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MedImmune Decision Permits Patent Licensee In Good Standing To Challenge Patent

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On January 9, 2007, the Supreme Court issued its opinion in *MedImmune, Inc. v. Genentech, Inc.*, No. 05-608 (U.S. Jan. 9, 2007) ("Slip. Op."), holding that the Article III requirement of a "case or controversy" does not require a patent licensee to terminate or breach its license before seeking a declaratory judgment that the underlying patent is invalid, unenforceable or not infringed. Slip. Op. at 18. The Federal Circuit had previously held that a licensee in good standing feels no apprehension of suit, and therefore no "actual controversy" for purposes of Article III and declaratory action jurisdiction exists between the licensee and the patent holder. In an 8-1 decision authored by Justice Scalia, from which Justice Thomas dissented, the Court rejected the Federal Circuit's position, holding that an action brought by the licensee was justiciable because there were real and adverse legal interests even though MedImmune continued to comply with the agreement.

The Court's decision leaves open a number of previously unsettled issues. An example is the question of whether common law principles or an express license provision can preclude a challenge to the validity or enforceability of a licensed patent. Similarly, the Court's language regarding the Federal Circuit's "reasonable apprehension of suit" standard for determining declaratory judgment jurisdiction raises uncertainty about its application when no license has been issued. What is clear, however, is that in rejecting the Federal Circuit's position on the "case or controversy" issue the Supreme Court decision tips the balance of power between licensees and patent holders in favor of licensees.

PREVIOUS LAW

In *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), the Supreme Court abolished the doctrine of licensee estoppel, holding that licensees cannot be barred from repudiating the license and challenging a patent. The Court saw a public interest in challenges to invalid patents and thought licensees "may often be the only individuals with enough economic incentive to challenge the patentability of

an inventor's discovery." *Id.* at 670. *Lear* did not address whether the policy rationale for rejecting licensee estoppel would also allow a licensee that was continuing to enjoy the benefits of its license to challenge a patent, leaving it to the lower courts to determine whether a breach was required to permit a licensee to challenge a patent. *MedImmune* leaves that issue unresolved as well.

While early Federal Circuit caselaw interpreted *Lear* to permit a licensee to "bring a federal declaratory judgment action to declare the patent subject to the license invalid without prior termination of the license," *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 882 (Fed. Cir. 1983), later Federal Circuit cases took a stricter view. In *Studiengsellschaft Kohle, M.B.H. v. Shell Oil Co.*, 112 F.3d 1561, 1566, 1567-68 (Fed. Cir. 1997), a case noted by the Supreme Court in its *MedImmune* decision, the Federal Circuit held that "a licensee … cannot invoke the protection of the *Lear* doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid." The rule was based on both the terms of the contract at issue and what the court saw as "the injustice of allowing Shell to exploit the protection of the contract and patent rights and then later to abandon conveniently its obligations under those same rights." *Id.* at 1568.

In 2004, the Federal Circuit added an Article III basis for its *Studiengesellschaft* rule, holding in *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1382 (Fed. Cir.), *cert. dismissed*, 543 U.S. 941 (2004), that where a licensee was in compliance with its patent license, there was no "actual case or controversy" under the Declaratory Judgment Act or Article III. *Id.* at 1382. The court distinguished the facts of *C.R. Bard*, where the licensee had stopped paying royalties. *Id.* at 1380. *Gen-Probe* required that "a licensee must, at a minimum, stop paying royalties (and thereby materially breach the [patent license] agreement) before bringing suit to challenge the validity or scope of the licensed patent." *Id.* at 1381. The court reasoned that a "license, unless materially breached, obliterated any reasonable apprehension of a lawsuit …" *Id.* at 1381.

THE *MEDIMMUNE* CASE

In 1997 MedImmune licensed, from Genentech, a patent relating to the use of cell cultures in the manufacture of human antibodies and a related patent application. Slip Op. at 1-2. In 2001, the U.S. Patent and Trademark Office issued Genentech a patent from the pending application, the Cabilly II patent. *Id.* at 2. Genentech promptly informed MedImmune that the Cabilly II patent covered MedImmune's primary product, Synagis®, and MedImmune started paying license royalties to Genentech. *Id.* at 3. Without stopping those royalty payments, MedImmune brought a declaratory judgment action against Genentech, seeking a declaration that the Cabilly II patent was invalid or unenforceable and was not infringed. *Id.*

Relying on *Gen-Probe*, the district court dismissed MedImmune's suit, finding no case or controversy under the Declaratory Judgment Act because MedImmune was licensed and had no reasonable apprehension of being sued by Genentech. *MedImmune, Inc. v. Genentech, Inc.*, No. CV 03-2567 MPP (CTX), 2004 WL 3770589, at *5-6 (C.D. Cal. Apr. 26, 2004). The Federal Circuit affirmed, finding that absent a reasonable apprehension of suit, MedImmune did not have standing to challenge the Cabilly II patent. *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 965 (Fed. Cir. 2005).

The Supreme Court agreed to hear the case, but limited the question presented to whether there was a case or controversy for purposes of Article III (in other words, on the *Gen-Probe* jurisdictional rationale, but not the *Studiengesellschaft* "injustice" rationale for the Federal Circuit's decision).

THE *MEDIMMUNE* SUPREME COURT DECISION

The *MedImmune* holding is that there is a case or controversy under Article III and the Declaratory Judgment Act, even though by continuing to pay royalties, MedImmune "eliminate[d] the imminent threat of harm" in the case. Slip. Op. at 9. The Court held that an actual controversy existed for purposes of jurisdiction where there was a coercive threat from a private citizen, such as a patent holder, that resulted in "threat-eliminating behavior." *Id.* at 10. Relief from this coercion was the "very purpose of the Declaratory Judgment Act." *Id.* (citation omitted). It also found that it was not appropriate to "require a plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat." *Id.* at 9. While the Court acknowledged that there were fewer cases involving a private plaintiff than those involving situations where the government threatened the party seeking declaratory judgment, it noted that the Court's decision in *Altvater v. Freeman*, 319 U.S. 359, 365 (1943), was on point. Slip Op. at 11-12. In *Altvater* the Court held that a licensee paying royalties under protest did not defeat jurisdiction under the Declaratory Judgment Act. *Id.*

While the Court declined to set forth a hard-and-fast rule for determining whether a particular case meets the justiciability requirements, it was critical of the Federal Circuit's application of the "reasonable-apprehension-of-suit test" for Declaratory Judgment Act jurisdiction as "contradict[ing]," in "conflict[]" with and "in tension with" Supreme Court precedent. *Id.* at 13-14 n.11. The Court noted that justiciability can be described in terms of "standing" or "ripeness." Under the standing analysis the conflict is justiciable if the accused infringer is threatened with imminent injury in fact that can be traceable to the challenged action of the patentee. Under the ripeness analysis, the issue turns on "whether there is sufficient 'hardship to the parties in withholding court consideration' until there is [an] enforcement action." *Id.* at 9, n.8 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)).

Justice Thomas' dissent argued that the majority's rationale rendered all "contractual obligations [] sufficiently coercive to allow a party to bring a declaratory judgment action." Slip. Op. (Thomas, J., dissenting at 10). The Court's opinion replied that "the relevant coercion is not compliance with the claimed contractual obligation, but rather the consequences of failure to do so." *Id.* at 11 n.9. The Court found that "the threat of treble damages and the loss of 80 percent of petitioner's business" falls within "*Altvater's* coercion rationale." *Id.* at 12-13 n.10.

The Court's decision was limited to the Article III and Declaratory Judgment Act "case or controversy" issue. While the Court noted and quoted from the Federal Circuit's *Studiengesellschaft* decision, the Court "express[ed] no opinion" on whether under *Lear* a suit claiming patent invalidity can be barred by the terms of the license itself, or by the common-law doctrine that "a party to a contract cannot at one and the same time challenge its validity and continue to reap its benefits." Slip Op. at 5, 16. It thus remains unclear whether the policy concerns underlying *Lear* will be applied in a future case to overrule *Studiengesellschaft* and permit licensees to challenge licensed patents in all circumstances.

IMPLICATIONS OF THE *MEDIMMUNE* DECISION

Patent Licensing Negotiations

Given the Court's elimination of the Constitutional "case or controversy" barrier to declaratory judgment suits, it will be important for patent owners to expressly bar their licensees by contract from challenging patent validity during the term of the license (though there may be common law barriers to a suit by a licensee as well). While Genentech had argued that its license to MedImmune barred a challenge, the Court did not read the contract that way: "it is not clear where the prohibition against challenging the validity of the

patents is to be found." Slip Op. at 16. We anticipate the development of creative contractual provisions that make clear, where the facts support it, that the license terms and rates represent the resolution or compromise of a patent dispute without initiating litigation. Such provisions may include a requirement that the licensee terminate before challenging validity or infringement, automatic license termination (or a right to terminate) if the patent is challenged, licenses of limited duration that may be renewed absent litigation, penalty provisions that provide for higher royalties should the licensee lose a challenge to the patent, provisions for attorneys' fees, or arbitration clauses.

Patent owners must nevertheless recognize that these techniques may be open to legal challenge under the policy considerations enumerated in *Lear*—that "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," trumps "the technical requirements of contract doctrine." 395 U.S. at 670. As noted above, *Lear* does not address the question of whether a licensee must be permitted to keep his license *and* challenge the patent at the same time. But other cases suggest that there may be such a right. For example, outside the Federal Circuit, in *Massillon-Cleveland-Akron Sign Co. v. Golden State Advertising Co.*, 444 F.2d 425 (9th Cir. 1971), the Ninth Circuit struck down a written settlement agreement (which had been entered into as a result of threats by the patentee but before litigation had begun) that contained a provision in which the defendant acknowledged the validity of the relevant patents and agreed not to challenge the validity of the patent. The court reasoned that the *Lear* holding rendered that provision "void on its face and unenforceable." *Id.* at 427. The court refused to draw any distinction between a settlement and a licensing agreement because "it would be just as easy to couch licensing arrangements in the form of settlement agreements." *Id.*

However, more recent Federal Circuit law honors interests of finality where suit has been filed and then settled. In *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362 (Fed. Cir. 2001), the Federal Circuit upheld provisions in both a settlement agreement and license agreement in which the licensee agreed not to challenge the patentholder's patents. *Id.* at 1363-64. After entering into the agreements, the patentee brought a subsequent infringement arbitration action against the licensee and the arbitrators precluded the licensee from challenging the validity of the patent. *Id.* at 1367. The licensee challenged the enforceability of the invalidity waivers as against public policy based on *Lear*. *Id.* at 1368. *Flex-Foot* noted that *Lear* was distinguishable because in *Lear* the license agreement was not part of a settlement and did not contain a promise by the licensee "not to challenge the validity of the patent." *Id.* The court affirmed the validity of the licensee's agreement not to challenge the patent, and the preclusive effect of the agreements based on "the important policy of enforcing settlement agreements," and noted that the case was only dismissed after the licensee had had an opportunity to conduct discovery. *Id.* at 1368, 1370.[1] It is unclear whether a court would consider a license provision between private parties that waived the right to challenge invalidity and explicitly identified as a settlement would hold the same policy importance as the settlement of a filed case in which a settlement order or consent decree was entered by a court. *Cf. C.R. Bard*, 716 F.2d at 881 n.5 (the court did not question the enforceability of a provision that if the licensee asserted invalidity and stopped paying royalties then the patentholder "may terminate th[e] Agreement as to the Patent or Patents as to which invalidity is asserted.").

What is clear is that in the *MedImmune* decision, the Supreme Court expressly refused to opine on the scope of the *Lear* doctrine in this context. The *MedImmune* Court's Article III holding, however, makes it more

likely that licensees and licensors will focus more heavily on drafting provisions limiting patent challenges. Future courts will therefore likely be required to draw the contours of the *Lear* doctrine more clearly.

Future of the Reasonable Apprehension Standard

It remains to be seen whether the Court's decision will be applicable in other declaratory judgment patent cases, including when a warning letter/notice to an accused infringer triggers jurisdiction or whether a generic company would be able to bring a declaratory judgment action based simply on patents being listed in the Orange Book.[2] The Court purports to limit its reasoning to existing licensees by construing the *MedImmune* controversy as involving "contract claims," Slip Op. at 6 n.6; *see also* Slip Op. (Thomas, J., dissenting at 10) (holding of the Court is that "contractual obligations are sufficiently coercive to allow a party to bring a declaratory judgment action."). Yet the opinion's broad language and criticism of the Federal Circuit's decision, including *dicta* noting that whether the claims were contract or patent invalidity claims "makes no difference to the ultimate issue of subject-matter jurisdiction," *id.* at 3, and even "modest penalties for misdemeanor trespass" could meet the coercion test, *id.* at 15 n.12, suggest that until further clarification by the Federal Circuit, we may be entering a period of uncertainty regarding the continued application of the reasonable apprehension standard outside the licensing context. This uncertainty counsels that patentees be even more cautious about crafting infringement notices or be in jeopardy of being defendants in patent litigation in a forum and a time chosen by the accused infringer.

ENDNOTES

1 *See also Foster v. Hallco Mfg. Co., Inc.*, 947 F.2d 469 (Fed. Cir. 1991) (preventing licensee from challenging the validity and enforceability of a patent in a case where a summary judgment motion was filed soon after the complaint was (and apparently before any discovery), because a previous consent decree contained a provision in which the licensee acknowledged the validity and enforceability of the patent; the court considered *Massillon* but rejected its holding); *Hemstreet v. Spiegel, Inc.*, 851 F.2d 348 (Fed. Cir. 1988) (settlement entered into one week after trial started precluded subsequent challenge to the validity and enforceability of a patent).

2 *See Fina Research, S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1482 (Fed. Cir. 1998) ("The law states that a letter threatening an infringement suit unless the alleged infringer ceases the offending activity satisfies the first prong [*i.e.,* the "explicit threat" requirement] of the justiciability test."); *SRI Int'l, Inc. v. Advanced Tech. Labs.*, 127 F.3d 1462, 1469-70 (Fed. Cir. 1997) (letter including copy of a patent and the statement that the recipient's products "may infringe" the patent satisfied notice of infringement requirement but was not adequate to create case or controversy); *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005) (holding that in analyzing a jurisdictional claim based on reasonable apprehension, "listing a patent in the Orange Book" does not "evince[] an intent to sue" because the listing is made pursuant to a statutory requirement and "the Orange Book is a listing of patents with respect to which claims of infringement '*could* be reasonably asserted.'") (quoting 12 U.S.C. § 355(b)(1), (c)(2))). (Note that the *Teva* case was specifically criticized in the *MedImmune* opinion for applying an "imminent" requirement to the reasonable apprehension test. Slip Op. 13-14 n.11.)

If you would like more information about the MedImmune decision or its implications for IP licensing, please contact your Arnold & Porter attorney or:

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