NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 11-1734

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SIGMAPHARM, INC.,
Appellant

v.

MUTUAL PHARMACEUTICAL COMPANY, INC.;
UNITED RESEARCH LABORATORIES, INC.;
KING PHARMACEUTICALS, INC.

_____

Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Civil No. 2-10-cv-00430)
District Judge: Honorable Cynthia M. Rufe

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Argued November 17, 2011

Before: RENDELL, AMBRO and NYGAARD, Circuit Judges

(Opinion Filed: December 12, 2011)

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OPINION OF THE COURT

RENDELL, Circuit Judge.

This case comes to us on appeal from the District Court's order granting Defendants' motion to dismiss Plaintiff's amended complaint for failure to state a claim. The District Court dismissed Plaintiff's federal antitrust causes of action for failure to adequately plead antitrust standing and declined to exercise supplemental jurisdiction over Plaintiff's state law claims.[1] We will affirm.

[1] The District Court had jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337, as well as 15 U.S.C. § 15. We have jurisdiction under 28 U.S.C. § 1291.

I. Background[2]

Plaintiff, SigmaPharm, Inc., is a Delaware corporation that develops pharmaceutical technologies and products, and enters into agreements with other entities to commercialize them. Defendants Mutual Pharmaceuticals Company, Inc. and United Research Laboratories, Inc. (collectively, "Mutual") are Pennsylvania corporations that develop, manufacture, market, sell, and distribute pharmaceutical drugs. Defendant King Pharmaceuticals, Inc. ("King") is a Tennessee corporation that develops, manufactures, markets, sells, and distributes pharmaceutical drugs.

In March 1999, SigmaPharm and Mutual entered into a "development agreement," pursuant to which SigmaPharm granted Mutual certain rights in future "innovations" developed by SigmaPharm in exchange for payments from Mutual. "Innovations" are inventions, improvements, or enhancements to Mutual's pharmaceutical products developed by SigmaPharm for which Mutual secures a patent or which Mutual otherwise deems to be an "innovation." (App. 121.) The development agreement states that Mutual "shall be the sole and exclusive owner of all right, title and interest in and to the Innovations in the United States market." (App. 73, 122.) Likewise, it states that SigmaPharm "shall remain the sole and exclusive owner of all right, title and interest in and to the Innovations in all markets other than the United States market." (App. 73, 122.)

[2] As we write primarily for the parties, we discuss only those facts necessary for our disposition of this appeal. We borrow heavily from the District Court's recitation of the facts.

For generic equivalents of name-brand drugs developed by SigmaPharm that required approval under the Food and Drug Administration's ("FDA") Abbreviated New Drug Application ("ANDA") process, SigmaPharm was to receive 20% of the gross profits from Mutual's U.S. sales. But if additional generic competitors entered the market, the royalties would decrease based on the number of competitors. The development agreement further provided that if Mutual licensed or sold the right to sell a product incorporating a SigmaPharm "innovation," or "agree[d] to refrain from selling such product," SigmaPharm was to receive 25% of the gross profit from the licensing fees or royalties from that license, sale, or agreement. (App. 74, 123.)

Pursuant to the development agreement, SigmaPharm developed a generic equivalent of the brand-name muscle relaxant SKELAXIN, which is owned and marketed by King.[3] SKELAXIN's active ingredient, metaxalone, is no longer protected by patent. In March 2003, Mutual filed an ANDA for this SigmaPharm-developed generic product, including a certification that one of King's patents did not claim a use for which Mutual was seeking approval. In January 2004, after King received another method patent related to SKELAXIN, Mutual filed a certification with the FDA that its generic product would not infringe that patent.

In March 2004, King brought a patent infringement lawsuit against Mutual in the District Court for the Eastern District of Pennsylvania and petitioned the FDA to require

[3] This was, in fact, the second generic SKELAXIN product that SigmaPharm had developed. The relevant product for this appeal is the second product SigmaPharm developed, so we will not discuss the first generic product.

that those seeking to market a generic version of SKELAXIN include information on the generic product's label that implicated King's method patents. King also asked the FDA to stay approval of any ANDAs for generic competitors to SKELAXIN until it had decided the petition. Mutual opposed each of these requests in multiple filings with the FDA between April 2004 and February 2005.

King and Mutual's adversarial behavior seemed to end on December 6, 2005, when King agreed to pay tens of millions of dollars for co-exclusive licensing rights for one of Mutual's metaxalone-related patents. Two days later, Mutual withdrew its opposition to King's petition for labeling requirements for generic SKELAXIN, even though that petition would have threatened Mutual's ability to market its generic product without infringing certain of King's patents. Then, in 2007, when King made a supplemental submission to the FDA in support of its petition and request for a stay of approval of any generic SKELAXIN ANDAs, Mutual submitted comments in support of King.

Meanwhile, following a joint filing under seal on May 15, 2006, an indefinite stay of the proceedings was issued in the patent case between Mutual and King. Despite the fact that another district court had found the relevant patents to be invalid in January 2009, *see King Pharm., Inc. v. Eon Labs, Inc.*, 593 F. Supp. 2d 501, 515 (E.D.N.Y.

2009), Mutual did not inform the district court handling its patent litigation with King of this development until August 2010, in a court-ordered status report.[4]

Based on these facts, SigmaPharm's amended complaint alleges that, sometime between February 2005 and December 2005, Mutual and King entered into an agreement "to restrict the output of, and thereby to raise the price of, pharmaceutical products that are bioequivalent to" SKELAXIN. (App. 82.) SigmaPharm claims this agreement was a horizontal restraint of trade in violation of Section 1 of the Sherman Act (Count I), Pennsylvania common law barring restraint of trade (Count II), and California statutes barring unlawful and unfair competition (Count III). The amended complaint also asserts that Mutual breached its contract with SigmaPharm by failing to pay SigmaPharm 25% of the revenues it received from King pursuant to the allegedly unlawful agreement (Count IV). SigmaPharm's amended complaint sought injunctive and monetary relief, including treble damages under the federal antitrust laws.

The defendants moved to dismiss Counts I through III of the amended complaint because, *inter alia*, SigmaPharm's pleadings failed adequately to allege antitrust injury, a necessary component of so-called "antitrust standing." In a thorough and thoughtful opinion, the District Court found that SigmaPharm had failed adequately to plead antitrust injury, dismissed Count I of the amended complaint without prejudice, and

[4] The Federal Circuit affirmed the holding of the District Court for the Eastern District of New York that the patents at issue in the King-Mutual dispute were invalid. *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267 (Fed Cir. 2010).

declined to exercise supplemental jurisdiction over the remaining state law claims. SigmaPharm did not seek to amend its complaint, but instead filed the instant appeal.

II. Discussion[5]

Since the Supreme Court's decision in *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477 (1977), plaintiffs suing under the federal antitrust laws have been required to show that, in addition to the prerequisites of constitutional standing, *see Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), they possess so-called "antitrust standing." Mere injury resulting from conduct that violated the antitrust laws is insufficient to confer antitrust standing. Instead, a plaintiff can only recover under the federal antitrust laws if its injury is "of the type the antitrust laws were intended to prevent and . . . flows from that which makes defendants' acts unlawful." *Brunswick*, 429 U.S. at 489; *see also Alberta Gas Chems. Ltd. v. E.I. Du Pont De Nemours & Co.*, 826 F.2d 1235, 1240 (3d Cir. 1987).

The Supreme Court has articulated a number of factors to consider in determining whether a plaintiff has antitrust standing:

> (1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages.

[5] The District Court thoroughly discussed the relevant law in this area, and we again borrow heavily from Judge Rufe's well-reasoned opinion.

In re Lower Lake Erie Iron Ore Antitrust Litig., 998 F.2d 1144, 1165–66 (3d Cir. 1993) (citing *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 545 (1983)). The second factor, antitrust injury, is a necessary (though insufficient) condition of antitrust standing. *Cargill, Inc. v. Monfort of Colorado, Inc.*, 479 U.S. 104, 110 n.5 (1986); *Lower Lake Erie*, 998 F.2d at 1166. "As a general matter, the class of plaintiffs capable of satisfying the antitrust-injury requirement is limited to consumers and competitors in the restrained market and to those whose injuries are the means by which the defendants seek to achieve their anticompetitive ends." *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 102 (3d Cir. 2010) (citations omitted).

The District Court was correct to note that SigmaPharm is neither a consumer nor a competitor in the United States market for products that are bioequivalent to SKELAXIN. SigmaPharm does not allege that it marketed or manufactured a generic version of SKELAXIN, nor could it under its development agreement with Mutual. *See* App. 73, 122 ("[Mutual] shall be the sole and exclusive owner of all right, title and interest in and to the Innovations in the United States market."); *Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178, 182 (3d Cir. 1997) ("Because it is undisputed that B&P never 'sold' or 'distributed' or sought to sell or distribute any vaccine to anyone, however, it is plain that B&P was not a competitor in the market for sales of the vaccine."). Its allegation that it is a "participant" in the market for SKELAXIN-equivalent products "[t]hrough its Development Agreement with Mutual" (App. 87) is

insufficient as a matter of law to establish that it is a competitor in the relevant market. *Barton & Pittinos,* 118 F.3d at 182-83.

In *Barton & Pittinos*, we held that a plaintiff, B&P, was not a competitor of the defendant for antitrust standing purposes because what the plaintiff provided to the market was not "reasonably interchangeable" with what was offered by those in the relevant market. *Id.* at 182. This was because B&P, a provider of marketing services, did not actually sell the product whose market was allegedly restrained: a vaccine. *Id.* at 179-80, 182-83. Instead, B&P participated in a "program" in which the vaccine-maker paid B&P to market the vaccine to, and solicit orders from, nursing homes and then pass those orders on to a third-party, which would buy the vaccine from the manufacturer and sell it to the nursing homes. *Id.* We held as a matter of law that B&P's reliance on the third-party to participate in the vaccine-market rendered it not a competitor in that market for purposes of antitrust standing. *Id.* at 182-83.

Like B&P, SigmaPharm was not providing a product or service that was "reasonably interchangeable" with an existing product or service in the relevant market—here, the market for SKELAXIN-equivalent products. *See id.* at 182. Its reliance on a third-party—viz. Mutual—to sell the product in the relevant market, like B&P's, renders SigmaPharm a non-competitor in the relevant market for purposes of antitrust standing.

Although not a competitor in the market for SKELAXIN-equivalent products, SigmaPharm provided an input into what could have been *Mutual's* entrée into that market. This input—the formulation for a drug that is bioequivalent to SKELAXIN—is certainly a crucial one, but this does not transform SigmaPharm into a competitor in that

market for purposes of our antitrust-standing analysis. *See Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 990 (N.D. Ill. 2003) (finding supplier of active ingredient for drug lacked antitrust standing to allege anticompetitive agreement to apportion market for the drug). Consumers in the market could not have "abandoned [King] in favor of [SigmaPharm] alone. Doing so would [leave] [such consumers] without the most important part of the package of goods and services [that could have been] offered by [SigmaPharm and Mutual] together: the [SKELAXIN-equivalent product] itself." *See Barton & Pittinos*, 118 F.3d at 182-83.[6] Therefore, we agree with the District Court that SigmaPharm was neither a consumer nor a competitor in the relevant market.

The District Court was also correct in finding that SigmaPharm did not adequately plead that its injuries were "the means by which the defendants [sought] to achieve their anticompetitive ends." *W. Penn Allegheny Health Sys.*, 627 F.3d at 102; *see Blue Shield of Va. v. McCready*, 457 U.S. 465, 479 (1982). In *McCready*, the case that established this way of showing antitrust injury, the Supreme Court held that a health insurance subscriber had antitrust standing to bring a claim that her insurer conspired with psychiatrists to restrain competition in the market for psychotherapeutic services by

[6] It is true that SigmaPharm's circumstances are different from B&P's in that SigmaPharm alleges that the very third-party on which it would rely to become a "participant" in the relevant market—Mutual—was part of the allegedly unlawful agreement. Under *Barton & Pittinos*, however, this does not appear relevant in the determination of whether SigmaPharm itself is a competitor in the relevant market.

providing insurance coverage only for visits to psychiatrists, not psychologists. *Id.* The *McCready* Court stated:

> Denying reimbursement to subscribers for the cost of treatment was the very means by which it is alleged that Blue Shield sought to achieve its illegal ends. The harm to McCready and her class was clearly foreseeable; indeed, it was a necessary step in effecting the ends of the alleged illegal conspiracy. Where the injury alleged is so integral an aspect of the conspiracy alleged, there can be no question but that the loss was precisely "the type of loss that the claimed violations . . . would be likely to cause."

Id. at 479 (quoting *Brunswick*, 429 U.S. at 489). Here, defendants could have effectuated their conspiracy even if SigmaPharm did not exist. *See Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 923 (3d Cir. 1999) (rejecting union health funds' argument that they had antitrust standing under *McCready* to sue tobacco companies for alleged conspiracy to hide dangers of smoking because tobacco companies could have achieved their alleged aims without the existence of the health funds). Therefore, SigmaPharm's injuries were not the means by which the defendants sought to achieve their allegedly illegal ends, and SigmaPharm therefore has not adequately pled antitrust injury under *McCready*.[7]

[7] We express no opinion as to whether a plaintiff that manufactures a product, but uses a third-party to sell that product to consumers, suffers antitrust injury when the market for that product is unlawfully restrained. *See Ethylpharm S.A. France v. Abbott Labs.*, 598 F. Supp. 2d 611 (D. Del. 2009) (holding that foreign drug manufacturer that used U.S. licensee to market and distribute its drug had alleged antitrust injury based on restraint of drug sales in the U.S.); *Chemi SpA v. GlaxoSmithKline*, 356 F. Supp. 2d 495 (E.D. Pa. 2005) (denying judgment on pleadings based on antitrust standing where foreign drug manufacturer sold its drug to U.S. companies for resale in the U.S.). As the District Court noted, SigmaPharm does not claim that it manufactures any pharmaceuticals in the United States, and it expressly disclaimed any right to do so in its development agreement with Mutual.

Undoubtedly, SigmaPharm alleges that it was injured by the claimed anticompetitive agreement because it did not receive royalties. This, however, does not mean that they have pled *antitrust* injury, even if the alleged anticompetitive conduct is a *per se* violation of the antitrust laws. *See Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 335 (1990); *Pace Elecs., Inc. v. Canon Computer Sys., Inc.*, 213 F.3d 118, 120 (3d Cir. 2000) ("To state a claim for damages under [15 U.S.C. § 15], a plaintiff must allege . . . antitrust injury . . . even where . . . the alleged acts of the defendants constitute a per se violation of the antitrust laws."); *see also Brunswick*, 429 U.S. at 489. Ultimately, the question comes down to whether the injury alleged is of the type that the antitrust statute was intended to forestall. *Associated Gen. Contractors of Cal., Inc.*, 459 U.S. at 540 (citing *Brunswick*, 429 U.S. at 487-88). We conclude, based on our precedent, that Congress, in enacting the federal antitrust laws, did not intend to prevent losses like those SigmaPharm alleges: loss of a contractually agreed upon profit-share in a product manufactured and sold by a market-participant. SigmaPharm may have avenues of recovery, but the federal antitrust laws are not among them.[8]

Finally, SigmaPharm argues that the District Court erred by not telling it that it had leave to amend its complaint and not telling it that curative amendments to its complaint would be inequitable or futile. We have held that a dismissal without

[8] Although the District Court recognized that its determination that SigmaPharm did not suffer antitrust injury was sufficient to conclude that SigmaPharm lacked antitrust standing, it nevertheless examined another factor in the antitrust standing analysis: whether there are more direct victims of the alleged antitrust violation. Concluding as we do that the District Court correctly found that SigmaPharm failed to plead antitrust injury, we need not and do not address any other factor in the antitrust standing analysis.

prejudice will be treated as a final order if the plaintiff has elected to "stand upon the original complaint" by not offering or seeking to amend the complaint and instead filing a notice of appeal and arguing that the allegations in the complaint were legally sufficient. *Frederico v. Home Depot*, 507 F.3d 188, 192-93 (3d Cir. 2007). This is exactly the situation we face here. Although SigmaPharm requests, in the alternative, an opportunity to attempt to cure its pleading deficiencies, it presents no basis upon which to amend its complaint adequately to allege antitrust injury.

III. Conclusion

For the reasons stated above, we will affirm the District Court's order dismissing SigmaPharm's amended complaint in its entirety.