NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 24-2184, 24-2185, 24-2189, 24-2194, 24-2202, 24-2203, 24-2256 & 24-2257

IN RE: LIPITOR ANTITRUST LITIGATION

Appeal from the United States District Court
For the District of New Jersey
(D.C. No. 3:12-cv-2389)
(MDL No. 2332)
District Judge: Peter G. Sheridan

Argued September 30, 2025

Before: SHWARTZ, MATEY, and SCIRICA,[*] Circuit Judges.

(Filed: August 13, 2026)

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[*] The Honorable Anthony J. Scirica was unavailable to participate in the decision in this case after argument before the merits panel. The opinion is filed by a quorum of the panel pursuant to 28 U.S.C. § 46(d) and 3d Cir. I.O.P. 12.1(b).

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OPINION*

SHWARTZ, Circuit Judge.

Plaintiffs—direct purchasers, end payors,[1] and certain retailers of the brand-name cholesterol-lowering drug Lipitor—brought an antitrust suit against Defendants, Pfizer, Inc., Lipitor's manufacturer, and Ranbaxy, Inc.,[2] the first generic manufacturer that sought FDA approval to market a generic version of Lipitor. Plaintiffs allege that Defendants entered a settlement agreement regarding certain patent disputes under which Ranbaxy agreed not to sell generic Lipitor until November 30, 2011, several months after Pfizer's contested patent protections were to lapse.[3] This effectively extended Pfizer's

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* This disposition is not an opinion of the full court and pursuant to 3d Cir. I.O.P. 5.7 does not constitute binding precedent.

[1] Direct purchasers are a group of wholesale pharmaceutical distributors that purchased Lipitor or its generic version directly from Pfizer or Ranbaxy. End payors are a collection of organizations including insurance carriers, Taft-Hartley funds, employee-benefit plans, municipalities, and individuals who purchased or provided at least some of the payment for Lipitor or its generic version on the consumer market.

[2] Plaintiffs also sued Pfizer-related entities and Ranbaxy-related entities, and our reference to "Pfizer" and "Ranbaxy" herein captures them all.

[3] This is known as a "reverse payment" agreement. See FTC v. Actavis, Inc., 570 U.S. 136, 140-41 (2013) (defining reverse-payment agreements and holding that they "can sometimes violate the antitrust laws").

monopoly and blocked competitors from offering less expensive generic versions of Lipitor to purchasers.

Defendants moved for summary judgment, asserting that Plaintiffs lack antitrust standing[4] and Plaintiffs moved for class certification. Because the District Court correctly held that Plaintiffs lack antitrust standing, and thus are inadequate class representatives, we will affirm the orders granting Ranbaxy summary judgment and denying Plaintiffs' class certification motions.

I

A

Under the Hatch-Waxman Act (the "Act"),[5] a drug manufacturer seeking to market a brand-name drug must submit a New Drug Application ("NDA") to the FDA, undergo a rigorous review process, and receive FDA approval. See 21 U.S.C. § 355(b)(1); In re Lipitor Antitrust Litig., 868 F.3d 231, 240 (3d Cir. 2017) ("Lipitor II"). A generic manufacturer may later "obtain similar marketing approval" by submitting an Abbreviated New Drug Application ("ANDA") demonstrating that "the generic has the 'same active ingredients as,' and is 'biologically equivalent' to, the already-approved brand-name drug," effectively "allowing the generic to piggy-back on the pioneer's approval efforts," which "speed[s] the introduction of low-cost generic drugs to market.'"

[4] Pfizer and Ranbaxy jointly sought summary judgment, but Pfizer settled with all Plaintiffs before the District Court resolved the motion. Accordingly, the orders on appeal are limited to Plaintiffs' claims against Ranbaxy.

[5] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

FTC v. Actavis, Inc., 570 U.S. 136, 142 (2013) (quoting Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 404-05 (2012)); 21 U.S.C. § 355(j)(2)(A)(ii), (iv).

The Act sets forth procedures to resolve patent disputes between brand name and generic manufacturers. See Lipitor II, 868 F.3d at 240. When seeking FDA approval, brand-name drug manufacturers must provide a list of patents relating to the drug's composition or methods of use, see 21 U.S.C. § 355(b)(1)(A)(viii), and, upon approval, the FDA publishes the patent information in its "Approved Drug Products with Therapeutic Equivalence Evaluations" report, known as the "Orange Book," see Lipitor II, 868 F.3d at 240. Generic manufacturers are required to "consult[] the Orange Book" and "assure the FDA that [their] proposed generic drug[s] will not infringe the brand[s' listed] patents." Caraco, 566 U.S. at 406. One method of assurance is known as a "paragraph IV certification," id. at 407, wherein generic manufacturers certify that the relevant listed patents are "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Paragraph IV certifications act as litigation triggers, allowing brand-name manufacturers to file patent suits immediately. See 35 U.S.C. § 271(e)(2)(A). If they do so within forty-five days, the FDA must withhold approval of the generic drug for at least thirty months so courts may resolve the patent issues. See 21 U.S.C. § 355(j)(5)(B)(iii).[6]

[6] If courts are unable to resolve the matter within the thirty-month period, the FDA may approve the generic drug for marketing. In re Lipitor Antitrust Litig., 868 F.3d 231, 241 (3d Cir. 2017) ("Lipitor II").

To incentivize generic drug manufacturers to use paragraph IV certifications, the Act provides that the first generic manufacturer to file such a certification enjoys a 180-day exclusivity period upon approval during which no other generic may enter the market. See 21 U.S.C. § 355(j)(5)(B)(iv); Lipitor II, 868 F.3d at 241. However, the first-filing generic manufacturer can lose this exclusivity period if the FDA concludes that its ANDA was not "substantially complete" when filed. See 21 U.S.C. § 355(j)(5)(B)(iii), (iv)(II)(cc).

B

Lipitor is a drug that treats high cholesterol and contains the active pharmaceutical ingredient atorvastatin calcium. Pfizer secured several patents protecting Lipitor and atorvastatin calcium beginning in 1987, received FDA approval in 1996, and brought Lipitor to market in 1997.

In 2002, Ranbaxy became the first manufacturer to file an ANDA for generic Lipitor containing a paragraph IV certification.[7] Ranbaxy thus certified that its generic drug did not infringe on Pfizer's patents because its atorvastatin calcium had a different form than that used in Pfizer's Lipitor. Pfizer successfully sued Ranbaxy for patent infringement,[8] and the District Court enjoined the FDA's approval of Ranbaxy's ANDA until March 24, 2010, the date one of Pfizer's infringed patents would expire. See Lipitor

[7] At some point, the FDA deemed Ranbaxy's 2002 application as being "substantially complete" when it was originally filed. App. 1084.

[8] See Pfizer, Inc. v. Ranbaxy Lab'ys Ltd., 457 F.3d 1284, 1286, 1290-92 (Fed. Cir. 2006) (holding all but one of Pfizer's contested patent claims were valid and would be infringed by Ranbaxy's product, and remanding).

II, 868 F.3d at 243. While this dispute was ongoing, Pfizer and Ranbaxy litigated a patent dispute concerning a branded hypertension treatment drug, Accupril and, in 2008, Pfizer filed another Lipitor-related patent suit against Ranbaxy based on process patents. See id. at 243-44. Thereafter, Pfizer and Ranbaxy settled their patent litigations and agreed that (1) Ranbaxy would pay Pfizer $1 million to settle the Accupril litigation, (2) Ranbaxy would stop contesting one of Pfizer's Lipitor patents set to expire in June 2011, and (3) Pfizer would grant Ranbaxy a license to launch its generic Lipitor product on November 30, 2011, assuming it obtained FDA approval. Id. at 244-45.

Before that settlement—and while Ranbaxy's Lipitor ANDA was pending—the FDA issued Ranbaxy Warning Letters in 2006 and 2008 stating that, because of problems at Ranbaxy's facility in Paonta Sahib, India, it would recommend withholding approval of any ANDAs that listed this facility as the manufacturer for various drugs, including the generic Lipitor product, until the problems were corrected. Because of these letters, Ranbaxy acknowledged that it did not know when or if the FDA would approve the generic Lipitor ANDA.

In February 2009, the FDA invoked its Application Integrity Policy ("AIP") against Ranbaxy's Paonta Sahib facility, finding that Ranbaxy had submitted untrue statements of fact to the agency, which raised questions regarding the reliability of the data and information contained in ANDAs listing the Paonta Sahib facility. Accordingly, the FDA halted review of Ranbaxy's ANDAs involving the facility, including the generic Lipitor ANDA.

In August 2009, after its settlement with Pfizer but while the AIP remained in place, Ranbaxy informed the FDA that it planned to launch the generic Lipitor product on November 30, 2011, pending approval of its ANDA. In December 2009 and November 2010, Ranbaxy submitted two amendments to its Lipitor ANDA, including switching some manufacturing from the Paonta Sahib facility to a Pfizer-operated facility, starting production at a different plant in India, and adding its own New Jersey-based Ohm Laboratories as a manufacturing site. Because the AIP remained in place, the FDA did not immediately review the amendments.

By early 2011, the FDA still had not approved Ranbaxy's generic Lipitor ANDA, which was delaying other generic Lipitor manufacturers from entering the market due to Ranbaxy's first-filer exclusivity privilege. The FDA was aware of this logjam. Its then-Deputy Director emailed that he had discussed other generic Lipitor ANDAs with FDA senior personnel "due to the unique nature and medical necessity of Atorvastatin Calcium Tablets," and concluded that the agency would grant expedited review of Ranbaxy's and two other generic manufacturers' ANDAs "to have a generic product in the marketplace as soon as possible."[9] App. 2116.

[9] From November 2010 to January 2011, other generic pharmaceutical manufacturers submitted Lipitor ANDAs and asked the FDA to revoke Ranbaxy's first-filer privileges. In July 2011, the FDA denied revoking Ranbaxy's exclusivity because it had already found that Ranbaxy's initial ANDA was substantially complete.

Separately, in December 2010, Ranbaxy and another generic manufacturer, Teva Pharmaceuticals USA, entered into an agreement that Ranbaxy would either relinquish or selectively waive its 180-day exclusivity period if (1) the FDA tentatively approved Teva's Lipitor ANDA by November 30, 2011 (or provided written confirmation by November 30, 2011, that Teva would be eligible for final approval but for Ranbaxy's

In May 2011, the FDA granted Ranbaxy an exception from the AIP so that the agency could review the company's generic Lipitor ANDA on an expedited basis. The FDA explained that while it "anticipate[d] that [its] review of [the ANDA could] be completed by" November 30, 2011, "[p]rompt review of the ANDA does not, of course, guarantee that the application will be ready for final approval by" that date. App. 5610.

During the FDA's review, Ranbaxy initiated five more ANDA amendments and, on July 29, 2011, the FDA determined that Ranbaxy's ANDA was "substantially complete" when it was originally submitted to the FDA in 2002. App. 1084. Ranbaxy subsequently made at least two requests that the FDA approve its ANDA before its planned November 30, 2011 entry date, but these requests were rebuffed**.** In fact, on November 29, 2011, the FDA stated that "it did not appear that [completion of a component of its review that pertained to the fitness of the Paonta Sahib facility] could be reached by tomorrow because multiple parties are involved, and [the FDA] did not venture to guess when resolution would be reached." App. 1169. When Ranbaxy asked whether the ANDA could be approved the next day if the company amended its ANDA again to obviate the need to complete that review component, the FDA replied that "it was possible, but [the agency] could not guarantee it." Id. Later that day, Ranbaxy filed a response to certain concerns the FDA had raised. The next day, November 30, 2011—

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exclusivity rights), and (2) Teva manufactured certain quantities for commercial sale. Because of various regulatory violations and the need for multiple inspections, the FDA did not give tentative approval to Teva's ANDA until December 1, 2011. All other companies remained subject to Ranbaxy's 180-day exclusivity period and thus could not enter the market, despite also receiving expedited FDA review.

the same day Lipitor and Ranbaxy had agreed Ranbaxy could enter the market—the FDA approved Ranbaxy's ANDA,[10] and its generic Lipitor product entered the market.

C

Plaintiffs sued Pfizer and Ranbaxy, alleging, among other claims, that the companies' settlement agreement constituted an anticompetitive scheme to delay the market entry of generic Lipitor in violation of state and federal antitrust laws.[11] Pfizer and Ranbaxy moved for summary judgment in March 2023, principally arguing that Plaintiffs lacked antitrust standing because they did not show that Pfizer and Ranbaxy's allegedly anticompetitive conduct caused them antitrust injury. Specifically, they argued that Plaintiffs could not show that but for the settlement agreement, the FDA would have approved Ranbaxy's ANDA and its generic Lipitor product would have entered the market before November 30, 2021.[12] While the summary judgment motion was pending, the direct purchaser and end payor plaintiffs filed separate motions for class certification.

The District Court granted the summary judgment motion because Plaintiffs failed to demonstrate antitrust standing as they merely showed that the FDA "may have been able" to approve Ranbaxy's Lipitor ANDA earlier than November 30, 2011, absent Ranbaxy's agreement with Pfizer, rather than that it "would have" approved it. In re

[10] The FDA completed its expedited review in six and one-half months, faster than the median ANDA review periods in 2010 (27.85 months) and 2011 (29.52 months).

[11] The Judicial Panel on Multidistrict Litigation transferred the cases to the United States District Court for the District of New Jersey for consolidated proceedings. See In re Lipitor Antitrust Litig., 856 F. Supp. 2d 1355, 1356 (J.P.M.L. 2012).

[12] Although Pfizer filed this motion with Ranbaxy, it is no longer a party in this litigation.

Lipitor Antitrust Litig., No. 3:12-cv-12-2389, 2024 WL 2866654, at *30 (D.N.J. June 6, 2024) (quoting In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 167 (3d Cir. 2017) (emphasis omitted)). The Court also denied the direct purchaser and end payor plaintiffs' motions for class certification. See In re Lipitor Antitrust Litig., No. 3:12-cv-12-2389, 2024 WL 2866650, at *2 (D.N.J. June 6, 2024) ("DPP Class Op."); In re Lipitor Antitrust Litig., No. 3:12-cv-12-2389, 2024 WL 2865074, at *2 (D.N.J. June 6, 2024) ("EPP Class Op.").

Plaintiffs appeal.

II[13]

To prevail on an antitrust claim, private plaintiffs must show that they have antitrust standing, which is "properly viewed as an element of an antitrust claim that can be resolved at summary judgment." In re Wellbutrin, 868 F.3d at 160, 163-64.[14] To establish antitrust standing, a private plaintiff must show, among other things, that "it has suffered an antitrust injury—that is, an injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful." Id. at

[13] The District Court had jurisdiction under 28 U.S.C. §§ 1331 and 1337, and we have jurisdiction under 28 U.S.C. § 1291. We exercise plenary review over a district court's order granting summary judgment, Mylan, Inc. v. SmithKline Beecham Corp., 723 F.3d 413, 418 (3d Cir. 2013), viewing the facts and making all reasonable inferences in the non-movant's favor, Hugh v. Butler Cnty. Fam. YMCA, 418 F.3d 265, 267 (3d Cir. 2005). Summary judgment is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

[14] Defendants are entitled to judgment as a matter of law when plaintiffs fail to make "a sufficient showing on an essential element," such as antitrust standing for which they have "the burden of proof." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

164 (alteration, footnote, citations, and internal quotation marks omitted). In a reverse payment case like this one, Plaintiffs must show that "the harm they say they experienced—increased drug prices for [Lipitor]—was caused by the settlement they are complaining about." Id. at 164-65. In other words, they must show that, absent the Pfizer-Ranbaxy agreement, a generic version of Lipitor would have entered the market with FDA approval earlier—even if only by one day—than the entry date, which would have lowered prices. See id. Evidence that a generic equivalent "may" have entered the market with FDA approval is insufficient to withstand summary judgment. Id. at 167 (emphasis omitted). Rather, Plaintiffs must show that it is more likely than not that approval "would" have occurred. Id. (emphasis omitted).[15]

Plaintiffs rely on evidence that the FDA (1) was aware of the November 30, 2011 entry date contemplated by the Pfizer-Ranbaxy agreement, (2) targeted that date for completing its review, and (3) took steps to complete the review by that date to argue that the jury has a basis to infer that the FDA would have been "motivated . . . to shave at least a day (or more) off of [its] approval period had Pfizer and Ranbaxy agreed to an

[15] To the extent plaintiffs argue that the issue of causation is ill-suited to summary judgment, that suggestion is belied by In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, which affirmed the district court's order granting summary judgment on this very basis. 868 F.3d 132, 170 (3d Cir. 2017).

earlier date." Pls.' Br. at 43.[16] Although the undisputed evidence demonstrates that the FDA would have endeavored to approve the entry of a generic Lipitor product before November 30, 2011, in the but-for world, Plaintiffs have not shown that the FDA would have succeeded in doing so. Thus, they lack antitrust standing.[17]

It is undisputed that the FDA was aware of the entry date to which Pfizer and Ranbaxy agreed throughout its ANDA review process. At every stage of that process, however, the FDA emphasized that although it would target ANDA approval by that date, it could not guarantee it would hit that target. The FDA was motivated to get a generic Lipitor product on the market as soon as possible, but a generic competitor would

[16] It is undisputed that the FDA had effectively completed the scientific portion of its review by October 25, 2011, leaving only its review of Ranbaxy's Paonta Sahib, India facility. Nevertheless, despite Ranbaxy's request that it complete its facility review by mid-November, the FDA did not do so. When Ranbaxy asked the FDA on November 29, 2011, whether the agency could approve its ANDA the next day if the company amended the application to remove the Indian facility, the FDA said it could not guarantee next-day approval.

[17] Even if evidence existed that showed, absent the settlement agreement, the FDA would have granted Ranbaxy an exception to the AIP earlier than it did in the real world, that only removed one impediment to its entry into the market. Plaintiffs still needed to show that the FDA would have given final approval to a generic ANDA, which is necessary to enter the market. See 21 U.S.C. § 355(j)(2)(A)(ii), (iv); In re Wellbutrin, 868 F.3d at 167.

enter the market only if it complied with the law.[18] Despite this motivation, it still took the FDA six and one half months to complete its "[e]xpedited" review, which was substantially below the median amount of time taken to complete its review of other ANDAs. App. 1180. Even the day before it granted final approval to Ranbaxy, the FDA again cautioned that it could not guarantee that approval would follow on November 30, 2011.

In short, although it is perhaps "possible" that the FDA could have acted more quickly, it is "also certainly possible" that it would not have, and "[w]ithout more specific or concrete evidence" that the FDA would have granted earlier approval, Plaintiffs cannot establish antitrust standing and summary judgment in favor of Ranbaxy was appropriate. In re Wellbutrin, 868 F.3d at 167-70.

[18] We note that the law would not permit the entry of any other manufacturer's generic product regardless of whether the FDA approved their ANDA because Ranbaxy had first-filer exclusivity since its application was "substantially complete" at filing. 21 U.S.C. § 355(j)(5)(B)(iv). Ranbaxy only waived that exclusivity as to Teva, whose ANDA did not receive FDA approval until after November 30, 2011. Although the FDA recognized the importance of getting a generic Lipitor product on the market and considered alternatives to Ranbaxy's, Plaintiffs adduce no evidence that the FDA would have revoked Ranbaxy's exclusivity privilege and approved another manufacturer's ANDA before November 30, 2011, absent the settlement agreement. Thus, the potential entry of another manufacturer's generic Lipitor product does not create a genuine issue of material fact. In re Wellbutrin, 868 F.3d at 170.

We also note that the FDA granted expedited ANDA review to other generic manufacturers, but none received approval before Ranbaxy and Plaintiffs offer no evidence to suggest the FDA would have responded more quickly to any of these applications absent the Ranbaxy-Pfizer agreement. Even with Teva Pharmaceuticals, for whom Ranbaxy agreed to waive its exclusivity privilege, the FDA did not approve its ANDA until after November 30, 2011.

B[19]

Having properly granted Ranbaxy summary judgment, the District Court correctly concluded that the class certification motions should be denied. DPP Class Op., 2024 WL 2866650, at *2; EPP Class Op., 2024 WL 2865074, at *2.[20] The result of the summary judgment motion was that the named Plaintiffs had no claim to bring. "[I]f [a plaintiff] has no . . . claim, she cannot represent others who may have such a claim, and her bid to serve as a class representative must fail." Lierboe v. State Farm Mut. Auto. Ins. Co., 350 F.3d 1018, 1022 (9th Cir. 2003); see also Fed. R. Civ. P. 23(a)(4) ("One or more members of a class may sue or be sued as representative parties on behalf of all members only if . . . the representative parties will fairly and adequately protect the interests of the class."); cf. O'Shea v. Littleton, 414 U.S. 488, 494 (1974) ("[I]f none of the named plaintiffs purporting to represent a class establishes the requisite of a case or controversy with the defendants, none may seek relief on behalf of himself or any other member of the class."). Accordingly, because the named Plaintiffs no longer have claims

[19] "We review a class certification order for abuse of discretion, which occurs if the district court's decision rests upon a clearly erroneous finding of fact, an errant conclusion of law or an improper application of law to fact." In re Suboxone (Buprenorphine Hydrochlorine & Naloxone) Antitrust Litig., 967 F.3d 264, 269 n.6 (3d Cir. 2020) (citation omitted).

[20] The District Court explained, among other things, that because it granted summary judgment to Ranbaxy, "[t]here is no cause of action, and accordingly, there is no class," requiring denial of the class certification motions. In re Lipitor Antitrust Litig., No. 3:12-cv-2389, 2024 WL 2866650, at *2 (D.N.J. June 6, 2024) ("DPP Class Op."); In re Lipitor Antitrust Litig., No. 3:12-cv-2389, 2024 WL 2865074, at *2 (D.N.J. June 6, 2024) ("EPP Class Op."). We express no view on the rest of the District Court's opinions on the class certification motions.

against Ranbaxy and thus cannot adequately represent the class, the District Court correctly denied the motions for class certification.[21]

IV

For the foregoing reasons, we will affirm the orders granting Ranbaxy summary judgment and denying the class certification motions.

[21] Contrary to Plaintiffs' suggestion, the District Court did not issue an advisory opinion when it denied their class certification motions. We have said that "so long as a plaintiff files a motion to certify a class when he still has a live claim, the mooting of that claim while the motion is pending precludes the court from reaching the merits but does not preclude it from deciding the certification motion." Gayle v. Warden Monmouth Cnty. Corr. Inst., 838 F.3d 297, 305 (3d Cir. 2016). Because Plaintiffs filed their class certification motions before the District Court granted Ranbaxy summary judgment, the Court still had jurisdiction to resolve the motions. See id.