NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

2007-1362

MERCK & CO., INC.,

Plaintiff-Appellee,

v.

APOTEX, INC.,

Defendant-Appellant.

Appeal from the United States District Court for the District of Delaware in case no. 06-CV-230, Judge Gregory M. Sleet.

DECIDED: July 16, 2008

Before GAJARSA, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and PROST, Circuit Judge.

GAJARSA, Circuit Judge.

This case presents the issue of whether there is an Article III case or controversy between a patentee drug company and a generic drug company in the context of the Hatch-Waxman Act. In Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278 (Fed. Cir. 2008) ("Caraco"),[1] this court considered several aspects of the Hatch-

[1] Petition for Rehearing and Rehearing En Banc denied on June 24, 2008.

Waxman Act that are relevant to the determination of Article III jurisdiction in the Hatch-Waxman context. We incorporate the Caraco decision and rely on that background but do not repeat it in full detail here.

Plaintiff-Appellee Merck & Co., Inc. ("Merck") obtained approval from the Food and Drug Administration ("FDA") for the drug FOSOMAX® which is used to treat and prevent osteoporosis. Defendant-Appellant Apotex, Inc. ("Apotex") is a generic drug company that is seeking FDA approval to commercialize a generic version of FOSOMAX®. This case was instituted by Merck against Apotex for patent infringement when Apotex filed an Abbreviated New Drug Application ("ANDA") with the FDA and so notified Merck. Apotex counterclaimed for a declaratory judgment of patent invalidity and noninfringement. Following discovery, Merck granted Apotex a covenant not to sue for infringement of all patents-in-suit and moved to dismiss all claims and counterclaims on the grounds that the case no longer presented an Article III case or controversy. Apotex then moved to amend its counterclaims to add a claim for a violation of the Sherman Antitrust Act, 15 U.S.C. § 2. The district court denied Apotex's motion to amend its counterclaims and granted Merck's motion to dismiss all claims and counterclaims for lack of Article III jurisdiction.

Apotex appeals the district court's dismissal for lack of Article III jurisdiction and the denial of Apotex's motion to add an antitrust counterclaim. Because this action arises in part under the patent laws, we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1). We affirm the district court's denial of Apotex's motion to add an antitrust counterclaim as within the district court's discretion. In addition, because the infringement and invalidity counterclaims have been rendered moot during the

pendency of this appeal, we vacate the district court's decision regarding those claims and remand with instructions to dismiss the claims as moot. See Duke Power Co. v. Greenwood County, 299 U.S. 259, 267 (1936) ("Where it appears upon appeal that the controversy has become entirely moot, it is the duty of the appellate court to set aside the decree below and to remand the cause with directions to dismiss.").

BACKGROUND

As part of the process for obtaining FDA approval for FOSOMAX®, Merck listed ten patents in the FDA's Orange Book, including United States Patent Nos. 4,621,077 ("the '077 patent"); 5,358,941 ("the '941 patent"); 5,681,590 ("the '590 patent"); 5,849,726 ("the '726 patent"); 6,008,207 ("the '207 patent"); 6,090,410 ("the '410 patent"); 6,194,004 ("the '004 patent"); 5,994,329 ("the '329 patent");[2] 6,015,801 ("the '801 patent"); and 6,225,294 ("the '294 patent"). The '077 patent covers alendronate sodium, the active ingredient of FOSOMAX®. Six of the listed patents—the '941, '590, '726, '207, '410, and '004 patents—cover various formulations for the FOSOMAX® tablets. The remaining three patents—the '329, '801, and '294 patents—are directed to FOSOMAX® dosing schedules.

Merck's '077 patent expired on August 6, 2007. However, Merck obtained an additional six-month period of regulatory exclusivity from the FDA in exchange for Merck's submission of certain pediatric studies pursuant to 21 U.S.C. § 355a. As a result, no generic drug company could obtain FDA approval for alendronate sodium—which was protected by the '077 patent—until February 6, 2008. Merck's nine

[2] In Merck & Co., Inc. v. Teva Pharms. USA, Inc., this court held dependent claims 23 and 37 of the '329 patent invalid for obviousness. 395 F.3d 1364, 1377 (Fed. Cir. 2005), reh'g and reh'g en banc denied, 405 F.3d 1388 (Fed. Cir. 2005), cert. denied, 126 S. Ct. 488 (2005).

remaining Orange-Book-listed patents expire on dates ranging from 2012 to 2018. Merck also obtained an additional six-month period of regulatory exclusivity beyond the patent terms of each of these remaining patents under 21 U.S.C. § 355a.

On February 24, 2006, Apotex sent Merck a letter informing Merck that Apotex had filed an ANDA with the FDA to obtain approval for a generic version of FOSOMAX®. As discussed in Caraco, ANDA filers must submit one of four certifications addressing each Orange-Book-listed patent covering the FDA approved drug upon which the ANDA is based. See 527 F.3d at 1282-83. For the '077 patent, Apotex filed a Paragraph III certification stating that Apotex would not market its generic drug until six months[3] after the expiration of the '077 patent. For Merck's nine other Orange-Book-listed patents for FOSOMAX®, Apotex filed a Paragraph IV certification stating that the patents were invalid or not infringed by Apotex's generic drug. Merck then sued Apotex under 35 U.S.C. § 271(e)(2)(A)[4] for infringement of the nine Orange-Book-listed patents for which Apotex filed a Paragraph IV certification (the "patents-in-suit"). Upon Merck's filing of this infringement action, the FDA stayed approval of Apotex's ANDA for thirty months as required by 21 U.S.C. § 355(j)(5)(B)(iii).[5]

---

[3] As noted above, Merck is entitled to six additional months of exclusivity beyond the terms of each of its Orange-Book-listed patents pursuant to 21 U.S.C. § 355a.

[4] Section 271(e)(2)(A) provides that "it shall be an act of infringement" to submit an ANDA to the FDA "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

[5] Section 355(j)(5)(B)(iii) provides that "[i]f the patentee files an infringement action within forty-five days after receiving notice of the paragraph IV certification, an automatic thirty-month 'stay' goes into effect, during which the FDA cannot approve the ANDA unless the suit is resolved or the patent expires." Teva Pharms. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1328 (Fed. Cir. 2005).

Following discovery, Merck granted Apotex a covenant not to sue on all the patents-in-suit. The covenant provides:

> Merck unconditionally represents, stipulates, agrees, and covenants that it will not sue Apotex for infringement of, or otherwise assert, enforce, or hold Apotex liable for infringement of any of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents based on the importation, manufacture, use, sale, or offer for sale of the alendronate sodium tablets that are the subject of and described in Apotex's ANDA No. 077-982.

Merck & Co., Inc. v. Apotex, Inc., No. 06-CV-230 (D. Del. Aug. 16, 2006).

Importantly, Apotex was not the first Paragraph IV ANDA filer with respect to Merck's drug FOSOMAX®. The first Paragraph IV ANDA filer was Teva Pharmaceuticals USA, Inc. ("Teva"), which filed a Paragraph IV ANDA on September 29, 1999.[6] As a result, Teva is entitled to 180 days of generic market exclusivity for its generic version of FOSOMAX®. See 21 U.S.C. § 355(j)(5)(B)(iv) (2000);[7] see generally Caraco, 527 F.3d at 1283-85 (discussing the pre-MMA 180-day exclusivity provisions of the Hatch-Waxman Act). After Teva filed its Paragraph IV ANDA, Merck sued Teva under 35 U.S.C. § 271(e)(2)(A) for infringement of the '077 patent. Merck ultimately obtained a judgment that the drug described in Teva's ANDA infringed the '077 patent and that the '077 patent was not invalid. Merck & Co., Inc. v. Teva Pharms. USA, Inc., 228 F. Supp. 2d 480, 505 (D. Del. 2002), aff'd, 347 F.3d 1367 (Fed. Cir. 2003). Following its decision, the district court issued an order prohibiting the FDA from

[6] It is unclear from the record before us whether Zenith Goldline Pharmaceuticals, Inc. ("Zenith") filed a Paragraph IV on the same date as Teva, but the parties do not dispute that the issue is moot now that Teva has acquired Zenith.

[7] The amendments made to the Hatch-Waxman Act's 180-day exclusivity provisions by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") are inapplicable to this case because the first Paragraph IV ANDA for a generic version of FOSOMAX was filed (by Teva) before the December 8, 2003 enactment of the MMA. See MMA § 1102(b); see also Caraco, 527 F.3d at 1284 n.2.

approving Teva's ANDA earlier than the expiration date of the '077 patent on August 6, 2007. Merck & Co., Inc. v. Teva Pharms. USA, Inc., No. 00-035-JJF (D. Del. Dec. 3, 2002) (Final Judgment Order). Due to Merck's additional sixth-month regulatory exclusivity pursuant to 21 U.S.C. § 355a, Teva's ANDA could not be approved until February 6, 2008.

On June 26, 2008, Apotex informed this court via letter that the FDA approved Teva's ANDA on or about February 6, 2008 and that Teva immediately began marketing its generic version of FOSOMAX®. As a result, Teva has triggered its 180-day exclusivity period pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2000). The parties agree that Teva's 180-day exclusivity period will expire on or about August 5, 2008.[8] In addition, Apotex informed this court that the FDA decided to treat the thirty-month stay on Apotex's ANDA as dissolved once this suit was dismissed by the district court for lack of Article III jurisdiction. Accordingly, Apotex concedes that it will receive final approval for its ANDA when Teva's 180-day exclusivity period expires on August 5, 2008, rather than August 24, 2008, when the thirty-month stay was set to expire.

DISCUSSION

I.

In its decision dismissing this case for lack of Article III jurisdiction, the district court found that Apotex's alleged injury-in-fact—namely, delayed entry into the market—is not fairly traceable to any actions taken by Merck. Moreover, the district court found

[8] In its June 26, 2008 letter, Apotex states that Teva's 180-day exclusivity period will expire on August 5, 2008; however, in a separate letter dated July 1, 2008, Merck states that Teva's 180-day exclusivity period will expire on August 6, 2008. Whether Teva's exclusivity period actually expires on August 5 or August 6 has no effect on this appeal.

that Merck's grant of a covenant not to sue Apotex eliminated the controversy between the parties. However, depending on the circumstances, a justiciable Article III controversy may continue to exist between a patentee drug company and a Paragraph IV ANDA filer in the context of the Hatch-Waxman Act even after the patentee drug company has granted the Paragraph IV ANDA filer a covenant not to sue. Caraco, 527 F.3d at 1296-97.

This case, however, has been rendered moot by two factual developments that were brought to this court's attention after oral argument. First, the FDA decided to treat the thirty-month stay on Apotex's ANDA as dissolved once the district court dismissed this case. Second, the first Paragraph IV filer (i.e., Teva) triggered its 180-day exclusivity period under 21 U.S.C. § 355(j)(5)(B)(iv) (2000) by marketing its generic drug on or about February 6, 2008. As a result, Apotex no longer suffers a delay in entering the market under either the thirty-month stay provision or the 180-day exclusivity provision that is traceable to Merck and redressible by a court judgment. Cf. Caraco, 527 F.3d at 1292-94. Indeed, Apotex's only remaining delay in entering the market is the balance of Teva's 180-day exclusivity period, which expires on or about August 5, 2008. Teva is entitled to this exclusivity under 21 U.S.C. § 355(j)(5)(B)(iv) (2000). Although the statute provides that a judgment for Apotex in this case could have *triggered* Teva's 180-day exclusivity period, nothing in the statute provides that such a judgment can *eliminate* Teva's exclusivity period. See 21 U.S.C. § 355(j)(5)(B)(iv) (2000). Accordingly, Apotex's noninfringement and invalidity counterclaims are moot.

II.

The parties also dispute whether the district court abused its discretion in denying Apotex's motion to file an amended counterclaim for a violation of the Sherman Antitrust Act, 15 U.S.C. § 2. "In review of an order denying a motion to amend, a subject which is not unique to patent law, we look to the law of the regional circuit court." Kalman v. Berlyn Corp., 914 F.2d 1473, 1480 (Fed. Cir. 1990). As this case is on appeal from the U.S. District Court for the District of Delaware, we look to the law of the Third Circuit.

Under Federal Rule of Civil Procedure 15(a), courts "should freely grant leave [to amend] when justice so requires." Fed. R. Civ. Pro. 15(a). A court, however, has discretion to deny a motion to amend for reasons of "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc." Foman v. Davis, 371 U.S. 178, 182 (1962). "In assessing 'futility,' the district court applies the same standard of legal sufficiency as [it] applies under Rule 12(b)(6)." In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3d Cir. 1997). Thus, an amendment to add a counterclaim is futile if the amendment fails to state a claim upon which relief could be granted. Id. Under the Rule 12(b)(6) standard, a court should "accept as true all of the allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the plaintiff." Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997). However, "a court need not credit a complaint's 'bald assertions' or 'legal conclusions.'" Id.

Here, the district court held that Apotex failed to sufficiently plead an antitrust injury. In particular, the district court found that Apotex failed to allege facts sufficient to support its antitrust counterclaim, and that Apotex's antitrust allegations were "bald and conclusory." Merck & Co., Inc. v. Apotex, Inc., No. 06-CV-230 (D. Del. May 21, 2007). On this basis, the district court denied Apotex's request to add an antitrust counterclaim on the grounds that such an amendment would be futile. In light of the record before us, the district court did not abuse its discretion in denying Apotex's motion to add an antitrust counterclaim.

CONCLUSION

For the foregoing reasons, we affirm the district court's denial of Apotex's motion to amend its counterclaims to add an antitrust counterclaim. In addition, because Apotex's noninfringement and invalidity counterclaims have been rendered moot during the pendency of this appeal, we vacate the district court's decision regarding those claims and remand with instructions to dismiss the claims as moot.

No costs.