NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 13-3981

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ENDO PHARMACEUTICALS INC.,

Appellant

v.

ACTAVIS INC.; ACTAVIS SOUTH ATLANTIC LLC,

_____

No. 13-4096

_____

ENDO PHARMACEUTICALS INC.,

v.

ACTAVIS INC.; ACTAVIS SOUTH ATLANTIC LLC,

Appellants

_____

Appeal from the United States District Court
for the District of New Jersey
(No. 2-12-cv-07591)
District Judge: Hon. Dennis M. Cavanaugh

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Submitted Pursuant to Third Circuit LAR 34.1(a)
November 21, 2014

Before: CHAGARES, HARDIMAN, and SHWARTZ, Circuit Judges.

(Filed: December 5, 2014)

OPINION*

CHAGARES, Circuit Judge.

Plaintiff Endo Pharmaceuticals Inc. appeals the District Court's September 3, 2013 order granting Defendants Actavis, Inc. and Actavis South Atlantic LLC's (together, "Actavis") motion to dismiss the Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons that follow, we will vacate the District Court's order and remand the case to the District Court.

I.

We write solely for the parties and therefore recite only the facts that are necessary to our disposition. Endo developed and marketed the pain reliever Opana® ER and its alternate, crush-resistant formula (which also bears the name Opana® ER). Appendix ("App.") 26–27. Actavis sold a generic version of Opana® ER. That generic was "AB rated" to the original Opana® ER by the FDA, meaning the FDA approved it as bioequivalent to the brand-name drug. See App. 32, 573–74. Actavis's generic was not AB rated to the newer, crush-resistant formula. App. 33. In May 2012, Endo voluntarily discontinued the original Opana® ER, leaving the crush-resistant formula the only Opana® ER on the market. App. 31. Actavis, however, continued to market its generic as "AB Rated to Opana® ER." App. 34. In August 2012, Endo filed a petition with the

* This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

FDA seeking a determination that it had withdrawn Opana® ER from the market for safety reasons. App. 188. Endo requested that the FDA refuse to approve any pending applications for generic versions of the original Opana® ER and withdraw approval of any formerly-approved generics, like Actavis's. Id. Then, in December 2012, Endo filed suit against Actavis in United States District Court for the District of New Jersey, bringing federal and state law claims for false advertising and unfair competition.

The District Court dismissed Endo's Complaint without prejudice pursuant to Rule 12(b)(6), citing the doctrine of primary jurisdiction. App. 4–5. It reasoned that although the action was otherwise within its jurisdiction, Endo's claims required a fact determination — "whether Actavis's generic is still AB equivalent to Opana® ER" — that was best left to the FDA in the first instance. App. 4. Endo appealed.

After briefing in the District Court was complete, the FDA issued a ruling on Endo's petition. It determined that the original Opana® ER was not withdrawn for reasons of safety or effectiveness. 78 Fed. Reg. 38053-01. Accordingly, the FDA would not withdraw approval of generics related to the original Opana® ER and would continue to approve new generics so long as they met all other legal and regulatory requirements. Id.

II.

The District Court had subject matter jurisdiction over the Lanham Act Claim pursuant to 15 U.S.C. § 1121 and 28 U.S.C. § 1331. It had supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367. This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

We review a district court's decision to abstain on primary jurisdiction grounds for abuse of discretion. Baykeeper v. NL Indus., Inc., 660 F.3d 686, 690 (3d Cir. 2011); P.R. Mar. Shipping Auth. v. Valley Freight Sys., 856 F.2d 546, 549 (3d Cir. 1988). But the District Court's analysis of the law of abstention is subject to de novo review. Baykeeper, 660 F.3d at 690.

III.

The doctrine of primary jurisdiction applies where a claim is originally cognizable in the courts[1] but "enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." United States v. W. Pac. R.R. Co., 352 U.S. 59, 64 (1956). "[I]n such a case the judicial process is suspended pending referral of such issues to the administrative body for its views." Id. "No fixed formula exists for applying the doctrine," id., but we have previously focused our analysis on four factors:

> (1) Whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) Whether the question at issue is particularly within the agency's discretion; (3) Whether there exists a substantial danger of inconsistent rulings; and (4) Whether a prior application to the agency has been made.

Baykeeper, 660 F.3d at 691.

The District Court applied the doctrine of primary jurisdiction because it believed that the FDA had special competence to determine "whether Actavis's generic is still AB

[1] Actavis argues that Endo's claims are not in fact cognizable in federal court. We need not decide that issue, however, because the District Court's decision will be vacated and remanded on other grounds.

equivalent to Opana® ER." App. 4. It noted that Endo had already made an application to the FDA on this issue. App. 5.

Endo argues that the District Court's application of the primary jurisdiction doctrine was misguided because the fact question at issue in the case was not whether Actavis's generic was biochemically equivalent to Opana® ER — a determination committed to the FDA's special competence — but whether it had been approved as AB rated to Opana® ER, a question the District Court could answer by consulting the FDA's catalog of generics listed for Opana® ER. Put another way, the District Court had to answer the history question, not the science one. And because the FDA has approved no drugs as AB rated to crush-resistant Opana® ER, Endo argues the history question is a simple one.

In its focus on the absence of AB-rated generics to crush-resistant Opana® ER, Endo overlooks the possibility that the District Court would be interested in the continued effectiveness of an AB rating to the original, discontinued Opana® ER. But that is the import of the District Court's primary jurisdiction ruling. Before considering whether Actavis engaged in false advertising by marketing its generic as AB rated to Opana® ER, the District Court sensibly wanted to know whether approval for Actavis's generic would be withdrawn as a result of Endo's petition to the FDA. This has some bearing on whether Actavis can fairly describe its drug as AB rated to Opana® ER.

Now that the FDA has issued its determination, however, the District Court's rationale for applying the primary jurisdiction doctrine is moot. The logical course is to remand for the District Court to address the remaining arguments in the first instance.

See Bass v. Butler, 258 F.3d 176, 179–80 (3d Cir. 2001) (remanding to the district court because subsequent developments had rendered the district court's rationale for abstention moot).

IV.

For the foregoing reasons, we will vacate the District Court's September 3, 2013 order and remand for further proceedings.