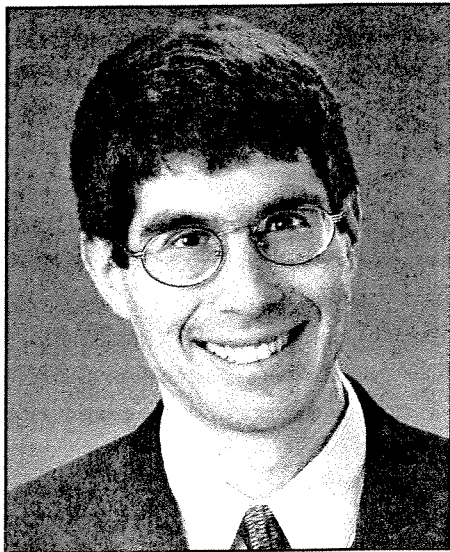


The Supreme Court Opens the Door to More Patent Challenges:

MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764, 166 L. Ed. 2d 604 (2007)



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ued to pay the royalties, it had no fear of being sued, but it could not attack the patent. The *Gen-Probe* holding was followed by the Federal Circuit in subsequent cases, including *Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings*, 370 F.3d 1354 (Fed. Cir. 2004), and *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005).

On January 9, 2007, the Supreme Court overturned the *Gen-Probe* rule in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 166 L. Ed. 2d 604 (2007), holding that a patent licensee in good standing could still sue for a declaratory judgment of non-infringement, invalidity, or unenforceability of the patent.

THE PATENT LICENSE AND MEDIMMUNE'S DECISION TO SUE

THE SUPREME COURT HAS REVERSED a key precedent in patent cases, holding that a licensee of a patent may sue the licensor of the patent for a declaration of non-infringement, invalidity, or unenforceability of the patent, while continuing to pay royalties under the license.

Previously, the law has been clear that a patent licensee was barred from contesting the scope and validity of the patent while paying royalties. Under *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (2004), the Federal Circuit held that a patent licensee in good standing could not establish an Article III case or controversy respecting such issues because the license "obliterates any reasonable apprehension" that the licensor will sue the licensee for patent infringement. *Id.* at 1381. The upshot of this was that as long as the licensee contin-

The key facts of the *MedImmune* case are as follows: Plaintiff MedImmune, Inc. makes Synagis, a drug used to prevent respiratory tract disease in babies and young children. In 1997, MedImmune entered into a patent license with Defendants Genentech, Inc and City of Hope (collectively, "Genentech"). The license concerned a patent relating to the production of "chimeric antibodies" and a pending patent application relating to "the coexpression of immunoglobulin chains in recombinant host cells." MedImmune agreed to pay royalties on sales of "Licensed Products," and Genentech gave MedImmune permission to make, use, and sell them. The license agreement defined "Licensed Products" as an antibody, "the manufacture, use or sale of which...would, if not



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licensed under th[e] Agreement, infringe one or more claims of either or both of [the covered patent and patent application,] which have neither expired nor been held invalid by a court or other body of competent jurisdiction from which no appeal has been or may be taken." The agreement gave MedImmune the right to terminate the license upon six months' written notice.

In December 2001, Genentech's "coexpression" application issued as the "Cabilly II" patent. Soon after the patent issued, Genentech sent MedImmune a letter asserting that the Synagis product was covered by the Cabilly II patent and asking MedImmune to pay royalties for it starting March 1, 2002. MedImmune took the position that it did not owe royalties, that the Cabilly II patent was

invalid and unenforceable, and that the claims of the Cabilly II were not infringed by Synagis.

But MedImmune was concerned that, if it refused to pay the royalties, then Genentech would terminate the 1997 license agreement and sue MedImmune for patent infringement. If Genentech won such a suit, the court could order MedImmune to pay treble damages and attorneys' fees, and could enjoin MedImmune from selling its main product, Synagis. Loath to risk a drug that accounted more for more than eighty percent of its sales revenue since 1999, MedImmune paid the demanded royalties "under protest and with reservation of all of [its] rights."

After paying the royalties and reserving its rights, MedImmune sued Genentech for, among other things, a declaratory judgment of non-infringement, invalidity, and unenforceability. Genentech moved to dismiss the declaratory judgment claims for lack of subject-matter jurisdiction. The district court granted the motion, relying upon *Gen-Probe*. The Federal Circuit, also relying upon *Gen-Probe*, affirmed. The Supreme Court subsequently granted *certiorari*.

THE SUPREME COURT OVERRULES GEN-PROBE

On January 9, 2007, the Supreme Court issued its decision, reversing the dismissal of the case for lack of subject-matter jurisdiction. The Supreme Court began its opinion by reviewing the standards for determining whether a particular declaratory judgment action meets the Constitutional Article III case-or-controversy requirement—*i.e.*, "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." *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U. S. 270, 273 (1941).

The Supreme Court proceeded to frame the issue as whether there could be a case or controversy within the meaning of Article III where "[p]etitioner's own acts...eliminate the imminent threat of harm." Looking to analogous areas of the law, the Court noted that, "where threatened action by *government* is concerned, we do not require a plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat.... The plaintiff's own action (or inaction) in failing to violate the law eliminates the imminent threat of prosecution, but nonetheless does not eliminate Article III jurisdiction." The Court cited *Terrace v. Thompson*, 263 U.S. 197 (1923), a case in which the Court allowed a plaintiff to test the validity of an anti-alien land law without requiring him to actually break the law, and *Steffel v. Thompson*, 415 U.S. 452 (1974), a case in which the Court allowed a plaintiff to seek a declaratory judgment regarding the constitutionality of a state criminal trespass law without risking actual prosecution.

Having analyzed the case law concerning threatened government action, the Court turned to the situation here of threatened private action to infringe a patent. The Court noted that, where a private party has threatened enforcement actions, lower courts have often consented to jurisdiction, citing several decisions. This was also the outcome in the one Supreme Court case on point, *Altwater v. Freeman*, 319 U.S. 359 (1943). In *Altwater*, the Court held that the district court could hear a suit concerning patent validity despite the continued payment of royalties. *Id.* at 364.

In *Gen-Probe*, the Federal Circuit had distinguished *Altwater* because "[t]he royalty payments in *Altwater* were not paid under the terms of a license agreement; rather, they were paid 'under the compulsion of an injunction decree.'" *Gen-Probe*, 359 F.3d at 1382.(quoting *Altwater*). In his *MedImmune* dissent, Justice Thomas noted additional differences. In *Altwater*,

the affirmative defense of patent invalidity arose in a declaratory judgment motion filed as a counterclaim to a patent infringement suit. Also, the underlying license in *Altwater* had been terminated before the case was filed, with royalties being paid under the injunction decree. According to Justice Thomas, "*Altwater* simply held that under the unique facts of that case, the Court of Appeals erred in considering the declaratory judgment counterclaim moot because the 'involuntary or coercive nature of the exaction preserve[d] the right to recover the sums paid or to challenge the legality of the claim,'" (quoting *Altwater*, 319 U.S. at 365).

But the *MedImmune* Supreme Court majority found *Altwater* to be on point. Although *Altwater* concerned an injunction, the Court noted that the "opinion acknowledged that the licensees had the option of stopping payments in defiance of the injunction, but explained that the consequence of doing so would be to risk 'actual [and] treble damages in infringement suits,'" (quoting *Altwater*, 319 U.S. at 365). *MedImmune* was threatened with the same consequences. Such infringement suits would be private actions, and nowhere did the *Altwater* opinion mention any threat of prosecution or other governmental sanction.

Having decided that *Altwater* governed the case at bar, the Court turned to licensor Genentech's other contentions. Genentech argued that the parties effectively resolved the dispute when they entered into their license agreement. The Court disagreed, stating that "[p]romising to pay royalties on patents that have not been held invalid does not amount to a promise *not to seek* a holding of their invalidity."

Genentech also argued under that common law a party to a contract cannot both challenge its validity and continue to reap its benefits. The Court again disagreed, holding that the common law rule did not apply: "Petitioner is not repudiating or impugning the contract while continuing

to reap its benefits. Rather, it is asserting that the contract, properly interpreted, does not prevent it from challenging the patents, and does not require the payment of royalties because the patents do not cover its products and are invalid.”

Lastly, Genentech asked the Court to affirm the dismissal on discretionary grounds. The text of the Declaratory Judgment Act “confer[s] on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants.” *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995). The Court declined Genentech’s invitation to exercise its discretion, opting to remand that issue to the lower courts.

The majority Opinion was authored by Justice Scalia. Justice Thomas, wrote a lone dissent, to state his position that there was no jurisdiction to obtain a declaratory judgment ruling on such matters by a licensee, that, in his view, “remain hypothetical and conjectural.”

WHAT DOES IT ALL MEAN?

This decision will greatly change the landscape of the bargaining power between a patent licensee and licensor. The solace that a patent owner licensor received in a granting a license, knowing that its licensee could not attack the validity of the patent under the shield of the license, is a very valuable consideration. If the licensor knows that large amounts will be paid under the license, thus justifying a licensee to gamble at taking a shot at the patent, knowing that if it fails, the licensee will have the comfort of continuing the license by paying royalties, is very important. Licensees, who expect to pay substantial royalties, will seek to negotiate licenses, with a “back pocket” dream of the license being a “worst case scenario,” as the licensee seeks to gather evidence and later bring an action to challenge the patent.

The decision may well discourage traditional patent licenses, even entered into in the settlement of patent infringement

suits. Will the courts, whose crowded dockets benefit from the settlement of patent litigation, and stand to be even more crowded by licensees suing later to challenge the licensed patents, provide limitations on the rights to challenge licensed patents in the future?

Are there drafting considerations which will help licensors prevent licensees from challenging the license to patents? Can licensees put in express language prohibiting such challenges, notwithstanding this decision, as part of the bargained-for consideration of a patent license? Will consent judgments of validity and infringement, in, or recessitations of patent validity by a licensee in such judgments, or in agreements, prevent later challenges?

These are some of the questions raised by this decision.

Will it matter whether the licensee entered into the license having studied the validity of the patent, perhaps in the context of a lawsuit, make a difference where, as in *MedImmune*, the challenge was as to a patent which had not yet issued when the licensee entered into the patent license.

Surely the case will change the landscape and considerations of patent licensing where substantial royalties are being paid, in numerous ways in the future. Look for more cases refining what may be exceptions to the broad pronouncement of *MedImmune*, as the courts seek to provide more certainty and finality in patent licenses, in view of the insecurity now raised by the Supreme Court decision. ©

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