United States Court of Appeals for the Federal Circuit

04-1499

MEDIMMUNE, INC.,

Plaintiff-Appellant,

v.

CENTOCOR, INC.,

Defendant-Appellee,

and

THE TRUSTEES OF COLUMBIA UNIVERSITY IN
THE CITY OF NEW YORK
and THE BOARD OF TRUSTEES OF THE
LELAND STANFORD JUNIOR UNIVERSITY,

Defendants-Appellees.

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Appealed from: United States District Court for the District of Maryland

Judge Alexander Williams, Jr.

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DECIDED: June 1, 2005

Before SCHALL, BRYSON, and GAJARSA, Circuit Judges.

SCHALL, Circuit Judge.

MedImmune, Inc. ("MedImmune") appeals from the final decision of the United States District Court for the District of Maryland that dismissed, for lack of subject matter jurisdiction, MedImmune's declaratory judgment action against Centocor, Inc. ("Centocor"), the trustees of Columbia University in New York City, and the Board of Trustees of the Leland Stanford Junior University in California. In its suit, MedImmune

sought to have U.S. Patent No. 5,807,715 ("the '715 patent") declared invalid and/or unenforceable. The court dismissed the action after it determined that MedImmune had failed to establish that an actual controversy existed between it and Centocor, as required under the Declaratory Judgment Act, 28 U.S.C. § 2201(a). MedImmune, Inc. v. Centocor, Inc., No. AW-02-1135 (D. Md. June 17, 2004). We affirm.

BACKGROUND

I.

The '715 patent is titled "Methods and Transformed Mammalian Lymphocytic Cells for Producing Functional Antigen-Binding Protein Including Chimeric Immunoglobulin and Fragments." Columbia University and Leland Stanford Junior University are the assignees of the '715 patent. Centocor is the exclusive licensee of the patent, with the right to sublicense the patent to others.

The '715 patent issued in September of 1998. In a May 1999 letter, Centocor offered MedImmune a sublicense under the patent to cover MedImmune's Synagis® product. In August of 1999, MedImmune responded to Centocor's letter. In its response, MedImmune stated that it did not agree that Synagis® was covered by the '715 patent, and it indicated that it would not take a license.

In May of 2000, representatives from Centocor and MedImmune began license negotiations. The negotiations spanned several months. In these negotiations, MedImmune took the position that Synagis® did not infringe the '715 patent, that the patent was invalid and, alternatively, that MedImmune could design around the '715 patent. MedImmune claims that "facing mounting pressure and fearing an imminent infringement suit," it finally concluded a sublicense agreement with Centocor. The

agreement was executed on December 29, 2000. Thereafter, MedImmune began paying royalties on Synagis® under the agreement. It is undisputed that MedImmune continues to make timely royalty payments and is not otherwise in breach of the license agreement.

After concluding the license agreement, MedImmune asserted to Centocor that it did not infringe the '715 patent and that the patent was invalid and/or unenforceable. In response, Centocor told MedImmune that it expected MedImmune to continue to adhere to its license obligations.

II.

In April of 2002, MedImmune filed the present declaratory judgment suit in the District of Maryland, seeking a declaration that it owes no royalties under the license agreement with Centocor and that the '715 patent is invalid and/or unenforceable. Shortly thereafter, Centocor and the universities filed what they characterize as a "mirror-image" declaratory judgment suit against MedImmune in the Northern District of California. In their suit, Centocor and the universities alleged that, in view of MedImmune's suit in Maryland, a case or controversy existed between them and MedImmune. They sought a declaratory judgment that the '715 patent is valid and enforceable, and that MedImmune's manufacture and sale of Synagis® infringes the patent.

The Maryland district court granted Centocor and the universities' motion to dismiss for lack of jurisdiction. Relying on Gen-Probe, Inc. v. Vysis, Inc., 359 F.3d 1376 (Fed. Cir. 2004), the court determined that MedImmune had failed to establish that an actual controversy existed between it and Centocor, as required under 28 U.S.C.

§ 2201(a). Centocor and the universities' suit in the Northern District of California was also dismissed, on the ground that there was "no actual controversy to satisfy the Declaratory Judgment Act" in light of the Maryland suit.

MedImmune timely appeals the decision of the Maryland district court dismissing its suit. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

ANALYSIS

I.

Whether an actual case or controversy exists so that a district court may entertain an action for a declaratory judgment of non-infringement and/or invalidity is governed by Federal Circuit law. Minn. Mining & Mfg. Co. v. Norton Co., 929 F.2d 670, 672 (Fed. Cir. 1991); Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 954 n.3 (Fed. Cir. 1987). The determination of whether an actual controversy exists under the Declaratory Judgment Act in a patent case is a question of law that we review de novo. Vanguard Research, Inc. v. PEAT, Inc., 304 F.3d 1249, 1254 (Fed. Cir. 2002).

The Declaratory Judgment Act provides that "[i]n a case of actual controversy within its jurisdiction . . . [a court] may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). Paralleling Article III of the Constitution, the Act "requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment." Teva Pharms. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1331 (Fed. Cir. 2005) (quoting EMC Corp. v. Norand Corp., 89 F.3d 807, 810 (Fed. Cir. 1996)). "Basically, the question in each case is 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." Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941).

To keep watch over the subtle line between an "abstract question" and "a controversy contemplated by the Declaratory Judgment Act," id., an inquiry has been formulated that focuses on the conduct of both the patentee and the accused infringer. When a potential infringer seeks declaratory relief in the absence of a lawsuit by the patentee, there must be both (1) a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity. Teva, 395 F.3d at 1330; Gen-Probe, 359 F.3d at 1380; EMC Corp., 89 F.3d at 811.

II.

As noted above, the district court relied on our decision in Gen-Probe to dismiss MedImmune's declaratory judgment suit for lack of Article III jurisdiction. In Gen-Probe, we considered the case of a licensee in good standing who sought a declaratory judgment that it was not infringing the licensed patent, and that the licensed patent was invalid. 359 F.3d at 1377. The licensee sought a declaratory judgment while timely paying royalties and remaining faithful to the license agreement in all other respects. Id. at 1380.

In holding that there was no actual case or controversy for purposes of the Declaratory Judgment Act, we determined that the license, "unless materially breached, obliterated any reasonable apprehension of a lawsuit," and that once the licensor and licensee "formed the license, an enforceable covenant not to sue, the events that led to the formation [of the license] became irrelevant." Id. at 1381.

We agree with the district court that Gen-Probe is determinative of this case. Any controversy that may have existed between MedImmune and Centocor prior to and during their various negotiations vanished when MedImmune executed the license agreement, which is a covenant by Centocor not to sue. Quite simply, once the license agreement was in place and MedImmune was in compliance with the terms of the agreement, MedImmune could not be under a reasonable apprehension that it would face an infringement suit by Centocor.[1]

III.

MedImmune does not seriously dispute that Gen-Probe is virtually on "all fours" with this case. Rather, it contends that we should not follow Gen-Probe. MedImmune argues that Gen-Probe is inconsistent with Supreme Court precedent and with prior Federal Circuit precedent. Consequently, it urges that, as a panel, we are not obligated to follow it. See Atl. Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 839 n.2 (Fed. Cir. 1992) (positing that "[a] decision that fails to consider Supreme Court precedent

[1] MedImmune argues that the license agreement contemplated that it could institute a declaratory judgment action of invalidity and/or unenforceability with respect to the '715 patent. This is so, MedImmune asserts, because "the sublicense agreement contained . . . no agreement not to litigate." (Br. of Appellant at 22.) This assertion overlooks the fact that a license is, by its nature, an agreement not to litigate. A licensor agrees to receive royalties or other consideration from the licensee in exchange for a covenant not to sue or disturb the licensee's activities.

does not control if the court determines that the prior panel would have reached a different conclusion if it had considered controlling precedent"); Newell Cos. v. Kenney Mfg. Co., 864 F.2d 757, 765 (Fed. Cir. 1988) ("Where there is direct conflict" between two Federal Circuit panel decisions, "the precedential decision is the first."). We do not agree with MedImmune that Gen-Probe is inconsistent with controlling Supreme Court and Federal Circuit authority.

First, MedImmune argues that Gen-Probe is fatally flawed because it failed to recognize the decision of the Supreme Court in Cardinal Chemical Co. v. Morton International, 508 U.S. 83 (1993). We think, however, that Gen-Probe's failure to mention Cardinal Chemical reflects the fact that Cardinal Chemical was inapposite to Gen-Probe, rather than oversight on the part of the Gen-Probe court. The Supreme Court stated in Cardinal Chemical that its decision did not concern the jurisdiction of federal district courts:

> Under its current practice, the Federal Circuit uniformly declares that the issue of patent validity is "moot" if it affirms the District Court's finding of noninfringement and if, as in the usual case, the dispute between the parties does not extend beyond the patentee's particular claim of infringement. That practice, and the issue before us, therefore concern the jurisdiction of an intermediate appellate court — not the jurisdiction of either a trial court or this Court.

Id. at 95 (emphasis added). Consistent with the Court's statement of the limited issue before it in Cardinal Chemical, we have twice rejected the idea that Cardinal Chemical was meant to alter how a federal trial court determines whether a case or controversy exists over a declaratory judgment suit. See Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1060 (Fed. Cir. 1995) (Cardinal Chemical "does not revolutionize the justiciability of declaratory judgment actions attacking a patent's

validity. . . and nothing in Cardinal undermines our decisions on declaratory justiciability at the trial court level."); Lamb-Weston, Inc. v. McCain Foods, Ltd., 78 F.3d 540, 545 (Fed. Cir. 1996) ("The Supreme Court's decision in Cardinal Chemical is limited to the specific facts of that case.").

MedImmune also argues that Gen-Probe is inconsistent with the Supreme Court's rejection of the doctrine of licensee estoppel in Lear, Inc. v. Adkins, 395 U.S. 653 (1969). This argument was addressed and rejected in Gen-Probe, 359 F.3d at 1381, and we likewise reject it here. Although Lear held that a licensee is not estopped from challenging the validity of a licensed patent, 395 U.S. at 670-71, "Lear . . . left unresolved the question when a federal court has jurisdiction of a licensee's claim of patent invalidity." C.R. Bard, Inc. v. Schwartz, 716 F.2d 874, 878 (Fed. Cir. 1983). In other words, the fact that a party is not estopped from making an argument does not mean that federal courts have jurisdiction to entertain that argument in all circumstances.

Second, MedImmune urges that Gen-Probe is at odds with three decisions of this court: C.R. Bard, Cordis Corp. v. Medtronic, Inc., 780 F.2d 991 (Fed. Cir. 1985), and Intermedics Infusaid, Inc. v. Regents of the University of Minnesota, 804 F.2d 129, 133 (Fed. Cir. 1986). We do not agree.

C.R. Bard noted that complete termination of the license may not be required for a licensee to sustain a declaratory judgment suit. 716 F.2d at 880. It does not follow from that proposition, however, that all licensees in good standing can challenge the validity of the licensed patent at their discretion, without regard to whether an actual controversy exists with the licensor.

Specifically, in determining that there was a case or controversy supporting jurisdiction over a licensee's declaratory judgment suit for, among other things, invalidity of the licensed patent, the C.R. Bard court found two facts to be important. First, the licensee had ceased paying royalties. Although this fact did not itself terminate the license, it constituted "a material breach of the agreement that, under the very terms of the agreement, enabled [the licensor] to terminate the agreement." Id. at 881. Second, the licensor had shown a willingness to enforce its rights by filing a state court action to recover the royalty payments. Id. at 881. This court then applied the "reasonable apprehension" test to these facts, determining that the licensee had a reasonable apprehension of suit. Id.

By contrast, in this case MedImmune can have no reasonable apprehension of suit—indeed, it can have no apprehension of suit at all—because there is nothing for which Centocor can sue MedImmune. It is undisputed that MedImmune continues to pay timely royalties for Synagis® and is not otherwise in breach of the agreement. The fact that Centocor did sue MedImmune, after MedImmune filed its declaratory judgment suit, does not alter the analysis. The presence or absence of a case or controversy is based on facts at the time the complaint was filed. See, e.g., GAF Bldg. Materials Corp. v. Elk Corp. of Dallas, 90 F.3d 479, 483 (Fed. Cir. 1996) ("Later events may not create jurisdiction where none existed at the time of filing. Rather, the presence or absence of jurisdiction must be determined on the facts existing at the time the complaint under consideration was filed." (citations omitted)).

MedImmune's reliance on Cordis also is misplaced. Cordis did not address the question of whether there is a case or controversy sufficient to support subject matter

jurisdiction over a licensee's suit for a declaratory judgment of patent invalidity where the licensee is not in breach of the license agreement. See generally 780 F.2d at 993-95. In Cordis, the licensee sought a declaration that the licensed patent was invalid. Id. at 993. However, the licensee also sought to pay royalties into escrow pendente lite, and to enjoin the licensor from canceling the license agreement. Id. It was these latter two requests, granted by the district court, that were before this court on appeal. See id.[2]

MedImmune points to Intermedics for the proposition that when a licensee wishes to maintain its license, it must continue to pay royalties to the licensor. See 804 F.2d 129, 133 (citing Cordis). That proposition, however, does not explain how there could be a case or controversy where, as here, the licensee is fully paying royalties directly to the licensor and is maintaining the license.

IV.

Finally, MedImmune urges us—assuming we conclude that we are bound by Gen-Probe—to recommend to the full court that it act en banc to overrule that decision. Although a three-judge panel of this court may not overrule a precedential decision of a previous panel, see, e.g., Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1366 (Fed. Cir. 2002), it may recommend en banc review of the decision. See Federal Circuit Rule 35(a)(2) (2004). We decline to do that in this case. Most importantly, as we have just explained, Gen-Probe is consistent with both Supreme Court precedent and with prior precedent of this court.

[2] These issues were before the court based upon 28 U.S.C. §§ 1292(a) & (c), which confer jurisdiction upon this court to hear appeals from orders granting injunctions.

Beyond that, we reject MedImmune's argument that Gen-Probe should be overruled because it creates a "Hobson's choice." Specifically, MedImmune argues that it must "choose between paying tribute to a suspect patent and tying its fate to the uncertainty of patent litigation," with all of the attendant risks of such litigation. (Reply Br. of Appellant, at 2.) MedImmune's argument proves too much. Every potential infringer who is threatened with suit, or who is sued, for patent infringement must decide whether to settle or fight. In short, the "Hobson's choice" about which MedImmune complains arises not from Gen-Probe, but from Article III's requirement that, before a district court exercises jurisdiction in a declaratory judgment suit, there must be an actual controversy between the parties. For the reasons set forth above, such a controversy does not exist here.

CONCLUSION

Because the district court did not err in ruling that no Article III case or controversy existed to support MedImmune's declaratory judgment suit, it properly dismissed the suit for lack of jurisdiction. Therefore, the judgment of the district court is

AFFIRMED.