United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued September 7, 2007 Decided July 25, 2008

No. 05-7066

MEIJER, INC.,
ON THEIR OWN BEHALF AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED AND
MEIJER DISTRIBUTION, INC., ON THEIR OWN BEHALF AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED,
APPELLANTS

v.

BIOVAIL CORPORATION,
APPELLEE

Consolidated with
05-7069, 05-7084, 06-7118

Appeals from the United States District Court
for the District of Columbia
(No. 01cv02197)
(No. 03cv02075)
(No. 04cv00799)
(No. 04cv02235)

Bruce E. Gerstein argued the cause for appellants. With him on the briefs were *Kevin S. Landau*, *Anne Fornecker*,

Richard J. Kilsheimer, *Robert F. Muse*, *David Fierst*, *David Wallace Stanley*, *Erin Cathleen Burns*, *Joseph M. Vanek*, and *Jeffrey J. Corrigan*. *Scott L. Adkins* entered an appearance.

Steven Edward Obus argued the cause for appellees. With him on the brief were *Ronald S. Rauchberg*, *Stefanie S. Kraus*, *Peter J. Venaglia*, and *Andrew Kanter*. *Mark J. Biros* entered an appearance.

Before: GINSBURG, ROGERS, and KAVANAUGH, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* GINSBURG.

GINSBURG, *Circuit Judge*: The plaintiff-appellants in these four antitrust class actions are wholesale purchasers of Tiazac (extended-release Diltiazem Hydrochloride, hereinafter Diltiazem HCl), a controlled-release drug for hypertension and angina. They alleged that Biovail Corporation, which manufactures Tiazac, misused a patent to keep off the market a generic equivalent manufactured by Andrx Pharmaceuticals, Inc., in violation of federal and state antitrust laws. The district court entered summary judgment for Biovail, which we affirm.

I. Background

The would-be manufacturer of a "generic" bioequivalent to a previously approved "branded" drug may file an abbreviated new drug application (ANDA) with the Food and Drug Administration while the branded drug is purportedly protected by a patent.[*] *See generally* 21 U.S.C. § 355(j); 21 C.F.R. § 314.94; *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir.

[*] The FDA maintains in its Orange Book a list of the patents that, according to the manufacturer, protect each branded drug.

2006). In its ANDA the applicant may certify under Paragraph IV of the governing section of the Food, Drug, and Cosmetic Act either that the patent is invalid or that the generic drug would not infringe it. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12).* The FDA may tentatively approve an ANDA with such a certification, but that approval does not become "effective" (*i.e.*, final) for 45 days; if within that time the manufacturer of the branded drug brings an action for infringement of its patent, then the effective date of the approval is stayed for 30 months from the date of the Paragraph IV certification or until the patent case is resolved, whichever occurs first. 21 U.S.C. § 355(j)(4), (j)(5)(B)(iii); *see also* 21 C.F.R. §§ 314.105(d), 314.107(b).

Tentative approval of an ANDA does not entail the right to market the subject drug. *See* §§ 314.105(d), 314.107(b)(3)(v) ("Tentative approval of an application does not constitute 'approval'" under FDCA "and cannot, absent a final approval letter from the agency, result in an effective approval"). Nor does it guarantee final approval, which may depend upon an "additional review of the application" by the FDA. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(BB); *see also* 21 C.F.R. § 314.107(b)(3).

In June 1998 Andrx filed an ANDA seeking approval to market Diltiazem HCl under the name Taztia; Andrx included a Paragraph IV certification both challenging the validity of Biovail's U.S. Patent No. 5,529,791 (filed Sept. 23, 1994) (the '791 patent), which Biovail claimed protected the formula for Tiazac, and asserting Taztia would not infringe that patent.

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* The FDA may not approve an application that does not account for a claimed patent, *see* 21 U.S.C. § 355(j)(2)(A)(vii), (j)(4)(J), or that "contains an untrue statement of material fact," § 355(j)(4)(K).

Biovail sued Andrx in federal district court in Florida, thereby extending the statutory stay for up to 30 months. In March 2000, the district court determined Andrx's product would not infringe Biovail's patent, *Biovail Corp. v. Andrx Pharms., Inc.*, 158 F. Supp. 2d 1318 (S.D. Fla.), whereupon Biovail appealed to the Federal Circuit.

In September 2000 the FDA "tentative[ly]" approved Andrx's ANDA, noting that Biovail's pending appeal prevented it from giving final approval at that time.[*] The agency went on to explain that, if and when Andrx prevailed on appeal, the FDA would have to be "assured there is no new information that would affect whether final approval should be granted."

On January 8, 2001, with its appeal still pending, Biovail claimed its newly acquired U.S. Patent No. 6,162,463 (filed Apr. 28, 1998) (the '463 patent) also protected Tiazac, and the FDA asked Andrx for its position with regard to that patent. On February 13 the Federal Circuit affirmed the judgment for Andrx in the '791 patent litigation, 239 F.3d 1297, thereby terminating the statutory stay. Three days later, Andrx filed a Paragraph IV declaration challenging the '463 patent, thereby

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[*] The statute provides that the stay terminates when "the court" determines the patent at issue is invalid or would not be infringed. 21 U.S.C. § 355(j)(5)(B)(iii). The FDA at that time took the position that the stay would expire only upon the resolution of any appeal. After *Torpharm v. Shalala*, No. Civ.A. 97-1925, 1997 WL 33472411 (D.D.C. Sept. 15, 1997), and *Mylan Pharmaceuticals v. Shalala*, 81 F. Supp. 2d 30 (D.D.C. 2000), were decided, however, the FDA adopted the district court's view that the judgment of a district court in favor of the generic applicant terminates the stay. FDA, Guidance for Industry (Mar. 2000), *available at* http://www.fda.gov/cder/guidance/3659fnl.pdf. The FDA amended 21 C.F.R. § 314.107 accordingly, 65 Fed. Reg. 43,233 (July 13, 2000), but did not apply the rule to ANDAs, such as Andrx's, then pending, *id.* at 43,234-35.

triggering a new 45-day stay, which Biovail extended by suing Andrx anew in Florida. Meanwhile, Andrx had filed its own action against Biovail and the FDA in the same district court, challenging as baseless Biovail's claim that the '463 patent covered Tiazac and seeking an injunction requiring the FDA to remove the '463 patent from the Orange Book. *See Andrx Pharms., Inc. v. Biovail Corp.*, 175 F. Supp. 2d 1362 (S.D. Fla. 2001), *vacated*, 276 F.3d 1368 (Fed. Cir. 2002). On May 14, 2001, while these suits were pending, the FDA tentatively approved Andrx's ANDA a second time. In April 2002, Biovail withdrew its claim the '463 patent covered Tiazac.

Meanwhile, Andrx had begun to encounter problems manufacturing its version of Diltiazem HCl. In December 2000, shortly after having received tentative approval from the FDA, Andrx identified problems in its methodology for testing Taztia for dissolution in the human body. In January 2001 Andrx manufactured a new batch of the drug, which it initially found satisfactory pursuant to a new testing methodology, but on May 18, 2001 the Company discovered that samples from the new batch also failed to dissolve as required. Andrx eventually rejected that entire batch because the manufacturing process was faulty, and continued to encounter manufacturing problems into 2003. Because of those problems, the FDA did not finally approve Andrx's ANDA until April 2003 -- a full year after Biovail had withdrawn its claim that the '463 patent covered its drug.

Much as Andrx had done in its suit against Biovail, *see* 175 F. Supp. 2d 1362, the plaintiffs in these four class actions alleged in the district court that Biovail unlawfully forestalled the FDA's final approval of Andrx's ANDA by filing with the FDA documents claiming falsely and in bad faith that the '463 patent covered Tiazac, and by engaging in bad faith or "sham" litigation over that patent. According to the plaintiffs, Biovail

thus unlawfully excluded Andrx from "the market for Tiazac and its generic equivalents," in violation of federal and state antitrust laws,[*] *see United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001) (en banc) ("Whether any particular act of a monopolist is exclusionary, rather than merely a form of vigorous competition, can be difficult to discern: the means of illicit exclusion, like the means of legitimate competition, are myriad"); *see also City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 379-80 (1991) ("The federal antitrust laws" exempt "the conduct of private individuals in seeking anticompetitive action from the government," but they do reach "sham[s]," as when "persons use the governmental *process* -- as opposed to the *outcome* of that process -- as an anticompetitive weapon"). But for Biovail's exclusionary conduct, the plaintiffs claim, the FDA would have finally approved Andrx's ANDA on or about February 13, 2001, when the Federal Circuit ruled against Biovail in the '791 patent litigation; the plaintiffs could have begun soon thereafter purchasing Taztia from Andrx at a lower price than they had to pay Biovail for Tiazac.

Biovail moved for summary judgment in two of the four present class actions on the ground that, regardless whether Biovail had violated the antitrust laws, the plaintiffs could not show Biovail had caused them any harm. The district court agreed, *Twin Cities Bakery Workers Health & Welfare Fund v. Biovail Corp.*, Nos. Civ.A. 01-2197, Civ.A. 03-2075, 2005 WL 3675999 (Mar. 31, 2005), and subsequently entered judgment for Biovail in a third case, *SAJ Distribs., Inc. v. Biovail Corp.*, No. Civ.A. 04-799 (May 25, 2005), which it found indistinguishable.

Seeking to avoid the same fate, the plaintiffs in the fourth action, *Louisiana Wholesale Drug Co.* (*LWD*) *v. Biovail Corp.*,

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[*] Plaintiffs make no argument specific to the law of any state.

No. Civ.A. 04-2235, amended their complaint to allege that, but for Biovail's wrongful use of the '463 patent, they could have purchased generic drugs manufactured and sold either by Andrx or by Biovail itself. According to their amended complaint, Biovail and its exclusive distributor, Forest Laboratories Inc. -- which was a defendant in the original action but not the subject of any allegation of wrongdoing -- had conspired to distribute a generic version of Tiazac before Andrx and other manufacturers could get to market, but abandoned that plan in favor of using the '463 patent to forestall final approval of Andrx's ANDA; they cite no overt act in furtherance of this conspiracy after Biovail dropped its claim the '463 patent protected Tiazac. The *LWD* plaintiffs also sought further discovery pursuant to Federal Rule of Civil Procedure 56(e). *See also* FED. R. CIV. P. 56(f) (2007).

Applying its *Twin Cities* ruling to *LWD* without addressing the Rule 56(e) affidavit, the district court entered summary judgment for the defendants insofar as the *LWD* plaintiffs claimed the defendants had prevented the plaintiffs from purchasing Taztia from Andrx; the court held that no reasonable juror could find Biovail's use of the '463 patent prevented the FDA's final approval of Andrx's ANDA. 437 F. Supp. 2d 79, 82-84 (2006). The court then entered judgment for the defendants insofar as the *LWD* plaintiffs advanced in their amended complaint their new theory that they could have purchased generic Diltiazem HCl from the defendants but for Biovail's misuse of the '463 patent; the court reasoned that the amendment did not relate back to the filing of the original complaint and was thus time-barred. *Id.* at 85-87.

II. Analysis

The plaintiffs in all four class actions appeal, contending they proffered evidence sufficient to defeat Biovail's motion for

summary judgment. In addition, the *LWD* plaintiffs argue the district court improperly dismissed the amendment to their complaint as untimely and erroneously failed to address their affidavit seeking further discovery under Rule 56(e).

A. Inability to Purchase Taztia from Andrx (Original Theory)

A plaintiff seeking damages under the antitrust laws must prove the defendant has caused the plaintiff "antitrust injury," meaning an "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977) (emphasis omitted); *see also Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 806 (D.C. Cir. 2001); 2 PHILIP E. AREEDA & HEBERT HOVENKAMP, ANTITRUST LAW ¶¶ 337, 338 (3d ed. 2007). Just as a would-be entrant suing an incumbent firm for excluding it from a relevant market in violation of the Sherman Act must demonstrate it intended and was prepared to enter that market, *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 126-29 (1969); 2 AREEDA & HOVENKAMP, *supra*, ¶ 349, so a would-be purchaser suing an incumbent monopolist for excluding a potential competitor from which it might have bought a product at a lower price must prove the excluded firm was willing and able to supply it but for the incumbent firm's exclusionary conduct, *see Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990) (injury must be "attributable to an anti-competitive aspect of the practice under scrutiny"). Here, that means the plaintiffs must prove Andrx was prepared to sell Taztia and could have obtained approval from the FDA to do so at some point between February 2001, when the '791 patent no longer barred the FDA's final approval, and April 2002, when Biovail withdrew its claim that the '463 patent protected Tiazac. *See Twin Cities*, 2005 WL 3675999, at *5 n.2; *see also Zenith*

Radio Corp., 395 U.S. at 126; *Andrx Pharms.*, 256 F.3d. at 806-07.

Biovail argues, and the district court held, no reasonable juror could conclude Biovail caused the plaintiffs any harm. The plaintiffs submit they presented evidence sufficient for a reasonable juror to find that but for Biovail's conduct, the FDA would have granted Andrx final approval in February 2001 and that Andrx would have marketed Taztia soon thereafter.[*] Reviewing the summary judgment *de novo*, *Galvin v. Eli Lilly & Co.*, 488 F.3d 1026, 1031 (D.C. Cir. 2007), we hold no reasonable juror could conclude that, but for Biovail's alleged misuse of the '463 patent, the FDA would have granted Andrx final approval in February 2001. Accordingly, we affirm the judgment of the district court without reaching Biovail's alternative argument that the plaintiffs could not show Andrx was ever prepared to manufacture a safe drug.[**] *See* Fed. R.

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[*] In principle, the plaintiffs could establish antitrust injury by showing that, but for Biovail's misuse of the '463 patent, they could have purchased generic Diltiazem HCl from Andrx at any time during the pendency of the stay caused by the '463 patent. The plaintiffs, however, have not argued that Andrx would have obtained approval from the FDA and been ready to market the drug at any time after February 2001 but before the expiration of the statutory stay -- a wise strategy in view of the problems Andrx encountered trying to manufacture Taztia during that period. Therefore, it is crucial to the plaintiffs' case, as counsel acknowledged at oral argument, that they make the showing stated in the text.

[**] Not all the plaintiffs invoked all the evidence upon which they all now rely; because we find the totality of competent evidence insufficient to defeat the defendants' motion for summary judgment, however, we need not concern ourselves with the effort of certain of the plaintiffs to rely on appeal upon evidence they did not adduce before the district court.

Civ. P. 56(c) (district court must enter summary judgment when "there is no genuine issue as to any material fact and ... the movant is entitled to judgment as a matter of law").

In arguing that a reasonable juror could find the FDA would have approved Andrx's ANDA in February 2001 but for misconduct by Biovail, the plaintiffs first point to the affidavits of Dr. Nicholas Fleischer and Mr. Jeffrey Gibbs, each of whom had once worked for the FDA. The district court, invoking Federal Rules of Evidence 702 (admissibility of expert testimony) and 403 (exclusion of otherwise admissible evidence on ground of unfair prejudice), excluded those affidavits because they were speculative and ungrounded in fact and, in any event, "their value is substantially outweighed by the danger of unfair prejudice or misleading the jury." *See* 2005 WL 3675999 at *4-*5. The plaintiffs challenge the district court's reliance upon Rule 702 but not upon Rule 403. In keeping with good sense and our established practice, we will not disturb the ruling of a district court where, as here, an independent basis for that ruling is uncontested. *N.Y. Rehab. Care Mgmt., LLC v. NLRB*, 506 F.3d 1070, 1076 (D.C. Cir. 2007); *Veitch v. England*, 471 F.3d 124, 132 (D.C. Cir. 2006).

The plaintiffs next direct us to decisions of courts they claim determined, in litigation involving Andrx, Biovail, and the FDA, that the agency would have finally approved Andrx's ANDA in February 2001 but for Biovail's misuse of the '463 patent, *see Andrx Pharms., Inc. v. Biovail Corp. Int'l*, No. 01-6194-Civ (S.D. Fla. Mar. 6, 2001); *Andrx Pharms., Inc.*, 175 F. Supp. 2d at 1365-66; *Andrx Pharms., Inc.*, 276 F.3d at 1372 & n.2. As the district court pointed out in the present case, however, none of those decisions made "a finding of disputed fact," 437 F. Supp. 2d at 83-84, and none determined whether a reasonable juror could conclude the FDA would have granted final approval in February 2001. Although the likely timing of

the FDA's final approval was placed at issue in the Southern District of Florida when Andrx sought a preliminary injunction -- thus requiring it to prove irreparable harm -- that court did not reach the issue because it determined that it lacked subject matter jurisdiction. *Andrx Pharms.*, No. 01-6194-Civ, slip op. at 18-19. Neither did that court in its decision of September 2001, which addressed various motions to dismiss and for summary judgment, decide when the FDA would have granted final approval of Andrx's ANDA. *See* 175 F. Supp. 2d 1362. Instead, in its recitation of the facts the court assumed, as did the Federal Circuit on appeal, *see* 276 F.3d at 1372 & n.2, that because the FDA had given its initial approval in September 2000 it would have given its final approval as soon as the statutory bar was lifted in February 2001, 175 F. Supp. 2d at 1365-66. The likely timing of the FDA's approval was not a disputed issue of fact before either court.

Of the evidence upon which the plaintiffs rely in their brief to this court, we accordingly confine our analysis to the FDA's tentative approval in September 2000, a February 2001 fax from the FDA to Andrx, the FDA's filings in the case Andrx brought to compel the agency to withdraw the '463 patent from the Orange Book, and the affidavit of an Andrx employee.[*] Upon

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[*] In addition to the evidence described in the text, the plaintiffs refer in their brief to the FDA's "conclu[sion] in writing ... that [Andrx's] generic drug would be approved, but for the ... infringement suit." No such conclusion is to be found in the record of this case, however, and the plaintiffs do not provide the statement itself but instead quote the opinion in *Andrx Pharmaceuticals, Inc.*, 175 F. Supp. 2d at 1366. We disregard that purported "evidence"; if the underlying evidence exists and is in the record of the cited case, then the plaintiffs, who have access to that record, should have produced it. *Cf. Cmty. Hosps. of Cent. Cal. v. NLRB*, 335 F.3d 1079, 1086-87 (D.C. Cir. 2003) (presumption may arise from failure to produce evidence to which party has access) (citing *United States v. Young*,

the basis of this evidence, we hold no reasonable juror could conclude that but for Biovail's misuse of the '463 patent the FDA would have approved Andrx's ANDA in February 2001.

The plaintiffs maintain the tentative approval of September 2000 demonstrates that, apart from the '463 patent, the only hurdle to final approval was resolution of the '791 patent dispute. That first tentative approval made clear, however, that final approval was also subject to the FDA being "assured there is no new information that would affect whether final approval should be granted." For that reason, the FDA instructed the applicant, "when you believe that your application may be considered for final approval," file "[u]pdated information related to labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in th[e] abbreviated application." A reasonable juror would not infer upon the basis of this letter that final approval would have been forthcoming in February 2001.

As Biovail points out, the FDA's second tentative approval, issued in May 2001, further undermines the plaintiffs' treatment of the September 2000 tentative approval as tantamount to final approval subject only to the lifting of the statutory stay. The plaintiffs belittle the May 2001 approval as "simply a reaffirmance of the September 2000 approval," but the record contradicts that contention. The FDA's letter of May 14, 2001 referred not only to the September 2000 tentative approval but also to several amendments to Andrx's ANDA that postdated the decision of the Federal Circuit in the '791 patent dispute; had the FDA meant merely to "reaffirm" its previous tentative

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463 F.2d 934, 939 (D.C. Cir. 1972)).

approval, it could easily have said so.[*] At best the second tentative approval suggests the FDA could have given final approval of Andrx's ANDA in May, not February, 2001.

Nor is the FDA's fax of February 2, 2001 helpful to the plaintiffs. It states only that a division of the FDA "ha[d] completed its review" of the December 2000 amendment (relating to Andrx's testing methodology) and "ha[d] no further questions at this time," and even that explicitly "preliminary" observation was made "subject to revision after review of the entire application." In the same fax the FDA also asked Andrx to "provide a ... certification" as to the '463 patent, but the FDA nowhere suggested the agency would approve Andrx's ANDA when Biovail's patents were no longer a bar.

The plaintiffs also point out that in the litigation Andrx brought against Biovail and the agency, "FDA briefing demonstrat[es] that because [Biovail] listed the '463 Patent, Andrx's ANDA was no longer eligible for final FDA approval in February 2001." Relatedly, the plaintiffs note that when Andrx filed a statement of undisputed facts in that litigation -- to the effect that only litigation over the '791 patent prevented the FDA's final approval -- the FDA responded that the '463 patent also barred final approval. These documents are unhelpful, however, because they demonstrate only that ending the patent litigation was a necessary condition for the FDA's

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[*] The plaintiffs assert in a footnote in their reply brief that the various amendments were minor matters (relating to product labeling) that would not have prevented final approval in February 2001, but that assertion is as conclusory as it is untimely. *See United States v. Whren*, 111 F.3d 956, 958 (D.C. Cir. 1997) ("absent extraordinary circumstances (not present here) we do not entertain an argument raised for the first time in a reply brief or for that matter, in a footnote" (citations omitted)).

final approval; a reasonable juror could not infer from them that it was a sufficient condition. In keeping with applicable law, 21 C.F.R. § 314.107(b); 21 U.S.C. § 355(j)(5)(B)(iii), (j)(5)(B)(iv)(II)(dd)(BB), the FDA's brief stated only that upon the termination of the litigation Andrx would be "eligible for," not that it would be "entitled to," final approval. Similarly, the FDA's response to Andrx's statement of undisputed facts does not imply it would have granted final approval but for Biovail's misuse of the second patent. Nor could it have: The FDA's final approval was by law subject to Andrx updating its application to the satisfaction of the FDA once the statutory bar was lifted.

The plaintiffs finally rely upon the February 9, 2001 affidavit of Scott Lodin, then the General Counsel of Andrx. When Andrx sought to compel the FDA to remove the '463 patent from the Orange Book, Lodin filed an affidavit stating "the FDA had informed Andrx that it was prepared to grant final approval to Andrx's ANDA upon the expiration of the 30-month stay period" triggered by Biovail's first patent infringement case. The Lodin affidavit, however, cites only the tentative approval of September 2000, which we have already determined is an insufficient basis for a reasonable juror to find the FDA would have granted final approval in February 2001; beyond that it is merely conclusory. *Cf. Greene v. Dalton*, 164 F.3d 671, 675 (D.C. Cir. 1999) ("Although, as a rule, statements made by the party opposing a motion for summary judgment must be accepted as true for the purpose of ruling on that motion, some statements are so conclusory as to come within an exception to that rule"); *see also Ginger v District of Columbia*, 527 F.3d 1340, 1346-47 (D.C. Cir. 2008). Nor could Lodin know how the FDA would react to any update Andrx would file in order to obtain final approval.

We conclude the plaintiffs have not adduced evidence sufficient for a reasonable juror to find the FDA would have approved Andrx's ANDA in February 2001 but for Biovail's claim the '463 patent covered Tiazac and Biovail's subsequent suit for infringement of that patent. The plaintiffs' original theory of the case, in which they blamed Biovail for their inability to purchase Taztia from Andrx, turned upon the jury being able to make that finding. Accordingly, we affirm the entry of summary judgment in favor of the defendants in all four cases inasmuch as the plaintiffs blame Biovail for their inability to purchase Taztia from Andrx.

B. Inability to Purchase Generic Diltiazem HCl from Biovail (Amended Complaint)

The *LWD* plaintiffs alleged in their amended complaint that Biovail and Forest conspired preemptively to manufacture and distribute their own generic version of Diltiazem HCl while the '791 patent litigation precluded competitors from entering the market, a scheme they abandoned in late 2000 or early 2001 in favor of misusing the '463 patent to exclude potential competitors.[*] The defendants argue, and the district court held, the complaint does not relate back and does not allege facts sufficient to establish a claim of injury within the limitation period. Reviewing the court's dismissal *de novo*, while "assum[ing] 'all the allegations in the complaint are true (even if doubtful in fact),'" *Aktieselskabet AF 21. November 2001 v. Fame Jeans Inc.*, 525 F.3d 8, 17 (D.C. Cir. 2008) (quoting *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1965 (2007)), and "giv[ing] the plaintiff 'the benefit of all reasonable inferences

[*] The plaintiffs do not allege the defendants engaged in any misconduct after April 2002, when Biovail dropped its claim that the '463 patent protected Tiazac.

derived from the facts alleged,'" *id.* (quoting *Stewart v. Nat'l Educ. Ass'n*, 471 F.3d 169, 173 (D.C. Cir. 2006)), we affirm.

(1) Relation Back

Federal Rule of Civil Procedure 15(c)(1)(B) provides: "An amendment ... relates back to the date of the original pleading when ... the amendment asserts a claim ... that arose out of the conduct, transaction, or occurrence set out -- or attempted to be set out -- in the original pleading." *See also* Fed. R. Civ. P. 15(c)(2) (2007). The underlying question is whether the original complaint adequately notified the defendants of the basis for liability the plaintiffs would later advance in the amended complaint. *United States v. Hicks*, 283 F.3d 380, 388 (D.C. Cir. 2002); 6A CHARLES ALAN WRIGHT, ARTHUR R. MILLER, & MARY KAY KANE, FEDERAL PRACTICE & PROCEDURE § 1497 ("if the alteration of the original statement is so substantial that it cannot be said that defendant was given adequate notice of the conduct, transaction, or occurrence that forms the basis of the claim ... then the amendment will not relate back"); *see also Aktieselskabet*, 525 F.3d at 16 (complaint must "give a defendant 'fair notice of the claims against him'" (quoting *Ciralsky v. CIA*, 355 F.3d 661, 668-70 (D.C. Cir. 2004)). The defendants argue, and we agree, that the original complaint in this case does not give that notice and therefore does not, as amended, relate back.

The *LWD* plaintiffs alleged for the first time in the amended complaint that Biovail and Forest had conspired to exclude new entrants into the market for generic Diltiazem HCl and (before Biovail acquired the '463 patent) had planned preemptively to capture that market by launching their own generic drug. For prior notice, they point out that their original complaint referred to their inability to purchase "generic versions of Tiazac," *i.e.*, in the plural, and contend the amendment "simply add[ed] detail

regarding *which* generic versions [of Diltiazem HCl] would have been marketed but for Defendants' scheme."

As we read their original complaint, however, it did not put Biovail and Forest sufficiently on notice the plaintiffs might be claiming the defendants' decision not to sell their own generic Diltiazem HCl violated the antitrust laws. The original complaint chronicles the tale of a single firm, Biovail, bent upon preventing the FDA from granting final approval of the generic drug proposed by Andrx (and perhaps others), but it did not allege Forest had engaged in any specific misconduct; Forest was made a defendant solely because, as Biovail's exclusive distributor, it "benefitted from [Biovail's] wrongful conduct to extend the Tiazac monopoly" unlawfully. The amended complaint alleges for the first time that Biovail and Forest unlawfully conspired to extend their lawful monopoly, that they planned preemptively to introduce their own generic Diltiazem HCl, and that they unlawfully abandoned that plan in favor of misusing the '463 patent to prevent the FDA from approving the applications of their would-be generic competitors. Although the original and amended claims have some elements and some facts in common, the whole thrust of the amendments is to fault both Biovail and Forest, and to fault them for conduct different from that identified in the original complaint. Consequently, the amended complaint does not relate back.

(2) Adequacy of the Amendment to the Complaint

The *LWD* plaintiffs filed their amended complaint on June 1, 2005; because that complaint does not relate back to the filing of the original complaint, the *LWD* plaintiffs, who claim the defendants violated § 2 of the Sherman Act, 15 U.S.C. § 2, must allege the defendants injured them during the four year period starting June 1, 2001, or state facts sufficient reasonably to give rise to an inference of such an injury. *See* § 4B of the Clayton

Act, 15 U.S.C. § 15b (providing any suit for damages under the federal antitrust laws "shall be forever barred unless commenced within four years after the cause of action accrued"); *see also Twombly*, 127 S. Ct. at 1966; *Aktieselskabet*, 525 F.3d at 17.

On appeal the *LWD* plaintiffs argue that, but for Biovail's acquisition of the '463 patent, Biovail and Forest in February 2001 would have entered into long-term contracts to sell to wholesalers, including the plaintiffs, generic Diltiazem HCl beyond June 1, 2001 and the plaintiffs were injured because they were unable to purchase generic drugs from the defendants pursuant to those hypothetical contracts. They made no similar allegation, however, in the amended complaint, their opposition to Biovail's motion to dismiss, or their request under Rule 56(e) for further discovery. At oral argument, counsel for the *LWD* plaintiffs was unable to say when, if ever, they made this argument in the district court and as far as we can tell they never did. Absent a showing that "'injustice might otherwise result,'" and the plaintiffs offer none, we do not entertain an argument made for the first time on appeal. *Ben-Kotel v. Howard Univ.*, 319 F.3d 532, 535 (D.C. Cir. 2003).

As the defendants argue, without the allegation that Biovail and Forest would have entered into long-term contracts to sell wholesalers generic Diltiazem HCl, the *LWD* plaintiffs have no basis upon which to claim that, but for Biovail's acquisition of the '463 patent, the defendants would have sold them generic Diltiazem HCl after June 1, 2001. Because, as we have held, the *LWD* plaintiffs cannot show Andrx would have sold Diltiazem HCl prior to May 2003, when Andrx received final approval and long after they allege either defendant had engaged in any misconduct, it follows that the defendants would have faced no

competition until then.[*] There is no provision of law that would have required Biovail and Forest to sell or continue selling a generic version of Diltiazem HCl in competition with Biovail's branded product once it became clear, as it would have done in early 2001, that Andrx could not get FDA approval to enter the market. Nor does the complaint advance any fact suggesting Biovail and Forest would have done so. (The plaintiffs do not argue on appeal that any firm other than Andrx sought to enter the market.) These gaps are fatal to the plaintiffs' case.

In sum, the factual allegations of the *LWD* plaintiffs' amended complaint, taken as true, are inadequate to make out a timely action under the antitrust laws. Therefore, we affirm the dismissal of the amended complaint.

C. The Rule 56(e) Affidavit

Finally, we turn to the *LWD* plaintiffs' objection to the failure of the district court to address their Rule 56(e) affidavit before entering judgment. The *LWD* plaintiffs sought to discover from Andrx any communications between it and the FDA tending to show the FDA would have given final approval of Andrx's ANDA in February 2001. They also sought to discover from Andrx information regarding what it would have

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[*] Rule 12(b)(6) requires us to assume the truth of the facts alleged in the complaint but not to disregard our own holding that the plaintiffs cannot show Andrx would have competed with Biovail but for the latter company's misconduct. *Cf.* 5B WRIGHT, MILLER & KANE, *supra*, § 1357 ("Numerous cases ... have allowed consideration of matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint whose authenticity is unquestioned; these items may be considered by the district judge without converting the motion into one for summary judgment").

done had it obtained final approval from the FDA in February 2001 but subsequently discovered problems manufacturing the drug, and from Biovail and Forest information relating to their alleged plan preemptively to sell a generic version of Tiazac.

If the district court's inattention to the plaintiffs' affidavit was an error, then it was surely harmless. 28 U.S.C. § 2111; *Colbert v. Potter*, 471 F.3d 158, 165, 168 (D.C. Cir. 2006). As for the first request, the communications the plaintiffs seek would be insufficient to sustain a jury verdict in their favor; the FDA did not again even tentatively approve Andrx's ANDA until May 2001 and final approval remained by law subject to the FDA being satisfied with any update Andrx might file.[*] Any information responsive to the plaintiffs' second request would be immaterial because, as we have held, no reasonable juror could find that but for Biovail's conduct the FDA would have finally approved Andrx's application in February 2001. Because the proposed amendments to the complaint were untimely and insufficient, any information responsive to the third request is likewise immaterial.

III. Conclusion

With respect to their original theory of the case, the plaintiffs have not shown a reasonable juror could find the FDA would have granted Andrx final approval in February 2001 and, without such proof, they are unable to show Andrx was ready and able to market generic Diltiazem HCl at any time prior to

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[*] In any event, the plaintiffs have not explained why they would need additional discovery: It is undisputed that the *LWD* plaintiffs have had access to the full record of the litigation in Florida; Andrx obviously would have introduced in that case any document responsive to this request in its attempt to have the FDA remove the '463 patent from the Orange Book.

the expiration of the statutory stay. Therefore, the plaintiffs are unable to establish the facts required to make out antitrust injury.

The amendment to the *LWD* complaint was both untimely and insufficient because (1) the amended complaint claiming that Biovail and Forest conspired to prevent the plaintiffs' purchase of generic Diltiazem HCl from Biovail does not relate back to the filing of their original complaint and (2) the plaintiffs have not alleged facts sufficient to establish Biovail and Forest would have harmed them within the four-year limitation period for antitrust claims, which began to run in June 2001. Nor does their affidavit for additional discovery under Rule 56(e) require a remand.

Accordingly, the judgment of the district court is in all respects

Affirmed.