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Divided Panel of the Federal Circuit Affirms Dismissal of Declaratory Judgment Action Despite MMA Provisions

Most generic pharmaceutical companies expected that the enactment of the Medicare Modernization Act (“MMA”) in December 2003 would alleviate the difficulties previously encountered in bringing declaratory judgment suits for patent noninfringement or invalidity. Among the changes brought about by MMA was a provision for a “civil action to obtain patent certainty.” Under this provision, an ANDA applicant can bring a declaratory judgment suit against an NDA-holder and/or patentee if: (1) the NDA-holder/patentee does not bring suit within 45 days after receipt of a paragraph IV notice letter; and (2) the ANDA applicant has made an offer of confidential access to its ANDA to the NDA-holder/patentee. The purpose of the declaratory judgment provision of MMA, consistent with the enactment of Hatch-Waxman, was to expedite entry of generic pharmaceuticals into the market. A recent decision by the Federal Circuit, however, presents a hurdle for generic pharmaceutical companies seeking declaratory relief under MMA. But the dissent in that case, along with a concurring opinion in a 2002 Federal Circuit opinion and the legislative purpose behind MMA, offers hope to generic pharmaceutical companies.

On January 21, 2005, a divided panel of the Federal Circuit ruled that Teva could not bring an action under MMA’s declaratory judgment provision against Pfizer for invalidity and non-infringement of a patent covering Zolofit® (sertraline). The Federal Circuit rejected Teva’s arguments that Pfizer had created a reasonable apprehension of imminent suit based on Pfizer’s patent covering sertraline, and also rejected Teva’s argument that MMA disposed of the reasonable apprehension part of the two-prong test for determining whether a court has jurisdiction to hear a declaratory judgment action.

Teva filed an ANDA to market a generic version of sertraline accompanied by a paragraph IV certification to Pfizer’s ‘699 patent. When Pfizer failed to sue Teva within 45 days of

receiving the paragraph IV notice letter, Teva filed a declaratory judgment suit on January 24, 2003. Teva took the position that Pfizer had created a reasonable apprehension of imminent suit by: (1) listing the ‘699 patent; (2) refusing to grant Teva a covenant not to sue; (3) aggressively asserting its patent rights in litigation; and (4) suing Ivax, the company that filed the first ANDA and paragraph IV certification relating to sertraline.

APPREHENSION OF IMMINENT SUIT NEEDED

On appeal, the Federal Circuit affirmed the district court’s decision to dismiss Teva’s suit for lack of “an actual controversy.” The Federal Circuit applied the traditional two-prong test for determining whether an “actual controversy” exists, which requires both “(1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity.” In this case, Teva and Pfizer agreed that the filing of an ANDA with a paragraph IV certification satisfied the second prong of the test, so the appeal focused on the first prong.

Teva argued on appeal that the first prong was satisfied because an ANDA applicant always has a reasonable apprehension of facing an infringement suit when the NDA applicant lists a patent and an ANDA applicant files a paragraph IV certification to that patent. The Federal Circuit disagreed. The Federal Circuit refused to hold that Pfizer’s listing of the ‘699 patent in the Orange Book, without more, created a reasonable apprehension of imminent suit, reasoning that Pfizer was following a statutory requirement. The Federal Circuit further held, based on the facts, that a suit against Teva was not imminent.

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MMA DOES NOT SATISFY “IMMINENT” REQUIREMENT

In the alternative, Teva argued that an ANDA applicant is not required to establish a reasonable apprehension of imminent suit to bring a declaratory judgment action under MMA. The Federal Circuit examined the language of MMA, which states in relevant part that “the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under [the Declaratory Judgment Act] for a declaratory judgment that such patent is invalid or not infringed.” Since the “actual controversy” requirement is considered to be mandated by the Constitution, the Federal Circuit interpreted the phrase “consistent with the Constitution” as importing the “actual controversy” requirement into MMA. The court also rejected the argument by the Federal Trade Commission, which filed an amicus curiae brief, that MMA automatically bestows declaratory judgment jurisdiction in Hatch-Waxman cases.

JUDGE MAYER’S DISSENT: LISTING SATISFIES FIRST PRONG

Judge Mayer, former Chief Judge of the Federal Circuit, dissented. He agreed with Teva that the filing of an NDA and the listing of a patent “is conduct giving rise to a reasonable apprehension that an [ANDA] filer and declaratory judgment plaintiff will face a patent infringement suit...” Judge Mayer advocated an interpretation of MMA in light of the Congressional purpose—in cases such as this, requiring an analysis of the totality of the circumstances to determine whether declaratory judgment jurisdiction exists. Judge Mayer repeatedly looked at the Hatch-Waxman regime as a whole and concluded that declaratory judgment jurisdiction exists when a NDA-holder/patentee lists its patent in the Orange Book and a generic competitor files a paragraph IV certification to that patent. Judge Mayer recognized that:

[s]ubsequent ANDA applicants suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic drug prod-

uct...By permitting generic drug companies to bring declaratory judgment claims, Congress has not sought to create a hypothetical injury-in-fact; it has simply recognized the harm that exists absent such relief.

ADDITIONAL SUPPORT FOR JUDGE MAYER’S POSITION

Teva has until February 4, 2005 to petition for an *en banc* rehearing of this matter. This important question has been subject to considerable litigation and differing opinions. In addition to Judge Mayer’s dissent, Judge Gajarsa (not on this panel) issued a concurring opinion in *Minnesota Mining and Manufacturing Co. v. Barr Laboratories* advocating the same position taken by Teva and Judge Mayer. Although decided before the enactment of MMA, Judge Gajarsa wrote that listing a patent in the Orange Book in conjunction with an NDA application was a statement by the NDA holder that a lawsuit could “reasonably be asserted” based on that patent, and that the listing of the patent was “conduct giving rise to a reasonable apprehension on the plaintiff’s part that it will face an infringement suit or the threat of one.”

The two acts of (1) a patentee listing a patent in the Orange Book through the filing of an ANDA, and (2) a generic manufacturer filing an ANDA, together meet the case or controversy requirement so as to allow a declaratory judgment action of noninfringement.

Also, as evidenced by Judge Gajarsa’s opinion, declaratory judgment suits were not prohibited prior to the enactment of MMA. Therefore, the Federal Circuit has not addressed Congress’ rationale for including the declaratory judgment provision in MMA for a “civil action to obtain patent certainty.”

ABOUT THE AUTHORS

Keith Parr, Michael Gaertner, Scott Feder and Kevin Nelson represent pharmaceutical industry companies in litigation, intellectual property and regulatory matters.

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