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## INTELLECTUAL PROPERTY & *Life Sciences*

### A New License To Sue?

Licensees enjoy greater freedom to challenge patents while keeping their licenses intact

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Over the past several years, the Federal Circuit Court of Appeals has decided several cases involving the right of a licensee to sue for patent invalidity without first having to breach a license agreement. See *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380-81 (Fed. Cir. 2004) (licensee in good standing estopped from suing licensor for patent invalidity), overruled by *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 774 (2007); *MedImmune v. Centocor*, 409 F.3d 1376, 1381-82 (Fed. Cir. 2005); *MedImmune, Inc. v. Genentech, Inc.* 427 F.3d 958, 964 (Fed. Cir. 2005), *rev'd*, 127 S. Ct. 764 (2007). In these cases, the Federal Circuit applied a declaratory judgment (DJ) standard requiring that there be an

explicit threat by the patentee to give the plaintiff a reasonable apprehension of a lawsuit by a patentee before the DJ action could be ripe for adjudication. The U.S. Supreme Court granted cert. on one of these cases, *MedImmune, Inc. v. Genentech, Inc.*, 126 S. Ct. 1329 (2006).

In 1997, Genentech entered into a patent license with MedImmune. The license covered Genentech's issued patent, known as Cabilly I, and one pending with the U.S. Patent and Trademark Office (PTO), known as Cabilly II. The Cabilly II patent issued in 2001. In 2001, Genentech advised MedImmune that Cabilly II had granted, and of Cabilly II's purported application to one of MedImmune's main products — Synagis — a drug used to prevent respiratory tract disease in infants and young children. Rather than terminating its license agreement with Genentech, MedImmune, as a licensee in good standing, initiated a DJ action to invalidate Cabilly II. Genentech opposed with a motion to dismiss for lack of subject matter jurisdiction, which was granted by the district court. At the Federal

Circuit, MedImmune asserted that it must be allowed to bring suit as licensee estoppel had been long since abolished under *Lear, Inc. v. Atkins*, 395 U.S. 653 (1969). The Federal Circuit disagreed: *Lear* simply allowed a former licensee to sue after breaching or terminating a licensing agreement; and in the opinion of the Federal Circuit, a current licensee in good standing has no justiciable case or controversy. The Supreme Court granted certiorari, and reversed the Federal Circuit.

The Declaratory Judgment Act, 28 U.S.C. Section 2201, is rooted in Article II of the U.S. Constitution and requires that an "actual case or controversy" exist before a court can exercise jurisdiction over the matter. Given the ongoing contractual agreement between the parties and the license agreement, the Supreme Court had to determine whether a licensee could establish an "actual case or controversy" where the license that it seeks to challenge is still in force.

In support of its decision to reverse the Federal Circuit, the Supreme Court held that the standard for determining whether a particular DJ action satisfies the "actual case or controversy" requirement 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" relief. *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270,

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273 (1941). The Court held the standard was satisfied in the present case even though MedImmune had not refused to make royalty payments under the license agreement. The Court cited *Altwater v. Freeman*, 319 U.S. 359 (1943), which held that a licensee's failure to stop paying royalties — which were paid under protest and under an injunction decree — did not make the patent dispute non-justiciable. If the licensee failed to pay royalties, it risked actual and treble damages in infringement suits. The case or controversy requirement is met, the *Altwater* Court held, "where payment of a claim is demanded as of right and where payment is made, but where the involuntary or coercive nature of the exaction preserves the right to recover the sums paid or to challenge the legality of the claim."

In a footnote, the *MedImmune* Court noted, "Even if *Altwater* could be distinguished as an 'injunction' case, it would still contradict the Federal Circuit's 'reasonable apprehension of imminent suit' test."

The *MedImmune* holding has substantially muddied the waters for patent holders desirous of licensing their patents to interested parties. Prior to *MedImmune*, so long as the patentee made no explicit threat of filing an infringement suit, *Gen-Probe* gave a degree of assurance that patent license negotiations did not constitute an actual controversy to which DJ jurisdiction attached. *MedImmune* effectively eliminated that assurance by extending the definition of "case or controversy" to include both explicit and implicit threats. Worse, the test for an implicit threat to trigger jurisdiction is subjective and highly one-sided, as evidenced by the post-*MedImmune* decisions of the Federal Circuit.

In the first holding of the Federal Circuit after *MedImmune*, the Court held in favor of DJ jurisdiction *prior* to the signing of a license, even though there had been no threat to sue and the DJ defendant had expressly promised not to

sue for patent infringement. *Sandisk Corp. v. ST Microelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007). *Sandisk* is troubling to say the least — in his concurring opinion, Judge Bryson stated, "the rule adopted by the court in this case will effect a sweeping change in our law regarding declaratory judgment jurisdiction." He went on to point out, "I see no practical stopping point short of allowing declaratory judgment actions in virtually any case in which the recipient of an invitation to take a patent license elects to dispute the need for a license and then to sue the patentee."

In the wake of *MedImmune*, licensees have greater freedom to challenge the validity of patents while keeping their licenses intact. Licensees now enjoy greater bargaining power to renegotiate existing licenses, thus it may be practical to renegotiate existing licenses before a lawsuit is filed. Patent owners, on the other hand, may choose to forgo licensing opportunities in light of the sword of freedom to challenge patent validity now provided to prospective licensees.

There are a number of contractual workarounds that can be considered when drafting license agreements after *MedImmune*. Workarounds can become critical if the same patents are already licensed to other third parties (as is often the case in Life Science technology). The licensor should consider adding a provision to terminate the license in the event that the licensee challenges the validity of any underlying patented technology. Licensors should be mindful, however, of the 1969 case of *Lear, Inc. v. Atkins*, which treats as a nullity any attempt by a patent licensor to withhold from the licensee the ability to contest the validity of licensed patents. Nevertheless, certain provisions may be crafted to ease the impact of the "no-challenge" bar.

First, the licensor should consider requiring front-loaded royalty payments or lump sum payments at the time of license execution to decrease the

licensee's financial incentive to challenge the patented technology. In the life sciences industry, however, this can be difficult to attain, as many growth-stage companies lack the resources to pay such lump sums at the outset. Moreover, many companies will make royalty payments only in the event that certain regulatory milestones are achieved. Second, the licensor should consider requiring good-faith discussions between the parties prior to the ability of the licensee to challenge patent validity. Third, the licensor must conduct negotiations without alleging or implying infringement, lest the licensee invoke the *Sandisk* doctrine and pursue a DJ alternative. Other contractual workarounds include: (1) variable royalty rates that escalate during the pendency of any lawsuit challenging patent validity; (2) mandatory arbitration in the event of a patent validity or non-infringement lawsuit; (3) forum selection clauses in the event of a lawsuit; and (4) mandatory administrative proceedings (such as re-examination, and if the current patent law reform bills pass, cancellation) prior to challenging the patents in federal court. Optional termination clauses in the event of a patent validity challenge can also be considered, however, the enforceability of such provisions may be questionable in light of *Lear*.

*MedImmune* has obscured the heretofore bright-line test for DJ jurisdiction in patent challenges by licensees. The Federal Circuit, by its opinions in the *Sandisk* case, has suggested that the jurisdictional test is now heavily weighted in favor of both current and prospective licensees. Licensors, especially those with multiple licensees for the same patents, must tread lightly to avoid triggering DJ jurisdiction that could place an entire family of important patents in jeopardy. From a business standpoint, this seems to decrease the long-term value of licenses, especially where the relationship between the respective parties is or has been less than harmonious. ■