

Keywords: subject-matter jurisdiction; Article III case or controversy; license; declaratory judgment

General: A licensee is not required to break or terminate a license agreement to create an actual case or controversy prior to seeking declaratory judgment that a patent covered by the license agreement is unenforceable, invalid, or not infringed.

MedImmune, Inc. v. Genentech, Inc.
549 U.S. ___, 127 S. Ct. 764 (2007)
Decided January 9, 2007

I. Facts

MedImmune is the manufacturer of Synagis, a drug used to prevent respiratory tract disease in young children. In 1997, MedImmune entered into a patent license agreement with Genentech. The license covered both an existing Genentech patent, U.S. Patent No. 4,816,567 (the “Cabilly I” patent), and a pending continuation, which later matured into U.S. Patent No. 6,331,415 (the “Cabilly II” patent).

Shortly after the Cabilly II patent issued in 2001, Genentech notified MedImmune of its belief that Synagis was covered by the claims of the Cabilly II patent, and of its expectation for royalty payments to be made under the terms of the license. While MedImmune did not believe that the claims of this patent were valid or infringed by Synagis, MedImmune recognized that failure to pay the royalties could result in termination of the license and litigation, which could potentially result in an order to pay treble damages and attorney’s fees, as well as an injunction prohibiting the sale of Synagis. To avoid such risks, MedImmune paid the royalties for Synagis under protest and then filed a declaratory-judgment action in federal district court, alleging that the claims of the Cabilly II patent were unenforceable, invalid, and not infringed by Synagis, as well as alleging violations of certain antitrust regulations.

The district court dismissed the suit as non-justiciable under the Declaratory Judgment Act, which provides that “[i]n a *case of actual controversy* within its jurisdiction ... any court of the United States ... 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) (emphasis added). Particularly, the district court found that MedImmune was a licensee in good standing that did not have a reasonable apprehension of suit and, applying *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004), held that MedImmune lacked standing to bring a declaratory challenge to the Cabilly II patent (i.e., the challenge did not rise to the level of an “actual controversy” under the statute and, consequently, the court lacked subject-matter jurisdiction). The district court also dismissed MedImmune’s antitrust counts. On appeal, the Federal Circuit affirmed the decision of the district court. The Supreme Court granted certiorari and heard oral arguments in 2006.

II. Issue

Did the Federal Circuit err in affirming the dismissal of MedImmune’s invalidity, unenforceability, and non-infringement claims for lack of subject-matter jurisdiction?

III. Discussion

Yes. In an opinion written by Justice Scalia on behalf of the eight-justice majority, the Court held that MedImmune was not required to break or terminate its 1997 license agreement before seeking a declaratory judgment that the underlying patent was invalid, unenforceable, or not infringed.

In the majority opinion, the Court refers to its decision in *Aetna Life*, which explained that the phrase “case of actual controversy” in the Declaratory Judgment Act refers to the type of “Cases” and “Controversies” that are justiciable under Article III.¹ In order to satisfy the case-or-controversy requirement, *Aetna Life* stated that the dispute must be “definite and concrete, touching the legal relations of parties having adverse legal interests”; and that the dispute be “real and substantial” and “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.” Further, in *Maryland Casualty*, the Court summarized the case-or-controversy requirement, noting: “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.”²

The Court posits that there is no dispute that these requirements would have been satisfied if MedImmune had refused to make royalty payments under the 1997 license agreement and that, but for the payment of such royalties, nothing about the case would suggest that it is unfit for judicial resolution. The Court further notes that MedImmune’s own actions (i.e., making the royalty payments) eliminate the imminent threat of harm (e.g., infringement damages, termination of the license, an injunction preventing sale of the product). Thus, the Court frames the legal question of the present case as “whether this causes the dispute no longer to be a case or controversy within the meaning of Article III.”

The Court begins its analysis of this question through reference to several cases related to threatened *government* action; these cases generally provide that plaintiffs are not required to expose themselves to liability in order to gain standing for a suit challenging the basis for such a threat. For example, a plaintiff is not required to violate a law in order to challenge its constitutionality. The Court notes that, although the plaintiff’s own action (or inaction) may remove the imminent threat of prosecution (e.g., by not violating the law at issue), such action does not eliminate Article III jurisdiction “because the threat-eliminating behavior was effectively coerced.”

Recognizing a scarcity of Supreme Court precedent as to situations in which a plaintiff’s self-avoidance of imminent harm is coerced by threatened enforcement action by a *private party*, the majority opinion states that the only Court decision on point is *Altwater*, which the majority characterized as holding that “a licensee’s failure to cease its payment of royalties did not render non-justiciable a dispute over the validity of the patent.”³ Particularly, in *Altwater*, the patentee was collecting royalties from licensees under a court injunction, and again sued its licensees to enforce territorial restrictions in the license. The licensees counterclaimed for declaratory judgment that the patents were invalid. The *Altwater* Court found subject-matter jurisdiction to be present, concluding that “the requirements of [a] case or controversy are met where payment of a claim is demanded as of right and where payment is made, but where the involuntary or coercive nature of the exaction preserves the right to recover the sums paid or to challenge the legality of the claim.” Finding that the threat of treble damages and an injunction that could result in a loss of eighty percent of MedImmune’s business fell within *Altwater*’s coercion rationale, the Court held that subject-matter jurisdiction was present and reversed the judgment of the Federal Circuit.

¹ *Aetna Life Ins. Co. v. Haworth*, 200 U.S. 227 (1937).

² *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941).

³ *Altwater v. Freeman*, 319 U.S. 359 (1943).

IV. Conclusion

In addition to finding that subject-matter jurisdiction exists in a declaratory-judgment action by a licensee in good standing, the Court also expressly criticized the “reasonable apprehension of suit” test articulated in *Gen-Probe* and other Federal Circuit cases. The Court noted that this test conflicts with its previous decisions in *Altvater*, *Maryland Casualty*, and *Aetna Life*, and is in tension with another Supreme Court decision. Based on a recent Federal Circuit panel decision, *Sandisk Corp. v. STMicroelectronics, Inc.*, slip op. 05-1300 (Fed. Cir. 2007), it appears that the Federal Circuit is abandoning the “reasonable apprehension of suit” test altogether in view of the disapproval of this test by the Supreme Court.