United States Court of Appeals for the Federal Circuit

APOTEX INC.,
Plaintiff-Appellant

v.

DAIICHI SANKYO, INC., DAIICHI SANKYO CO., LTD.,
Defendants-Appellees

v.

MYLAN PHARMACEUTICALS INC.,
Movant-Cross-Appellant

2014-1282, 2014-1291

Appeals from the United States District Court for the Northern District of Illinois in No. 1:12-cv-09295, Judge Sharon Johnson Coleman.

Decided: March 31, 2015

STEVEN ERIC FELDMAN, Husch Blackwell LLP, Chicago, IL, argued for plaintiff-appellant. Also represented by SHERRY LEE ROLLO, JAMES PATRICK WHITE, DANIEL RONALD CHERRY.

DOMINICK A. CONDE, Fitzpatrick, Cella, Harper & Scinto, New York, NY, argued for defendants-appellees. Also represented by CHARLES AUSTIN GINNINGS, NINA SHREVE.

MICHAEL SHUMSKY, Kirkland & Ellis LLP, Washington, DC, argued for movant-cross-appellant. Also represented by JOHN KEVIN CRISHAM, STEPHEN S. SCHWARTZ.

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

TARANTO, *Circuit Judge*.

Apotex, Inc. brought this action against Daiichi Sankyo Co., Ltd. and Daiichi Sankyo, Inc. (collectively, Daiichi) to obtain a declaratory judgment that Apotex will not infringe a patent owned but disclaimed by Daiichi if Apotex manufactures or sells a generic drug bioequivalent to Daiichi's Benicar®. Apotex cannot infringe the patent, because Daiichi has disclaimed it, but Apotex nevertheless claims a concrete interest in obtaining a judgment of non-infringement for its generic drug because such a judgment would enable Apotex to receive marketing approval from the United States Food and Drug Administration and to enter the market sooner than otherwise. The district court dismissed Apotex's complaint for lack of a case or controversy. We reverse. Under the statute that governs marketing approval of generics, Apotex has a concrete, potentially high-value stake in obtaining the judgment it seeks; and Daiichi has a concrete, potentially high-value stake in denying Apotex that judgment and thereby delaying Apotex's market entry—as does Mylan Pharmaceuticals, Inc., the first applicant for approval of a generic version of Benicar®. We also reverse the district court's denial of Mylan's motion to intervene in this action.

BACKGROUND

Under the authority of the FDA's approval of its New Drug Application (NDA), 21 U.S.C. § 355(a), (c), Daiichi markets Benicar® for treating hypertension. In seeking FDA approval for Benicar®, Daiichi listed two patents in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* publication, or "Orange Book." *See* 21 U.S.C. § 355(b)(1) (requiring listing of patents that "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug"); 21 C.F.R. §§ 314.3, 314.53. The first, U.S. Patent No. 5,616,599, covers the active ingredient of the drug, olmesartan medoxomil. It expires on April 25, 2016, but because Daiichi provided the FDA certain data concerning the drug's effects on children, the FDA must wait six months longer—*i.e.*, until October 25, 2016—before approving a generic version of the drug. *See* 21 U.S.C. § 355a(b)(1)(B)(i). Daiichi's second listed patent, U.S. Patent No. 6,878,703, covers methods of treatment. It expires on November 19, 2021.

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

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

under § 355(b)(1)'s "could reasonably be asserted" standard.

Having disclaimed the '703 patent, Daiichi sued Mylan for infringing the '599 patent, invoking the declaration of 35 U.S.C. § 271(e)(2)(A) that the submission of a paragraph IV certification constitutes an act of infringement. Only validity was disputed in the case, and after a full trial, the district court upheld the validity of the '599 patent and entered judgment of infringement against Mylan. *Daiichi Sankyo Co. v. Mylan Pharm. Inc.*, 670 F. Supp. 2d 359, 387 (D.N.J. 2009). We affirmed. *Daiichi Sankyo Co. v. Matrix Labs., Ltd.*, 619 F.3d 1346 (Fed. Cir. 2010). With the '703 patent disclaimed and the '599 patent upheld, Mylan's earliest date of market entry—the earliest effective date of any FDA approval for Mylan—is October 25, 2016, six months after the expiration date of the '599 patent.

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

As is undisputed here, non-infringement of the '703 patent follows as a matter of law from the fact that Daiichi has formally disclaimed it. *See Altoona Publix Theatres, Inc. v. American Tri-Ergon Corp.*, 294 U.S. 477, 492 (1935); *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996). Indeed, in its July 2006 letter asking the FDA to

remove the '703 patent from the Orange Book, Daiichi stated: "The effect of the disclaimer is that the 6,878,703 patent no longer exists." J.A. 99. And in July 2012, it wrote to Apotex stating that, because of its disclaimer of the '703 patent, it "cannot . . . sue any entity . . . for infringement of that patent." J.A. 104.

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

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

tan 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 argu-

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[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).

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

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

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

DISCUSSION

We review de novo a district court's dismissal of a declaratory-judgment action for lack of subject-matter jurisdiction. *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1277 (Fed. Cir. 2014). Where, as here, no timeliness issue is present, we review denial of intervention as of right de novo. *See Stauffer v. Brooks Bros., Inc.*, 619 F.3d 1321, 1328 (Fed. Cir. 2010) (denial of intervention reviewed under regional circuit's law); *Sokaogon Chippewa Cmty. v.*

Babbitt, 214 F.3d 941, 945 (7th Cir. 2000) (de novo review of denial of motion to intervene).

A

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

In this action, Apotex seeks to cause a forfeiture of Mylan's presumed market-exclusivity period, and Mylan has a concrete monetary interest in retaining such exclusivity—six months of more sales and/or higher prices than are likely when Apotex enters the market. Although Daiichi likely benefits from the 180-day exclusivity period as well, Mylan's interest exists apart from that of Daiichi, which, as a rival of Mylan's, has its own incentives affecting decisions about how to conduct this litigation. *Keith v. Daley*, 764 F.2d 1265, 1268 (7th Cir. 1985) (interest must "belong[] to the proposed intervenor rather than to an existing party in the suit"). Mylan's interest here is " 'of such a direct and immediate character that [Mylan] will either gain or lose by the direct legal operation and effect of the judgment' " sought by Apotex. *Am. Mar. Transp., Inc. v. United States*, 870 F.2d 1559, 1561 (Fed. Cir. 1989) (emphases removed) (quoting *United States v. AT&T Co.*, 642 F.2d 1285, 1292 (D.C. Cir. 1980)). And Apotex does not defend the district court's conclusion that Mylan's interest in the case was rendered moot by the dismissal of the case, where, as here, Apotex is seeking to reverse the dismissal. Mylan has a strong, concrete interest in de-

fending the dismissal on this appeal. Accordingly, we reverse the denial of Mylan's motion to intervene.

B

We also reverse the district court's dismissal of Apotex's complaint for lack of a case or controversy. The stakes over which the parties are vigorously fighting are concrete and substantial: the amount of revenue there will be from sales of olmesartan medoxomil, and who will get what portions of it, during a period of at least six months. We conclude that "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (internal quotation marks and citation omitted).

The case-or-controversy analysis, as relevant here, has borrowed from decisions on standing and ripeness. *See Sandoz*, 773 F.3d at 1277–78; *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1335–36 (Fed. Cir. 2008). "Standing under Article III of the Constitution requires that an injury be concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling." *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010). Where, as here, no further facts are needed for the requested adjudication (non-infringement is beyond dispute, given the disclaimer), ripeness depends on any harm to the plaintiff from delaying adjudication and the degree of uncertainty about whether an adjudication will be needed. *Sandoz*, 773 F.3d at 1277–78. In this case, these overlapping formulations have led the parties to focus on (1) whether Daiichi's disclaimer of the patent means that the parties lack concrete stakes in the dispute over the declaratory judgment; (2) whether the alleged harm is traceable to Daiichi; (3) whether the real-world impact is

too contingent on future events—specifically, FDA tentative approval of Apotex's ANDA; and (4) whether Apotex's alleged harm would not be redressed even if Apotex receives the requested judgment because ultimate relief is independently blocked by the statutory standards for triggering forfeiture of Mylan's exclusivity period. We address those issues in turn.

1

We first reject Daiichi's contention, adopted by the district court, that Daiichi's statutory disclaimer of the '703 patent itself means that there is no adversity between it and Apotex over stakes of a concrete character. *See Hollingsworth v. Perry*, 133 S. Ct. 2652, 2662 (2013) ("To have standing, a litigant . . . must possess a 'direct stake in the outcome' of the case.") (quoting *Arizonans for Official English v. Arizona*, 520 U.S. 43, 64 (1997)); *Warth v. Seldin*, 422 U.S. 490, 498–99 (1975). The concrete stakes over which Daiichi and Apotex are fighting are the revenues to be earned through selling olmesartan medoxomil. The patent disclaimer eliminates one, but only one, potential legal barrier to Apotex's ability to make such sales sooner rather than later. The *listing* of the patent, with its current consequence of preventing FDA approval during Mylan's presumptive exclusivity period, is another, and the parties have adverse concrete interests in the truncation or preservation of that period.

Apotex, Daiichi, and Mylan are all likely affected, though not in perfect mirror-image ways, by whether Apotex can cause the forfeiture of Mylan's exclusivity period. Until that period ends, Apotex cannot make sales, and delay of entry may have lingering adverse effects on market share. *See Teva Pharm., USA, Inc. v. FDA*, 182 F.3d 1003, 1011 n.8 (D.C. Cir. 1999) (second-filing generic manufacturers "face continued harm because of their denied access to the market . . . , harm potentially heightened because of [the first filer's] period of market exclusiv-

ity"). 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.

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-

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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/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/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).

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

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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

eligible for an exclusivity period had Daiichi never listed the '703 patent. Oral Argument at 2:30–46 (Apotex), *Apotex Inc. v. Daiichi Sankyo, Inc.*, No. 2014-1282, -1291; *id.* at 16:50–17:10 (Daiichi). It is only Daiichi's original listing of that patent—which Daiichi has disclaimed—that now supports Mylan's exclusivity period, which Apotex filed this action to bring to an end.

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

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

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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).

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 depends on the action of a third party (here, the FDA's approval of the ANDA to allow marketing), is whether there is too high a degree of uncertainty about whether the judicial resolution, if in the plaintiff's favor, will matter in alleviating the harm alleged by the plaintiff. *See Lujan*, 504 U.S. at 560–61 (likely, as opposed to speculative); *Warth*, 422 U.S. at 504, 507 ("substantial probability," not "remote possibility"); *Linda R.S. v. Richard D.*, 410 U.S. 614, 618 (1973) (not too "speculative"). That context-dependent standard has been applied to allow adjudication to remove one legal barrier to the plaintiff's obtaining the concrete

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

Because the likelihood of ultimate alleviation of harm involves a judgment call about a causal chain, congressional action is relevant. The Supreme Court and our court have recognized the potential significance of congressional action in "articulat[ing] chains of causation that will give rise to a case or controversy where none existed before." *Massachusetts v. EPA*, 549 U.S. 497, 516 (2007); *see Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1261 (Fed. Cir. 2014). By deeming certain series of links from conduct to harm or from judgment to alleviation of harm not to be unduly speculative, Congress may "effectively creat[e] justiciability that attenuation concerns would otherwise preclude." *Sandoz*, 773 F.3d at 1281.

In the present context, the congressional judgment embodied in the "Hatch-Waxman Amendments" to the

Food, Drug, and Cosmetic Act,[4] as consistently implemented in our case law, makes clear that tentative approval for Apotex is not a precondition to adjudicating the patent issue. When a generic manufacturer seeks to enter the market, the concrete stakes are the market sales upon entry. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1292 (Fed. Cir. 2008) ("exclud[ing] 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, 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

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[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).

(2012) ("The patent statute treats such a filing as itself an act of infringement, which gives the brand an immediate right to sue."). Moreover, Congress required the ANDA filer to provide prompt notice to the relevant patent owners (and NDA holder), 21 U.S.C. § 355(j)(2)(B), and for the patent owners to bring suit within 45 days to obtain a 30-month delay in any effective date of approval for the ANDA, § 355(j)(5)(B)(iii). It is undisputed that it would be rare for tentative approval to have occurred 45 days into the ANDA process. *See also* § 355(j)(5)(D)(i)(IV) (provision triggering forfeiture based on first filer's failure to obtain tentative approval, presumptively giving first filer a full 30 months to obtain tentative approval). The statute evidently contemplates litigation well before such tentative approval.

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

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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);

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 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 provi-

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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).

sions—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 no

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[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

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

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

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

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

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[7] No one here disputes that the "later of" language applies only if one of the (bb)-specified events occurs, *i.e.*,

> (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 [§ 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).

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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.

The first step in applying that provision to the present case is to note that, although Mylan (the "first applicant") initially made a paragraph IV certification for both the '599 and '703 patents, the '599 certification is no longer "lawfully maintained," because Mylan lost its litigation over that patent. As a result, the only lawfully maintained certification involves the '703 patent, and the (bb) standards must be applied only to that patent. As to that patent, then, (bb)(AA) specifies that Mylan forfeits its exclusivity period if it has not entered the market by the following date: with respect to Apotex, a second-filing applicant, "which other applicant has received tentative approval," 75 days after what we may, for convenience, call the "non-infringement finality date"—more precisely, when the appeal time ends without an appeal after the district court enters a non-infringement judgment, *see* 28 U.S.C. § 2107(a) (30-day period); Fed. R. App. P. 4, or when this court enters its judgment affirming the non-infringement judgment if there has been an appeal.

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

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

contends that the text of (bb) and (AA) taken together unambiguously mandates that tentative approval is a prerequisite for entry into court if the action is ultimately to have a forfeiture effect. We reject that reading of the provision.

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

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

Indeed, it would be surprising to find an entry-into-court prerequisite in the forfeiture provision, given how the forfeiture provision is plainly intended to operate. The only role to be played by the declaratory-judgment action referred to in § 355(j)(5)(D)(i)(I)(bb)(AA) is a role played at the *end* of the action—a "final decision" in the defined sense of completing as-of-right appeals—namely,

forfeiture no earlier than 75 days after that event. The provision does not give the mere filing of the action any effect. It makes no sense, where not compelled by the text or context, to give the provision an interpretation extraneous to its evident function.

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

Not only does it make no sense to read the forfeiture provision as requiring tentative approval at the outset of the second filer's declaratory-judgment action. It makes good sense to read the provision as providing for forfeiture simply when there has been no entry 75 days after the non-infringement finality date and the date of tentative approval. That reading serves the evident congressional policy of triggering forfeiture when a second filer is ready to launch. *See* 149 Cong. Rec. 31,200 (2003) (statement of Sen. Schumer) ("If it forfeits, then the exclusivity is lost

and any other generic applicant that is ready to be approved and go to market can go.").

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

Mylan argues that its view is required by the statutory policy underlying the exclusivity period. But its argument is too detached from the particulars of the statute. The exclusivity period, § 355(j)(5)(B)(iv), rests on a balancing of interests: encouraging early entry by generics into the market by providing a reward to first filers (substantially higher prices for a time and a first-mover advantage, *see Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 n.6 (D.C. Cir. 1998)), but only up to a point (as that reward creates higher prices for consumers, *see Teva*, 595 F.3d at 1318). There is no a priori right balance. We must look to what Congress enacted—specifically, the MMA provisions that reset the statutory balance. *See Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005) ("Because the balance struck between these competing goals is quintessentially a matter for legislative judgment, the court must attend closely to the terms in which the Congress expressed that judgment."). Here, as we have explained, when Mylan lost its case regarding the '599 patent, it lost its right to invoke that patent to support an exclusivity period. And there is no

evident "policy" supporting maintenance of that period based on the '703 patent once (it is 75 days after) Apotex secures a no-longer-appealable judgment of 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