Generics Still Unable to Resolve ANDA Patent Issues by Declaratory Judgment, But is Supreme Court Resolution on the Way?

The Supreme Court recently denied certiorari to review the Federal Circuit’s ruling in Apotex v. Pfizer (S. Ct. 906-1006, October 16, 2006). The ruling was predictable. Pfizer had mooted the case by providing a covenant not to sue Apotex on its Quinapril patent. But the underlying legal issue – subject matter jurisdiction in declaratory judgment cases – is currently pending before the Supreme Court in MedImmune v. Genentech (S. Ct. 05-608), which was argued on October 4, 2006.

Declaratory judgment cases, which are statutorily governed by 28 U.S.C. § 2201 (1988), are common in patent practice. In the usual instance, a patent owner writes a notice letter to a competitor, informing the competitor of the patent, of the potential infringement, and demanding cessation of the infringement. These notice letters, which have the effect of commencing damage liability for the infringer, can also create an “actual controversy” between the parties, and provide the basis for a declaratory judgment jurisdiction, thus permitting an alleged infringer to challenge the patent in a forum of its own choice.

The Federal Circuit, which has exclusive appellate jurisdiction over most patent disputes, has developed its own unique legal criteria for determining whether a patent holder’s threat is sufficiently real to confer to the federal courts subject matter jurisdiction under 28 U.S.C. § 2201. In Shell Oil Co. v. Amoco Corp., 970 F.2d 885 (Fed. Cir. 1992), the court recognized:

The test for determining whether an actual controversy exists in a patent case is two pronged. First, the defendant’s conduct must have created on the part of the plaintiff a reasonable apprehension that the defendant will initiate suit if the plaintiff continues the allegedly infringing activity. Second, the plaintiff must actually have either produced the device or have prepared to produce the device.

Id. at 888 n.2, citing Good Year Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 955 (Fed. Cir. 1987).

Both Apotex and the MedImmune involve unusual fact patterns for declaratory judgment cases. The facts in Apotex involve issues that arise in Hatch-Waxman litigation between innovative drug companies and generic drug companies where the innovative drug company’s product has patent protection. Under Hatch-Waxman, a generic company seeking to market a generic drug before

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1 The declaratory judgment act provides: “in a case of actual controversy within its jurisdiction...any court of the United States, upon filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.”


3 The innovative drug company identifies patents covering its product to the FDA which publishes these identified patents in the book entitled “Approved Drug Products with Therapeutic Equivalence Evaluations.”
any of the patents covering the product expire, can file an Abbreviated New Drug Application (ANDA) with the FDA that alleges that the patent or patents at issue are invalid and/or the drug product that the generic company seeks to have approved does not infringe, 21 U.S.C. § 355.

The filing of the ANDA starts a 45-day clock, and the innovative drug company must initiate patent litigation during that period or the FDA will begin the approval process for the generic product.4 The Hatch-Waxman patent litigation only resolves the patent validity and/or infringement issues – since the generic company has not yet commercialized any product, there are no damages. Any in-house drug development conducted by or on behalf of the generic company during the term of a patent in furtherance of filing with the FDA is statutorily exempt from damages and injunction under 35 U.S.C. § 271(e)(1).

In the past, innovative drug companies have been able to elect to delay bringing a suit against the generic and wait until the generic obtains FDA approval. Because the suit is not filed until after marketing, the innovative drug company can obtain additional recovery, namely damages, an injunction and the possibility of enhanced damages and attorney fees. 35 U.S.C. §§ 283, 284 and 285. However, Congress believed that allowing innovative drug companies to wait until the generic company had obtained approval was contrary to the purpose of the Hatch-Waxman, and therefore passed legislation in 2003 specifically permitting the generic companies to bring a declaratory judgment suit against the innovative company failing to initiate suit within the 45-day statutory window. 21 U.S.C. § 355(j)(5)(C)(i).5 Specifically, the new statute provides: “The district courts shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought…under Section 2201 of Title 28 for declaratory judgment that such patent is invalid or not infringed.”

However, the Federal Circuit has rendered this provision toothless. It has consistently held that, under Article III of the Constitution, there can be no justiciable case or controversy where the innovative drug company has declined to bring suit within the 45-day window. According to the Federal Circuit, the first prong of the declaratory judgment test has not been met – namely, the generic company lacks a “reasonable apprehension” that the innovative company will initiate suit. See, e.g., Teva Pharmaceuticals USA Inc. v. Pfizer, Inc. 395 F.3d 1324 (Fed. Cir. 2005) rehearing in banc denied, 405 F.3d 990 (Fed. Cir. 2005).

In denying jurisdiction in Teva, the Federal Circuit concluded:

We conclude that the plain language of the statute, as well as the legislative history, support the proposition that Congress did not intend for the Medicare Amendments to cause courts to alter the requirement of the two-part test that a declaratory judgment plaintiff must demonstrate a “reasonable apprehension” that the innovative company will initiate suit. See, e.g., Teva Pharmaceuticals USA Inc. v. Pfizer, Inc. 395 F.3d 1324 (Fed. Cir. 2005) rehearing in banc denied, 405 F.3d 990 (Fed. Cir. 2005).

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395 F.3d at 1337.


4 If the innovative drug company does bring an infringement action, the suit commences a 30-month stay during which the FDA cannot approve the ANDA unless the patent expires or the suit is resolved. 21 U.S.C. § 355(j)(2)(B)(i).

The \textit{Apotex v. Pfizer} case is factually similar to \textit{Teva v. Pfizer}, 405 F.3d 990 (Fed. Cir. 2005) and the Federal Circuit predictably held that it lacked jurisdiction to hear the case because there was no case or controversy between the parties within the meaning of Article III. Apotex sought review at the Supreme Court, but before the Supreme Court could consider Apotex's \textit{certiorari} petition, Pfizer mooted the dispute by giving Apotex a covenant not to sue on the patent at issue. The Supreme Court had no other choice than to refrain from considering the case.

The issue of declaratory judgment jurisdiction in patent cases may be decided by the Supreme Court this term. The \textit{Medimmune v. Genentech} appeal to the Supreme Court also involved a fact pattern unusual in a declaratory judgment case. There, Medimmune and Genentech had settled a patent infringement suit that involved the use of cell cultures to manufacture human antibodies, and Medimmune had taken a license under the Genentech patent. Thereafter, Medimmune sought to have the Genentech patent invalidated by filing a declaratory judgment in district court, but continued paying Genentech royalties as they became due. As in the ANDA cases, the Federal Circuit held that there was no case or controversy between the parties and hence, no declaratory judgment jurisdiction. The court reasoned that, as long as Medimmune continued to pay royalties, Medimmune had no reasonable apprehension that Genentech would bring suit.

The Supreme Court granted \textit{certiorari} in \textit{Medimmune}, and the case was argued on October 4, 2006.\footnote{The specific question presented in \textit{Medimmune} was: “Does Article III’s grant of jurisdiction of “all Cases…arising under…the Laws of the United States,” implemented in the “actual controversy” requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), require a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable or not infringed?”} Although the facts in \textit{Medimmune} are completely different from the ANDA cases, the legal issue before the court was jurisdictional standards under the declaratory judgment statute. In comments that might portend the outcome of the case, Justice Breyer noted he had thoroughly reviewed the case law and had failed to find precedent for the Federal Circuit’s “reasonable apprehension” requirement for jurisdiction under 28 U.S.C. § 2201. (See transcript of Oral Argument at 27-28). If Justice Breyer’s reasoning is adopted by the court, it is likely that the standard for jurisdiction under 28 U.S.C. § 2201 will be modified, and that ANDA filers may be able to pursue declaratory judgment cases against the innovative company that declines to bring suit within the 45-day window.

In the meanwhile, innovative drug companies can insulate weak patents from validity challenges by simply refusing to bring suit. Thus, the innovative drug companies can avoid having the courts interpret the scope of their patent protection, and frustrate a generic company’s attempts at inventing around the patented invention. Moreover, generic companies remain at a disadvantage while the declaratory judgment option is unavailable to them. With the declaratory judgment option unavailable, the generic who is not sued must market at risk to generate a dispute that rises to the level of a case or controversy under Article III, according to current Federal Circuit law. The generic faces the possibility of enhanced damages (due to willfulness), and of an injunction after going through the time and expense of marketing its generic product. Even more troubling is the situation where the innovative company that has listed multiple patents in the Orange Book elects to sue the generic on some of the patents within the 45-day window and delay suit on the remaining patents until the generic has launched its product. The generic in that instance is faced with the prospect of multiple litigations with the same innovative drug company on the same product.

The pending decision in \textit{Medimmune} also creates a current uncertainty for innovative drug companies not wanting to litigate one or more of their patents listed in the Orange Book. If \textit{Medimmune} broadly holds that declaratory judgment jurisdiction does not require imminent threat of suit, then the innovative drug company will realistically be forced to make the strategic
decision to either sue the generic company within the 45-day window or provide it with a covenant not to sue.

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