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'MedImmune v. Genentech': Unanswered Questions

On Jan. 9, 2007, the U.S. Supreme Court held in *MedImmune, Inc. v. Genentech, Inc.* that a patent licensee has Article III jurisdiction to seek a declaratory judgment of noninfringement, patent invalidity or unenforceability against the licensor-patentee, even if the licensee continues to pay royalties under the license agreement.¹

The decision reversed the U.S. Court of Appeals for the Federal Circuit, which previously ruled that no Article III controversy exists between a licensor and licensee in good standing.

Case Facts

Genentech held a patent for a process of synthesizing "chimeric" monoclonal antibodies for use in medication ("the Cabilly I patent"). MedImmune developed Synagis, a "humanized" monoclonal antibody used to prevent a respiratory virus in infants and young children. In 1997, MedImmune licensed the Cabilly I patent, as well as any future related patents, from Genentech. In 1998, the FDA approved Synagis. MedImmune concluded that the Cabilly I patent did not cover Synagis, and MedImmune did not pay royalties for Synagis. In 2001, Genentech was awarded a second, broader patent ("the Cabilly II patent").

Genentech demanded MedImmune pay royalties under the 1997 license based on the Cabilly II patent. MedImmune began paying royalties, and continued to do so, but "under protest and with reservation of all of [its] rights." MedImmune then sued Genentech seeking a declaratory judgment that the Cabilly II patent was not infringed, invalid and unenforceable. The district court dismissed for lack of subject matter jurisdiction. MedImmune appealed to the Federal Circuit.

Earlier Federal Circuit cases, such as *Gen-Probe*, clearly held that a licensee must cease royalty payments, thereby materially breaching the license agreement, before challenging patent validity in



order to satisfy subject matter jurisdiction under Article III of the Constitution.² However, such an act would allow the licensor to terminate the license, exposing the licensee to a patent infringement suit, with a threat of treble damages and an injunction.³ MedImmune urged the court to overturn its precedent. The Federal Circuit declined, reasoning that a licensee in good standing could have no "reasonable apprehension of suit"—the test to establish Article III jurisdiction that the Federal Circuit articulated years earlier.⁴

The Supreme Court rejected the Federal Circuit's "reasonable apprehension of suit" test as an absolute test for jurisdiction and determined that a controversy existed between MedImmune and Genentech sufficient to satisfy Article III. The court did not dispute that the continued payment of royalties under the license made the threat of an infringement suit "at least remote, if not nonexistent" and "eliminate[d] the imminent threat of harm."⁵ However, the payments did not negate the underlying controversy between the parties.

The Supreme Court's decision is narrow, addressing only the Article III jurisdictional issue. Importantly, the court expressly declined to decide the lurking licensee estoppel issue.

Licensee Estoppel

Prior to 1969, licensee estoppel was law—a patent licensee could not challenge the validity of the licensed patent. This was true even where a licensee ceased payment and the licensor sued to collect

royalties. While arguably this equitable doctrine was slowly being narrowed through exceptions, it was not until 1969 that the Supreme Court, in *Lear v. Adkins*, eliminated in part the doctrine of licensee estoppel based on patent policy considerations.⁶ The Court embraced a licensee's strong economic incentive to challenge patents and, as later discussed by the Supreme Court, made clear that "an accused infringer [may] accept a license, pay royalties for a time, and cease paying when financially able to litigate validity, secure in the knowledge that invalidity may be urged when the patentee-licensor sues for unpaid royalties."⁷ Significantly, *Lear* did not address important questions such as whether licensee estoppel arises where a licensee continues to pay royalties or where the licensee initiates the lawsuit, as in the *MedImmune* case.

The circuits split regarding the implementation of *Lear* under varying circumstances.⁸ The circuit court decisions lacked precedential effect after the creation of the Federal Circuit in 1982, which now hears all appeals in cases arising under the patent statute. The Federal Circuit construed *Lear* narrowly and several times declined to apply the *Lear* doctrine under varying fact patterns. The question of whether a licensee must stop paying royalties prior to challenging a patent's validity was directly addressed in 1997. In *Shell Oil*, the Federal Circuit held that a licensee must stop paying royalties to invoke the *Lear* doctrine.⁹ While the *Shell Oil* facts varied significantly from those of *MedImmune*, in 2004 the Federal Circuit, in *Gen-Probe*, made clear the *Shell Oil* holding's broad reach.

In *Gen-Probe*, where the licensee continued to pay royalties under protest, the Federal Circuit went one step further than *Shell Oil*. The court essentially converted the *Lear* doctrine into an Article III jurisdictional bar, finding that a nonrepudiating licensee has no reasonable apprehension of suit:

In *Shell Oil*, this court decided that a licensee is liable for unpaid royalties that accrued under the terms of the license before invalidation of the subject patent's claims. While that case did not discuss jurisdiction under the Declaratory Judgment Act, this court stated: "[A] licensee...cannot invoke the protection of the *Lear* doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice

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