

Challenging Patents Becomes Easier

A Supreme Court decision in January has made it easier for patent licensees to challenge patents by fundamentally altering the standard for declaratory judgment actions.

Some background on this issue is instructive. In 1969, in *Lear v. Adkins*, 395 U.S. 653 (1969), the Supreme Court overruled the doctrine of patent licensee estoppel, holding that a licensee that repudiated a license could not be estopped from challenging the validity of the patent and could not be made to pay royalties during a validity challenge. The decision was based on “the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain.” It recognized that “[l]icensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor’s discovery” and that, “[i]f they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification.”

The Federal Circuit has applied *Lear* narrowly and with some apparent disdain. In a 1997 case, the Federal Circuit described *Lear* as speaking “[i]n tones that echo from a past era of skepticism over intellectual property principles....” *Studiengesellschaft Kohle, M.B.H., v. Shell Oil Co.*, 112 F.3d 1561, 1567 (Fed. Cir. 1997). Since *Lear*, the Federal Circuit has declined to apply *Lear* in several situations that do not involve licenses, holding that an assignor is estopped from challenging the validity of a patent and that *Lear* does not bar enforcement of a settlement agreement and consent decree recognizing patent validity or a settlement agreement that provided for the payment of royalties even if the patent is later held invalid. See *Diamond Scientific Co. v. Ambico Inc.*, 848 F.2d 1220 (Fed. Cir.), cert. dismissed, 487 U.S. 1265 (1988); *Foster v. Hallco Mfg. Co.*, 947 F.2d 469 (Fed. Cir. 1991); and *Hemstreet v. Spiegel Inc.*, 851 F.2d 384 (Fed. Cir. 1988).

In 2004, the Federal Circuit was presented with the question of whether a licensee in good standing could bring a declaratory judgment

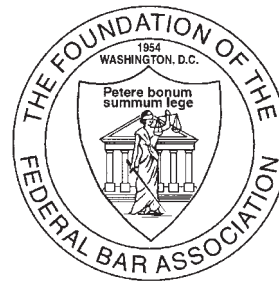
action alleging that the licensed patent was invalid. In *Gen-Probe Inc. v. Vysis Inc.*, 359 F.3d 1376 (2004), cert. dismissed, 543 U.S. 941, the Federal Circuit held that such a licensee could not establish an Article III case or controversy with regard to the validity, enforceability, or scope of the patent because the license agreement “obliterate[s] any reasonable apprehension that the licensee will be sued for infringement.” In essence, the court concluded that a licensee must materially breach the agreement before bringing suit to challenge the validity or scope of the licensed patent.

MedImmune v. Genentech, 127 S. Ct. 764, (2007), presented the same issue to the Supreme Court. Genentech had entered into a license agreement with MedImmune, covering Genentech’s existing patent and continuations of that patent. After a new patent was issued, Genentech sent MedImmune a letter stating that a drug that MedImmune had manufactured was covered by the new patent and that MedImmune owed royalties to Genentech. MedImmune disputed both the validity of the patent and its application to its drug but paid the royalties under protest, while concurrently filing an action for declaratory relief. The district court, relying on the *Gen-Probe* decision, dismissed the action for lack of subject matter jurisdiction, and the Federal Circuit affirmed.

The Supreme Court noted that the case was clearly ripe for a decision but for the plaintiff’s own action in paying the royalties and thereby avoiding imminent injury. The Court began its analysis by noting that, in cases where the government threatens an action, a plaintiff is not required to expose itself to liability before bringing suit to challenge the basis for the threat. While noting that Supreme Court jurisprudence in nongovernmental cases was sparse, Justice Scalia (joined by the rest of the Court, except Justice Thomas) held that Article III does not require a patent licensee to “bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business before seeking a declaration of its actively contested legal rights.” The result is that a licensee is no longer required to terminate or materially breach its license agreement in order to bring suit challenging the validity of the patent or the fact of infringement.

The decision has implications for licensors and licensees. In deciding the now overruled *Gen-Probe* decision, the Federal Circuit had warned that the rule now adopted by the Supreme Court would discour-





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age patentees from granting licenses, because “the licensor would bear all the risk, while licensee would benefit from the license’s effective cap on damages or royalties in the event its challenge to the patent’s scope or validity fails.” *Gen-Probe*, 359 F. 3d at 1382.

When licenses are granted, their contractual terms may be affected by the *MedImmune* ruling. Licensors may seek provisions allowing for termination of the license in the event of a validity challenge. Royalties might also be adjusted, with licensors seeking licenses that have been paid up rather than running royalties and, perhaps, setting different royalty rates in the event of a challenge or an unsuccessful challenge. Whether such clauses would be enforceable in view of *Lear* is specifically left open by the *MedImmune* decision.

The decision also has implications outside of the context of patent licensing. The Federal Circuit’s test for declaratory judgment jurisdiction has required both a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit *and* present activity by the declaratory judgment plaintiff that could constitute infringement. *MedImmune* notes that the “reasonable apprehension of suit” test conflicts with at least three Supreme Court opinions. The ruling summarizes the actual test by citing the 1941 decision in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941): “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 interest, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” **TFL**

William H. Hollander is chair of the Intellectual Property and Technology Licensing Group of Wyatt, Tarrant & Combs LLP, where he counsels clients and focuses on litigation involving trademarks, copyrights, patents, and unfair competition. He is based in the firm’s Louisville office and can be reached at wbollander@wyattfirm.com.

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