

The Legal Intelligencer

THE OLDEST LAW JOURNAL IN THE UNITED STATES

ALM

I P L A W

A New License to Challenge — Court Decides *MedImmune*

BY LYNDA L. CALDERONE

Special to the Legal

U p until Jan. 9, the Federal Circuit Court of Appeals' decision in *Gen-Probe Inc. v. Vysis Inc.* was the leading precedent that applied to evaluate subject matter jurisdiction when a licensee paying royalties under a patent license agreement decided to challenge the validity of the licensed patent in court under the U.S. Declaratory Judgment Act, 28 U.S.C. Section 2201(a).

In *Gen-Probe*, the court held that a licensee who is in good standing and paying royalties under a patent license agreement, not otherwise breached, lacked declaratory judgment standing because a justiciable case or controversy did not exist. The underlying principle was that a licensee in good standing was not in a reasonable apprehension of suit, i.e., there is no imminent threat from the patentee.

The Federal Circuit's rationale was based in part on the concern that a patentee, in licensing a would-be infringer, gives up its right to sue in favor of a license and to receive royalties in a business arrangement. The payment of royalties from the licensee who also desires to avoid a lawsuit and wants such rights (in some cases exclusive rights) is the quid pro quo of that compromise. In entering the agreement, the patentee believes that it is avoiding a lawsuit and a controversy, such that there is no underlying dispute that would give rise to an apprehension of suit sufficient to support Declaratory Judgment Act jurisdiction. This would be consistent with the view that the Declaratory Judgment Act should not be

used for mere advisory opinions on the interpretation of a contract.

Gen-Probe, however, was perceived by many to go farther down a path leading away from long-standing public policy principles established in the Supreme Court's 1969 decision in *Lear v. Adkins* and its progeny. *Lear* clarified that estopping a licensee from challenging a patent's validity (licensee estoppel) was inappropriate. The basis for this public policy view is that licensees are not purchasers for value; many licenses are, to some degree, covenants-not-to-sue; and licensees tend to be the parties in the best position to challenge invalid patents in the public interest. However, it is to be noted that in *Lear*, the challenge to validity arose during a bona fide dispute, the license agreement had been repudiated, and the licensee had stopped paying royalties.

On Jan. 9, the U.S. Supreme Court overturned the standard set forth in *Gen-Probe*, shifting the declaratory judgment boundary line in a direction that favors licensee challenges, making it more consistent with the public policy underlying the *Lear* decision. In *MedImmune Inc. v. Genentech Inc., et al.*, the court held that a licensee in good standing need not breach or terminate its license agreement before it can seek a declaratory judgment that the licensed patent is invalid, unenforceable or infringed. Thus, the court approved Article III, Declaratory Judgment Act jurisdiction for the licensee in that case, giving it standing to challenge the validity of the licensed patent.

The *MedImmune* decision, long-watched and awaited by the patent bar as well as many in licensing institutions, both at the university and industry levels, expands the



LYNDA L. CALDERONE, shareholder and chairwoman of the intellectual property group at Flaster Greenberg, concentrates her practice in the preparation and prosecution of U.S. patent applications, re-examination, interference and appellate practice, foreign patent prosecution and opposition proceedings as well as intellectual property litigation

ability to challenge patent validity and will impact licensing and litigation strategy for accused infringers and patentees alike.

In 1997, MedImmune licensed from Genentech a first-issued patent on production of chimeric antibodies as well as a second, related continuation patent application filing that related to co-expression of immunoglobulin chains in certain cells. The application was ultimately involved in an interference proceeding — a U.S. Patent and Trademark Office (PTO) proceeding for resolving inventorship disputes — with another patent owned by Celltech R&D Inc. The Celltech patent was also licensed by MedImmune. The interference was resolved after seven and a half years at the PTO in favor of Celltech, but Genentech then sued on the issue in district court.

After the district court found disputed facts warranting trial, Celltech and Genentech settled. The settlement included a determination that Genentech was entitled to priority on its patent and resulted in a cross licensing arrangement between the companies encompassing royalty sharing. After further proceedings at the PTO based

on the district court resolution, and 11 years after the interference was declared at the PTO, the second patent was issued in the name of Genentech. After the second patent issued, Genentech wrote to MedImmune to notify the company that one of its significant products, Synagis, was covered by the new patent and royalties were due.

While MedImmune objected to Genentech's view that Synagis was within the license scope, it paid the royalties due under the license. *MedImmune*, the licensee, then sought a declaratory judgment in district court that the patent was invalid. The district court granted a motion to dismiss on the pleadings for lack of subject matter jurisdiction, which dismissal was appealed by MedImmune to the Federal Circuit. The Federal Circuit affirmed the lower court's decision, which was based on the circuit's earlier *Gen-Probe* decision. MedImmune then appealed the Federal Circuit ruling to the Supreme Court.

The current Supreme Court has been very active in the last few years in the patent law area, in stark contrast to prior years when such cases were very few and far between. The *MedImmune* decision also occurs at a time when Congress, industry leaders, small companies and the PTO are all pushing in one direction or another for "patent reform" with varied goals, interests and targets in mind.

Some are seeking, on the side of patentees and owners of large patent portfolios, to strengthen U.S. patents and to uphold their presumed validity, while others are pushing to weaken the presumption of validity of U.S. patents, in attempts to thwart what are commonly, and not-so-fondly, referred to as "patent trolls" (otherwise known as patent owners who enforce their constitutional right to exclude against manufacturing and selling entities, but who are not themselves manufacturers).

To some extent, these real-world views and concerns appear to some observers to be impacting this new activism of the Supreme Court in the patent area.

The Supreme Court based its decision to grant jurisdiction in *MedImmune* on a 1943 Supreme Court case, *Altvator v. Freeman*, in which a patent licensee that did not stop pay-

ment of royalties was entitled to Declaratory Judgment Act jurisdiction. While some, including the Federal Circuit, have viewed *Altvator* as distinguishable from the facts at issue in *MedImmune* due to the imposition of an injunction mandating payment of royalties in *Altvator*, the Supreme Court did not rely on this distinction. Instead, the Supreme Court said that the same concerns that gave rise to jurisdiction in *Altvator* also apply in *MedImmune*. That is, that payments demanded as of right and paid by the licensee, but whose exaction had an "involuntary or coercive nature," preserve the right to recover the sums or to challenge legality.

In *MedImmune*, the court commented that in *Altvator* the opinion was based on the fact that the consequence of defying the payments due under the injunction would be that the challenger would "risk 'actual [and] treble damages in infringement suits' by the patentees." Further, the court noted that *Altvator* acknowledged that actual or threatened serious business injury could constitute coercion that supports the need for declaratory judgment jurisdiction.

Important to the outcome in *MedImmune* was that the case was appealed at the pleading level and the Supreme Court took as uncontradicted fact that there was a threat by the licensors "to enjoin sales if royalties are not forthcoming" and that "but for [MedImmune's] ... continuing to make royalty payments, nothing about the dispute would render it unfit for judicial resolution."

So the court was able to analogize the situation to that of *Altvator* in that, but for the royalty payments, MedImmune would face an injunction or patent infringement damages on a major product making the license payments appear "coercive" and paid to avoid business injury. If other license situations arise having different facts in which a licensee is not faced with an infringement suit or injunction if royalties are not paid, it will be interesting to see if a district court follows or distinguishes *MedImmune*.

For example, if facts establish that a patent license agreement resulted from a friendly business partnership and that the licensor was not in a position to sue, or had made statements that it would not bring a patent lawsuit in the face of a license dispute, it is

unclear that the same rationale would apply.

There is some suggestion in the court hearings and in the court's recent opinion that the wording of the license in *MedImmune* had bearing on the outcome as well. Royalties were due under the agreement on patents that covered the product and which had not been held invalid in court. The wording did not preclude MedImmune from challenging validity. There are, of course, issues as to the enforceability of including a clause prohibiting a validity challenge, due to *Lear*'s prohibition of licensee estoppel, but whether the language of a license agreement can be crafted to alter subject matter jurisdiction analysis under the Declaratory Judgment Act also remains an issue.

Finally, in deciding whether a licensee that is in compliance with the license, but challenges a patent is still responsible for royalty payments while the challenge is pending, the court made it clear that it was not passing on that issue. While the court acknowledged that *Lear* rejected that a licensee who repudiated a contract had to continue to pay royalties while the challenge was pending, the court explicitly stated that it expresses "no opinion on whether a nonrepudiating licensee is similarly relieved of its contract obligation during a successful challenge to a patent's validity."

Patent practitioners and licensing attorneys alike will want to carefully weigh the implications of this decision. It provides, to some extent, a new bargaining chip and potential litigation strategy for a licensee or potential infringer, who can take a license while continuing to try to challenge a patent under the right factual circumstances. It also provides issues for patentee/licensors in terms of how to craft license agreements with respect to such validity challenges, how to best word license scope and coverage, and how to find a strategy that is sufficient to safeguard powerful patents from unwarranted validity challenges while attempting to avoid undesirable litigation.

Expect more to come on the scope and impact of this case as licensees begin to contemplate challenging patents through litigation in the future and district courts prepare to interpret *MedImmune* in declaratory judgment jurisdictional challenges. •