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Phone: +1 212 537 6331 | Fax: +1 212 537 6371 | customerservice@portfoliomedia.com

Fed. Circ. Draws The Line On DJ Jurisdiction

Law360, New York (August 25, 2008) -- In the face of the Supreme Court's decision in *MedImmune* and its own recent decisions liberalizing the standard for establishing jurisdiction in declaratory judgment actions, the Federal Circuit drew a line in the sand this past week in *Prasco LLC v. Medicis Pharm. Corp.*, 2007-1524, ruling that the patent holder's marking of its products and enforcement of unrelated patents against different products is not sufficient to establish a case or controversy.

This decision may signal an effort by the Federal Circuit to halt the growing trend of potential infringers filing declaratory judgment actions against patent holders.

Interestingly, the Federal Circuit may have carved out the pharmaceutical industry from this ruling, potentially signaling that the court will continue to encourage declaratory judgment actions in that industry. The development of the law in this area will certainly be interesting and requires attention from both patent holders and potential infringers.

How We Got Here

In January 2007, the Supreme Court in its now famous footnote in *MedImmune* questioned the Federal Circuit's decades-old "reasonable apprehension of suit" test, which had been applied to preclude declaratory judgment actions against patent holders unless the potential infringer could demonstrate that it possessed a reasonable apprehension of facing an imminent suit.

Later that year, in *Teva Pharms. USA Inc. v. Novartis Pharms. Corp.*, the Federal Circuit concluded that *MedImmune* had, in fact, overruled the reasonable apprehension of suit test.

As a result, the proper test for subject matter jurisdiction in declaratory judgment actions was recognized as: "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient

immediacy and reality to warrant the issuance of a declaratory judgment."

The Federal Circuit then went another step further in the pharmaceutical context in *Caraco Pharm. Labs. Ltd. v. Forest Labs. Inc.* (No. 2007-1404). In that decision, the court determined that a generic drug applicant could bring a declaratory judgment action to challenge a brand company's patent even after the brand company granted a covenant not to sue.

Specifically, the court held that an actual and justiciable controversy existed as to the generic applicant's right to come to market because the patent at issue was listed in the U.S. Food and Drug Administration's Orange Book and was the basis for an earlier generic applicant's 180-day generic marketing exclusivity period under the Hatch-Waxman regulatory regime.

The Federal Circuit Draws The Line

In *Prasco*, the Federal Circuit may have now halted the trend of liberalizing the declaratory judgment jurisdiction standard. In this case, the patent holder had marked its product with four patent numbers.

In addition, the patent holder had sued *Prasco* and other defendants in the past for patent infringement based upon unrelated patents and products. Before launching its product, *Prasco* filed the declaratory judgment action, seeking a declaration that its product did not infringe the patents at issue.

Prasco also sent a product sample to the patent holder and requested a covenant not to sue. The patent holder refused to grant the covenant not to sue, and *Prasco* launched its product onto the market.

Considering the totality of the circumstances, the Federal Circuit determined that there was no controversy of sufficient "immediacy and reality" to support jurisdiction. The court held that the mere existence of the patents and the patent marking by the patent holder was not enough to create jurisdiction.

The court also minimized *Prasco's* alleged "paralyzing uncertainty" from the risk of being sued by the patent holder, noting that such an allegation was undercut by *Prasco's* decision to launch its product.

Addressing MedImmune, the court reasoned: "Although MedImmune clarified that an injury-in-fact sufficient to create an actual controversy can exist even when there is no apprehension of suit, it did not change the bedrock rule that a case or controversy must be based on a real and immediate injury or threat of future injury that is caused by the defendants — an objective standard that cannot be met by a purely subjective or speculative fear of future harm."

Because the patent holder had not taken any position adverse to Prasco and had not interfered with its right to market its product, the court concluded that there was no jurisdiction to maintain the declaratory judgment action.

Carve Out For Generic Pharmaceuticals?

In rendering its decision in Prasco, the Federal Circuit implied that the situation would be different for generic pharmaceutical products that are governed by the Hatch-Waxman regulatory regime.

Citing its decision in Caraco, the court noted that the mere existence of a patent, which may be listed by the brand company in FDA's Orange Book, can create a regulatory barrier to approval of the generic company's proposed product.

As a result, the Federal Circuit may have left the window open for generic pharmaceutical companies to continue to bring declaratory judgment actions merely based upon a brand pharmaceutical company listing a patent in FDA's Orange Book.

Where Does This Leave Us?

While the courts have been liberalizing the declaratory judgment jurisdiction standard, the Federal Circuit appears to have drawn a line in Prasco.

In bringing a declaratory judgment action, a potential infringer may now have to jump through some additional hoops in order to get the court to recognize jurisdiction in the case.

While Prasco may signal another shift in the pendulum of declaratory judgment law, this will certainly be an area worth watching for both patent holders and potential infringers.

--By Chad A. Landmon, Axinn Veltrop & Harkrider LLP

Chad Landmon is a partner with Axinn Veltrop & Harkrider LLP in the firm's Hartford, Conn.

office.

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