NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

2008-1133

MERCK & CO., INC.,

Plaintiff-Appellee,

v.

APOTEX, INC. and APOTEX CORPORATION,

Defendants-Appellants.

Robert L. Baechtold, Fitzpatrick, Cella, Harper & Scinto, of New York, New York, argued for plaintiff-appellee. With him on the brief was John D. Carlin. Of counsel on the brief were Edward W. Murray and Karen M. Stoffan, Merck & Co., Inc., of Rahway, New Jersey.

William A. Rakoczy, Rakoczy Molino Mazzochi Siwik LLP, of Chicago, Illinois, argued for defendants-appellants. With him on the brief were Christine J. Siwik and Andrew M. Alul. Of counsel on the brief was Shashank Upadhye, Apotex, Inc., of Toronto, Ontario, Canada.

Appealed from: United States District Court for the District of New Jersey

Judge Mary L. Cooper

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2008-1133

MERCK & CO., INC.,

Plaintiff-Appellee,

v.

APOTEX, INC. and APOTEX CORPORATION,

Defendants-Appellants.

Appeal from the United States District Court for the District of New Jersey in case no. 06-CV-5789, Judge Mary L. Cooper.

DECIDED: August 21, 2008

Before MAYER and LINN, Circuit Judges, and ILLSTON, District Judge[*].

PER CURIAM.

Appellants Apotex, Inc. and Apotex Corporation appeal from the final judgment of dismissal of their counterclaims for declaratory judgment against appellee Merck & Co., Inc. Because we find that the current dispute does not "'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts,'" MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, ___, 127 S. Ct. 764, 771 (2007) (quoting Aetna Life Ins. Co. v. Haworth,

[*] Honorable Susan Illston, District Judge, United States District Court for the Northern District of California, sitting by designation.

300 U.S. 227, 240-41, 57 S. Ct. 461 (1937)), and, thus, does not present a justiciable case or controversy, we affirm the judgment of dismissal.

I. BACKGROUND

Appellee Merck manufactures and sells glaucoma medications Trusopt® and Cosopt®. Each of these medications received approval by the Food and Drug Administration ("FDA") after completion of the extensive procedures required by the FDA for New Drug Applications ("NDAs"). In the course of the NDA approval process, Merck informed the FDA that three patents – U.S. Patents No. 4,797,413 ("the '413 patent"), No. 6,248,735 ("the '735 patent") and No. 6,316,443 ("the '443 patent") – covered the drugs, and these three patents were listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book").

At least two generic drug manufacturers have taken steps pursuant to the Hatch-Waxman Act[1] to obtain permission to manufacture generic versions of Trusopt® and Cosopt®. The first to file was Hi-Tech Pharmacal Co., which filed its Abbreviated New Drug Application ("ANDA") on October 11, 2005. Hi-Tech submitted a Paragraph IV certification, see 21 U.S.C. § 355(j)(2)(A)(vii)(IV), setting forth a factual and legal basis for asserting that the three Orange-Book-listed Merck patents are invalid or would not be infringed by Hi-Tech's product.

[1] The Hatch-Waxman Act is the name commonly used to refer to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000), as amended by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

The Hatch-Waxman Act provides that the filing of a Paragraph IV certification constitutes an act of patent infringement. 35 U.S.C. § 271(e)(2). On January 18, 2006, Merck sued Hi-Tech for infringing the '413 patent. Merck did not assert the '735 and '443 patents against Hi-Tech. Rather, on April 18, 2006, Merck filed disclaimers of the '735 and '443 patents under 35 U.S.C. § 253. Merck asserts that the legal effect of the disclaimers is that the claims of the patents were expunged nunc pro tunc.[2]

The infringement action against Hi-Tech as to the '413 patent was resolved in Merck's favor in the trial court on April 25, 2006, and that decision was affirmed by this Court on March 29, 2007. As a consequence, Hi-Tech was enjoined from marketing its generic versions of Merck's Trusopt® and Cosopt® until October 28, 2008,[3] and lost its generic marketing exclusivity on the '413 patent. See 221 U.S.C. § 355(j)(5)(D)(i)(VI). However, Hi-Tech potentially retained 180 days of generic marketing exclusivity on the '735 and '443 patents, which it could exercise at will unless a forfeiture event forced it to begin marketing.[4]

Appellants Apotex, Inc. and Apotex Corporation (collectively "Apotex") attempted to supply such a forfeiture trigger. In March 2006, approximately six months after Hi-

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[2] Merck has since several times requested that the FDA de-list the '735 and '443 patents from the Orange Book. As of the time of argument in this case, the de-listing had not occurred.

[3] The '413 patent expired on April 28, 2008, but Merck was entitled to six months of pediatric exclusivity, taking the period of exclusivity to October 28, 2008.

[4] Exclusivity forfeiture provisions were added by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA"), in order to reduce potential bottlenecks to competition which could be created by the Hatch-Waxman exclusivity periods. The MMA provides that the 180-day exclusivity period "shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant." The forfeiture events are spelled out in 21 U.S.C. § 355(j)(5)(D)(i). The "failure to market" forfeiture events, 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa) and (bb), are the ones primarily implicated in this action.

Tech filed its ANDA, Apotex filed an ANDA to market its own generic versions of Trusopt® and Cosopt®. Like Hi-Tech, Apotex included in its ANDA a Paragraph IV certification as to all three of Merck's Orange-Book-listed patents. When Merck learned of Apotex's application, it filed suit on December 4, 2006 alleging infringement of the '413 patent only. Apotex counterclaimed alleging non-infringement and invalidity of the '735 and '443 patents, despite the fact that these patents had been disclaimed over six months earlier.

Apotex agreed to be bound by the results of Hi-Tech's appeal to this Court on the '413 infringement issue. Thus, when Merck prevailed in that action, Apotex was similarly enjoined from marketing any generics infringing the '413 patent until October 28, 2008.

The district court dismissed Apotex's counterclaims as to the '735 and '443 patents for failure to state an Article III case or controversy. It is this dismissal which is now challenged on appeal. We have jurisdiction over this appeal under 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

Apotex seeks a judgment of invalidity and non-infringement of the two disclaimed patents. It is Apotex's theory that if it can obtain a final judgment in its favor (invalidity or non-infringement) on these patents, such a judgment would act as a forfeiture trigger should Hi-Tech fail to market its generic version of Cosopt® within 75 days of the date of Apotex's final judgment.[5] Since Hi-Tech is enjoined from marketing its generics any time before October 28, 2008, Apotex asserts that a final judgment of invalidity or non-

[5] The forfeiture trigger referred to is found in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

infringement as to the ’735 and ’443 patents obtained on or before August 14, 2008 would create a forfeiture of exclusivity for Hi-Tech and would allow Apotex to market its competing generic immediately upon final approval of its ANDA.

As a practical matter, this Court is unable to provide any realistic relief. Oral argument on this appeal took place on August 7, 2008. The relief sought by Apotex in its briefs was that “this Court should reverse and vacate the dismissal of Apotex’s declaratory judgment action and remand this matter to the district court for resolution of Apotex’s counterclaims for declaratory relief on the merits, including directions to enter summary judgment as a matter of law for Apotex.” Even with prompt action by this panel, the final judgment sought by Apotex cannot be provided in time to be meaningful.

The mandate issued by this Court will issue “7 calendar days after the time to file a petition for rehearing expires, or 7 calendar days after entry of an order denying a timely petition for panel rehearing, petition for rehearing en banc, or motion for stay of mandate, whichever is later.” Fed. R. App. P. 41. The time to file a petition for rehearing expires 14 days after entry of judgment. Fed. R. App. P. 40. Thus, any judgment by this Court will be “final” no earlier than 21 days after the date of this opinion, without consideration of time to petition the Supreme Court. At oral argument, Apotex’s counsel argued that this Court itself could enter judgment of invalidity or non-infringement, without remanding to the district court. Even if such an unusual step were taken, the action would be too late to provide the relief requested.

Accordingly, this Court finds that standards set by the Supreme Court in MedImmune require affirmance of the district court’s judgment of dismissal. As we noted in Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc., the

Supreme Court framed the proper standard for determining whether a declaratory judgment action satisfies the Article III case or controversy requirement as "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." 527 F.3d 1278, 1290 (Fed. Cir. 2008) (quoting MedImmune, 127 S. Ct. at 771). "[T]he Supreme Court emphasized that Article III requires that the dispute be 'definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial, and admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" Id. (quoting MedImmune, 127 S. Ct. at 771) At this juncture, the dispute presented does not "admit of specific relief through a decree of a conclusive character" and, thus, does not present a justiciable case or controversy.

III. CONCLUSION

For the aforementioned reasons, we affirm the judgment of dismissal.