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The Evolving Declaratory Judgment Standard

Law360, New York (September 04, 2008) -- In January, 2007, the Supreme Court, in a footnote, reaffirmed an old standard for declaratory judgment jurisdiction. MedImmune Inc. v. Genentech Inc., 127 S.Ct. 764, 767, ftnt. 11, 2007 U.S. LEXIS 1003 (January 9, 2007). The Court criticized the "reasonable apprehension of suit" test and instead explained, "the question in each case is 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."

After MedImmune, courts have worked to interpret this footnote and the declaratory judgment standard has evolved through several important decisions. Below is a brief attempt to point out some of those important decisions and their effect.

"Reasonable apprehension of suit" is no longer required for declaratory judgment jurisdiction. After MedImmune, the effect of the criticizing footnote was not entirely clear.

However, in March, 2007, the Federal Circuit confirmed that the "reasonable apprehension of suit" aspect of the declaratory judgment test had indeed been rejected by the Supreme Court in MedImmune, but clarified that declaratory judgment jurisdiction still requires "some affirmative act by the patentee." SanDisk v. STMicroelectronics, 480 F.3d. 1372 (Fed. Cir. 2007).

Applying the new standard, the Court held that declaratory judgment jurisdiction was proper where the patentee had taken the affirmative action of offering a license and setting up a meeting for license negotiations.

The SanDisk Court went on to explain that declaratory judgment jurisdiction may exist "where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do."

Only a few days later, in Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp., 482 F.3d 1330, 1339 (Fed. Cir. 2007), the Federal Circuit again concluded that MedImmune had effectively overruled the reasonable apprehension of suit test.

Although not required, "reasonable apprehension of suit" is still relevant. On Aug. 15, 2008, the Federal

Circuit clarified that "[w]hile the Supreme Court rejected the reasonable apprehension of suit test as the sole test for jurisdiction, it did not completely do away with the relevance of a reasonable apprehension of suit."

In fact, "proving a reasonable apprehension of suit is one of multiple ways that a declaratory judgment plaintiff can satisfy the more general all-the-circumstances test." Prasco LLC v. Medicis Pharm. Corp., Case No. 2007-1524 (Aug. 15, 2008).

All of the circumstances must be considered. Although an individual action may be insufficient for declaratory judgment jurisdiction, multiple actions considered as a whole may be sufficient.

In Teva, the Federal Circuit found that declaratory judgment jurisdiction existed when considering all the circumstances, but it emphasized that each circumstance on its own may not have been sufficient to warrant jurisdiction. Teva, 482 F.3d at 1339.

The Teva Court, along with considering the ANDA declaratory judgment provision and the purpose of the Hatch-Waxman Act, found the following circumstances relevant to declaratory judgment jurisdiction:

(1) Novartis listed its patents in the Orange Book and thus represented that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale" of a generic covered by the claims of the patents;

(2) Teva submitted an Abbreviated New Drug Applications (ANDA) certifying that it did not infringe Novartis' Orange Book patents or that the patents were invalid (establishing adverse interests);

(3) Novartis filed litigation against Teva regarding related patents.

Creating a barrier to the regulatory approval of a product that is necessary for marketing can lead to declaratory judgment. First in Teva and then in Caraco Pharms. Labs. Ltd. v. Forest Labs., 527 F.3d 1278, 1290 (Fed. Cir. 2008), the Federal Circuit found that regulatory actions are affirmative actions that can result in declaratory judgment jurisdiction.

Similar to the Teva case, in Caraco, Forest listed its patents in the FDA's Orange Book and Caraco submitted an ANDA. The Court explained that pursuant to the Hatch-Waxman Act, by listing its patents in the Orange Book, Forest effectively delayed Caraco's ANDA and thereby created "an independent barrier to the drug market that deprives Caraco of an economic opportunity to compete" that that "the creation of such barriers to compete satisfies the causation requirement of Article III standing."

Claiming a lack of intent to sue cannot avoid declaratory judgment jurisdiction. In SanDisk, the Court found that the patentee's claim that it "has absolutely no plan whatsoever to sue SanDisk" did "not moot the actual controversy created by its acts."

A few months later, in August, 2007, the Federal Circuit, in Sony Electronics, Inc. v. Guardian Media

Technologies Ltd., 497 F.3d 1271(Fed. Cir. 2007), again confirmed the new standard and found that letters written to alleged infringers that offered a license were sufficient affirmative action to establish declaratory judgment jurisdiction.

The Sony Court rejected the patentee's argument that the letters "were simply part of [it's] efforts to license its patents," Sony, 497 F.3d at 1282, and that it was "at all times willing to negotiate a business resolution to the dispute." Sony, 497 F.3d at 1286.

Going even further, in Caraco, the Federal Circuit held that even a covenant not to sue did not deny declaratory judgment jurisdiction where the covenant did not completely resolve the dispute between the parties.

In Caraco, Forest signed a covenant not to sue Caraco on its patent however it would not agree that the patent was invalid or Caraco did not infringe the patent.

Thus, the Court found, the independent barrier created by the Hatch-Waxman Act still existed, a controversy remained, and declaratory judgment jurisdiction was proper.

Marking a product with a patent number is not an affirmative action establishing declaratory judgment jurisdiction. In Prasco, the plaintiff based its claim of the declaratory judgment jurisdiction on (1) Medicis' marking of its products with the numbers of the four patents-in-suit and (2) an infringement suit brought in 2005 by Medicis against Prasco and another generic company concerning a different product and an unrelated patent.

The Federal Circuit held that this was insufficient for declaratory judgment jurisdiction because the "mere existence of a potentially adverse patent does not cause an injury nor create an imminent risk of an injury."

This is so because it is "a case or controversy must be based on a real and immediate injury or threat of future injury that is caused by the defendants."

While apprehension of suit is no longer required, some affirmative action is required to create a case or controversy. Marking a product with a patent number, pursuant to 35 U.S.C. § 287(a), even in combination with enforcing different patents on different products, was not sufficient affirmative action to create a case or controversy.

By reasonable extension, marking a product with an ® or © symbol is similarly insufficient, on its own, to warrant declaratory judgment.

Other litigation may be relevant to a determination of jurisdiction. As stated above, the Federal Circuit held in Prasco that filing litigation that enforced different patents on different products was not sufficient affirmative action to create a case or controversy.

However, in Teva, finding declaratory judgment jurisdiction, the Federal Circuit held that "related litigation involving the same technology and the same parties is relevant in determining whether a justiciable declaratory judgment controversy exists on other related patents."

While these cases may seem somewhat unpredictable, they appear to focus on several elements and provide that declaratory judgment standard requires that (1) a rights holder takes some sort of affirmative action that, (2) after considering all of the circumstances, (3) creates a real and immediate injury or threat of future injury because (4) the parties have adverse legal interests and (5) the controversy between the parties can be resolved by the Court.

Some of the opinions mention only some of these factors and some blend these factors, however, as a whole, they are the primary focus of the evolving declaratory judgment standard and by evaluating them, declaratory judgment jurisdiction is simplified.

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