at 128 n.8).

Already only if Nike's trademark were struck down." *Id.* at 730 (internal quotation marks omitted).

The Court rejected Already's argument, explaining that Nike's challenged conduct—*i.e.*, enforcement of its trademark against Already—"cannot reasonably be expected to recur." 133 S. Ct. at 730 (internal quotation marks and citation omitted). Moreover, "the fact that some individuals may base decisions on 'conjectural or hypothetical' speculation does not give rise to the sort of 'concrete' and 'actual' injury necessary to establish Article III standing." *Ibid.* (citation omitted). "Taken to its logical conclusion," the Court continued, "the theory seems to be that a market participant is injured for Article III purposes whenever a competitor benefits from something allegedly unlawful," such as the "mere existence" of an allegedly invalid trademark. *Id.* at 730-731. Rejecting that "remarkable proposition," the Court explained that it has "never accepted such a boundless theory of standing." *Id.* at 731.

Here, as in *Already*, petitioners' enforcement of the '703 patent cannot reasonably be expected to recur; indeed, it never occurred in the first place. Respondent seeks a declaratory judgment not to prevent petitioners from enforcing their patent or otherwise engaging in any challenged conduct, but rather to set in motion a chain of events that might lead to its entering the market with its ANDA product sooner. But respondent's only "*relevant* injury in fact"—*i.e.*, an "injury-in-fact *caused by the violation of [a] legal right*" by petitioners—does not, and will never, exist. *Lewis* v. *Casey*, 518 U.S. 343, 353 n.4 (1996). And while it is true that petitioners may benefit financially from respondent's later entry into the market, this Court has squarely rejected the "boundless theory" of Article III jurisdiction under which such a financial benefit would be sufficient. *Already*, 133 S. Ct. at 731.

4. The Federal Circuit's approach in the decision under review is plainly an outlier. Outside the context of patent law, other courts of appeals have routinely recognized that non-legal interests are insufficient to give rise to an Article III case or controversy. For example, in *Shell Gulf of Mexico, Inc.* v. *Center for Biological Diversity, Inc.*, 771 F.3d 632 (2014), the Ninth Circuit considered whether an Article III case or controversy existed between an oil company that had received federal approval for its plans to respond to an oil spill and several environmental groups likely to challenge those plans. The Ninth Circuit held that the oil company and the environmental groups "[did] not have adverse legal interests," and thus there was no case or controversy under Article III. *Id.* at 636 (internal quotation marks and citation omitted). The court reasoned that the "sincerity of [the oil company's] legal disagreement with the environmental groups and the substantial economic effects it would suffer" from a possible future judgment against the federal agency regarding the plans "alone do not create a justiciable case or controversy." *Id.* at 637. The court explained that "Article III requires the existence of adverse legal interests arising from a legal claim, and that is absent from this case." *Ibid.*

Similarly, in *Collin County* v. *Homeowners Association for Values Essential to Neighborhoods*, 915 F.2d 167 (1990), the Fifth Circuit held that there was no Article III case or controversy between a county and a homeowner's group. In that case, the county sought a declaratory judgment against the homeowners that an environmental impact statement approved by the federal government was sufficient as a matter of law. *Id.* at 169. While the county had "interests in the outcome of potential litigation," the Fifth Circuit nonetheless reasoned that "these interests are not adverse legal interests," be-

cause the homeowner's group "could not have sued [the county] or any of the other plaintiffs over the sufficiency" of the environmental impact statement. *Id.* at 170-171. "While the [Declaratory Judgment] Act should be liberally applied when the plaintiff has a legal interest in an actual case or controversy," the court continued, "the Act does not allow a stranger to intended litigation to use a declaratory judgment action as a vehicle to create a cause of action for which it has no legal liability." *Id.* at 172. That reasoning is consistent with this Court's Article III precedent and is directly applicable here. The Court should grant review to correct the Federal Circuit's contrary reasoning.[5]

B. The Question Presented Is An Exceptionally Important One That Warrants The Court's Review

If allowed to stand, the Federal Circuit's decision will work mischief in the federal judiciary by permitting lawsuits to proceed in the absence of *legal* adversity between the parties. Under the Federal Circuit's reasoning, a party may sue an economic competitor that took no unlawful action and cannot prevent the alleged harm, as long as the party can allege lost profits or some other

[5] To the extent the Federal Circuit suggested that the Hatch-Waxman Act itself gave rise to Article III jurisdiction, the Court may wish to consider holding this petition pending its decision in *Spokeo, Inc.* v. *Robins*, No. 13-1339. The question presented in *Spokeo* is "[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 authorizing a private right of action based on a bare violation of a federal statute." Pet. at i, *Spokeo*, *supra*. While the Federal Circuit's reasoning in this case is irreconcilable with this Court's existing Article III precedent, the Court's decision in *Spokeo* could confirm that conclusion.

form of economic injury. This Court's review is necessary to protect the fundamental principle that "[t]he presence of a disagreement, however sharp and acrimonious it may be, is insufficient by itself to meet Art[icle] III's requirements." *Diamond* v. *Charles*, 476 U.S. 54, 62 (1986).

1. As a preliminary matter, the absence of a circuit conflict on the specific question presented is unremarkable, because the Federal Circuit has exclusive jurisdiction over appeals relating to patents. See 28 U.S.C. 1295; *Octane Fitness, LLC* v. *ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1754 (2014). Absent review by this Court, therefore, the Federal Circuit's decision in this case will stand as the final word on whether Article III permits a party to seek a declaration of non-infringement of a patent that was previously disclaimed and thus cannot be enforced. And as noted above, outside the context of patent law, other courts of appeals have held that no case or controversy exists for Article III purposes in the absence of legal adversity. See pp. 18-19, *supra*.

2. This Court routinely grants certiorari in cases involving the scope of federal-court jurisdiction under Article III of the Constitution. That practice reflects the Court's role as the ultimate gatekeeper of Article III; as the Court has noted, "lowering the [Article III] gates for one party lowers the gates for all." *Already*, 133 S. Ct. at 732.

Here, the consequences of allowing access to federal court based solely on economic injury, in the absence of legal adversity, are potentially enormous. In patent cases, the immediate result would be to undermine the Hatch-Waxman Act's incentive for early patent challenges by deputizing federal courts to aid the efforts of later-filing generic manufacturers that bring suit solely to defeat the exclusivity rights of first filers. Under the

Federal Circuit's decision, later-filing generic manufacturers may seek declaratory judgments of non-infringement even where there is no risk that the patent-at-issue will be enforced. And they will be permitted to obtain such a judgment so long as it may strip a first-filing generic manufacturer—a manufacturer that undertook the substantial risk of filing the initial challenge to the patent—of its exclusivity rights.

The Federal Circuit's reasoning also gravely destabilizes a well-established maxim of patent law: that disclaimed patents cannot provide the legal basis for a case or controversy under Article III. See, *e.g.*, *3V, Inc.* v. *CIBA Specialty Chemicals Corp.*, 587 F. Supp. 2d 641, 645-46 (D. Del. 2008); *W.L. Gore & Associates, Inc.* v. *Oak Materials Group, Inc.*, 424 F. Supp. 700, 702 (D. Del. 1976). Because the Federal Circuit held in the decision below that a justiciable case or controversy existed only by virtue of an interest distinct and apart from the patent—namely, an interest based on the listing of the patent in the Orange Book—a future litigant seeking to litigate a disclaimed patent's validity or scope will need only identify such an ancillary interest in order to gain access to federal court.

Such cases are not hard to imagine. For example, suppose that two patentees have claimed the same invention and dispute which of their patents is enforceable over the other. Suppose further that the Patent and Trademark Office rules that Party A's patent anticipates Party B's (rendering some of its claims invalid), and Party B sues Party A in federal court seeking a judgment that its patent is not anticipated. If Party A then disclaims its patent, no legal adversity would exist. That was exactly the scenario in *3V*, *supra*. Given that Party A had no "legally cognizable interest" in the issue and Party B had "identifie[d] no dispute whatsoever" with

Party A, the court properly dismissed the case for lack of Article III jurisdiction. *3V*, 587 F. Supp. 2d at 645-646 (internal quotation marks omitted). Under the Federal Circuit's reasoning, however, because Party B had a financial stake in obtaining a judgment, it would be allowed to proceed in its action against Party A.

Such a result illustrates the enormous risk of leaving the Federal Circuit's approach undisturbed: federal courts could be asked to consider a never-ending stream of patent cases where no legal dispute exists between the parties. And the Federal Circuit's reasoning would enable parties to haul competitors into federal court in non-patent contexts as well: for instance, to answer for profits lost when benefits are granted by government agencies. Those consequences fly in the face of the fundamental principle that a party cannot enlist the aid of the federal judiciary absent a cognizable legal dispute that requires resolution.

* * * * *

While the regulatory backdrop to this case is complicated, the relevant facts are not: one party has hauled another party against which it has no legally cognizable claim into federal court simply to obtain the court's imprimatur on the proposition that a disclaimed, non-existent patent that cannot be enforced would not be infringed. The Federal Circuit permitted the action to go forward on the "theory * * * that a market participant is injured for Article III purposes whenever a competitor benefits from something allegedly unlawful." *Already*, 133 S. Ct. at 731. But this Court has never accepted such a "boundless theory" of Article III jurisdiction. *Ibid.* The Court should grant certiorari and reverse the Federal Circuit's clearly flawed decision.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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APPENDIX

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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-Appellees

v.

Mylan Pharmaceuticals Inc., Movant-Cross-Appellant

March 31, 2015

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

OPINION

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 in-

fringe 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 (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 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

[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).

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 (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 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.

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

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 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] 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 Or-

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[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 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).

ange 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 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 de-

pends 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 (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] non-infringing 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,

[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).

the focus of infringement 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 gener-

ic 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 situation from those in which we

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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); *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003); *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002); *Minn. Mining And Mfg. Co. v. Barr Labs.*, Inc., 289 F.3d 775 (Fed. Cir. 2002). *See also Teva Pharm. USA, Inc. v. EISAI Co.*, 620 F.3d 1341, 1350 (Fed. Cir. 2010), judgment vacated for mootness, 131 S. Ct. 2991 (2011).

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 pre-MMA statute contained

[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. 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

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 validity. *See supra* p. 1363 & 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

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view that exclusivity is not lost upon certification change after adjudication of validity and infringement).

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 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

[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.

> 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 pol-

icy. 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 non-infringement, 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, 2014-1291

Apotex, Inc., Plaintiff-Appellant

v.

Daiichi Sankyo, Inc., and Daiichi Sankyo Co., Ltd.
Defendants-Appellees

v.

Mylan Pharmaceuticals Inc., Movant-Cross-Appellant

June 8, 2015

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

Per Curiam.

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

ORDER

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

FOR THE COURT

June 8, 2015
Date

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

APPENDIX C

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

No. 12-9295

Apotex, Inc., Plaintiff

v.

Daiichi Sankyo, Inc. and Daiichi Sankyo Co., Ltd.
Defendants

January 9, 2014

Before: JOHNSON COLEMAN, United States District Judge.

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

1. 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.*

2. 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").[8] 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.

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

[8] 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.

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 pre-

sent 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, (2) the issues presented are ripe for judicial review, *Abbott Labs. v. Gardner,* 387 U.S. 136, 149 (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 (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. According-

ly, 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.

Date: January 9, 2014

/s/
Sharon Johnson Coleman
United States District Judge

APPENDIX D

21 U.S.C. 355(j) provides:

Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

> (i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");
>
> (ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;
>
> (II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or
>
> (III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which

does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under

subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) Notice of opinion that patent is invalid or will not be infringed

(i) Agreement to give notice. — An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) Timing of notice. — An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) Recipients of notice. — An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) Contents of notice. — A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of ad-

ministration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on

the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division

determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the

listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active

ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredi-

ents included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph

(2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the

drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(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.

(C) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action. —

(I) In general. — No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action. — If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met,

the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application. — For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an

application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action. —

(I) In general. — If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this

section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action. — Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages. — An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(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.

(II) Withdrawal of application. — The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application

does not meet the requirements for approval under paragraph (4).

(III) Amendment of certification. — The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) Failure to obtain tentative approval. — The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) Agreement with another applicant, the listed drug application holder, or a patent owner. — The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint 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 agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that

that section applies to unfair methods of competition).

(VI) Expiration of all patents. — All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture. — The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) Subsequent applicant. — If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required

for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning Janu-

ary 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under

subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under simi-

lar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this chapter, be eligible for approval and shall not be considered misbranded under section 352 of this title if—

(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

(ii) the labeling revision described under clause (i) does not include a change to the "Warnings" section of the labeling;

(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.