SUPREME COURT REVERSES RULE THAT A PATENT LICENSEE IN GOOD STANDING CANNOT SEEK A DECLARATORY JUDGMENT THAT THE LICENSED PATENT IS INVALID, UNENFORCEABLE, OR NOT INFRINGED

The Supreme Court's January 9, 2007 opinion in *MedImmune, Inc. v. Genentech, Inc.*[1] alters the balance of power between patent holders and their licensees. A patent licensee is no longer required to terminate or breach its license agreement in order to seek a declaratory judgment that the licensed patent is invalid, unenforceable, or not infringed. Overruling prior Federal Circuit decisions to the contrary, the Court majority held that an "actual controversy" sufficient to exercise subject matter jurisdiction under the U.S. Constitution and the Declaratory Judgment Act can exist even when the patent licensee has not refused to pay royalties and has not materially breached the license agreement.

The Court's decision has far-reaching implications. It likely will result in increased litigation against patent licensors, who thought that their current license agreements effectively protected their patents from attack. The decision also will undoubtedly affect the terms of future license agreements, as licensors seek to implement new contractual mechanisms to lessen the impact of this decision. Finally, this decision will affect relations between brand-name and generic drug manufacturers, because in deciding this case the Court also criticized the Federal Circuit's test for exercising subject matter jurisdiction over declaratory judgment actions in the context of the Hatch-Waxman Act.

Background

MedImmune, Inc. manufactures Synagis, a drug that prevents respiratory tract disease in infants and young children. In 1997, MedImmune entered a license agreement with Genentech, Inc. that covered an existing patent and a pending patent application. MedImmune agreed to pay royalties on sales of products whose manufacture, use, or sale would infringe claims of the covered patents. When Genentech's pending application issued in 2001, Genentech informed MedImmune that it believed Synagis infringed the patent and that MedImmune should pay royalties under the 1997 agreement.

MedImmune believed it did not owe royalties because the patent was invalid, unenforceable, and not infringed by Synagis. However, faced with the threat of treble damages, attorney's fees, and an injunction against selling Synagis (which accounted for more than 80 percent of its revenues from sales since 1999), MedImmune paid the royalties under protest and filed a declaratory judgment action. The district court dismissed the action for lack of subject matter jurisdiction, and the United States Court of Appeals for the Federal Circuit affirmed.[2]

[1] *MedImmune, Inc. v. Genentech, Inc.,* No. 05-608 (U.S. Jan. 9, 2007).
[2] *MedImmune, Inc. v. Genentech, Inc*., 427 F.3d 958 (Fed. Cir. 2005).

Subject Matter Jurisdiction

Article III of the U.S. Constitution limits the jurisdiction of federal courts to cases and controversies arising under the Constitution and other laws of the United States.[3] This jurisdictional requirement is implemented in the Declaratory Judgment Act, which specifies that in "a case of actual controversy" an interested party may seek a declaration of its rights and legal relations from a federal court.[4]

In determining the justiciability of declaratory judgment actions, the Supreme Court has eschewed bright-line rules in favor of contextual analysis. The Court summarized the jurisdictional requirements by stating: "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a *substantial controversy*, between parties having *adverse legal interests*, of *sufficient immediacy and reality* to warrant the issuance of a declaratory judgment."[5]

The Federal Circuit had developed its own two-part test for determining whether federal courts have subject matter jurisdiction over patent disputes. Under the Federal Circuit's test, a declaratory judgment plaintiff needed to show that (1) it had a reasonable apprehension that it faced an infringement suit and (2) it conducted activities that could constitute infringement.[6] Under the Federal Circuit's rule, a licensee in good standing would not meet the Article III case-or-controversy requirement because the license agreement "obliterated any reasonable apprehension of a lawsuit."[7] As such, the Federal Circuit's rule required a licensee to *terminate or breach* its agreement and face the threat of an infringement suit before it could seek a declaratory judgment on the validity, enforceability, or infringement of the licensed patent.

In *MedImmune*, the Supreme Court overruled the Federal Circuit and held that the subject matter jurisdiction requirement of Article III does *not* require a licensee to terminate or breach its license agreement before seeking a declaratory judgment that the patent involved is invalid, unenforceable, or not infringed.

The Court pointed out that the case-or-controversy requirement would have been met if MedImmune had "taken the final step" of refusing to make royalty payments under the license agreement.[8] Thus, MedImmune's own acts (paying the royalties) removed the threat of imminent harm. The Court applied the reasoning of earlier decisions involving the threat of government action, in which the Court held that a plaintiff does not have to expose itself to liability before bringing suit to challenge the validity of a law. When "the threat-eliminating behavior was effectively coerced," the Court does not require a plaintiff to "bet the farm" and

[3] U.S. Const. art. III.
[4] 28 U.S.C. § 2201 (2006).
[5] *MedImmune, Inc.*, No. 05-608, slip op. at 8 (citing *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)) (emphasis added).
[6] *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380 (2004).
[7] *Id.* at 1381.
[8] *MedImmune, Inc.*, No. 05-608, slip op. at 8.

face imminent injury in order to challenge the validity of a law.[9] The same rationale applies when the plaintiff's actions are coerced by a private party rather than by the government. In this case, MedImmune did not have to "risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights."[10]

The Court also rejected Genentech's argument that the parties effectively settled this dispute when they entered the license agreement. Genentech argued that when a licensee enters into a license agreement, it purchases an "insurance policy" that immunizes it from infringement suits so long as it pays the royalties and does not challenge the licensed patents.[11] According to Genentech, allowing the licensee to challenge the patent while enjoying its immunity from suit eliminates this *quid pro quo* between the patentee and the licensee.[12] The Court countered that "it is not clear where the prohibition against challenging the validity of the patent is to be found. It can hardly be implied from the mere promise to pay royalties on patents [which have neither expired nor been held invalid]."[13] The Court emphasized that "[p]romising 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."[14]

Implications Of The Case

The most obvious impact of this case will be to increase the number of declaratory judgment actions brought by licensees against their licensors. However, this possibility should not be overstated. Even though a licensee *can* seek a declaratory judgment, that does not necessarily mean that it *will* do so in every instance.

A licensee still might hesitate before challenging the validity or enforceability of a patent in court, given that issued patents are presumed valid, litigation costs might exceed the amount of royalties due under the license agreement, and an invalidity ruling would also help any of the licensee's competitors who license the same patent. That being said, if a licensee *does* seek a declaratory judgment of invalidity, it is probably because it has a strong invalidity case or because the agreement calls for significant royalties -- and these are exactly the cases that should most concern licensors.

A licensee is more likely to seek a declaratory judgment of noninfringement than of invalidity. In that case, the burden will be on the patent holder to prove that the licensee's product infringes the patent. If the licensee wins, it will no longer have to pay royalties, but it will not invalidate the patent for its competitors.

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[9] *Id.* at 10.
[10] *Id.* at 15.
[11] *Id.* at 15-16.
[12] *Id.* at 16.
[13] *Id.*
[14] *Id.*

The second impact of the Court's decision will be on the terms of future license agreements. Because patent licensors are no longer assured peace, they can be expected to (1) charge more for patent licenses to compensate for the uncertainty of patent challenges or (2) negotiate up-front, lump sum payments rather than running royalties.

Licensors also might want to include explicit "trigger provisions" in the license agreement. That is, if the licensee files a declaratory judgment action challenging the patent's validity or enforceability, the filing would trigger one or more events, such as termination of the license, payment of a higher royalty rate, or forfeiture of a sum placed in escrow when the license was signed. Licensees in turn might accede to such provisions in exchange for lower royalty rates or to avoid lump sum payments.

The Court seemed to hint at this result when it said that there was no clear prohibition on challenging the patent in the MedImmune license agreement. As the Court pointed out, promising to pay royalties on patents that are not found invalid is *not* the same as promising not to seek a holding of their invalidity.[15] If the license agreement had contained an explicit promise not to challenge the validity of the patents, would it have been enforceable? Not necessarily. Contractual clauses that prevent a licensee from challenging the validity of a patent might raise public policy concerns. As the Court pointed out in *Lear, Inc. v. Adkins*, there is an important public interest in challenging the validity of patents, and licensees are often the only ones with an economic incentive to do so. "If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification."[16] Thus, the next battle in this arena might involve no-challenge clauses or other contractual terms designed to restrict the ability of licensees to challenge licensed patents.

Finally, this decision will affect declaratory judgment actions in pharmaceutical cases that do not even involve license agreements. In deciding this case, the Court criticized the Federal Circuit's reasonable-apprehension-of-imminent-suit test as applied in *Teva Pharm. USA, Inc. v. Pfizer, Inc.* because it conflicted with Supreme Court precedent.[17] This criticism is noteworthy because the Supreme Court had denied a petition for *certiorari* filed by Teva in 2005, after the Federal Circuit had dismissed its declaratory judgment suit.[18]

The *Teva* case involved a declaratory judgment action brought by a generic pharmaceutical company in the context of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act.[19] Teva filed an abbreviated new drug application ("ANDA") with a "paragraph IV certification" asserting that one of Pfizer's patents related to Zoloft™ was invalid and not infringed by Teva's product.[20] Pfizer listed the patent in the FDA's "Orange Book," which contains a list of all patents "with respect to which a claim of infringement could reasonably be

[15] *Id.*
[16] *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969).
[17] *MedImmune, Inc.*, No. 05-608, slip op. at 13 n.11.
[18] 126 S. Ct. 473 (Oct. 11, 2005).
[19] *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1326-27 (Fed. Cir. 2005).
[20] *Id.*

asserted" against a generic equivalent of the brand-name drug.[21] Under the Hatch-Waxman framework, Pfizer could have filed an infringement suit against Teva within forty-five days in order to get a thirty-month "stay" on the FDA's approval of Teva's ANDA.[22] Pfizer, however, did not file an infringement suit, and Teva filed a declaratory judgment action seeking a declaration that Pfizer's patent was invalid and not infringed. The district court dismissed the case for lack of subject matter jurisdiction. The Federal Circuit affirmed, holding that Teva had failed to establish an "actual controversy" as required by the Declaratory Judgment Act because Teva failed to prove that it had a "reasonable apprehension of imminent suit."[23] However, because the Supreme Court declined to review the *Teva* case directly, it is unclear when generic companies will be able to bring declaratory judgment actions.

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If you have any questions concerning this memorandum, please contact Kelsey Nix (212-728-8256, knix@willkie.com), Heather Schneider (212-728-8685, hschneider@willkie.com) or the attorney with whom you regularly work.

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[21] *Id.* at 1328.
[22] *Id.*
[23] *Id.* at 1334.