

MedImmune: The Practical Implications*

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The Supreme Court issued the long-awaited decision on *MedImmune, Inc. v. Genentech, Inc.*, No. 05-608, on January 9, 2007. In an 8-1 decision authored by Justice Scalia, the Court held that the Federal Circuit's standard for declaratory judgment jurisdiction was too strict in cases that involved disputes between a patent holder and its licensee. Specifically, the Court held that the licensee need not "break or terminate its ... license agreement before seeking a declaratory judgment ... that the underlying patent is invalid, unenforceable or not infringed." (Slip Op. at 18) Justice Thomas was the lone dissenter; the majority had frequent footnote criticisms of the dissent going beyond the merits.

The *MedImmune* Case Itself

MedImmune had entered into a patent license agreement with Genentech but did so under protest and stated specifically that it was reserving its rights. MedImmune subsequently filed a declaratory judgment action, seeking to have the licensed patent declared invalid, unenforceable or not infringed. The district court had dismissed the declaratory judgment action, reluctantly concluding that it was compelled to do so by the Federal Circuit's decision in *Gen-Probe v. Vysis, Inc.*, 359 F.3d 1376 (2004), which had held that a licensee cannot establish a case or controversy under Article III of the Constitution to satisfy the declaratory judgment statute because the license "obliterates any reasonable apprehension that the licensee will be sued for infringement." (Slip Op. at 3). The Federal Circuit affirmed and the Court granted *certiorari*.

*This paper represents the personal views of the author and does not necessarily reflect the views of any colleague, organization or client thereof.

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As an initial matter, the Court reaffirmed that the Declaratory Judgment Act, 28 U.S.C. § 2201(a), is constitutional. Relying on *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, (1937), the Court noted that the phrase “Case of actual Controversy” set forth in the Act refers to the type of Cases and Controversies that are justiciable under Article III. The Court went on to note that *Aetna Life* and its progeny have required that cases brought under the Act must be “ ‘definite and concrete, touching the legal relations of parties having adverse legal interests and ‘admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical states of facts.’” (Slip op. at 8 citing *Aetna Life* and *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). The Court rejected the Federal Circuit’s “reasonable apprehension of suit” test and its more recent “reasonable apprehension of *imminent* suit” test set forth in *Teva Pharm USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (2005). (Slip Op. at 13 n.7; emphasis added by the Court).

The Court then noted that in cases involving a private plaintiff and a governmental agency, the plaintiff is not required to expose itself to liability before bringing declaratory judgment suit. The Court further noted that the private plaintiff-governmental agency cases consistently hold that the private party need not have to choose between abandoning its rights and risking prosecution. (Slip Op. at 10, citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 152 (1967)). While the Court noted that there were far fewer cases dealing with private litigants, those that did had similarly accepted jurisdiction and that the Court’s decision in *Altwater v. Freeman*, 319 U.S. 59 (1943), was directly on point. In *Altwater*, the Court had held, in similar circumstances, that a licensee paying royalties under protest does not defeat jurisdiction under the Declaratory Judgment Act. (Slip Op. at 12 n.10.)

While the Court declined to set forth a hard and fast rule for determining whether a particular case meets the justiciability requirements of Article III, it noted that the issue 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 fairly 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.” (Slip Op. at 9 n.8, quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)).

Open Questions After *MedImmune*

With the Court's rejection of the Federal Circuit's "reasonable apprehension of imminent suit" test that it quotes from *Teva*, *MedImmune* has implications in patent litigation that reaches far beyond the licensee-licensor situation.

Warning Letters: First, *MedImmune* will affect declaratory judgment standing in instances where the patentee writes a warning/notice letter to an accused infringer. The patentee will need to craft that letter very carefully or be in jeopardy of finding itself a defendant in a patent litigation in a forum chosen by the accused infringer.

Orange Book Disputes: It remains to be seen whether the Court's decision will be applicable to other declaratory judgment patent issues, including whether a generic company would be able to bring a declaratory judgment case against a branded company that declined to bring suit on patents listed in the Orange Book after the generic company had filed a Paragraph IV notice that it intended to seek approval for a generic version of the branded company's product.

With the Court's rejection of the Federal Circuit's holding in *Teva*, a generic company that seeks to have a patented product approved will now be able to bring a declaratory judgment action against the branded company seeking to have the patents covering the product declared invalid or noninfringed. In *Teva*, the Federal Circuit had declined jurisdiction when the branded company had declined to bring suit against the generic company after the generic company had given notice that it intended to seek FDA approval for the branded patented product. What remains to be seen is what new test the Federal Circuit will implement in light of *MedImmune*.