

13-1232
Louisiana Wholesale Drug Co. v. Shire LLC

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2013
(Argued: March 17, 2014 Decided: June 9, 2014
Corrected: June 19, 2014)
Docket No. 13-1232

In re ADDERALL XR ANTITRUST LITIGATION

LOUISIANA WHOLESALE DRUG COMPANY, INC.,
on behalf of itself and all others similarly situated,
VALUE DRUG COMPANY, on behalf of itself and all
others similarly situated,

Plaintiffs–Appellants,

v.

SHIRE LLC, SHIRE U.S., INC.,

*Defendants–Appellees.**

Before: JACOBS, SACK, and LOHIER, *Circuit Judges.*

Appeal from a judgment of the United States District Court for the Southern District of New York (Victor Marrero, *Judge*), dismissing the plaintiffs' complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. The plaintiffs, wholesale dealers in pharmaceutical products, brought this putative class action asserting that the defendant drug manufacturers

* The Clerk of the Court is respectfully directed to amend the official caption in this case to appear as set forth above.

violated the Sherman Act by breaching their contracts to supply competing manufacturers with an unbranded version of the defendants' widely prescribed patented drug. The plaintiffs argue that these contracts gave rise to a "duty to deal" enforceable by third-party customers such as themselves under the antitrust laws. We disagree. The judgment of the district court is therefore

AFFIRMED.

JOSEPH OPPER (Bruce E. Gerstein, Elena K. Chan, Kimberly Hennings, *on the brief*), Garwin Gerstein & Fisher LLP, New York, NY, *for Plaintiffs–Appellants*,

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SACK, *Circuit Judge*:

The plaintiffs are wholesale dealers in pharmaceutical products including Adderall XR, a widely prescribed drug manufactured by the defendants. They brought this putative class action alleging that the defendants violated the anti-monopolization provision of the Sherman Act by breaching defendants' contracts to supply two of their competitors—who in turn supply the plaintiffs—with an unbranded version of the defendants' patented drug for resale under the competitors' own labels. Although the contracts were executed in connection with settlements of patent litigation, the plaintiffs disclaim any reliance on that fact. They argue instead that the contracts themselves gave rise to a "duty to deal" under antitrust law. We disagree and therefore affirm the judgment of the United States District Court for the Southern District of New York (Victor Marrero, *Judge*) dismissing the complaint.

BACKGROUND

Defendants Shire LLC and Shire U.S., Inc. (together, "Shire") hold patents covering Adderall XR ("AXR"), a drug approved by the U.S. Food and Drug Administration ("FDA") in 2001 to treat attention-deficit/hyperactivity disorder. AXR enjoyed significant commercial success. In 2002, Teva Pharmaceuticals USA, Inc.,¹ sought FDA approval to produce a generic equivalent. Compl. ¶¶ 2–3. Impax Laboratories, Inc., followed suit in 2003. *Id.* ¶ 3.

¹ In 2008, Teva acquired Barr Pharmaceuticals, which was the entity actually seeking approval to produce generic AXR in 2002. For the sake of simplicity, both the complaint and this opinion refer to those entities collectively as "Teva." *See* Compl. ¶ 3 n.1.

Teva and Impax took advantage of the streamlined drug approval process established by a 1984 amendment to the Federal Food, Drug, and Cosmetic Act generally referred to as the "Hatch-Waxman Amendments." *See* 21 U.S.C. § 355(b), (j). The Act allows a generic maker to piggyback on the efforts of an approved drug's manufacturer by filing an Abbreviated New Drug Application ("ANDA") showing, among other things, that its proposed product is biologically equivalent to the approved drug. *Id.* § 355(j)(2)(A)(iv). An ANDA must also include a certification that the proposed generic does not infringe the approved drug's patents. *Id.* § 355(j)(2)(A)(vii).

If an ANDA contains a certification that an approved drug's patents are "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted," the applicant must notify the drug's patent holder of the pending application. *Id.* § 355(j)(2)(A)(vii), (B)(iii). The patent holder then has forty-five days to file suit against the applicant for patent infringement. If the patent holder acts within this window, any FDA action on the ANDA is stayed for thirty months. *Id.* § 355(j)(5)(B)(iii). That is what happened here.

In their applications to the FDA, both Teva and Impax certified that Shire's patents for AXR were either "invalid or will not be infringed by the manufacture, use, or sale" of their proposed generic equivalents. *See* Compl. ¶ 39; 21 U.S.C. § 355(j)(2)(A)(vii). Shire responded by bringing suit against both companies for patent infringement.

In 2006, Shire settled its patent litigation with Teva and Impax. Compl. ¶¶ 5, 41. The agreements memorializing the settlement terms each reflected the

same basic bargain: The generic manufacturers would stay out of the market for AXR for three years (even if their applications to produce generic AXR were approved by the FDA before then). *Id.* ¶¶ 5, 41. In exchange, Shire would grant the generic manufacturers licenses to make and sell generic AXR starting in 2009 (Teva in April; Impax in October). *Id.* ¶¶ 6, 42. If the FDA had not approved their ANDAs by that time, Shire would supply Teva's and Impax's requirements for unbranded AXR for resale under their own labels. *Id.* ¶¶ 6, 43. In short, Shire undertook to give its competitors both the rights and the supplies necessary to participate in the market for AXR. *Id.* ¶¶ 6, 44.

Because the FDA had not approved their ANDAs by the close of Shire's contractual period of exclusivity, Teva and Impax both began purchasing unbranded AXR from Shire for resale in 2009 pursuant to their settlement agreements with Shire. Compl. ¶¶ 47, 49, 51. Several months after their respective entries into the market, both Teva and Impax complained that Shire was only partially filling their orders.² *Id.* ¶¶ 53–60. The effect of this alleged shortfall on the price of AXR paid by wholesalers—the members of the plaintiffs' proposed class—gave rise to the litigation now before us on appeal.

In May 2012, Louisiana Wholesale Drug Company, Inc., based in Sunset, Louisiana, filed a putative class action against Shire in the Southern

² Shire, Teva, and Impax have already settled litigation arising from these contract disputes. *See* Stipulation of Dismissal, *Teva Pharms. USA, Inc. v. Shire LLC*, No. 09 Civ. 8860 (MGC) (S.D.N.Y. Nov. 20, 2009), ECF No. 17; Stipulation of Dismissal, *Impax Labs., Inc. v. Shire LLC*, No. 10 Civ. 8386 (MGC) (S.D.N.Y. Feb. 14, 2013), ECF No. 211.

District of New York. See *Louisiana Wholesale Drug Co. v. Shire LLC*, No. 12 Civ. 3711 (VM) (S.D.N.Y.). That case was subsequently consolidated with a nearly identical action brought by Value Drug Company of Altoona, Pennsylvania. Consent Order Consolidating Related Actions, *Louisiana Wholesale Drug Co.*, No. 12 Civ. 3711 (VM) (S.D.N.Y. Oct. 17, 2012), ECF No. 22. We refer to the plaintiffs collectively as "LWD." Neither Teva nor Impax is a party to this litigation.

LWD alleged that by supplying Teva and Impax with less than their requirements of unbranded AXR, Shire relegated them to 50–60% of the market, instead of the 90% share they might have been expected to capture had they received the quantity of unbranded pills they had demanded. Compl. ¶¶ 6, 8, 52, 67. This, in turn, allowed Shire to "fix[], raise[], maintain[], and/or stabilize[] the price of AXR Product at supra-competitive levels," and thereby to "overcharge[] Plaintiff and other direct purchasers of AXR Product hundreds of millions of dollars" in violation of section 2 of the Sherman Act. Compl. ¶ 9.

Shire moved to dismiss LWD's complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. It argued in pertinent part that Shire's alleged breaches of its contracts with Teva and Impax were not a valid basis for a monopolization claim because any actions taken within the scope of Shire's patent monopoly were immune from antitrust scrutiny.³ See Mem. of Law in

³ Shire also argued that LWD had failed to properly allege a "relevant product market," and that LWD was an "indirect purchaser" not entitled to damages with respect to any purchases of AXR from Teva or Impax. The district court declined to address these arguments, and neither has been

Support of Mot. to Dismiss at 2, *Louisiana Wholesale Drug Co.*, No. 12 Civ. 3711 (VM) (S.D.N.Y. June 29, 2012), ECF No. 12. In opposition, LWD asserted that once Shire had agreed to "relinquish its monopoly control over AXR . . . vis-à-vis Teva and Impax" by entering into the patent litigation settlements, it had a "duty to deal" with its competitors under the Supreme Court's decision in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985). See Mem. of Law in Opp'n at 8, *Louisiana Wholesale Drug Co.*, No. 12 Civ. 3711 (VM) (S.D.N.Y. July 20, 2012), ECF No. 19. That duty, LWD contended, converted Shire's ordinary breach of contract into an unlawful act of monopolization. *Id.*

The district court rejected LWD's arguments and dismissed the complaint. *Louisiana Wholesale Drug Co. v. Shire LLC*, 929 F. Supp. 2d 256, 257 (S.D.N.Y. 2013). The court relied principally on our decision in *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), *abrogated by F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). The plaintiffs in that case challenged the legality of a type of patent litigation settlement known as a "reverse payment" settlement—not unlike the agreements here. *Id.* at 193–94. The defendant generic drug manufacturer in *Tamoxifen* agreed to join the defendant patent holder in obtaining *vacatur* of a district court judgment invalidating the patents it had challenged, and agreed to refrain from marketing its own product until those patents expired. *Id.* In exchange, the patent holder provided its erstwhile challenger with a large cash payment—the "reverse payment"—a patent license, and a supply of unbranded drugs for resale. *Id.* We rejected the plaintiffs' Sherman

reiterated on appeal.

Act claims, holding that "[w]hatever damage is done to competition by [such a] settlement is done pursuant to the monopoly extended to the patent holder by patent law" and is therefore not barred by the antitrust statutes, "unless the terms of the settlement enlarge the scope of that monopoly." *Id.* at 212–13.

Although LWD does not challenge the legality of the agreements in this case, the district court found its claims analogous to those in *Tamoxifen*. *Louisiana Wholesale Drug Co.*, 929 F. Supp. 2d at 262. The court concluded that the effect on competition of Shire's alleged refusal to supply all of the AXR that Teva and Impax demanded could be no greater than the effect of paying them to stay off the market altogether. *Id.* And, in light of *Tamoxifen*, the court was

not convinced that . . . a patent holder granting multiple licenses that by their terms do not extend the scope of the patents in question, would nevertheless be subject to antitrust claims based on its conduct under those otherwise unchallenged licenses where that same patent holder would not face such liability if it refused outright to issue a license in the first instance.

Id. at 264. Addressing LWD's *Aspen Skiing* argument, the district court stressed the narrowness of the "duty to deal" doctrine. *Id.* And it distinguished the two cases LWD cited applying that doctrine in the context of drug patents, stating that they could not "alter the [district c]ourt's conclusion that, notwithstanding Shire's alleged conduct under the agreements, because the terms of those settlement agreements . . . do not exceed the scope of the patents in question, LWD's claims fail." *Id.* at 265.

Three months after the district court's ruling, while this appeal was pending but before any briefs had been filed, the Supreme Court issued its decision in *Federal Trade Commission v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), abrogating *Tamoxifen*. The *Actavis* Court held that the potentially significant anticompetitive effects of reverse payment settlements are not immune from antitrust scrutiny merely because they may "fall within the scope of the exclusionary potential of the patent" at issue. *Id.* at 2230–31 (internal quotation marks omitted). The Court concluded that because such settlements necessarily prevent the adjudication of a patent's validity—thereby leaving open the question of the patent's "actual preclusive scope"—they should be scrutinized under antitrust law's traditional "rule of reason." *See id.* at 2230–31, 2237.

DISCUSSION

"We review *de novo* a district court's dismissal of a complaint under Rule 12(b)(6)." *Mayor & City Council of Balt., Md. v. Citigroup, Inc.*, 709 F.3d 129, 135 (2d Cir. 2013). In doing so, "we accept all factual allegations as true and draw every reasonable inference from those facts in the plaintiff's favor." *Id.* But this does not relieve the plaintiff from alleging "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted).

Section 2 of the Sherman Act provides that it is unlawful to "monopolize, or attempt to monopolize . . . any part of the trade or commerce

among the several States, or with foreign nations." 15 U.S.C. § 2. "[T]his offense requires, in addition to the possession of monopoly power in the relevant market, 'the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.'" *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966)). "To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*." *Id.* (emphasis in original). "[A]nticompetitive conduct is 'conduct without a legitimate business purpose that makes sense only because it eliminates competition.'" *Port Dock & Stone Corp. v. Oldcastle Ne., Inc.*, 507 F.3d 117, 124 (2d Cir. 2007) (quoting *Morris Commc'ns Corp. v. PGA Tour, Inc.*, 364 F.3d 1288, 1295 (11th Cir. 2004)).

As the *Actavis* decision illustrates, "[t]he tension between the objectives of preserving economic incentives to enhance competition while at the same time trying to contain the power a successful competitor acquires is heightened tremendously when the patent laws come into play." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1205 (2d Cir. 1981); see also *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) (noting that "a patent is an exception to the general rule against monopolies and to the right to access to a free and open market"). But any such tension is rendered irrelevant here by the plaintiff's theory of the case.

LWD expressly disclaims any reliance on the patent settlement context of its allegations, choosing to argue instead that Shire's requirements contracts with

Teva and Impax gave rise to an antitrust "duty to deal." The complaint urges that "from the moment the [settlement] agreements were signed, the patents were taken out of the picture, and this case must be viewed as one in which the patents did not exist as they relate to Teva and Impax." Compl. ¶ 42 (footnote omitted). Counsel for LWD reiterated this position at oral argument, assuring us that its claims would be no different if Shire had no patents respecting AXR. And while LWD argues that the abrogation of *Tamoxifen* undermines the district court's reasoning, it does not rely on *Actavis* or seek leave to re-plead in light of that decision. Thus freed from the complexities that attend cases at the intersection of antitrust and patent law, we proceed to explain our reasons for affirming the judgment of the district court.⁴

* * *

"In the absence of any purpose to create or maintain a monopoly, the [Sherman Act] does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal" *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). Today, "the sole exception to the broad right of a firm to refuse to deal with its competitors" comes into play only "when a monopolist seeks to terminate a prior (voluntary) course of dealing with a competitor." *In re Elevator Antitrust Litig.*, 502 F.3d 47, 52, 53 (2d Cir. 2007) (per

⁴ We may, of course, affirm on any ground that finds support in the record sufficient to permit a conclusion of law, even one not relied on by the district court. See *MLSMK Inv. Co. v. JP Morgan Chase & Co.*, 651 F.3d 268, 273 (2d Cir. 2011).

curiam) (citing *Trinko*, 540 U.S. at 409). The roots of this exception are in the *Aspen Skiing* decision, which is heavily relied on by LWD.

The Supreme Court has described its own decision in *Aspen Skiing* as follows:

The Aspen ski area consisted of four mountain areas. The defendant, who owned three of those areas, and the plaintiff, who owned the fourth, had cooperated for years in the issuance of a joint, multiple-day, all-area ski ticket. After repeatedly demanding an increased share of the proceeds, the defendant canceled the joint ticket. The plaintiff, concerned that skiers would bypass its mountain without some joint offering, tried a variety of increasingly desperate measures to re-create the joint ticket, even to the point of in effect offering to buy the defendant's tickets at retail price. The defendant refused even that. We upheld a jury verdict for the plaintiff, reasoning that "[t]he jury may well have concluded that [the defendant] elected to forgo these short-run benefits because it was more interested in reducing competition . . . over the long run by harming its smaller competitor."

Trinko, 540 U.S. at 408-09 (alterations in original) (citations omitted) (citing and quoting *Aspen Skiing*, 472 U.S. at 593-94, 608). Although *Aspen Skiing* stands for the proposition that a business with market power may be subject to a duty to deal with a smaller competitor, it is today a common refrain that the case lies "at or near

the outer boundary of [section] 2 liability." *Id.* at 409; see also *In re Elevator Antitrust Litig.*, 502 F.3d at 53 (same).

But wherever we locate *Aspen Skiing* with respect to that "boundary", it does not govern this case. LWD fails to allege that the facts here resemble those of *Aspen Skiing* in any of the particulars identified as significant by the *Trinko* Court, including "[t]he unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing suggest[ing] a willingness to forsake short-term profits to achieve an anticompetitive end" and the refusal "to renew the ticket *even if compensated at retail price.*" *Trinko*, 540 U.S. at 409 (emphases in original). And although *Trinko* does not purport to set out a "test," it usefully highlights the distinctions that made *Aspen Skiing* the rare case in which a refusal to deal amounted to a prohibited act of unilateral monopolization.

This is not such a case. Shire did not terminate any prior course of dealing—let alone a "presumably profitable" one that had, as in *Aspen Skiing*, "originated in a competitive market and had persisted for several years." *Aspen Skiing*, 472 U.S. at 603. Indeed, the agreements here were explicitly *unprofitable*—they introduced price competition into a market where none would otherwise have existed. Far from undermining existing competition, by entering into the agreements in question, Shire *created* competition in the market for AXR *ex nihilo*. And because, as LWD concedes, Shire did not "completely cut off supply to Teva and Impax," *id.* ¶ 77, Shire actually lost 50–60% of its market share, *id.* ¶ 67. The logical inference from these allegations is that, unlike the defendant in *Aspen Skiing*, Shire accepted a below-retail price for its product. *Cf. Trinko*, 540 U.S. at 409. In short, the plaintiffs' allegations

amount to the self-defeating claim that Shire monopolized the market by ceding its monopoly.

Shire's breach of its agreements with Teva and Impax—if there was one—may have prevented the price of AXR from falling further than LWD theorizes it might have in a genuinely competitive market, but that alone does not give rise to a cause of action under *Aspen Skiing*. This is not a case where the alleged monopolist sought to "terminate a prior (voluntary) course of dealing with a competitor," *In re Elevator Antitrust Litig.*, 502 F.3d at 53 (citing *Trinko*, 540 U.S. at 409), under circumstances that evince an intent willfully to acquire or maintain monopoly power, *Trinko*, 540 U.S. at 407. The mere existence of a contractual duty to supply goods does not by itself give rise to an antitrust "duty to deal." Cf. *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 450 (2009) (distinguishing defendant's regulatory duty to cooperate with competitors from an "antitrust duty to deal"); *Trinko*, 540 U.S. at 406 (concluding that statutorily imposed duties to cooperate with competitors did "not automatically lead to the conclusion that [the duties] can be enforced by means of an antitrust claim"). Nor do business disputes implicate the antitrust laws simply because they involve competitors. *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 225 (1993) ("Even an act of pure malice by one business competitor against another does not, without more, state a claim under the federal antitrust laws; those laws do not create a federal law of unfair competition or 'purport to afford remedies for all torts committed by or against persons engaged in interstate commerce.'") (quoting *Hunt v. Crumboch*, 325 U.S. 821, 826 (1945)).

Against this backdrop, we conclude that LWD's complaint fails to state a claim upon which relief can be

granted, and that it was therefore properly dismissed by the district court under Rule 12(b)(6). Indeed, the complaint does little more than attach antitrust "labels and conclusions" to what is, at most, an ordinary contract dispute to which the plaintiffs are not even parties. See *Iqbal*, 556 U.S. at 678. In view of the plaintiffs' theory of the case and their disclaimer of reliance on the patent litigation that gave rise to Shire's agreements with Teva and Impax, we have not considered that litigation and those agreements in our analysis. We have not, therefore, assessed the potentially anticompetitive effects, if any, of these settlements against "patent law policy [and] procompetitive antitrust policies." *Actavis*, 133 S.Ct. at 2231. And we intimate no view as to the viability of a monopolization claim based on similar factual circumstances in which the plaintiffs did not—as LWD unequivocally did here—narrow the scope of our inquiry.

CONCLUSION

LWD has failed to allege facts that would place this case within *Aspen Skiing's* narrow exception to the "long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal." *Colgate*, 250 U.S. at 307. We therefore AFFIRM the judgment of the district court dismissing the complaint.