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Recent Litigation Puts Hatch-Waxman Act Amendments Regarding Declaratory Judgments to the Test

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As part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (2003 Medicare Amendments), Congress amended the Hatch-Waxman Act to allow an Abbreviated New Drug Application (ANDA) applicant to bring a civil action for declaratory judgment that a patent claiming the applicant's intended drug product is invalid or would not be infringed by the ANDA applicant's drug product. Under this arrangement, the ANDA applicant is able to seek declaratory judgment if the patentee does not bring an infringement action within 45 days of receiving a certification by the applicant that the patent is invalid or would not be infringed (a paragraph IV certification). The 2003 Medicare Amendments provide that the courts of the United States have subject-matter jurisdiction in any action brought for a declaratory judgment that the patent is invalid or not infringed, "to the extent consistent with the Constitution."

Under the Declaratory Judgment Act, a federal court has jurisdiction over a declaratory judgment action only if an actual controversy exists between the parties of the action. The two-part test for determining whether an actual controversy exists in a declaratory judgment of patent noninfringement or invalidity requires a finding of, (1) an explicit threat or other action by the patentee that 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 that could constitute infringement, or concrete steps taken by the declaratory judgment plaintiff with the intent to conduct such activity.

Teva Pharmaceuticals USA, Inc. v. Pfizer Inc.

In the recent case of *Teva Pharmaceuticals USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, (Fed. Cir. 2005), *reh'g en banc denied*, No. 04-1186, 2005 WL 834618 (Fed. Cir. Apr. 4, 2005), Teva filed an ANDA seeking FDA approval to market a generic version of Pfizer's Zoloft®. The ANDA was accompanied by a paragraph IV certification that Pfizer's patent was invalid or would not be infringed by Teva's drug product. Pfizer did not sue Teva for patent infringement within 45 days of receipt of the paragraph IV certification.

Teva then sought a declaratory judgment that Pfizer's patent was invalid or not infringed by Teva's generic drug product. With respect to the first prong of the declaratory judgment test, Teva asserted

that Pfizer had created a reasonable apprehension of suit by: (1) listing the 699 patent in the Orange Book; (2) refusing to grant Teva a covenant not to sue; (3) aggressively asserting its patent rights against alleged infringers of other patents; (4) suing Ivax Pharmaceuticals, the first generic manufacturer of Zoloft® to file an ANDA with a paragraph IV certification for the patent; and (5) leaving a "cloud of litigation" hanging over Teva with respect to generic Zoloft®.

Teva also asserted that the 2003 Medicare Amendments established jurisdiction without requiring that Teva have a "reasonable apprehension of suit," the first requirement in the two-prong test for declaratory judgments.

In turn, Pfizer requested that the suit be dismissed for lack of subject-matter jurisdiction.

According to the Federal Circuit, § 271(e)(2) provides that a generic drug manufacturer infringes a patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent. Since Teva had filed an ANDA accompanied by a paragraph IV certification, the Federal Court held that Teva met the second prong of the declaratory judgment test.

However, with respect to the first part of the test, the Federal Circuit held that listing a patent in the Orange Book is a statutory requirement and should not be construed as evidence of intent by Pfizer to sue any ANDA applicant who submits a paragraph IV certification with respect to the patent. The Federal Circuit agreed that Pfizer's history of defending its patents and its refusal to grant Teva a covenant not to sue was relevant to the issue of reasonable apprehension of suit, but stated that the facts were not dispositive and instead must be considered as part of the "totality of the circumstances."

Additionally, the Federal Circuit held that under Article III of the Constitution, Teva was required to show that it had a reasonable apprehension of an imminent suit. To this end, Teva virtually conceded that Pfizer would not file a lawsuit against them because Pfizer had entered into a settlement agreement with Ivax to grant Ivax a royalty-bearing license on the patent until it expired. As the first generic manufacturer of Zoloft® to file an ANDA, Ivax was entitled to a 180-day generic market exclusivity period. A suit against Teva could potentially trigger Ivax's 180-day exclusivity period before Ivax would be in a position to begin commercial marketing of generic Zoloft®. Such a result would jeopardize Pfizer's potential royalties for generic Zoloft®.

With respect to the 2003 Medicare Amendments, the Federal Circuit held that the amendments did not change the requirements for subject-matter jurisdiction for declaratory judgments under the Hatch-Waxman Act because the 2003 Medicare Amendments specifically stated that declaratory judgments could be brought "consistent with the Constitution."

Ultimately, the Federal Circuit dismissed the suit, holding that Teva had not satisfied the first prong of the declaratory judgment test.

Conclusion

The 2003 Medicare Amendments to the Hatch-Waxman Act did not change the requirements set forth in Article III of the Constitution for establishing subject matter jurisdiction over the courts in

declaratory judgment actions. As a result of *Teva*, innovative drug companies will not be subject to declaratory judgment jurisdiction merely by not filing a patent infringement lawsuit against an ANDA applicant within 45 days of the ANDA applicant's filing of a paragraph IV certification.

For more information on this or other intellectual property matters, contact either of the authors listed above.