

ATTORNEYS AT LAW

SPECIAL

REPORT

SUPREME COURT AUTHORIZES LICENSEE TO INITIATE CHALLENGE TO LICENSED PATENT WHILE REMAINING PROTECTED BY LICENSE

January 26, 2007

On January 9, in *MedImmune, Inc. v. Genentech, Inc.*, ¹ the United States Supreme Court held that a patent licensee, under a license agreement that does not prohibit challenges to a licensed patent, may make royalty payments under protest and at the same time bring an action seeking a declaratory judgment that the licensed patent is invalid, unenforceable and/or not infringed.

By way of brief legal background, under the U.S. Declaratory Judgment Act, 28 U.S.C. §2201(a), a party may initiate a legal action requesting a U.S. district court to declare that party's rights relative to another party, *e.g.*, to declare a patent to be invalid, unenforceable and/or not infringed. Such an action is referred to as a declaratory judgment action. A prerequisite to the district court's subject matter jurisdiction in such an action is that there be a genuine "case or controversy" under Article III of the U.S. Constitution, *i.e.*, a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

The Supreme Court's *MedImmune* decision reversed a ruling by the U.S. Court of Appeals for the Federal Circuit that a licensee in good standing cannot establish subject matter jurisdiction to bring a declaratory judgment action. The Federal Circuit had held that such a licensee cannot establish a "case or controversy" under Article III of the U.S. Constitution with regard to the validity, enforceability or infringement of the licensed patent, because the license agreement eliminated any reasonable apprehension that the licensee would be sued for infringement. The Supreme Court held, to the contrary, that the controversy between the licensee and licensor was definite and concrete. It held that the licensee's only alternative to continuing to make royalty payments was to repudiate the license agreement and risk a

virtually certain suit for infringement. Hence, the Supreme Court concluded that a district court has subject matter jurisdiction over a declaratory judgment action brought by a licensee in good standing who continues to pay royalties under protest.

This Special Report summarizes the Supreme Court's decision, including the majority opinion by Justice Antonin Scalia and the dissenting opinion by Justice Clarence Thomas (the lone dissenter), addresses potential future impacts of the decision, and provides recommendations for dealing with those potential impacts.

I. The Supreme Court's Decision

A. Background

MedImmune manufactures Synagis, a pharmaceutical product. In 1997, MedImmune entered into a patent license agreement with Genentech, which included an existing patent and a then-pending patent application that later issued as a patent, referred to as the Cabilly II patent. MedImmune agreed to pay royalties on sales of "Licensed Products," defined in the license agreement as a specified antibody "the manufacture, use or sale of which ... would, if not licensed under th[e] Agreement, infringe one or more claims of either or both of [the covered patents,] which have neither expired nor been held invalid by a court or other body of competent jurisdiction from which no appeal has been or may be taken."

After the Cabilly II patent issued, Genentech asserted that Synagis was covered by that patent, and demanded that MedImmune pay royalties. MedImmune did not believe that royalties were owing, because it believed that the Cabilly II patent was invalid and unenforceable, and that, in any event, Synagis did not infringe that patent. Nevertheless, to avoid the risk of loss of its license and an

¹ 127 S.Ct. 764, 2007 WL 43797, 81 USPQ2d 1225 (U.S. 2007).

Oliff & Berridge, plc

ATTORNEYS AT LAW

January 26, 2007

infringement suit by Genentech to enforce the Cabilly II patent (and the consequent possibility of treble damages, attorneys fees and an injunction against sales of Synagis, which accounted for more than 80% of MedImmune's revenues), MedImmune paid the royalties demanded by Genentech "under protest and with reservation of all of [its] rights."

MedImmune then filed an action seeking a declaratory judgment that the Cabilly II patent was invalid, unenforceable and not infringed. Genentech moved to dismiss the declaratory judgment action for lack of subject matter jurisdiction, and the district court granted that motion. More particularly, the district court held that MedImmune could not establish an Article III case or controversy, because its continued payment of royalties under the license agreement obviated any reasonable apprehension of suit by Genentech. The Federal Circuit affirmed, and the Supreme Court granted MedImmune's petition for a writ of certiorari.

B. The Majority Opinion

The Supreme Court characterized the essence of the dispute as a contractual dispute arising out of MedImmune's assertion that no royalties were payable under the license agreement because the Cabilly II patent was invalid, unenforceable and not infringed. The Court stated that, in order to establish declaratory judgment jurisdiction, MedImmune must establish that 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. The Court noted that there would have been no dispute that these standards were satisfied if MedImmune had refused to pay royalties under the license agreement, and that nothing else about the dispute between MedImmune and Genentech would have rendered it unfit for judicial resolution. The question presented, however, was whether MedImmune's continuing royalty payments, which rendered an otherwise imminent threat of suit by Genentech "remote, if not nonexistent," caused the dispute not to be a case or controversy within the meaning of Article III of the U.S. Constitution and the Declaratory Judgment Act.

The Court pointed out that a number of its precedents had permitted parties to seek declaratory judgments

challenging the validity of criminal statutes without first violating the law and thereby risking criminal prosecution as threatened by governmental entities. Although noting that Supreme Court jurisprudence is rare regarding coercive action threatened by a private party rather than the government, the Court referred to its prior decision in Altvater v. Freeman, 319 U.S. 359 (1943). That case had permitted patent licensees, in response to a suit by patentees to enforce territorial restrictions in a license agreement, to assert a counterclaim for a declaratory judgment that the licensed patents were invalid. The Court in that case rejected the argument that the licensees' continued payment of license royalties "under protest," as required by an injunction issued in an earlier action brought by the patentees, rendered the controversy only academic, not real. The Court stated that the fact that royalties were being paid did not render the dispute hypothetical or abstract, because the involuntary or coerced nature of the demanded royalties preserved "the right to recover the sums paid or to challenge the legality of the claim."

The Court noted that the Federal Circuit had erroneously distinguished the *Altvater* decision in *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004), the decision primarily relied upon on by the district court in dismissing MedImmune's declaratory judgment action and by the Federal Circuit in affirming that dismissal. The Court stated that the coercion that was dispositive of the case or controversy issue in *Altvater* was not governmental enforcement of the injunction, but rather the threat of actual and treble damages in an infringement suit brought by the patentees.

The Court considered an argument by Genentech that, by entering into the license agreement, MedImmune had, in essence, agreed not to challenge the licensed patent while continuing to reap the benefits of the license agreement. However, the Court found nothing in the license agreement prohibiting MedImmune from challenging the licensed patent, refusing to infer such a prohibition from MedImmune's mere promise to pay royalties on patents "which have neither expired nor been held invalid" In considering this argument, the Court did not question the enforceability of such a prohibition if one had been found in the license agreement.

On this subject, the Court considered its prior decision in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), which held

Oliff & Berridge, plc

ATTORNEYS AT LAW

January 26, 2007

that a licensee could stop paying royalties and challenge the validity of a licensed patent in court. Genentech distinguished *Lear* as being limited to a situation where a licensee has repudiated the license before bringing suit. The Supreme Court in *MedImmune* declined to opine on whether *Lear* was so limited. Rather, the Court held that, contrary to Genentech's argument, MedImmune was not impugning the license while continuing to reap its benefits, and that Genentech's argument in this regard was not relevant to the issue of Article III jurisdiction.

The Court concluded that MedImmune's continued payment of royalties under protest did not defeat subject matter jurisdiction, and that MedImmune was therefore "not required, insofar as Article III is concerned, to break or terminate its 1997 license agreement before seeking a declaratory judgment" with respect to the licensed patent. The payment was coerced by the risk that MedImmune would, if it repudiated the agreement, be exposed to a patent infringement suit by Genentech. Hence, a genuine Article III case or controversy was presented, and the Federal Circuit erred in affirming the dismissal of MedImmune's declaratory judgment action for lack of subject matter jurisdiction.

The Court further acknowledged that the Declaratory Judgment Act gives the district court discretion to decline to entertain a request for a declaratory judgment even if subject matter jurisdiction is present, and that the decision to exercise such discretion is vested in the district court in the first instance. The Court thus left open for consideration on remand the issue of whether the district court should dismiss the declaratory judgment action on equitable, prudential or policy grounds. The Court also left open for consideration on remand the issue of whether the district court should grant or deny the requested declaratory relief on the merits.

C. The Dissenting Opinion

Justice Thomas opined in dissent that there was no case or controversy under Article III of the Constitution and thus no subject matter jurisdiction. According to Justice Thomas, MedImmune was under no threat of being sued by Genentech for patent infringement, because MedImmune was a licensee in good standing that had made all necessary royalty payments. MedImmune's actions in entering into and complying with the license agreement deprived

Genentech of any cause of action against MedImmune for patent infringement, and, consequently, MedImmune had no cause of action for patent invalidity, which is an affirmative defense to patent infringement. Hence, according to Justice Thomas, MedImmune's prayer for declaratory relief was no more than a request for an advisory opinion about an affirmative defense that it might use in future litigation.

Justice Thomas concluded that the majority's holding, that contractual obligations are sufficiently coercive to allow a party to bring a declaratory judgment action, has "given every patent licensee a cause of action and a free pass around Article III's requirements for challenging the validity of licensed patents." Justice Thomas thus would have held that the case presents no real case or controversy and would have affirmed the dismissal of MedImmune's declaratory judgment action. More particularly, Justice Thomas would have held that a licensee must breach its license prior to seeking a declaratory judgment with respect to the licensed patent.

II. Analysis

A. Procedural Effects

The Supreme Court's *MedImmune* decision presents the possibility that, at least in some cases, a licensee that is in full compliance with its royalty and other obligations under a license agreement may nevertheless bring an action seeking a declaratory judgment that a patent covered by the agreement is invalid, unenforceable and/or not infringed. This is most likely under circumstances like those involved in *MedImmune*, where the licensee is not prohibited by the license agreement from challenging the licensed patent and is paying royalties under protest.

Whether and the extent to which the *MedImmune* decision may have broader application beyond its particular facts must await further litigation, testing the limits of the Supreme Court's decision. Nonetheless, *MedImmune* establishes that at least under some circumstances, such as where a licensor has demanded royalties under an existing license, the continued payment of royalties under protest does not deprive a court of jurisdiction to consider a licensee's declaratory judgment action challenging the licensed patent.

January 26, 2007

B. Substantive Effects

In light of *MedImmune*, a patent license agreement may not, at least in some cases, represent a conclusive resolution of a dispute between a patent owner and an accused infringer. At least a licensee that has not agreed to refrain from challenging a licensed patent, and is making royalty payments under protest, may be able to file a declaratory judgment action with respect to the licensed patent. Thus, accused infringers may well enter into license agreements and pay royalties under protest to avoid the risk of suit, with the hope of buying time to assess possible defenses to patent infringement allegations and to consider the possible availability and potential costs and benefits of a declaratory judgment action. Accused infringers may then try to carry on litigation without risking loss of the license or exposure to willfulness allegations and enhanced damages.

Correspondingly, patent owners may, in light of MedImmune, seek to strengthen the terms of their license agreements, to preclude or discourage the filing of declaratory judgment actions by licensees. For example, a patent owner may insist upon a license provision that (1) prohibits a licensee from challenging a licensed patent without first repudiating the license and/or (2) gives the patent owner the right to terminate the license if the licensee files a declaratory judgment action challenging the patent. While the propriety and enforceability of such provisions are beyond the scope of this Special Report and may be disputed during negotiation of a license and any subsequent litigation, it appears from the *MedImmune* decision that such contract provisions may be upheld if clearly expressed and not used under circumstances that violate antitrust laws. As noted above, in considering Genentech's patent challenge prohibition argument, the Supreme Court did not question the enforceability of such a prohibition against a non-repudiating licensee if one had been found in the license agreement. But see Lear v. Adkins, 395 U.S. at 661-71 (confirming the right of a repudiating licensee to challenge a licensed patent and discussing other cases in which courts have refused to estop licensees from challenging licensed patents, e.g., in situations involving price-fixing clauses whose legality depended upon the existence of a valid patent).

When licensing or policing a license to particularly important technologies, a patent owner could be more inclined to file an infringement action before or during a

negotiation, to improve the patent owner's bargaining position during the negotiation and to preempt a possible declaratory judgment action by a licensee after it has begun paying royalties. This would also make it possible to incorporate the terms of any agreement, including a provision prohibiting the licensee from challenging a patent, in a court-approved settlement agreement that is less subject to challenge later. *See, e.g., Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 475-77 (Fed. Cir. 1991) (distinguishing *Lear v. Adkins* in precluding validity challenge to patent previously admitted to be valid in consent judgment); *Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 349-51 (Fed. Cir. 1988) (distinguishing *Lear v. Adkins* in upholding courtapproved settlement requirement for royalty payments regardless of any subsequent determination of invalidity).

C. Caveat

It is important to note that the Court in *MedImmune* only actually decided the narrow issue of whether the "case or controversy" limitation on a court's jurisdiction requires a patent licensee to breach its license agreement before it can seek a declaratory judgment that the licensed patent is invalid, unenforceable, or not infringed. The Court otherwise expressly declined to opine "on the applicability of licensee estoppel under these circumstances," and stated that "available for consideration on remand are any meritsbased arguments for denial of declaratory relief." Thus, it is conceivable that district courts and the Federal Circuit may narrowly apply the MedImmune decision, and find a licensee to be estopped from challenging the validity, enforceability or infringement of a licensed patent even though the licensee has the right to raise the issue in a declaratory judgment action.

III. Conclusions and Recommendations

The Supreme Court's *MedImmune* decision could lead to at least some increased declaratory judgment litigation under existing patent license agreements, initiated by licensees that entered into license agreements reluctantly and/or have subsequently developed positions that the licensed patents are invalid, unenforceable and/or not infringed. The extent to which the particular facts and holding of *MedImmune* may limit the ability of licensees to seek and obtain declaratory relief remains to be seen. As to future license agreements, licensors will likely seek to

Oliff & Berridge, plc

ATTORNEYS AT LAW

January 26, 2007

strengthen the terms to reduce the potential for declaratory judgment actions by licensees. Such efforts could further increase or complicate litigation and license negotiations, as the parties test how far the licensor may go in attempting to preempt such declaratory judgment actions.

In view of *MedImmune*, we recommend consideration of the following:

- A licensee that previously entered into a license agreement reluctantly to avoid the expense and risk of patent infringement litigation, but who has developed viable positions that licensed patents are invalid, unenforceable and/or not infringed, may wish to consider whether it would be possible and cost-effective to file a declaratory judgment action while still complying with the terms of the license agreement. The availability of such a declaratory judgment action is most likely where the circumstances are the same or similar to those involved in the *MedImmune* case. In some instances, the mere filing (or threat) of a declaratory judgment action could induce the licensor to renegotiate the license on terms more favorable to the licensee.
- An accused infringer unsure of possible defenses to a patent infringement allegation should consider accepting a license agreement and then paying royalties under protest to avoid threatened infringement litigation, while assessing whether viable defenses to the infringement allegation can be developed. However, this course of action should be taken only with the realistic understanding that declaratory relief may not be available to a complying licensee under all circumstances.
- A prospective licensor should consider whether a future license agreement can be strengthened by inclusion of terms designed to preclude or reduce the likelihood of a declaratory judgment action by a licensee in good standing. For example, a licensor should consider provisions stating that (1) the licensee promises not to challenge the validity or enforceability of the licensed patent, or its applicability to the licensed product, without first repudiating the license, and/or (2) the licensor can terminate the license immediately if the licensee files a declaratory judgment action challenging the validity, enforceability or applicability of the licensed patent.

- As in the past, when licensing or policing a license to a particularly important technology, a prospective licensor may wish to consider filing a patent infringement action before or during a license negotiation. In addition to improving the licensor's bargaining power in the negotiation, and making it possible to incorporate agreed-upon terms in a court-approved settlement agreement, this may also serve to preempt a declaratory judgment action later by a licensee who has begun to make royalty payments.
- Where possible, in an effort to avoid *MedImmune* on its facts, a licensor or prospective licensor should (1) avoid actions that create a controversy with a licensee or prospective licensee, such as threatening suit, and (2) insist that a licensee or prospective licensee indicate that it is freely entering into and complying with a license agreement, and is not doing so under protest.

* * * * *

Oliff & Berridge, PLC is a full-service Intellectual Property law firm based in historic Alexandria, Virginia. The firm specializes in patent, copyright, trademark, and antitrust law and litigation, and represents a large and diverse group of domestic and international clients, including businesses ranging from large multinational corporations to small privately owned companies, major universities, and individual entrepreneurs.

This Special Report is intended to provide information about legal issues of current interest. It is not intended as legal advice and does not constitute an opinion of Oliff & Berridge, PLC. Readers should seek the advice of professional counsel before acting upon any of the information contained herein.

For further information, please contact us by telephone at (703) 836-6400, facsimile at (703) 836-2787, e-mail at email@oliff.com or mail at 277 South Washington Street, Suite 500, Alexandria, Virginia 22314. Information about our firm can also be found on our web site, www.oliff.com.

スペシャル·レポートの日本語版は、英語版の発行後、二週間以内にウエッブ·サイトでご覧いただけます。