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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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to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid.” *Shell Oil*, 112 F3d at 1568. This language posits that a licensee must, at a minimum, stop paying royalties (and thereby materially breach the agreement) before bringing suit to challenge the validity or scope of the licensed patent.¹⁰

Contrary to *Gen-Probe*, the Supreme Court’s analysis in *MedImmune* clearly establishes that Article III jurisdiction and licensee estoppel are separate considerations. Unfortunately, despite resolving the jurisdictional issue, the court refused to comment on the applicability of *Lear* to the *MedImmune* fact pattern. Indeed, the Court mentions *Lear* several times and distinguishes a “repudiating licensee” from a “nonrepudiating licensee.” The Court clearly stated it expressed no opinion on the applicability of *Lear* under the *MedImmune* facts, or *Lear*’s impact on the breadth of the licensee estoppel doctrine.¹¹

Genentech argued, based on *Commodity Credit Corp. v. Rosenberg Bros. & Co.*, 243 F2d 504, 512 (9th Cir. 1957) and *Kingman & Co. v. Stoddard*, 85 F. 740, 745 (7th Cir. 1898), that a license is a type of “insurance policy” and, based on the pre-*Lear* common-law rule, argued that a licensee cannot reap the benefits and immunity of a license while bringing suit. The Court placed great weight on the fact that the dispute revolved around the proper interpretation of the contract, and expressed doubt as to whether the common-law rule of licensee estoppel could apply in this situation. At the same time, the Court quoted, without apparent disapproval, the Federal Circuit’s *Lear* analysis in the *Shell Oil* decision. The Court expressly left the door open to licensee estoppel arguments, stating that, if Genentech is correct that licensee estoppel “precludes this suit, the consequences would be that [Genentech, et al.] win this case on the merits—not that...Article III jurisdiction is somehow defeated. In short, Article III jurisdiction has nothing to do with this ‘insurance policy’ contention.”¹² The Court concluded by stating that the lower courts are in the best position to decide whether discretionary dismissal or “merits-based arguments” warrant the denial of declaratory relief.

The Court’s failure to address licensee estoppel, and the effect of *Lear* on the doctrine, leaves open substantial questions on remand. A careful reading of *MedImmune* reveals that the Supreme Court overturned only the Federal Circuit’s Article III decision. On remand, the Federal Circuit may still reject *MedImmune*’s claims on the merits, based on the court’s interpretation of licensee estoppel.

The Aftermath

There is little doubt that *MedImmune* will create a flurry of increased declaratory judgment actions challenging patents—including between parties who had seemingly resolved their disputes.¹³ How such actions are framed (contract versus patent) and the specific language of the license agreement are clearly important. However, the long-term impact of the

MedImmune decision remains to be seen. How the courts interpret *MedImmune*, and how the case is handled on remand, is critical. Courts must evaluate the status of licensee estoppel and *Lear*. *MedImmune* does not require modification of the Federal Circuit’s pre-*MedImmune* narrow interpretation of *Lear* as set forth in *Shell Oil*. And, because the Supreme Court did not reach the *Lear* issue in *MedImmune*, the courts can apply a narrow interpretation of *Lear* on remand.

The *MedImmune* decision also will inevitably impact the drafting of license agreements. The language of the license becomes critical—because, as *MedImmune* demonstrates, even Article III jurisdictional determinations are intensely fact-specific. The Supreme Court in *MedImmune* implied that parties can contract away completely the right to challenge patent validity—“no-challenge clauses.” It is questionable whether such a provision would be enforceable under *Lear* and its progeny.

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However, one can envision numerous ways a licensor could attempt to contract around *MedImmune* while arguably respecting the spirit of *Lear*: allowing for patent challenges, but making such a challenge trigger a steep increase in royalty payments or a large lump sum payment (to cover the licensor’s litigation expenses); allowing the licensor to terminate the license upon the licensee’s challenge to the patents; limited-challenge, wherein licensee may only challenge patent validity when defending a suit for royalties or patent infringement; specifying that licensor keeps the money from royalty payments made during a successful challenge to patent validity; awarding attorney’s fees to the licensor upon an unsuccessful challenge; and choice of forum or venue clauses should the licensee decide to challenge the patents.

Obviously the parties’ relative bargaining power will greatly impact their willingness to include some or all of these provisions in the license agreement. One can also envision drafting such clauses to cover not only validity challenges, but scope of patent challenges (e.g., whether a “next generation” product is covered by a licensed patent). No case, including *Lear*, has directly addressed the validity of such clauses. It seems likely that the Federal Circuit will accept many of them as valid. In *Bard*, the Federal Circuit discussed a provision allowing the licensor to terminate the license if the licensee asserted invalidity, implicitly recognizing the validity of the provision.¹⁴

Other considerations involve the timing and types of payments. It is now increasingly advantageous to enter into front-loaded, fully paid-up patent licenses. Such a license structure makes patent challenges of little value to the licensee unless circumstances have changed (e.g., a new product triggers additional payments), because the full fee for use of the patent in the current product(s) is fully paid, and typically contracted to be nonrefundable.

Finally, it is worth noting that there remains uncertainty as to what law—Federal Circuit or regional circuit law—will be applied in interpreting and enforcing such license terms.¹⁵

Conclusion

The *MedImmune* decision is narrow and reaches only the Article III subject matter jurisdictional issue. Because the Supreme Court chose not to reach the issue of licensee estoppel, on remand *MedImmune*’s claims can be rejected on this basis. As a result, *MedImmune*, along with any other licensee seeking to maintain a license while challenging a patent’s validity, could have a right with no remedy—having won the jurisdictional battle only to be out of court, courtesy of licensee estoppel.



1. *MedImmune, Inc. v. Genentech, Inc.*, 549 US ___, No. 05-608, slip op. at 18 (Jan. 9, 2007).
2. *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F3d 1376, 1380 (Fed. Cir. 2004).
3. While the Supreme Court’s recent *eBay* decision reversed the general rule that permanent injunctions will issue against patent infringers absent exceptional circumstances, it by no means eliminated the risk of a permanent injunction. *eBay Inc. v. MercExchange, L.L.C.*, 547 US ___, 126 S Ct 1837 (2006).
4. *MedImmune, Inc. v. Genentech, Inc.*, 427 F3d 958, 962 (Fed. Cir. 2005).
5. *MedImmune*, No. 05-608, slip op. at 9.
6. *Lear, Inc. v. Adkins*, 395 US 653 (1969).
7. *Blonder-Tongue v. University Foundation*, 402 US 313, 346 (1971).
8. See, e.g., *Geni-Chlor Int’l, Inc. v. Multisonics Dev. Corp.*, 580 F2d 981 (9th Cir. 1978); *Warner-Jenkinson Co. v. Allied Chemical Corp.*, 567 F.2d 184 (2d Cir. 1977); *Milprint, Inc. v. Curwood, Inc.*, 562 F.2d 418 (7th Cir. 1977); *Hanes Corp. v. Millard*, 531 F.2d 585 (D.C. Cir. 1976); *Atlas Chem. Indus., Inc. v. Moraine Prods.*, 509 F.2d 1 (6th Cir. 1974); *Thiokol Chem. Corp. v. Burlington Indus., Inc.*, 448 F.2d 1328 (3d Cir. 1971); *Product Eng’g & Mfg., Inc. v. Barnes*, 424 F.2d 42 (10th Cir. 1970).
9. *Studiengesellschaft Kohle, mbH v. Shell Oil Co.*, 112 F.3d 1561, 1568 (Fed. Cir. 1997).
10. *Gen-Probe*, 359 F.3d at 1381.
11. *MedImmune*, No. 05-608, slip op. at 5, 16.
12. *MedImmune*, No. 05-608, slip op. at 17, emphasis in original.
13. The Federal Circuit previously held that the importance of upholding and enforcing settlement agreements and consent decrees outweighed the policy in *Lear* of promoting patent challenges. See *Foster v. Halco Mfg. Co.*, 947 F.2d 469 (Fed. Cir. 1991); *Hemstreet v. Spiegel, Inc.*, 851 F.2d 348 (Fed. Cir. 1988).
14. “In the event BARD asserts invalidity of any of the said Patents within the scope of this Agreement and refuses to pay royalties on account of such asserted invalidity, then GRANTOR may terminate this Agreement as to the Patent or Patents as to which invalidity is asserted.” C.R. *Bard, Inc. v. Schwartz*, 716 F.2d 874, 881 n. 5 (Fed. Cir. 1983).
15. See *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826 (2002); *Advanced Card Techs. LLC v. Versatile Card Tech., Inc.*, 410 F. Supp. 2d 158, 161 (SDNY 2006).