

IP Licensing and the Supreme Court's *Medimmune v. Genentech* Decision

PRESENTED TO THE WISCONSIN INTELLECTUAL PROPERTY LAW ASSOCIATION

MARCH 22, 2007

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MEDIMMUNE INC. v. GENENTECH, Inc., 127 S. Ct. 764 (2007), *reversing*, 427 F. 3d 958 (Fed. Cir. 2005)

I. Issue Presented: In *Medimmune*, the Supreme Court was asked to decide whether a patent licensee, in order to have standing to challenge a patent in a declaratory judgment action must terminate the license or refuse to pay royalties and materially breach the license agreement before suing to declare a patent invalid, unenforceable or not infringed.

II. Patent At Issue and Decision Below: Medimmune is a licensee of Genentech on two cell cultures patents used to make human antibodies. After Genentech asserted that an additional product that Medimmune was making was covered by the patent license and demanded royalties, Medimmune filed a declaratory judgment of invalidity or unenforceability based on prior art that anticipated the patent. The U.S. District Court for the Central District of California dismissed the action as nonjusticiable, because Medimmune was making timely royalty payments and was not otherwise in breach of the licensing agreement, therefore, the Court held that Medimmune did not have a reasonable apprehension it would be sued for infringement and consequently had no standing under Section 2201 (a) of the Declaratory Judgment Act of 1934, 28 U.S.C. § 2201. Medimmune had argued that under *Lear Inc. v. Adkins*, 395 U.S. 653, 89 S. Ct. 1902 (1969) it had the absolute right to challenge the validity or enforceability of a patent license regardless of whether or not it breached the license.

On appeal, the Federal Circuit yet again limited *Lear* and ruled that a licensee that continues to pay royalties does not have standing to bring a declaratory judgment action. The Federal Circuit followed *GenProbe v. Vysis Inc.*, 359 F. 3d 1376 (Fed. Cir 2004). There the Federal Circuit reasoned that allowing a licensee to sue a licensor when there was no breach

would effectively defeat those contractual covenants and discourage patentees from granting licenses. In other words, within this situation, the licensor would bear all the risk, while the licensee would benefit from the license's effective cap on damages or royalties in the event its challenge of the patent's scope or validity fails.

Id. at 1382.

III. Supreme Court Holding:

In an 8 to 1 decision written by Justice Scalia, (Justice Clarence Thomas dissented), the Court held that a patent licensee need not terminate or breach its license agreement before it can seek a declaratory judgment that the licensed patent is invalid, unenforceable or not infringed.

IV. Supreme Court Argument:

Medimmune had argued to the Justices, that it should not have to breach its license and expose itself to significant damages for patent infringement, and the possibility of an injunction on sales, to be able to challenge an invalid patent. Indeed, Medimmune has continued during the

pendency of the litigation to pay the royalties due under the license “under protest.” Medimmune argued at the Supreme Court, that disallowing licensees to challenge a patent’s validity without first materially breaching the license will encourage licensors to bundle unrelated bad patents with good ones, thereby betting that licensees will not risk losing the coverage of the valid patents in order to challenge the bad ones. Once again, the issue of invalid patent claims inhibiting innovation was raised to the Court. According to Medimmune, especially when medical products are involved, the public interest should encourage patent challenges. A point that was emphasized nearly forty years ago in the *Lear* case:

Surely the equities of the licensor do not weigh very heavily when they are balanced against 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. Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor’s discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification.

Lear, 395 U.S. at 670.

Genentech emphasized preservation and enforcement of the bargain that the patent licensee had agreed to. It argued that Medimmune was essentially trying to renege on a deal it made to an agreement that was the result of compromising a claim.

The Bush Administration citing the public interest in “ridding the economy” of invalid patents supported Medimmune’s position as did the Generic Pharmaceutical Association. Genentech’s position was supported by the Pharmaceutical Research and Manufacturers of America and a number of companies including General Electric, Procter & Gamble and DuPont.

NOTE: The patents at issue are undergoing reexamination at the PTO. On February 16, 2007 the Examiner issued a Final Rejection of the patent claims based on anticipation and obviousness. Genentech has stated it will exhaust all available PTO and court appeals.

V. Supreme Court Analysis:

In overturning the Federal Circuit the Supreme Court determined that Medimmune had raised a contract claim and a patent invalidity challenge. The contract claim was that Medimmune had no obligation under the license to pay royalties on an invalid patent. According to the Court, whether the Declaratory Judgment act, 28 U.S.C. §§ 2201(a) required a patent license to terminate or breach the license before seeking a declaratory judgment on patent invalidity, unenforceability or non-infringement, was a question of whether a party’s “self-avoidance of imminent injury” deprived the courts of jurisdiction under Article III and the Declaratory Judgment Act because there is no actual controversy. The Supreme Court pointed to the 1943 the case of *Altwater v. Freeman*, 319 U.S. 359 (1943), which held that the fact a licensee is paying royalties effectively under protest does not render a dispute “hypothetical or abstract”.

Specifically in quintessential Scalia language the Court held:

The rule that a plaintiff must destroy a large building, 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 finds no support in Article III.

The Court faced the issue of whether having settled a patent dispute by way of a license agreement the licensee should be permitted to immunize itself from an infringement suit while at the same time, allowing the licensee to challenge the validity of the patent. Genentech argued that Medimmune was permitted to alter the contract by eliminating its *quid pro quo* for the license: the licensee is immunized from suit as long as it pays royalties and does not challenge the license. The Court, citing the absence in the license at issue of a contractual provision prohibiting challenge to the validity of the patents, held that “promising to pay royalties on patents that have not been held invalid does not amount to a promise *not to seek* a holding of their invalidity.” 127 S. Ct. at 776. While licensors are likely to begin including specific language restricting the ability of the licensee to challenge the patent while the license is in effect and the license has not materially breached, the enforceability of such provisions are an open question.

VI. Potential Significance of the Case:

- Increase in patent litigation as licensees begin challenging patents whose validity they question.
- Inclusion of covenants not to sue and other contractual provisions to prevent the licensee from bringing suit while having the license continue in force (Query: is this permissible under *Lear v. Adkins*?)
- Licensors might be less interested in granting licenses because a license will no longer be a definitive means of stopping licensees from challenging a patent.
- License royalties may increase to account for the fact that litigation challenges will likely increase and those costs will have to be covered by the income generated by the licensing program.
- Inclusion of attorney fees provisions to cover the cost of litigation brought by the licensee that does not result in a declaration of invalidity or non-infringement