



LICENSING STRATEGIES AFTER *MEDIMMUNE*: THE POTENTIAL IMPACTS OF THE
SUPREME COURT ALLOWING LICENSEES IN GOOD STANDING TO FILE
DECLARATORY JUDGMENTS AGAINST LICENSORS

By Gregory L. Clinton¹ and James G. McEwen²

On January 9, 2007, the United States Supreme Court issued its decision in *MedImmune, Inc. v. Genentech Inc.*, 549 U.S. ____ (2007) that reversed a line of decisions by the Federal Circuit most recently set forth in *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004). Under *Gen-Probe*, unless the licensee breached the license as was done in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), the licensee was not in sufficient imminent threat of suit to satisfy the case or controversy requirement of Article III of the Constitution. Therefore, under *Gen-Probe*, the licensee could not file a declaratory judgment under the Declaratory Judgment Act, 28 U.S.C. § 2201(a), to contest the validity or enforceability of the licensed patent. In reversing this line of decisions, the Court held that a sufficient case or controversy exists to allow a licensee in good standing to file a declaratory judgment to determine whether, under the license, continued royalty payments are required where payments are not required if the licensed patent is invalid, unenforceable, or not infringed.

¹ Associate, Stein, McEwen & Bui, LLP.

² Partner, Stein, McEwen & Bui, LLP. The opinions expressed in this article do not represent the official positions of the authors' employers or former employers.

BACKGROUND

MedImmune, Inc. ("MedImmune"), the petitioner, manufactures the drug Synagis. Synagis is used to prevent respiratory tract disease in infants and children. Synagis currently represents 80% of MedImmune's total sales revenue. In 1997, MedImmune entered into a license agreement with Genentech, Inc. ("Genentech") and City of Hope, the respondents. The license agreement covered an existing patent, U.S. Patent No. 4,816,567 ("Cabilly I"), as well as a patent application then pending before the U.S. Patent and Trademark Office. Among other provisions, the license agreement required MedImmune to pay royalties under the Cabilly I patent (as well as the patent application, should it mature into a patent) until the patent(s) expired or were held invalid by a court.

The United States Patent and Trademark Office issued a patent for the licensed application, U.S. Patent No. 6,331,415 ("Cabilly II"), in December 2001. Upon receiving the Cabilly II patent, Genentech sent MedImmune a letter stating its belief that the Cabilly II patent covered Synagis.³ MedImmune, however, alleges it did not believe the Cabilly II patent was either valid or enforceable. Nevertheless, MedImmune made a strategic decision to pay the royalties under the 1997 license agreement instead of risking a potential injunction and payment of the attorney's fees and/or treble damages should MedImmune lose a subsequent infringement action. MedImmune paid the royalties "under protest" and "with reservation of all of [its] rights", but otherwise complied fully with the requirements of the 1997 license agreement.

Subsequently, and while continuing to pay royalties under the license agreement, MedImmune filed a declaratory judgment in the District Court for the Central District of California. The basis of the declaratory judgment was that no royalties were owed under the license because the patent was invalid and unenforceable, and since royalties were only owed if

³ Cabilly I was not alleged to cover Synagis such that no license royalties were owed prior to issuance of Cabilly II.

the patents were valid and enforceable under the terms of the license. As such, MedImmune filed suit to determine, under the terms of the license agreement, whether the patent was valid such that continued royalty payments should be made.

The district court dismissed the suit for lack of subject matter jurisdiction. Citing the Federal Circuit's decision in *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004), the district court held that the Declaratory Judgment Act, 28 U.S.C. § 2201(a) only allows parties to file declaratory judgments consistent with the limits of Article III of the Constitution, which requires an actual case or controversy to exist. As interpreted by the district court, the per se rule under *Gen-Probe* is that licensees in good standing could not establish an actual controversy regarding patent validity or enforceability since there was no imminent threat of litigation. As MedImmune was paying the required royalties, there was no *imminent* threat. Therefore, the district court, following *Gen-Probe*, held that MedImmune had not established an actual controversy and dismissed the suit for lack of subject matter jurisdiction.

The Federal Circuit affirmed the district court's dismissal of the case for lack of subject matter jurisdiction based upon its prior *Gen-Probe* decision.

QUESTION PRESENTED TO SUPREME COURT

Following the Federal Circuit's decision, MedImmune filed a writ of certiorari on the following question:

Does Article III's grant of jurisdiction of "all Cases . . . arising under . . . the Laws of the United States," implemented in the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), require a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable or not infringed?

The Supreme Court granted certiorari to determine whether the actual controversy requirement of the Declaratory Judgment Act and the case or controversy requirement of Article

III of the Constitution required a licensee to breach the contract before suing to declare the patent invalid, unenforceable, or not infringed.

HOLDING OF THE SUPREME COURT

In an 8-to-1 decision, the Supreme Court found that neither the Declaratory Judgment Act nor Article III of the Constitution is restricted to situations where there is an imminent threat of suit. In the context of a patent license, the threat of serious business injury should the royalty payment be stopped (i.e., an injunction, potential treble damages) presented a sufficient controversy that the licensee should not be required to breach the license merely to bring an existing validity or noninfringement dispute into court. As such, the Supreme Court overruled the Federal Circuit's prior holdings, as set forth more recently in *Gen-Probe*, and allowed the district court to exercise its discretion as to whether MedImmune can continue its suit against Genentech and to reach a decision on the merits of the case.

In reaching this conclusion, the Supreme Court extended a prior line of cases allowing people to file declaratory judgments against the government without first exposing themselves to criminal liability. The deciding factor in those cases was the degree of risk the plaintiffs would have borne had they been required to engage in a possibly illegal act before going to court. The Supreme Court found similar factors at play in the patent context, where a loss at trial could result in attorney's fees, treble damages, and an injunction. The combination of these factors could easily drive a losing defendant out of business such that the resulting serious business injury was sufficiently coercive to satisfy the case or controversy requirement of Article III.

Moreover, the Court drew heavily on its prior decision in *Atwater v. Freeman*, 319 U.S. 359, 364 (1943), for the proposition that a justiciable controversy exists even where payments are being made. As stated in *Atwater*, "[t]he fact that royalties were being paid did not make this

a 'difference or dispute of a hypothetical or abstract character.'" 319 U.S. at 364, *quoting Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937). As such, Justice Scalia, writing for the Court, found that existing precedent did not force licensees to "bet the farm" as the only way to create a case or controversy sufficient to support filing a declaratory judgment suit.

The Court turned aside Genentech's counter-arguments that a license was merely an insurance policy and that granting subject matter jurisdiction was contrary to the common law rule that "a party to a contract cannot at one and the same time challenge its validity and continue to reap its benefits." The Court held that the license was not an "insurance policy" protecting Genentech from an invalidity suit because the license did not explicitly forbid such suits. Nor was MedImmune barred from suit by the common law rule since MedImmune's argument was not that the contract was invalid, but was instead that the contract, if interpreted properly, did not require payment of royalties. As such, MedImmune's challenge was in the context of a valid contract, and the justifiable controversy was over the enforcement of a contractual requirement requiring payment only where the patent is infringed, valid, and enforceable.

In its decision, the Court noted that the existence of a case or controversy does not require that the district court exercise jurisdiction. Specifically, the Court noted that the Declaratory Judgment Act provides that a court "may declare the rights...." Moreover, the Court also noted that common law defenses and other contract law principles relied upon by Genentech do not preclude jurisdiction, but instead relate to any decision on the merits that the district court may make to resolve the case. As such, the Court explicitly limited the effect of its ruling to allowing the district court to exercise its discretion, which was not allowed under the Federal Circuit's *Gen-Probe* decision, and left for the district court on remand the "equitable, prudential

and policy arguments for such a discretionary dismissal" and "any merits-based arguments for denial of declaratory relief."

IMPACT ON LICENSORS

While the Court noted that the ruling is limited, *MedImmune* may have a wide-ranging impact on patent licensing. The Court in *MedImmune* made special note that the license itself did not prevent the challenge, and seemed to acknowledge that the licensor could place some restrictions on challenges. In contrast to *MedImmune*, the Court in *Lear v. Adkins*, 395 U.S. 653 (1969) held that clauses that prevent a repudiating licensee, who has stopped making royalty payments, from contesting the validity of a patent were unenforceable as contrary to public policy. However, the Court in *MedImmune* explicitly expressed "no opinion" on whether licenses can restrict such challenges by non-repudiating licensees who continue making royalty payments. As such, licensors hoping to avoid later challenges need to balance the lack of any prohibition on challenges, as was the case in *MedImmune*, with the Court's prior decision in *Lear*.

While the Court has not provided a great deal of guidance on the subject, *MedImmune* appears to indicate that licensors can be creative in avoiding or limiting a situation where a paying licensee can challenge the licensed patent without running afoul of *Lear*. By way of example, potential clauses might grant the licensor a right to terminate a license should the licensed patent be challenged. Alternately, relying on the distinction made by the Court in *MedImmune*, licensors might include a clause which contractually prohibits challenges while royalties are being paid (i.e., while the licensee is in good standing), but allows for challenges when royalties are not being paid. Further, licensees may want to ensure that the licensee pays the licensor's reasonable court costs and attorneys fees for an unsuccessful challenge of the

licensed patent. Moreover, licensors might be more inclined to avoid the situation entirely by demanding fully paid up licenses instead of ongoing royalties dependent on an amount of continued use of the patent. Whatever the form, licensors will need to consider changing their licensing practices such that licenses are not merely an insurance policy during a patent challenge.

IMPACT ON LICENSEES

From the perspective of the existing licensees, declaratory judgment suits may begin to rise as licensees in existing licenses take advantage of the new opportunity the Supreme Court has given them to challenge licensed patents without having to breach the license. From a strategic point of view, potential licensees who are likely to challenge a patent may want to copy the *MedImmune* model and obtain licenses prior to challenging the patent's validity or whether a product infringes in order to ensure that, should the patent ultimately be upheld and the product be infringing, the licensee is not exposed to willfulness damages or an injunction. Thus, for both existing and potential licensees, the licensee's ability to challenge the licensed patents while paying royalties would seemingly reduce the patent litigation risk as compared to where there is no license right.

This strategy is not without its risks, however. Specifically, such challenges will be limited to the license terms and conditions. Moreover, the district court has the discretion not to take the challenge under the Declaratory Judgment Act. For this reason and as Justice Kennedy hinted in the oral arguments for the case, the new issue in patent licensing arising from *MedImmune* will most likely be the enforceability of clauses prohibiting or limiting declaratory judgments, and whether the licensee is a repudiating licensee as in *Lear* or a non-repudiating licensee for which the status of licensee estoppel is unclear. Additionally, licensees should be

aware that the common law defenses as well as equitable defenses are available. Thus, the rule that "a party to a contract cannot at one and the same time challenge its validity and continue to reap its benefits" may still be available since the Court in *MedImmune* specifically did not comment on the effect of its ruling on these defenses.

CONCLUSION

In *MedImmune*, the Supreme Court continues to assert its authority in patent law by allowing patent licensees to file declaratory judgments of patent invalidity and unenforceability against the licensors, even though the licensee is still paying royalties under a license. *MedImmune* may also indicate the Supreme Court's direction in future patent cases. The *MedImmune* case continues the new tradition of patent skepticism at the Supreme Court that began with *eBay v. MercExchange* last year. If the Court hoped to use *MedImmune* as a way to cut down on the number of invalid patents as opposed to broadening the scope of the Declaratory Judgment Act, the decision provides a hint at the Court's possible decision in another patent case before the Court this term, *KSR v. Teleflex*. The issue in that case is the particular test for obviousness. If, as appears from the *MedImmune* decision, the Court is trying to rein in the number of invalid patents, the Court may well overturn the Federal Circuit's "teaching-suggestion-motivation" test and substitute a more lenient test of obviousness, or may clarify that this test is only one of the acceptable tests used for obviousness. Either way, currently with *MedImmune* and with *KSR* to follow, the Supreme Court is reshaping the field of U.S. patent law.