

## Supreme Court Backhands Key Federal Circuit Test

*Wednesday, January 10, 2007* --- On January 9, 2007, the Supreme Court issued its highly-anticipated decision in *MedImmune, Inc. v. Genentech, Inc.*, No. 05-608 (Scalia, J.), holding that a patent licensee may bring a declaratory judgment action seeking a decision that the licensed patent is invalid or not infringed even if the licensee is continuing to pay royalties under the license. Obviously, this decision will have a significant impact on licensor/licensee relationships and on the settlement of patent disputes.

Lost in most of the discussion of *MedImmune*, however, is the Supreme Court's undermining of the Federal Circuit's "reasonable apprehension of suit" test, which has been applied for decades to evaluate whether a court has subject matter jurisdiction over a declaratory judgment complaint. *MedImmune* may thus have a dramatic impact on declaratory judgment actions, especially those cases brought by generic pharmaceutical companies under the Hatch-Waxman Act.

### \* Reasonable Apprehension of Suit Test \*

The Declaratory Judgment Act vests United States courts with jurisdiction to declare the rights of parties in litigation where an "actual controversy" exists. Where a potential infringer brings suit for a declaration that the patent at issue is not infringed, invalid or unenforceable, the Federal Circuit has time and again required the plaintiff to demonstrate that it possessed a reasonable apprehension of facing an imminent suit by the patent holder.

This test has played a critical role in the development of generic pharmaceutical products. In order to obtain approval from the Food and Drug Administration ("FDA"), a generic manufacturer is required to submit an Abbreviated New Drug Application ("ANDA") to FDA, certifying to any patent listed by the brand company in the Orange Book. The first ANDA filer to challenge a patent listed in the Orange Book through a so-called Paragraph IV certification obtains a 180-day period of marketing exclusivity as the only generic on the market.

This period is triggered by the first commercial marketing. Prior to the 2003 Medicare Modernization Act ("MMA"), this period was also triggered by a court decision finding the patent at issue to be invalid, unenforceable or not infringed. Following the MMA, the exclusivity holder will forfeit its exclusivity period if it does not commence marketing within 75 days of a final, non-appealable decision that the patent is invalid, unenforceable or not infringed.

Given the Hatch-Waxman exclusivity regime and the potentially enormous

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patent damages that could be imposed if the generic company goes to market without certainty as to the patent issues, numerous generic challengers have attempted to bring declaratory judgment actions against patents listed in the Orange Book. These efforts have largely been unsuccessful under the Federal Circuit's "reasonable apprehension of suit" test, which was prominently displayed in the Federal Circuit's 2005 decision regarding Zolofit® in *Teva Pharmaceuticals USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir. 2005).

\* Supreme Court's Undermining of the Reasonable Apprehension Test \*

In *MedImmune*, the Supreme Court disposed of the Federal Circuit's "reasonable apprehension of suit" test with little fanfare and minimal discussion. In fact, the Court noted its disapproval of this decades-old test with little more than a footnote. Simply stated, the Court found that the test was inconsistent with Supreme Court precedent, including, among other cases, *Altwater v. Freeman*, 319 U.S. 359 (1943).

The Court did not set forth an alternative test specific to patent cases. Instead, the Court recognized that its precedent has not always drawn "the brightest of lines between those declaratory-judgment actions that satisfy the case-or-controversy requirement and those that do not." Quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 207, 273 (1941), the Court generally summarized the standard as follows:

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.

\* What Does This Mean? \*

By undermining the "reasonable apprehension of suit" test, the Court's decision in *MedImmune* may have a considerable impact on declaratory judgment actions. Depending upon how the district courts and the Federal Circuit react to this decision, the behavior of patentees and alleged infringers could appreciably change. For example, patent holders have often been able to send out pseudo-threatening letters, offering to "discuss the issues" in order to prevent the successful filing of a declaratory judgment action. Now, it's possible that such letters will not prevent jurisdiction from being established in a declaratory judgment action.

In the pharmaceutical industry, this decision may have a far-ranging impact. This decision opens up the possibility of ANDA filers establishing jurisdiction in a declaratory judgment action challenging patents listed in the Orange Book. At a minimum, this may help ANDA filers obtain patent certainty without having to make the decision of whether to launch at risk and face potentially enormous damages.

Perhaps more importantly, a subsequent ANDA filer without exclusivity rights

may be able to obtain a final, non-appealable court decision on a listed patent, forcing the first-filer to either launch its product or forfeit its exclusivity period. As such, this decision has the potential of increasing generic market penetration, benefiting consumers with less expensive alternatives and reducing overall healthcare costs.

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