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# PATENT LAW

# 'MedImmune' Ruling

## By Lewis R. Clayton

LAST MONTH, the U.S. Supreme Court decided an issue that affects nearly every patent license and technology transfer agreement across the country. In *MedImmune Inc. v. Genentech Inc.*, 2007 WL 43797 (U.S. Jan. 9, 2007), the court held that a patent licensee in good standing—one that is current in its obligation to pay royalties—nevertheless may sue for a declaratory judgment that a patent is invalid, unenforceable or not infringed. While it settles this issue of licensee standing, *MedImmune* has stimulated debate on a host of questions concerning the right of patent owners to discourage, without explicitly prohibiting, licensee challenges to patent validity or enforceability. It may also provoke re-examination of U.S. Court of Appeals for the Federal Circuit law governing when declaratory judgment actions may be filed by parties that have not taken a license from the patent holder.

MedImmune sells Synagis, a drug to prevent infections in young children, which represents 80% of its sales. MedImmune licensed from Genentech one issued drug patent and one pending patent application. When the application issued, Genentech sought additional royalties. MedImmune disputed that royalties were due, asserting that the patent was not infringed, as well as invalid and unenforceable. Rather than risk treble damages and an injunction, however, it continued to pay royalties "under protest and with reservation of all of [its] rights." It then sued for a declaratory judgment that the patent is invalid and not infringed. The district court dismissed for lack of subject-matter jurisdiction.

### Federal Circuit had held that licensee could not sue

Affirming, the Federal Circuit found the case controlled by *Gen-Probe Inc. v. Vysis Inc.*, 359 F.3d 1376 (Fed. Cir. 2004). *Gen-Probe* applied that circuit's test for declaratory judgment jurisdiction, which requires that the plaintiff show that it had a "reasonable apprehension" that "it will face an infringement suit." *Gen-Probe* held that a licensee in good standing cannot show an "actual controversy," because the license agreement "obliterates any reasonable apprehension of a lawsuit." *Gen-Probe* distinguished the high court's landmark ruling in *Lear Inc. v. Adkins*, 395 U.S. 653 (1969), which allowed a declaratory judgment suit when the licensee had repudiated the license, refusing to pay royalties.

The grant of certiorari in *MedImmune* produced an impressive group of amici supporting the *Gen-Probe* rule, including major technology companies, the American Bar Association and the American Intellectual Property Law Association. Many of these amici saw *Gen-Probe* as a rule of fairness: As a license agreement prevents the patent holder from suing for infringement, the licensee should not be given a one-way option to seek a declaratory judgment at the time of its choosing. Moreover, they argued, overruling *Gen-Probe* would raise the cost of licensed technology. If a licensor must agree to refrain from suit during the license term, without the assurance that the licensee is also prevented from going to court, the licensor presumably will charge more for IP rights.

The Supreme Court, however, was more persuaded by the views of the solicitor general, who argued that a declaratory judgment plaintiff need not "run the risks entailed in actually violating the law" in order to establish an "actual controversy" under the Declaratory Judgment Act. In an 8-1 opinion authored by Justice Antonin Scalia (Justice Clarence Thomas dissenting), the court conceded that its declaratory judgment case law does "not draw the brightest of lines between [cases] that satisfy the case-or-controversy requirement and those that do not." The court summarized the standard by quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941): "Basically, the question…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."

The court relied as well on *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937), the opinion that upheld the constitutionality of the Declaratory Judgment Act, which focused on whether a dispute is sufficiently clear and specific to avoid the rendering of an advisory

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opinion. *Aetna* required that a dispute be "definite and concrete," and allow for "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."

Rather than consider the kind of policy arguments advanced by the amici, the court began its analysis with established law providing 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—for example, the constitutionality of a law threatened to be enforced." It then framed the question by asking whether a party who acts to avoid liability in a civil suit should be entitled to the same treatment. The court found an affirmative answer to that question in *Altaver v. Freeman*, 319 U.S. 359 (1943). There, some patentees sued their licensees to enforce territorial restrictions in the license, and the licensees counterclaimed for a declaratory judgment of invalidity. Jurisdiction was sustained, although the licensees paid "under protest," as required by an injunction obtained in an earlier suit.

The court rejected the argument that declaratory judgment jurisdiction was divested by the "common-law rule that a party to a contract cannot at one and the same time challenge its validity and continue to reap its benefits." But it did not completely close the door to that position; it remarked that, if "the licensing agreement or the common-law rule precludes this suit, the consequence would be that [the patentees] win this case on the merits—not that the very genuine contract dispute disappears, so that Article III jurisdiction is somehow defeated."

To the extent that policy concerns—as opposed to a close analysis of the case-or-controversy requirement—animated the decision, those concerns may have been the ones expressed nearly 40 years ago in *Lear*. That decision emphasized the social interest in restricting the ability of licensors to prevent challenges to patent validity: "Surely the equities of the licensor do not weigh very heavily when they are balanced against the important public interest in permitting full and free competition in the use of ideas which are in reality part of the public domain." *Lear* observed that licensees may have unique incentives to challenge patentability.

Despite the *MedImmune* court's remarks about a common-law defense, *Lear* has been read by some courts and commentators to bar, as a matter of public policy, enforcement of a clause in an agreement prohibiting licensee challenges to validity. By removing a bar to declaratory judgment jurisdiction, *MedImmune* focused renewed attention on the issue of whether provisions that merely discourage challenges are enforceable.

On one hand, it seems clear that contracts entered into after substantial litigation are enforceable. Thus, if litigation results in a consent judgment after patent validity is sustained (*Diversey Lever Inc. v. Ecolab Inc.*, 191 F.3d 1350, 1352 (Fed. Cir. 1999)), or if a settlement agreement is signed after significant proceedings (*Flex-Foot Inc. v. CRP Inc.*, 238 F.3d 1362, 1369 (Fed. Cir. 2001)), an alleged infringer may agree not to challenge the patent. In those situations, we are presumably comfortable that contract law is not a bar to meritorious challenges, because significant court proceedings have taken place. What should be the result, however, when a settlement agreement prohibiting challenges is signed shortly after litigation begins, before any court or jury has passed on the patent?

**A licensee in good standing may sue for a declaratory judgment that the patent is invalid, unenforceable or not infringed.**

And if the important question is whether the patent's validity has been carefully considered, perhaps restrictions in certain license agreements—but not others—should be enforced. An agreement licensing a well-accepted patent, signed after intense study and negotiation between sophisticated, well-represented parties may be on a different footing from other licenses. Courts may also need to consider the enforceability of other restrictions on a challenge—provisions terminating the license or increasing royalties when a declaratory judgment action is filed, or barring the return of royalty payments made during the suit, even if a challenge is successful.

## 'Reasonable apprehension' test may need reconsidering

*MedImmune* may also require a new look at the Federal Circuit's "reasonable apprehension" test, which has barred declaratory judgment actions against patentees who contact potential infringers, but stop short of explicitly threatening suit. An amicus brief filed in *MedImmune* by three IP professors from the University of Akron complained that, under the test, patent holders may "notify the industry of their patents, enter licensing negotiations, grant licenses, or walk away from the table, all without" triggering declaratory judgment jurisdiction. Thus, they concluded, the Federal Circuit has "given patentees clear instructions for nullifying the Declaratory Judgment Act in the field of patent law." That court may have to decide whether its reasonable-apprehension doctrine is an unnecessary limitation on the case-or-controversy test applied in *MedImmune*.

What does the future hold? *MedImmune* may well lead to more patent litigation, as some patent owners decline to sign license agreements and take the risk of declaratory judgment actions. And issues concerning contractual restrictions on validity challenges and the application of the reasonable-apprehension test may come before a Supreme Court that has shown increasing interest in reviewing decisions of the Federal Circuit.