



Jan 17, 2023

Categories:

[Gibbons](#)

[Patent](#)

Authors:

[Charles H. Chevalier](#)

[Christine A. Gaddis](#)

Southern District of Florida Dismisses Patent Infringement Claims for Generalized Allegations and Declaratory Judgment Claims for Lack of Sufficient Immediacy

In *Scilex Pharmaceuticals Inc. v. Aveva Drug Delivery Systems, Inc., Apotex Corp., and Apotex Inc.*, the United States District Court for the Southern District of Florida recently granted defendant Apotex, Inc.'s ("Apotex") motion to dismiss various counts of the complaint. The case is a Hatch-Waxman litigation involving patents covering plaintiff Scilex Pharmaceuticals Inc.'s ("Scilex") topical lidocaine patch ZTlido® and an ANDA that was filed by defendant Aveva Drug Delivery Inc. ("Aveva"). Apotex's motion was based on three different grounds: (1) Rule 12(b)(2) for lack of personal jurisdiction; (2) Rule 12(b)(6) for the patent infringement counts of the complaint because Apotex was not the party that submitted the ANDA; and (3) Rules 12(b)(6) and 12(b)(1) of the declaratory judgment claims because Apotex did not submit the ANDA and/or because there was no immediacy to the controversy on claims for future infringement. See *Reckitt Benkiser Inc. v. Watson Labs., Inc.-Fla.*, No. 09-60609, 2009 WL 10667836, at *2 (S.D. Fla. Oct. 13, 2009) ("The mere filing of a Paragraph IV certification constitutes an act of patent infringement . . .").

With respect to the first two grounds, the district court granted Apotex's motion, but granted Scilex leave to amend the complaint with respect to the patent infringement claims. Apotex argued that the claims in the case were based on Aveva's ANDA and Notice Letter to Scilex, and that Scilex made general, conclusory allegations in the complaint that all of the defendants had "acted in 'concert.'" The district court agreed with Apotex, finding that the complaint did not sufficiently allege that Apotex was "actively involved in the preparation of the ANDA" and did not specifically set forth Apotex's role in the ANDA submission process. The district court also cited

the “on information and belief” allegations and that the complaint lumped all of the defendants together, rather than making individual allegations with respect to each individual defendant’s role. The district court did conclude, though, that Scilex could sufficiently allege that Apotex participated in the preparation of the ANDA and stood to benefit from the FDA’s approval, which would establish a *prima facie* case of specific personal jurisdiction over Apotex and patent infringement pursuant to Section 271(e)(2) –and thus granted Scilex leave to amend its complaint. The opinion highlights that a plaintiff should specifically address each defendant’s role in the preparation of, filing of, and/or benefit from an ANDA submission in a complaint.

With respect to the portion of the motion seeking to dismiss the declaratory judgment claims, the district court granted Apotex’s motion without leave for Scilex to amend. The court concluded that the controversy lacked “sufficient immediacy” because the acts of alleged future infringement were also dependent on two future events: (1) FDA approval of the ANDA; and (2) the defendants’ decision to market the ANDA product. The district court did note that “not all courts are in agreement as to this issue.” *Id.* at *13. At least one case in the District of New Jersey, considering similar facts, has found the controversy in a Hatch–Waxman litigation to be sufficiently immediate to support the court’s jurisdiction of a declaratory judgment claim. See *Abraxis Bioscience, Inc. v. Navinta LLC*, No. 07–1251, 2007 WL 7708588 (D.N.J. Oct. 9, 2007). Thus, a plaintiff might have more success in making a similar declaratory judgment claim in the District of New Jersey as compared to the Southern District of Florida.

Gibbons will continue to monitor and report developments in Hatch–Waxman litigation.

© 2026 FBT Gibbons LLP. May be considered attorney advertising in some jurisdictions.