

No way out?

Barry E Bretschneider, Morrison and Foerster, reports on a Court of Appeals order which could create a legal limbo for generic pharmaceutical companies

At least one generic drug maker, Teva Pharmaceuticals, is feeling that there is no way out, with the full court refusal by the US Court of Appeals for the Federal Circuit last month to allow Teva's declaratory judgment action against Pfizer to proceed. In advance of its entry into the market with its version of Pfizer's popular anti-depressant ZOLOFT, Teva had tried to get judgment that its product did not infringe patents listed by Pfizer in the "Orange Book". The upshot of this decision is that owners of pharmaceutical patents embodied in products have a means of putting generic competitors in a legal limbo, with no clear way out of the dilemma of whether to proceed with generic drug marketing, simply by essentially doing nothing.

Teva filed an Abbreviated New Drug Application (ANDA) on its version of ZOLOFT antidepressant, including a "Paragraph IV certification" that either its generic version did not infringe Pfizer's '699 patent or the '699 patent was invalid. Under the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act, filing an ANDA with a Paragraph IV certification constitutes an act of patent infringement. Performing the acts necessary to prepare the ANDA, however, does not constitute infringement. If Pfizer had brought suit for patent infringement within 45 days of its receipt of Teva's Paragraph IV certification, the Food and Drug Administration (FDA) would have imposed a 30-month stay, during which it could not approve Teva's ANDA unless the suit was resolved or the patent expired, but Pfizer did not. After the passage of the 45-day period, Pfizer still had the option of suing Teva for infringement, but without the benefits of the stay. Since Teva wanted to lift the cloud of Pfizer's patent from its marketing plans, it sued Pfizer for a declaratory judgment of non-infringement and invalidity of the '699 patent.

The district court dismissed the action on the ground that Teva had failed to demonstrate the existence of the "case or controversy" necessary to establish jurisdiction in federal court. The Federal Circuit panel affirmed. The full court subsequently denied rehearing, leaving the district court's dismissal in place. Three judges dissented from the denial of rehearing, two of them writing opinions.

The court's rationale for denying Teva its chance to challenge Pfizer's patent was that Teva did not have a "reasonable apprehension" that Pfizer would sue it for patent infringement for Teva's ANDA filing, even though Pfizer had listed the '699 patent in the Orange Book, had announced its intention to assert the patent aggressively and had even sued another generic drug company, Ivax, with which Pfizer later settled. The Federal Circuit majority found that although Teva had established the second prong of the two-prong test for establishing the existence of an actual controversy, that there was present activity by Teva that could constitute patent infringement, the Paragraph IV certification, Teva had not shown "an explicit threat or other action by the patentee" which would reasonably have led Teva to believe Pfizer would sue imminently. The court dismissed Teva's arguments that Pfizer had already refused to grant Teva a covenant not to sue and that Pfizer had a history of asserting patents as not being immediate enough to lead Teva reasonably to believe it might be sued for infringement of the '699 patent.

In 2003, amendments to the Medicare law came into effect that purported to grant an ANDA filer making a Paragraph IV certification the right to bring a declaratory judgment action "consistent with the Constitution" if the patentee did not sue during the initial 45-day period. Although the court found these amendments to be applicable to this case, it found that the amendments did not create jurisdiction in the absence of a case or controversy.

The impact of this decision is to put generic drug makers in a position that the US Congress did not intend in the Medicare amendments; in the conference

The case

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report the congressional conferees stated their expectation that the courts would find jurisdiction, where appropriate, and act to prevent improper delays in infringement litigation between generic drug manufacturers and pioneer drug companies.

The generic drug industry will argue that the court's reasoning that the Medicare amendments did nothing to change the reasonable apprehension analysis renders the amendments meaningless and deprives the generic drug companies of the ability to remove patent clouds where the pioneer drug companies choose, for tactical reasons, not to bring suit in the face of a Paragraph IV certification. They will also argue that the court's decision flies in the face of reality and the purpose of declaratory judgment actions: Pfizer, for example, refrained from suing not because it thought Teva was not infringing but simply to keep Teva in permanent apprehension of suit and to stunt its marketing of its version of Pfizer's drug.

Counterbalanced against the generics is the argument, with which the Federal Circuit agreed, that patentees have the right to sue or not, as they choose, and that refusing to sue under the circumstances presented by Teva attracts little attention in other, less-regulated industries. To accept Teva's position would put a pioneer drug company under a compulsion to sue once it receives a Paragraph IV certification. 

About the author

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The information in the article reflects the author's opinions.