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MedImmune v. Genentech: A Dilemma Removed for Patent Licensees

The law of patent licensing has been plagued for years by uncertainty regarding what can happen when the licensee, after entering into a royalty-bearing license agreement, wants to challenge the validity of the licensed patents and thus contest its obligation to pay royalties to the licensor. A recent Supreme Court decision issued on January 9, 2007, *MedImmune v. Genentech,* clarifies one area of uncertainty, but several others remain. As a result of this decision, both licensors and licensees should reassess their options and their strategies, both before and after entering into license agreements.

Background

Patent litigation is a high-stakes game. The ever-increasing flood of patent applications, coupled with a shortage of patent examiners at the budget-strapped Patent and Trademark Office who can review these applications, has resulted in the issuance of many patents of questionable validity, according to many critics. Yet many companies, fearing the possibility of injunctive relief, and often treble damages, along with the prospect of incurring millions of dollars in legal fees to litigate a case to its conclusion, choose to enter into royalty-bearing license agreements with patent holders rather than take their chances challenging the validity of the patents in court. In the wake of highly publicized cases (and settlements) such as last year's suit against the manufacturer of the Blackberry wireless device (which was ultimately settled for $612.5 million amid widespread warnings of a potential Blackberry service shutdown), calls for reform of the patent laws have reached a crescendo over the last year or two. These calls have not fallen on deaf ears at the U.S. Supreme Court.

In *MedImmune v. Genentech,* the Supreme Court gave patent licensees an option they previously did not have, and in so doing altered the delicate balance of power that underlies many patent licensing negotiations. Thanks to a landmark ruling by the Supreme Court in the 1969 *Lear v. Adkins case,*[1] patent licensees are not prevented (by a legal doctrine called estoppel) from challenging the validity of the patents they have licensed. Under a 2004 Federal Circuit decision,[2] however, a patent licensee faced a dilemma when deciding whether to mount such a challenge: in order to do so, the licensee would probably have to stop paying royalties to the licensor, which would place the licensee in breach of the license agreement and at risk of losing the license. This in turn would expose the licensee to injunctive relief and perhaps treble damages for willful infringement if the patents were found valid, a problem that would be compounded if the license covered not only the questionable patent, but also other patents that were not seriously contested by the licensee. After *MedImmune,* this dilemma no longer exists. In *MedImmune,* the Supreme Court held that it was not necessary for a patent licensee to break or terminate its license agreement (by not paying the royalties due under it) in order to challenge the validity of a patent it had licensed.

The *MedImmune* case

In 1997, MedImmune entered into a patent license agreement with Genentech, pursuant to which MedImmune agreed to pay royalties on sales of products covered by certain Genentech patents. In 2001, one of the patent applications covered by the license agreement matured into a patent. Genentech believed that one of MedImmune's new products, Synagis, was covered by the patent and sent a letter to MedImmune requesting royalties for the Synagis product. MedImmune considered the letter to be a threat by Genentech to terminate the license agreement and sue for infringement if MedImmune did not make the royalty payments. MedImmune believed that the patent was invalid and unenforceable and also that it was not infringed by

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the Synagis product. However, the Synagis product accounted for more than 80% of MedImmune's revenue. So rather than risk an injunction and perhaps treble damages if it did not pay the royalties, MedImmune paid the royalties "under protest" and filed an action for declaratory relief.

The Federal Circuit had ruled that there was no "case or controversy" within the meaning of Article III of the Constitution. In an 8-1 decision, the Supreme Court reversed this ruling. Writing for the majority, Justice Scalia relied on a 1943 case, *Altvater v. Freeman,*[3] in which the Court found that a "case or controversy" existed when a patent licensee, under the compulsion of an injunction, paid royalties to the licensor and challenged the validity of the licensed patent. Although MedImmune was not under an injunction, it would have faced the same risks (had it chosen not to pay the royalties)—injunctive relief and treble damages—that the Court in *Altvater* found to be a sufficient "threat" to create a case or controversy.

The Court distinguished an earlier case, *Willing v. Chicago Auditorium Association,*[4] in which a ground lessee wanted to demolish an antiquated auditorium and replace it with a modern commercial building. As Justice Scalia noted, "The lessee believed it had the right to do this without the lessors' consent, but was unwilling to drop the wrecking ball first and test its belief later. … One of the co-lessors had disagreed with the lessee's interpretation of the lease, but that happened in an 'informal, friendly, private conversation,' id. at 286, a year before the lawsuit was filed; and the lessee never even bothered to approach the other co-lessors." In light of this, the majority opinion concluded: "Had *Willing* been decided after the enactment (and our upholding) of the Declaratory Judgment Act, and had the legal disagreement between the parties been as lively as this one, we are confident a different result would have obtained. 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."

Genentech argued that when a licensee enters into a patent license agreement, it essentially purchases an insurance policy, immunizing it from infringement suits as long as it continues to pay royalties. Permitting the licensee to challenge the validity of the patent without terminating or breaking the agreement alters the deal, allowing the licensee to continue enjoying its immunity while bringing a suit, the elimination of which was part of the bargained-for quid pro quo. The majority opinion rejected this argument, reasoning that the license agreement did not prohibit MedImmune from challenging the validity of the licensed patents and therefore Genentech was not deprived of the benefit of its bargain. Furthermore, even if Genentech were correct that the license agreement precluded MedImmune's suit, the Court continued, Genentech would win on the merits, not on "case or controversy" grounds. The majority opinion did not address the widely held view that even if the license agreement had included a clause expressly prohibiting MedImmune from challenging the validity of the patents, such a clause would have been unenforceable (and thus there is no way Genentech could have won on the merits). This belief stems from the very strong public policy rationale in *Lear,* which reasoned that the public interest in having inventions enter the public domain rather than be protected by invalid patents outweighs the patent licensor's interest in preserving the benefit of its bargain.

The *MedImmune* decision can be read as an extension of *Lear.* In *Lear,* the licensee stopped paying royalties and repudiated the license agreement (which clearly created a case or controversy), and the Court held that it was not estopped (by virtue of its status as a licensee) from challenging the validity of the patent. In *MedImmune,* the Court established that a licensee can continue paying royalties "under protest" and still challenge the validity of the patents, as long as there is a sufficient threat of litigation by the licensor.

What is clear after *MedImmune*

MedImmune clarifies, to some extent, one previously unsettled area of patent licensing. Several others remain, however. To recap what is clear:

- A licensee can refuse to pay royalties and challenge the validity of the licensed patent *(Lear).*
- A licensee can continue to pay royalties "under protest" and challenge the validity of the licensed patent, if there is a sufficient threat of litigation by the licensor if the licensee does not pay royalties *(MedImmune).*
- As a logical consequence of *Lear* and *MedImmune,* a licensee can pay royalties "under protest" into an escrow account and challenge the validity of the licensed patent, if by doing so the licensee has breached or repudiated the agreement or if there is, in any event, a sufficient threat of litigation by the licensor.

What remains unsettled after *MedImmune*

Remaining areas of uncertainty include the following:

- What constitutes a sufficient threat of litigation by the licensor, to enable the licensee to challenge the validity of the licensed patent while still paying royalties to the licensor? In *MedImmune,* the letter Genentech sent to MedImmune requesting or demanding that royalties be paid for the Synagis product was considered a sufficient threat; apparently Genentech did not deny, in the course of litigation, that it would seek to enjoin further sales of Synagis if MedImmune did not pay the royalties. But keep in

mind the *Willing* case, where an oral (and reportedly "friendly") conversation with one of two co-lessors, which took place a year before the litigation began, was not considered a sufficient threat.[5]

- In what circumstances, if any, are contractual bars to challenging validity enforceable? Such bars could take different forms (covenants not to challenge the validity of the licensed patent, stipulations of validity, releases of claims of invalidity) and arise in different contexts. For example, there is a split in the Federal Circuit Court of Appeals regarding whether a consent decree or judgment prohibiting validity challenges is enforceable, though the prevailing view is that they are.[6] Even less clear is whether a prohibition on validity challenges in a settlement agreement is enforceable.[7]
- If contractual bars to challenging validity are not enforceable, are contractual impediments enforceable? There are many examples: a clause entitling the licensor to terminate the license agreement if the licensee challenges the validity of the patent; a clause increasing the royalty rate if the licensee challenges validity and loses; a clause requiring the licensee to pay the licensor's attorneys' fees (but not vice versa) if the licensee challenges validity and loses; a clause requiring the licensee to assert any validity challenges in a venue that is inconvenient for the licensee and convenient for the licensor; and so on. No cases have addressed these issues to date.[8]
- Can the licensee recover the royalties it has paid, if it continues paying royalties under protest after commencing a validity challenge and the patents are eventually found to be invalid? The *MedImmune* Court declined to rule on this issue.[9]
- Once patent is declared invalid, does the licensee still have to pay royalties that accrued (on sales of licensed products, for example) before the ruling of invalidity? What if the royalties had not only accrued, but were also due (that is, licensee was in breach of the license agreement, for not having paid the royalties in a timely manner) before the invalidity ruling? What if the invalidity ruling is being appealed?

After *MedImmune,* patent licensees may be inclined to reevaluate the patents on which they are paying royalties, and decide to challenge the validity of those patents while paying the royalties under protest. The licensee must remember, however, that there must be a sufficient threat of litigation by the licensor to create a case or controversy if the licensee continues paying royalties. If there has been no communication with the licensor regarding whether royalties are due for certain patents or certain products and the licensee wants to continue paying royalties under protest while challenging validity, it should consider ways of eliciting from the licensor a clear statement, preferably in writing, of the negative consequences that will befall the licensee if it ceases to pay royalties.

In addition, if there is strong evidence of invalidity, the licensee should carefully weigh the pros and cons of continuing to pay royalties while challenging validity. Before taking any legal action, the licensee would be well advised to obtain a formal legal opinion regarding the validity of the patents in question. A formal legal opinion that the patents are invalid may insulate the licensee from the treble damages associated with willful infringement if the licensee halts royalty payments. And after the Supreme Court's decision in *eBay v. MercExchange*[10] last year, the licensor's prospects of obtaining an injunction barring further sales of the licensee's products are less certain. Thus the licensee may conclude, if it believes it has a very strong invalidity case, that its best option is to stop paying royalties when it launches its invalidity challenge, lest it be unable to recover those royalties (if it continues paying them) later even if it wins.

To prevent licensees from challenging the validity of the licensed patents while continuing to pay royalties, licensors should be careful to refrain from taking actions or making statements that could be construed as a threat of litigation. Once the licensee stops paying royalties, of course, the licensor will have no choice but to initiate litigation if it wants to force the licensee to pay. If the licensee stops paying royalties, the licensor in most cases will have grounds to terminate the license. If the licensor sends a termination notice to the licensee, and the licensee then cures the breach by paying the royalties under protest and files a lawsuit challenging the validity of the patents, the licensor's termination notice may be enough of a threat to create a "case or controversy". Thus *MedImmune* could lead to a delicate game of cat and mouse, as licensees attempt to bait licensors into threatening litigation and licensors attempt to avoid taking the bait.

In addition, as patent licensors struggle to regain some of the power that has shifted to licensees as a result of *MedImmune,* they may be more inclined to negotiate for clauses that create impediments to challenging validity, or even different forms of bars to challenging validity. This in turn may lead to cases that answer some of the unsettled questions identified above. Licensors may attempt to modify the termination provisions of their license agreements so that licensees cannot cure a failure to pay royalties when due (which would deprive licensees of the opportunity to instigate a dispute by not paying royalties when due, but still pay royalties under protest after having cured the nonpayment breach and while challenging the validity of the patents). Moreover, patent holders may be more inclined to file infringement suits before granting licenses, in the hope that this will bolster the enforceability of any

contractual bars or impediments in licenses granted as part of consent decrees or settlements.

One thing is certain: the chess game between patent licensors and patent licensees—both during the negotiation of patent license agreements and after such agreements are entered into—will continue, and the stakes will remain as high as ever.

If you have any questions or would like to discuss any issues concerning patent licenses, please feel to contact one of the attorneys listed above.

Notes

[1] 395 U.S. 653 (1969).

[2] *Gen-Probe Inc. v. Vysis, Inc.,* 359 F.3d 1376 (2004).

[3] 319 U.S. 359 (1943).

[4] 277 U.S. 274 (1928).

[5] *Willing* was decided before the Declaratory Judgments Act was enacted, which was another basis the majority opinion used for distinguishing the facts of *MedImmune* from the facts of *Willing.*

[6] *Compare Interdynamics, Inc. v. Firma Wolf,* 653 F.2d 93 (3rd Cir. 1981) (stating that when a consent decree admits the validity of a patent, the validity and scope of the patent may not be reopened in a subsequent proceeding) and *Schlegal Mfg. Co. v. USM Corp.,* 525 F.2d 775 (6th Cir. 1975) (holding that where a consent decree states that the patent was valid, the doctrine of *res judicata* bars reviving and re-litigating patent validity) with *Kraly v. Nat'l Distillers and Chem. Corp.,* 502 F.2d 1366, 1369 (7th Cir. 1974) (holding that a license "is not estopped from challenging the validity of the patent, even though a prior consent decree incorporated an understanding not to challenge the validity of the patent").

[7] *Compare Massillon-Cleveland-Akron Sign Co. v. Golden State Adver. Co.,* 444 F.2d 425 (9th Cir. 1971) (holding that a covenant not to contest the validity of a patent in a settlement agreement is void on its face and unenforceable in light of Lear, reasoning that it is unimportant that the covenant was part of a settlement agreement rather than a license agreement) with *Flex-Foot, Inc. v. CRP, Inc.,* 238 F.3d 1362 (Fed. Cir. 2001) (explaining that once an accused infringer has challenged a patent's validity, has had an opportunity to conduct discovery on validity issues, and has elected to voluntarily dismiss the litigation with prejudice under a settlement agreement containing a waiver of future patent validity challenges, the accused infringer is estopped from raising any such challenges in any subsequent proceeding) and *Warrior Lacrosse, Inc. v. Brine, Inc.,* No. 04-71649, 2006 WL 763190 (E.D. Mich. March 8, 2006) (finding that where the accused infringer had chosen to settle its litigation through a settlement agreement, which included an agreement not to challenge the patent, the accused party must abide by the settlement agreement and therefore is precluded from contesting the validity and enforceability of the patent).

[8] In *Bayer AG v. Housey Pharms., Inc.,* 228 F. Supp.2d 467 (D. Del. 2002), the court held that a provision in a license agreement giving the licensor the right to require the licensee to continue making royalty payments if the licensee chooses to challenge the validity of the licensed patent is unenforceable under Lear, but the court did not address the enforceability of a provision giving the licensor the right to terminate the license if the licensee challenges the licensed patent's validity.

[9] It is well established that royalties paid *before* the licensee first challenges the validity of the patents cannot be recovered. See *Troxel Mfg. Co. v. Schwinn Bicycle Co.,* 489 F.2d 968 (6th Cir. 1973) (stating that the licensee is not entitled to a refund of any royalties paid prior to the eviction of the patent because during this time, the licensee had enjoyed benefits from the license, such as freedom from infringement suits). Because, before *MedImmune*, the licensee had to stop paying royalties before commencing a validity challenge, no cases have addressed whether licensees can recover royalties paid after commencing a validity challenge.

[10] 126 S.Ct. 1837 (2006).