NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

2009-1427, -1444

SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS, and DEBIOPHARM S.A.,

Plaintiffs-Appellants,

v.

SANDOZ, INC.,

Defendant-Appellee,

and

TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and PHARMACHEMIE BV,

Defendants-Appellees,

and

MAYNE PHARMA LIMITED, MAYNE PHARMA (USA) INC., HOSPIRA AUSTRALIA PTY LTD., and HOSPIRA, INC

Defendants-Appellees,

and

BARR LABORATORIES, INC. and PLIVA-LACHEMA A.S.,

Defendants-Appellees,

and

W.C. HERAEUS GMBH,

Defendant-Appellee,

and

APP PHARMACEUTICALS, INC. and ABRAXIS BIOSCIENCE, INC.,

Defendants-Appellees.

and

ACTAVIS TOTOWA LLC, ACTAVIS, INC., and ACTAVIS GROUP HF,

Defendants-Appellees.

and

FRESENIUS KABI ONCOLOGY PLC (formerly known as Dabur Oncology plc) and FRESENIUS KABI PHARMA LIMITED (formerly known as Dabur Pharma Limited),

Defendants-Appellees,

and

SUN PHARMACEUTICAL INDUSTRIES LTD. and CARACO PHARMACEUTICAL LABORATORIES, LTD.,

Defendants-Appellees,

and

EBEWE PHARMA GES.M.B.H. NFG KG,

Defendant,

and

MUSTAFA NEVZAT ILAC SANAYII A.S. (also known as MN Pharmaceuticals), PAR PHARMACEUTICAL COMPANIES, INC., and PAR PHARMACEUTICAL, INC.,

Defendants-Appellees.

On appeal from the United States District Court for the District of New Jersey in case no. 3:07-cv-2762, Judge Joel A. Pisano.

ON MOTION

Before LINN, PROST, and MOORE, Circuit Judges.

PER CURIAM.

ORDER

Sanofi-Aventis U.S. LLC et al. move for panel review and for reconsideration of this court's August 11, 2009 order denying their motion for an injunction. Teva Parenteral Medicines, Inc. et al. oppose.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The motion for panel review is granted.

(2) The motion for reconsideration is denied.

FOR THE COURT

Date

/s/ Jan Horbaly
Jan Horbaly
Clerk

cc: Dominick A. Conde, Esq.
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Patricia J. Thompson, Esq.
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and

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and

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On appeal from the United States District Court for the District of New Jersey in case no. 3:07-cv-2762, Judge Joel A. Pisano.

ON MOTION

MOORE, Circuit Judge, concurring in the denial of reconsideration

I agree with the court that we have no choice but to deny reconsideration of our August 11, 2009 order denying plaintiff-appellant's (Sanofi) motion to enforce our previous order staying the judgment of the district court. Sanofi sued nine generic drug

manufactures in the United States District Court for the District of New Jersey. On June 30, 2009, the district court entered a judgment of noninfringement that ended the case for two of the defendants—Teva and Mayne. That same day, Sanofi appealed the judgment to this court and filed a motion for a stay pending appeal and an emergency motion for a stay pending briefing and decision on the motion. Sanofi filed this emergency motion to prevent the Food and Drug Administration (FDA) from lifting the 30-month hold on the approval of generic ANDAs and ultimately approving the ANDAs pursuant to the Hatch Waxman Act. The judgment of noninfringement in this case means that Sanofi should not be able to delay the generics' FDA approval process because its patent is not being infringed by the generics—hence they should not be kept out of the market. Sanofi sought a stay of this judgment pursuant to its appeal in which it further sought reversal of the judgment. A stay halts the effectiveness of the judgment while a reversal would obviously entirely overturn the judgment as improperly granted. When a stay is granted, Sanofi ought to be able to maintain the status quo—the generics would be prevented from entering the market until the propriety of the judgment is resolved.

Obtaining a stay is by no means easy. The appellant has the burden of establishing entitlement under a test quite similar to the one for a preliminary injunction: (i) that it had a likelihood of success on appeal; (ii) that it would suffer irreparable harm; (iii) that the stay would not substantially injure other interested parties; and (iv) that the public interest would not suffer. On July 10, 2009, this court granted the stay and ordered expedited briefing on the merits.

On August 8, 2009, despite the fact that we had stayed the district court judgment, Sanofi learned that the FDA granted final approval for Teva's product, and

that Teva intended to launch its product in three days. On August 10, Sanofi filed an emergency motion to enforce our July 10, 2009 stay order, arguing that FDA did not have the legal authority to lift the Hatch-Waxman 30-month stay because we stayed the judgment giving FDA that authority. That same day, Sanofi also sued FDA in the District Court for the District of Columbia, seeking to force FDA to rescind the approvals on a similar theory. See Sanofi-Aventis et al. v. Food & Drug Admin. et al., No. 09-1495 (D.D.C.) The district court rejected Sanofi's arguments.

There is theoretical merit to Sanofi's motion to enforce our stay order because as Teva and FDA would have it, our stay is meaningless. We judged the factors of the test for granting a stay, and ruled that a stay was appropriate. It was our obvious intention to suspend alteration of the status quo. Nken v. Holder, 129 S. Ct. 1749, 1758 (2009); see id. ("[A] stay achieves [the same] result [as a preliminary injunction] by temporarily suspending the source of authority to act—the order or judgment in question—not by directing an actor's conduct."). The status quo was the imposition of the 30-month hold and abeyance of the approval of the ANDA applications. Nonetheless, because of FDA's actions, the way is clear for Teva and Mayne to enter the market, likely doing irreparable harm to Sanofi. FDA's position is that "[n]either a stay nor a reversal of a district court decision finding the patent invalid, unenforceable, or not infringed will have an effect on the approval of the ANDA or on the beginning, or continued running, of exclusivity." FDA Guidance for Industry: Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, 65 Fed. Reg. 16,922 (Mar. 30, 2000). Rather, according to FDA, the patentee must obtain an injunction in order to prevent ANDA applications from entering the market. The Hatch Waxman act, however, only permits FDA approval "effective on

. . . the date on which the court enters judgment reflecting the decision" of noninfringment or invalidity." 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa). We stayed that judgment prior to the FDA approval. FDA's decision to approve anyway is plainly contrary to Nken, which voids any legal effect from the stayed judgment, including the effect of triggering provisions of Hatch-Waxman. FDA's identical position with regard to reversals seems even more illogical. How could FDA lift the 30-month stay and approve the generic applications if we had already reversed the district court's judgment of noninfringment? But as the Supreme Court explained, the stay does not empower us to direct FDA's conduct—for now, that is the business of the District of Columbia.

Although FDA's position is dubious at best, our inability to rectify the problem is due to Sanofi's failure to file for a preliminary injunction against the generics seeking to prevent them from entering the market. Upon the termination of the 30-month stay in an ANDA case, the patentee has the option of filing for a preliminary injunction. Sanofi might have attempted to do so. Even when we generously interpret Sanofi's motion for enforcement of a stay of judgment as a motion to enjoin the generics from entering the market, we are still without the information necessary to rule in Sanofi's favor. While Sanofi argued likelihood of success with regard to the noninfringement determination, as appellees argue, it never addressed the likelihood of withstanding the validity challenge that the defendants had presented. See Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1376 (Fed. Cir. 2009) ("[T]he patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." (citing Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1364 (Fed. Cir. 1997)). Lacking facts or argument on the validity challenge, we are not equipped to

decide whether there is a likelihood of success on the merits and therefore could not grant an injunction Accordingly, I agree that we must deny reconsideration.