Case Nos. 13-3981; 13-4096

United States Court of Appeals
for the
Third Circuit

ENDO PHARMACEUTICALS INC.,

Plaintiff-Appellant/Cross-Appellee,

– v. –

ACTAVIS, INC., and
ACTAVIS SOUTH ATLANTIC LLC,

Defendants-Appellees/Cross-Appellants.

Appeal from the United States District Court
for the District of New Jersey in case no. 12-cv-7591

BRIEF OF DEFENDANTS-APPELLEES ACTAVIS, INC., AND ACTAVIS SOUTH ATLANTIC LLC

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Third Circuit LAR 26.1, Appellees Actavis, Inc., and Actavis South Atlantic LLC make the following disclosure:

1) For non-governmental corporate parties please list all parent corporations:

Actavis plc

2) For non-governmental corporate parties please list all publicly held companies that hold 10% or more of the party's stock:

Actavis plc

3) If there is a publicly held corporation which is not a party to the proceeding before this Court but which has a financial interest in the outcome of the proceeding, please identify all such parties and specify the nature of the financial interest or interests:

Actavis plc (ultimate parent corporation, publicly traded, of the named Appellees)

4) In all bankruptcy appeals counsel for the debtor or trustee of the bankruptcy estate must list: 1) the debtor, if not identified in the case caption; 2) the members of the creditors' committee or the top 20 unsecured creditors; and, 3) any entity not named in the caption which is an active participant in the bankruptcy proceeding. If the debtor or trustee is not participating in the appeal, this information must be provided by appellant.

N/A

s/ Charles A. Weiss Dated: 7/30/2014

Attorney for Appellees
Actavis, Inc., and Actavis South Atlantic LLC

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JURISDICTIONAL STATEMENT

Endo Pharmaceuticals Inc. ("Endo") filed this suit against Actavis, Inc., and Actavis South Atlantic LLC (collectively "Actavis") under the Lanham Act and New Jersey law. The district court had jurisdiction pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331, 1367.

On September 3, 2013, the district court entered an opinion and a separate order dismissing Endo's suit without prejudice. A1-A6. Endo timely filed a notice of appeal on September 27, 2013, and Actavis timely filed a notice of cross-appeal on October 10, 2013. A7-A12; *see* Fed. R. App. P. 4(a)(1), (3).

As further discussed in its letter brief of October 31, 2013, Actavis agrees with Endo that this Court has jurisdiction pursuant to 28 U.S.C. § 1291. A dismissal of a claim "without prejudice" is treated as a final, appealable decision when the plaintiff cannot cure the defect in its complaint. *Mitchell v. Horn*, 318 F.3d 523, 528 (3d Cir. 2003). That is the case here. The district court recognized that Endo's suit is barred because it depends on an interpretation of FDA rules that the FDA has not adopted. Endo cannot amend its complaint to cure that defect.

ISSUES PRESENTED

1. Whether adjudication of Endo's false advertising suit—which is premised on Endo's assertion that the description of Actavis's generic extended-release oxymorphone tablets as "AB rated to Opana ER" is false, even though the FDA approved the Actavis product as AB rated to Opana ER and has not withdrawn its approval or modified the AB rating—would improperly interfere with the FDA's authority to interpret and enforce its own rules. Actavis raised this issue below, A300-A307, Endo responded, A516-A521, and the district court addressed it in dismissing Endo's complaint, A3-A5.

2. Whether Endo's suit should be dismissed for the independent reason that Actavis did not make a false statement by describing its generic as AB rated to Opana ER, when the FDA undisputedly approved the Actavis product as AB rated to Opana ER and neither withdrew its approval nor changed the product's AB rating. Actavis raised this issue below, A308, Endo responded, A516, but the district court did not reach it.

3. Whether Endo's suit fails for the additional independent reason that, even under Endo's theory of the case, the statement Endo complains of did not become false until after Endo stopped marketing the original formulation of Opana ER in May 2012, but Endo failed to make adequate allegations or present admissible

evidence that Actavis used advertisements containing that statement after May 2012. Actavis raised this issue below as a basis both for dismissing Endo's complaint under Rule 12(b)(6) and as a ground for summary judgment. A549-A550; A571, A578-A580, A585. Endo responded. A759, A766-A767. The district court did not reach the issue.

4. Whether the district court erred by dismissing Endo's complaint without prejudice rather than with prejudice, *see* A5, when the defect in Endo's suit is not that it is premature, but that it fails to state a cognizable claim for relief. Actavis moved below to dismiss Endo's complaint with prejudice. A310.

STATEMENT OF RELATED CASES

This case has not previously been before this Court. Actavis agrees with Endo that the issues presented in the two patent infringement suits between the parties pending in the United States District Court for the Southern District of New York raise separate and distinct issues from those raised by this appeal. *See* Blue Br. at 5. Actavis is not aware of any other case or proceeding in any way related to this appeal.

STATEMENT OF THE CASE

The entirety of Endo's claims rest on the statement in Actavis literature that its generic extended-release oxymorphone tablets are "AB Rated to Opana® ER." A34. Endo does not dispute that (i) the FDA approved the Actavis product as AB rated to Opana ER in 2010, and (ii) the statement was true when the materials were printed in 2011. Endo's claim is that its subsequent decision to stop selling that formulation of Opana ER, in favor of a new version Endo calls "Opana ER with Intac," somehow deprives the Actavis product of the AB rating conferred by the FDA. But neither Congress nor the FDA have delegated to private parties like Endo the ability to change the regulatory status of their competitors' products. And despite Endo's vigorous attempts to compel or persuade the FDA to take the actions Endo desires, the FDA has declined to rescind its approval of the Actavis product and has not changed its AB rating.

Endo's attempt in this case to enforce regulations and procedures administered by the FDA is precluded under binding Circuit precedent. Claims of false advertising under the Lanham Act cannot be used to enforce regulatory standards established and administered by the FDA under the Food, Drug & Cosmetic Act, which does not provide a private right of action for alleged violations. *See Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990). For this reason, the district court correctly dismissed Endo's suit.

In the alternative, the judgment should be affirmed because the complained-of statements by Actavis were not false. Viewed most charitably to Endo, with a degree of indulgence even more favorable than required on a motion to dismiss, those statements set forth a permissible interpretation of how an AB rating awarded by the FDA is (or is not) affected on the unusual facts of this case. These facts include (i) Endo's unilateral decision to stop making its approved product called Opana ER in favor of a therapeutically equivalent product (protected by new patents) also called Opana ER, and (ii) the FDA's rejection of Endo's Citizen Petition seeking a ruling that would compel the withdrawal of already-approved generics such as the Actavis product.

Another, independent ground for affirmance is that, even under Endo's theory of the case, Actavis's advertisements were not false before June 2012, when Endo had exhausted its inventory of Opana ER and switched over completely to Opana ER with Intac. Even though Endo sought a preliminary injunction and moved for summary judgment, it did not present any admissible evidence that Actavis used those advertisements after that date.

I. Statutory and Regulatory Framework

The Food, Drug, and Cosmetic Act ("FD&C Act" or "Act"), 21 U.S.C. § 301 *et seq.*, establishes a "comprehensive scheme regulating the manufacture, sale, and importation of prescription drugs." *United States v. Genendo Pharm.*,

N.V., 485 F.3d 958, 960 (7th Cir. 2007). At the center of this regulatory scheme is the FDA, to which Congress has delegated the authority for approving and regulating drugs, including the labeling and promotion of drugs. *See Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223, 236 (3d Cir. 2013) (citing 21 U.S.C. §§ 355, 393); *see also* 21 U.S.C. § 352. Congress has also chosen to limit enforcement authority under the Act to the Government, or in a few circumstances to the States. *See* 21 U.S.C. § 337(a) ("Except as provided in subsection (b) of this section [relating to enforcement actions by States], all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). Thus, it is "well settled" that the FD&C Act creates no private right of action. *In re Orthopedic Bone Screw Prods. Liability Litig.*, 193 F.3d 781, 788 (3d Cir. 1999).

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, which amended the FD&C Act to "strike a balance between incentives, on the one hand, for innovation, and on the other, for quickly getting lower-cost generic drugs to market." *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005). The Hatch-Waxman Act provides that pharmaceutical companies seeking approval of a generic drug do not have to repeat the safety and efficacy studies that supported FDA approval of the original branded product. Because safety and

efficacy have already been established to the FDA's satisfaction, as shown by its approval of the brand, the applicant for a generic product may instead show that its generic is equivalent to the brand in all pertinent respects. This showing is made in an Abbreviated New Drug Application (ANDA), which in part must demonstrate that the proposed generic is bioequivalent to a reference listed drug (RLD), typically a brand-name drug that the FDA previously approved. *See* 21 U.S.C. § 355(j); 21 C.F.R. §§ 314.3, 314.94; *see also PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 & n.2 (2011).

The FD&C Act also requires the FDA to publish a list of all approved drugs. *See* 21 U.S.C. § 355(j)(7). Officially entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," this publication is commonly known as the Orange Book. A62; *see also* 78 Fed. Reg. 38053-01 (June 25, 2013). The Orange Book is the source of the term "AB rated." When the FDA approves a generic drug as the bioequivalent of an RLD, it assigns the appropriate therapeutic equivalence code. In the case of bioequivalent oral products like those at issue here, it is the AB code. A68, A71-A73; *see also* A32 ¶ 49 (Endo's complaint).

"AB" is not an abbreviation or acronym, nor is it defined in the FD&C Act. The term is defined solely and exclusively by the FDA. As explained in the Orange Book, the FDA's assignment of an AB rating indicates that it has approved the generic as bioequivalent to, and therefore the therapeutic equivalent of, the

RLD. *See* A66 ("A major premise underlying the 1984 law [Hatch-Waxman Act] is that bioequivalent drug products are therapeutically equivalent, and therefore, interchangeable."); *see also* A68, A71-A73.

The Orange Book also includes a "Discontinued Drug Product List" that "delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness." A95 (76 Fed. Reg. 53909 (Aug. 30, 2011)) (emphasis added); *see also* A81 (Orange Book). If a company voluntarily stops marketing a brand-name RLD, as for example in the case of an old drug with many generic competitors and few remaining branded sales, it is moved to the "Discontinued Drug Product List" of the Orange Book. *See id*. By contrast, if the FDA determines that a drug was discontinued for reasons of safety or efficacy, the FDA will remove it from the Orange Book entirely. 21 C.F.R. § 314.162.

A manufacturer's voluntary decision to stop selling an RLD, and the FDA's ministerial act of moving it to the Discontinued Product section of the Orange Book, has no effect on existing generics that were approved based on that RLD. It is only if the FDA determines that the RLD was discontinued for reasons of safety or effectiveness that the FDA may seek to withdraw approval of the corresponding generics. *See* 21 U.S.C. § 355(e); 21 C.F.R. §§ 314.153(b), 314.161; A94-95 (76 Fed. Reg. 53908, 53909); 78 Fed. Reg. 38053-01 (June 25, 2013); *see also* Donald

O. Beers, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements* § 3.02[B][1] (7th ed. 2008) (discussing procedures for withdrawal of approval).

II. Facts and Procedural History

A. The Introduction of Opana ER, Actavis's Generic Tablets, and Opana ER with Intac

In June 2006, the FDA approved Endo's New Drug Application (NDA) for extended release oxymorphone under the brand name Opana ER. A26 (Endo's complaint).

In 2008, Actavis filed an ANDA seeking approval for a generic version of Opana ER. A33 (Endo's complaint). The Actavis ANDA contained a paragraph IV certification, stating that Endo's patents for Opana ER were invalid, unenforceable, or would not be infringed by the proposed generic. A87 (FDA letter). Endo sued Actavis for patent infringement. In 2009, the parties settled, with Endo granting Actavis a license to sell its generic. A33 (Endo's complaint).

The FDA approved Actavis's ANDA for the 7.5 mg and 15 mg strengths of its generic version of Opana ER in December 2010. A86-A92. It is undisputed that the FDA approved Actavis's generic as AB rated to Opana ER, *i.e.*, the FDA determined it was therapeutically equivalent to Opana ER. *See* A27 ¶ 32, A32 ¶ 49 (Endo's complaint). As the FDA wrote in its letter approving the ANDA:

> The Division of Bioequivalence has determined your Oxymorphone Hydrochloride Extended-release Tablets 7.5 mg, and 15 mg, to be

> bioequivalent and, therefore, therapeutically equivalent to the RLD . . . Endo's Opana ER Tablets, 7.5 mg, and 15 mg.

A87. Under the license granted by Endo in settlement of the patent suit, Actavis began selling its generic tablets in July 2011. A84 (Actavis press release).[1]

Meanwhile, Endo had decided to apply for FDA approval of a new formulation of extended-release oxymorphone. This time, Endo was not required to conduct new clinical trials to establish safety and efficacy. Instead, Endo obtained approval simply by showing that the new formulation was bioequivalent to Opana ER, A99, A102, which is the same showing that Actavis had made previously to obtain approval of its generic. Endo received approval from the FDA in December 2011. A30 (Endo's complaint). This product is allegedly a crush-resistant formulation, and has thus been referred to in this litigation as Opana ER CRF. In public usage, however, Endo distinguishes its new formulation by using the name "Opana ER with Intac." A155 (page from Endo's website).

Endo's claim that the crush resistance of Opana ER with Intac is necessary to deter abuse, A27-A29 (complaint), has been soundly rejected by the FDA for lack of evidence, and the FDA rejected Endo's request to include label claims of abuse-deterrence. A264, A269, A274 (FDA brief in response to Endo's suit

[1] The FDA also tentatively approved the other strengths of Actavis's generic, pending exhaustion of the 180-day exclusivity period for a different generic applicant, Impax, which was the first-filer of an ANDA for those other generic strengths. *See* A90.

against the FDA, discussed *infra* pp. 12-13). Thus, the FDA-approved labels of Opana ER, the Actavis generic, and Opana ER with Intac are materially identical. A107-A154; A156-A186.

B. Although Endo Continues Selling the Original Formulation of Opana ER for Several Months After Approval of Opana ER with Intac, It Eventually Stops Marketing It, Represents to the FDA that It Had Withdrawn It for Safety Reasons, and Sues the FDA in a Failed Effort to Block the Generics

Despite its stated concern that Opana ER was subject to abuse, Endo continued to manufacture it for two months after it received approval for Opana ER with Intac. A30 (complaint). Nor did Endo stop distributing Opana ER once it began selling Opana ER with Intac. Not until May 31, 2012—six months after it received approval of Opana ER with Intac—did Endo write the FDA stating that it had finally stopped selling the original formulation. A30-A31.

Remarkably, although Endo had for months continued selling the original Opana ER, and did not recall product in the hands of distributors and pharmacies, it then represented to the FDA that it had stopped selling Opana ER for safety reasons. *See* A31. Endo further filed a Citizen Petition with the FDA seeking that determination. A188; *see also* 21 C.F.R. §§ 10.25(a), 10.30, 314.161(a)(3). In that filing, Endo also demanded that the FDA withdraw approval of the generics, such as Actavis's product:

> Upon determining that Opana® ER was discontinued for safety reasons, FDA should refuse to approve any pending ANDA for a

> generic version of the drug and promptly move to suspend and withdraw the approval of any ANDA referencing Opana® ER (NDA No. 021610) as the RLD.

A197.

Although the FDA had nine months (270 days) to act on Endo's Citizen Petition, 21 U.S.C. § 355(w), Endo sued the FDA in the District of Columbia less than four months later, seeking a preliminary injunction compelling the FDA to take immediate action on its petition. A229.

The FDA responded with a motion to dismiss, stating in part that "Endo's professed concerns for the public safety cannot be squared with its conduct." A276. Pointing to Endo's continued sales of the original product, the FDA wrote: "Tellingly, when Endo introduced the new Opana ER formulation in December 2011, it did not recall the old formulation from the market." *Id*. Moreover, "Endo did not recall any product that was already in the distribution channel as of May 31, 2012, despite Endo's now-professed safety concerns with the old formulation." A264; *see also* A269.

The FDA also found that Endo's claim of improved safety for Opana ER with Intac was unsubstantiated, concluding that Endo had not been "able to provide FDA with sufficient data to support labeling on abuse-deterrence for the new formulation." A264. Because Endo failed to demonstrate any safety advantage for Opana ER with Intac, "Endo's approved labeling for the new formulation contains

no suggestion that the new product reduces the potential for abuse." A269; *see also* A274. "Indeed, the 'abuse potential' sections of the old and new labeling are identical." A269.

The district court in Washington granted the FDA's motion to dismiss. A659. Endo did not appeal.

C. The FDA Denies Endo's Citizen Petition and Refuses to Withdraw Approval of the Generics

After briefing in the district court in this case had been completed, the FDA acted on Endo's Citizen Petition and denied all relief. In part, the FDA determined that the original formulation of Opana ER was "not withdrawn from sale for reasons of safety or effectiveness." 78 Fed. Reg. 38053-01 (June 25, 2013).

In its response to Endo's Citizen Petition, the FDA expressly "disagree[d] with Endo's conclusions" about the alleged safety advantages of Opana ER with Intac. Response to Citizen Petition at 5 (May 10, 2013), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0895-0014.[2] The FDA explained that, although Opana ER with Intac had an increased ability to resist crushing, "data from in vitro and pharmacokinetic studies show that [Opana ER with Intac's] extended-release features can be compromised, causing the product to 'dose dump' when subjected to other forms of manipulation such as

[2] In its response to Endo's Citizen Petition, the FDA referred to the original formulation of Opana ER as "OP" and to Opana ER with Intac as "OPR." *See id.* at 2.

cutting, grinding, or chewing, followed by swallowing." *Id*. The FDA further found that it "appears that [Opana ER with Intac] can be prepared for insufflation (snorting) using commonly available tools and methods." *Id*. at 6.

The FDA concluded, contrary to Endo's contentions, that Opana ER with Intac "can be readily prepared for injection," and that "certain data suggest that [Opana ER with Intac] can be more easily prepared for injection than [Opana ER]." *Id*. Indeed, one of the postmarketing investigations cited by Endo "suggests the troubling possibility that a higher (and rising) percentage of [Opana ER with Intac] abuse is occurring via injection than was the case with [Opana ER]." *Id*. at 6 n.21. Abuse by injection "is highly dangerous, and injection of [Opana ER with Intac] in particular has been associated with a serious thrombotic thrombocytopenic purpura (TTP)-like illness." *Id*.

In sum, after conducting an extensive review of the issues raised by Endo, the FDA determined there was no proof that Opana ER with Intac would deter abuse compared to Opana ER. *See id*. at 8. For that reason, the FDA ruled that Opana ER "was not withdrawn from sale for reasons of safety or effectiveness." *Id*.

In light of these determinations, the FDA concluded that "it will continue to list [the original formulation of] Opana ER . . . in the 'Discontinued Drug Product List' section of the Orange Book," *i.e.*, as a product that had "been discontinued

from marketing for reasons other than safety or effectiveness." 78 Fed. Reg. 38053-01. Because of this, the FDA determined that it "will not begin procedures to withdraw approval of ANDAs that refer to" the original formulation of Opana ER, and that more ANDAs citing the original formulation of Opana ER as the RLD could still be approved if they met the usual requirements. *Id*.

D. Proceedings Below

Less than two weeks after suing the FDA in an attempt to compel premature action on its Citizen Petition, Endo filed this suit against Actavis. A42; A256. Endo's suit turns on a single allegation, *viz.*, that Actavis marketed its "Generic Oxymorphone ER Tablets as 'AB Rated to Opana® ER.'" A34 (¶ 56). Endo alleged that this statement became false in June 2012, once Endo had finally stopped selling Opana ER and completely switched over to Opana ER with Intac. *See id*. (¶ 58). Endo attached as exhibits to its complaint two "[e]xamples of advertisements containing such statements," but they were both dated mid-2011, when Endo was still marketing Opana ER and before the FDA had even approved Endo's NDA for Opana ER with Intac. A34 (¶ 56); A43-A46.

Actavis moved to dismiss Endo's complaint on two independent grounds. First, Endo's complaint was closely bound up with a matter within the FDA's authority and expertise, and the FDA had not endorsed Endo's position. Thus, Endo's claim failed as a matter of law as an attempt to usurp the FDA's authority

and circumvent the FD&C Act, which does not authorize a private right of action. *See* A300-A307 (citing, *inter alia*, *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990)).

Second, as a factual matter, Actavis pointed out that the FDA had approved its product as AB rated to Opana ER and never changed that rating. Because the complained-of advertisements were not false, Endo's complaint failed on the merits. A308. Contrary to Endo's assertion, *see* Blue Br. at 19, Actavis did argue below that Endo failed to plead all the essential elements of a Lanham Act claim. A300-A308.

In addition to opposing Actavis's motion to dismiss, Endo moved for partial summary judgment that the advertisements were literally false. A512-A516. Actavis opposed and cross-moved for summary judgment, raising a third independent ground on which it was entitled to judgment. Specifically, Endo did not contend that Actavis's statement that its tablets were AB rated to Opana ER had always been false, but only that it became false after Endo stopped marketing the original version of Opana ER as of June 2012. But Endo failed to make a plausible allegation that Actavis continued to make that statement after that date, given that the only advertisements Endo attached to its complaint were dated mid-2011. A549-A550. Endo never presented any admissible evidence in support of its summary judgment motion, or in opposition to Actavis's cross-motion for

summary judgment, that Actavis used such materials after May 2012. A571, A579-A580; A851-A852; A877-A880. Nor did Endo make an application for discovery under Federal Rule of Civil Procedure 56(d) in opposition to Actavis's cross-motion for summary judgment.

The district court granted Actavis's motion to dismiss. A1-A6. The court relied on *Sandoz*, which it seemingly viewed as involving the primary jurisdiction doctrine, and did not reach Actavis's other grounds. A4. The court stressed that "Endo agrees that FDA approved Actavis's generic with an AB therapeutic equivalency rating to Opana® ER," and that Endo "does not contend that FDA revoked the AB rating." A4-A5. Absent a further determination by the FDA, the court "decline[d] to make a determination as to whether Actavis's generic is still AB equivalent to Opana® ER or whether the new CRF formulation changes this designation." A4. The district court noted that "an application has been made to the FDA on this issue," a reference to Endo's Citizen Petition, and dismissed the case without prejudice. A5.[3]

[3] At the time the parties submitted their briefs to the district court, the FDA had not yet acted on Endo's Citizen Petition.

SUMMARY OF ARGUMENT

The approval, labeling, therapeutic equivalence, and promotion of prescription drugs are under the FDA's authority pursuant to the FD&C Act, which does not confer a private right of action. Adjudicating these issues in suits between competitors would contravene Congressional intent and improperly substitute the judgments of judges and juries for expert determinations by the FDA's professional staff. This Court has therefore held that private parties cannot seek what are effectively FDA-like determinations in the guise of Lanham Act challenges to their competitors' characterizations of FDA-approved drugs. As the district court recognized, that principle is controlling here: Endo asserts that Actavis's generic is no longer AB rated to Opana ER, but that assertion cannot support a Lanham Act claim because it would require a court preemptively to interpret FDA rules and standards.

Endo's suit fails for the independent reason that the complained-of advertisements are not false. The FDA approved Actavis's tablets as AB rated to Opana ER and has not revoked or modified that approval. The advertisements' statement that the Actavis tablets are "AB rated to Opana ER" is true. At minimum, the advertisements are certainly not unambiguously false, as would be necessary for Endo to establish falsity within the meaning of the Lanham Act.

But, even if it were not for these dispositive problems with Endo's complaint, Endo's suit would fail on its own terms. According to Endo, the statement at issue in Actavis's advertisements only became false as of June 2012, after Endo stopped marketing the original formulation of Opana ER. But the advertisements Endo attached to its complaint are from the summer of 2011, predating by almost one year the event that supposedly rendered them false. Endo did not offer, in opposition to Actavis's cross-motion for summary judgment, any admissible evidence that Actavis used the advertisements after May 2012. The best Endo could do was a declaration from one of its sales representatives reporting a hearsay statement about an Actavis sales representative allegedly providing the materials to a doctor in November 2012. Because that hearsay statement would be inadmissible at trial, it cannot meet Endo's burden on summary judgment.

Finally, Actavis has filed a cross-appeal to secure its ability to urge the Court to direct that the dismissal of Endo's suit should be with prejudice. The problem with Endo's suit is not that it is premature, which could justify a without-prejudice dismissal, but that it does not present a cognizable claim on which relief may be granted. As such, the dismissal should be with prejudice.

ARGUMENT

I. Endo's False Advertising Suit Fails Because It Requires a Court to Invade the FDA's Authority, and Because Endo Has Not Alleged a False Statement

A. Standard of Review

This Court reviews the dismissal of Endo's complaint de novo, applying the same standards as the district court. *See Barefoot Architect, Inc. v. Bunge*, 632 F.3d 822, 826 (3d Cir. 2011). "To withstand a Rule 12(b)(6) motion to dismiss, 'a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face."'" *Id*. (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), and *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A complaint "that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555). "Nor does a complaint suffice if it tenders 'naked assertions' devoid of further factual enhancement.'" *Id*. (quoting *Twombly*, 550 U.S. at 557) (alteration omitted).

In determining whether a plaintiff has stated a claim for relief, a court may also consider certain materials outside the four corners of the complaint. *See Pryor v. Nat'l Collegiate Athletic Ass'n*, 288 F.3d 548, 559-60 (3d Cir. 2002). These include documents attached to the complaint, documents referred to in the

complaint whose authenticity is not in question, and facts of which a court may take judicial notice. *See id*. at 560.

Because appellate courts review judgments, not opinions, this Court is not limited to the grounds relied on by the district court for its dismissal of Endo's complaint. *Wiest v. Lynch*, 710 F.3d 121, 134-35 (3d Cir. 2013) (court may affirm on any ground supported by the record).

B. Endo's Claim Is Not Cognizable Because It Is Bound-up with Matters Under the FDA's Authority and Expertise

In the FD&C Act, Congress entrusted the FDA with the responsibility for approving prescription drugs, making determinations about therapeutic equivalence of those drugs, and determining whether approved drugs should be withdrawn for reasons of safety or effectiveness. Acting pursuant to that authority, the FDA devised the "AB" coding to describe a generic that has been approved as therapeutically equivalent to a reference listed drug. The FDA approved Actavis's generic as AB rated to Opana ER. The FDA has not revoked that approval or changed Actavis's therapeutic rating.

But Endo's entire suit depends on the premise that Actavis's generic is <u>not</u> AB rated to Opana ER. In other words, Endo is asking the courts to interpret FDA rules in a manner that the FDA has not accepted. This is fatal to Endo's suit.

1. Endo's Suit Is Barred by This Court's Precedent

Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 902 F.2d 222 (3d Cir. 1990), controls the outcome here. *Sandoz* concerned a statement in advertisements for a children's cough syrup that it began to work the instant it was swallowed. *See id.* at 224. The basis for this claim was that the syrup's sugary liquids (demulcents) affected cough receptors in the throat on contact. The product label, however, listed them as inactive ingredients. *See id*. at 224-25, 230. Sandoz alleged that if the demulcents enabled the product to begin working immediately, they must be "active" ingredients, thus rendering the characterization false. *See id*. at 230.

Affirming the district court's denial of a preliminary injunction, this Court held that Sandoz's suit improperly sought to use the Lanham Act to enforce the FD&C Act, which does not permit a private right of action, writing that what the FD&C Act does "not create directly, the Lanham Act does not create indirectly, at least not in cases requiring original interpretation" of the FD&C Act or implementing regulations. *Id*. at 231. Therefore, a Lanham Act claim is not cognizable when it requires a court to determine preemptively how the FDA will interpret its own rules. *See id*.

To rule otherwise would "usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations." *Id*. "Because 'agency decisions are frequently of a discretionary nature or frequently require expertise, the agency should be given the first chance to exercise that discretion or to apply that expertise.'" *Id*. (quoting *McKart v. United States*, 395 U.S. 185, 194 (1969)). Applying these principles, *Sandoz* concluded that "whether an ingredient is properly labeled 'active' or 'inactive' under FDA standards is not properly decided as an original matter by a district court in a Lanham Act case." *Id*. at 232.[4]

This case is easier than *Sandoz* because the term "AB rated" has no meaning as a matter of ordinary English. The plaintiff in *Sandoz*, by contrast, could argue credibly that if demulcents relieved coughs, they were active ingredients "'as a matter of common sense and normal English.'" 902 F.2d at 230. And, while Endo can point to nothing in FDA rules supporting its interpretation of "AB rated," the *Sandoz* Court acknowledged that "FDA standards seem to require that [the demulcents at issue] be labeled as 'active.'" *Id*.

Yet, even in that closer case, this Court concluded that Sandoz's Lanham Act claim was not cognizable. Because the FDA had "not found conclusively that

[4] Actavis agrees with Endo that, when a Lanham Act suit is dismissed under *Sandoz*, it is because the plaintiff's claim is not cognizable, which is distinct from a decision to refer an issue to an administrative agency under the doctrine of primary jurisdiction. *See* Blue Br. at 14, 19-20; *but see Dial A Car, Inc. v. Transportation, Inc.*, 82 F.3d 484, 492 (D.C. Cir. 1996) (Silberman, J., concurring in part and dissenting in part) (referring to *Sandoz* as "a 'primary jurisdiction' case").

demulcents must be label[ed] as active or inactive ingredients within the meaning of" the relevant regulation, Sandoz could not prevail. *Id*. The Court explained: "We decline to find and do not believe that the district court had to find, either 'as a matter of common sense' or 'normal English,' that which the FDA, with all of its scientific expertise, has yet to determine." *Id*. at 231.

2. The Holding and Rationale of *Sandoz* Have Been Consistently Embraced by Other Circuits

Sandoz has been influential nationwide. The Seventh, Ninth, and D.C. Circuits have relied on *Sandoz* to hold that Lanham Act claims are not cognizable if they would require a court to preempt an agency's interpretation of its rules, or of a statute the agency administers. No Court of Appeals has rejected *Sandoz*.

In *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 926 (9th Cir. 2010), PhotoMedex claimed that its competitor violated the Lanham Act by advertising its dermatological laser as FDA-approved even though the competitor had made significant post-approval modifications to the device. Noting that PhotoMedex had presented the same argument to the FDA, but "it [did] not appear that the agency ever reached the conclusion sought by PhotoMedex," the Court of Appeals affirmed the district court's rejection of PhotoMedex's claim. *Id*. Because adjudication of PhotoMedex's suit "would require litigation of the alleged underlying [FD&C Act] violation in a circumstance where the FDA has not itself concluded that there was such a violation," it was barred as an impermissible effort

to circumvent the FDA's exclusive enforcement authority under the FD&C Act. *Id*. at 924; *see also id*. at 928 (citing *Sandoz*).

Similarly, in *Schering-Plough Healthcare Products, Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500 (7th Cir. 2009), the Court of Appeals affirmed the district court's dismissal of a Lanham Act suit brought by Schering-Plough, the maker of MiraLAX (polyethylene glycol 3350), against generic manufacturers. Schering-Plough claimed that the generic labels were false because they bore the legend "Polyethylene Glycol 3350 . . . Rx Only," even after Schering-Plough obtained approval for an over-the-counter (OTC) version of MiraLAX. *See id*. at 503-04. The Court of Appeals, in an opinion by Judge Posner, held that Schering-Plough's suit was not cognizable absent action from the FDA, noting that it was unclear how consumers would understand the term "Rx Only" or how any disclaimer noting the existence of an OTC alternative should be worded. *See id*. at 508-09. The FDA was conducting a proceeding to determine whether the defendants' products were misbranded under the FD&C Act because of the "Rx Only" legend, *see id*. at 505, and the court explained that the "FDA should be given a chance to opine on the proper labeling before a Lanham Act suit is filed." *Id*. at 508 (citing *Sandoz*, 902 F.2d at 230-31).

Nor is the *Sandoz* rule unique to pharmaceutical cases. *Dial A Car, Inc. v. Transportation, Inc.*, 82 F.3d 484 (D.C. Cir. 1996), affirmed the district court's

dismissal of a taxi company's Lanham Act claim against its competitors. According to the plaintiff, its competitors' statements that they could lawfully serve corporate accounts were false because an administrative order of the D.C. Taxicab Commission forbade them from doing so. *See id*. at 485, 488. But the Commission had not determined whether the competitors' service violated the administrative order, and the Court of Appeals held that, "at a minimum, there must be a clear and unambiguous statement from the Taxicab Commission regarding [the competitors'] status before a Lanham Act claim can be entertained." *Id*. at 489 (emphasis in original); *see also id*. (citing *Sandoz*).

Thus, the Seventh, Ninth, and D.C. Circuits have all adopted this Court's holding in *Sandoz*: a court will not allow a "private action[] under the Lanham Act premised on enforcement determinations that the FDA and other regulatory agencies did not themselves make." *PhotoMedex*, 601 F.3d at 928 (citing *Sandoz* and other cases).

The cases cited by Endo are of no help to it for two reasons. First, all of those cases are from courts outside this Circuit, so they obviously cannot trump this Court's precedential decision in *Sandoz*. Second, none of the cases cited by Endo is contrary to *Sandoz*. Indeed, many of those cases explicitly adopt the rule established by *Sandoz*. *See, e.g.*, *PhotoMedex*, 601 F.3d at 928; *Mutual Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d 925, 934 (C.D. Cal. 2006) ("[C]ourts

have refused to allow a Lanham Act claim to proceed where, in order to determine the falsity or misleading nature of the representation at issue, the court would be required to interpret and then apply [FD&C Act] statutory or regulatory provisions."); *see also Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 940 (8th Cir. 2005) (distinguishing *Sandoz* because the plaintiff's Lanham Act claim did not require the court to make a "preemptive determination" about "'how a federal administrative agency will interpret and enforce its own regulations'") (quoting *Sandoz*, 902 F.2d at 231). In sum, in the words of another case cited by Endo, private parties are "not empowered to enforce independently" the FD&C Act by bringing claims under the Lanham Act, and courts must reject attempts "by ingenious pleading, to escape one principle of law by making it appear that another not truly appropriate rule is applicable." *Mylan Labs. Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993).

Endo's cases stand for the unremarkable proposition that Lanham Act claims concerning pharmaceuticals may proceed when they do not require interpretation of the FD&C Act or FDA rules, and would not invade the FDA's exclusive enforcement authority. Under those circumstances, the courts do not usurp the FDA's authority to interpret the FD&C Act and its regulations, and to serve as the only entity with authority to police violations.

For example, a plaintiff may bring a Lanham Act claim against a competitor for advertising as FDA-approved a drug, or indication for that drug, that clearly has not been approved. *See Alpharma*, 411 F.3d at 936, 940-41 (citing *Rhone-Poulenc Rorer Pharms., Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 513-14, 516 (8th Cir. 1996)); *Putney v. Pfizer*, No. 07-108, 2007 WL 3047159, *4-*6 (D. Me. Oct. 17, 2007); *see also PhotoMedex*, 601 F.3d at 924-25 ("If, for example, it was clear that an affirmative statement of approval by the FDA was required before a given product could be marketed and that no such FDA approval had been granted, a Lanham Act claim could be pursued for injuries suffered by a competitor as a result of a false assertion that approval had been granted."). In such a case, "a court can test the truth of the statement without any need to interpret FDA regulations; the question will simply be whether the FDA official conferred 'approval' or not." *Mutual Pharm.*, 459 F. Supp. 2d at 935 (citation, internal quotation marks, and alteration omitted); *see id*. at 942; *see also id*. at 939 (addressing a similar claim).

All of the cases relied on by Endo involve this fact pattern except *Mylan*, but it does not help Endo either. In that case, the Fourth Circuit permitted a portion of the plaintiff's Lanham Act claim to proceed based on allegations that, *inter alia*, a product was advertised as bioequivalent to a branded drug and "entitled to an AB rating," when FDA approval had been obtained by fraud and was ultimately

withdrawn. *See Mylan*, 7 F.3d at 1138. The adjudication of that claim would not preempt the FDA, since the FDA had already acted to withdraw approval of the fraudulent ANDAs.[5]

The Supreme Court's recent decision in *Pom Wonderful LLC v. The Coca-Cola Co.*, 134 S. Ct. 2228 (2014), likewise permitted a Lanham Act claim to proceed when the plaintiff's allegations did not require reference to—much less interpretation of—FDA regulations. In that case, Pom Wonderful alleged that the labeling of a Coca-Cola juice product, which prominently displayed the words "pomegranate blueberry" even though it contained only 0.3% pomegranate juice and 0.2% blueberry juice, violated the Lanham Act. *See id*. at 2233. Unlike drug labels, the FDA does not pre-approve food and beverage labels, and the FDA reported that it did not necessarily pursue enforcement measures against all objectionable food and beverage labels. *See id*. at 2239. Under those circumstances, the Court declined to hold that the FDA's potential role in food and beverage labeling categorically precluded a Lanham Act suit by private parties. *See id*.

[5] The legal analysis in *Mylan* is fully consistent with *Sandoz* and the other cases discussed above, but it should be noted that its facts were *sui generis*. That case arose out of the infamous generic drugs scandal of the 1980s, which "involved allegations and proof that various generic drug manufacturers had provided illegal gratuities to FDA reviewers to speed the review of their applications, had falsified data in abbreviated new drug applications, and had otherwise subverted the ANDA approval process." Beers, *supra*, § 8.01; *see also Mylan*, 7 F.3d at 1132.

The bottom line is that when adjudication of a Lanham Act claim requires original interpretation of the FD&C Act or FDA rules, or would usurp the FDA's exclusive enforcement authority, it is barred. *See Sandoz*, 902 F.2d at 231.

3. Endo's Suit Falls on the Wrong Side of the Line Established by *Sandoz*

Endo's brief here appears to recognize that Lanham Act suits are barred when they require interpretation of FDA rules. *See* Blue Br. at 23-24. In an attempt to avoid this precedent, Endo contends that "the Court need not interpret FDA regulations or invade FDA's scientific expertise to resolve Endo's claims." *Id*. at 23; *see also id*. at 24 (similar). Even though Endo did not mention the Orange Book in its Complaint, Endo now insists that a court "need only look to FDA's Orange Book, and assess whether that publication lists Actavis's Tablets as being AB rated to the Opana® ER product being sold at the time the advertising statements were made." *Id*. at 23 (emphasis added); *see id*. at 24.

The underlined portion of Endo's statement demonstrates the fallacy of its argument. As Endo correctly notes in its complaint, an AB rating refers to the basis on which a generic drug was approved. *See* A32, ¶ 49 ("An 'AB' rating signifies that FDA has approved a generic drug as being bioequivalent to, as safe and effective as, and substitutable for the brand-name drug."). The AB code means that the FDA approved the generic because a study was submitted demonstrating bioequivalence to the RLD. A73 (Orange Book). Thus, by its very

nature, an AB rating concerns the relationship between a generic and brand-name RLD at the time the generic was approved. *See also* A72 (Orange Book) (explaining that an AB designation "is assigned to pharmaceutical equivalents only if the approved [generic] application contains adequate scientific evidence establishing . . . the bioequivalence of the [generic] product to a select reference product"). Endo erroneously seeks to condition a generic's AB rating, which indicates the basis on which it was approved, on the business decision of the manufacturer of the RLD to keep marketing the RLD in perpetuity. That would usurp the FDA's authority. It is for the FDA to determine whether a generic loses its AB rating to the RLD product—which is determined as of the date of approval of the ANDA—because the manufacturer of the RLD subsequently decides to voluntarily discontinue the RLD for business reasons.

The contrary view argued by Endo, that Endo has the authority to change the status or AB rating of Actavis's FDA-approved product by voluntarily discontinuing the original formulation of Opana ER, would be a grossly improper delegation of governmental authority to a private party. It would also subvert a central purpose of the Hatch-Waxman Act, which is to establish a reliable and predictable regulatory pathway for the approval of generic drugs that benefit consumers by their reduced cost, to place in the hands of branded companies an obvious way to undermine the availability of generics.

Endo's position is not supported by the Orange Book. To the contrary, the Orange Book explains that the FDA determines if a change to the rating of an approved generic is necessary when the RLD is changed after the generic was approved:

> [O]ccasionally a situation may arise in which changes in a listed drug product after its approval (for example, a change in dosing interval) may have an impact on the substitutability of the already approved generic versions of that product that were rated by the Agency as therapeutically equivalent to the listed product. When such changes in the listed drug product are considered by the Agency to have a significant impact on therapeutic equivalence, the Agency will change the therapeutic equivalence ratings for other versions of the drug product unless the manufacturers of those other versions of the product provide additional information to assure equivalence under the changed conditions. Pending receipt of the additional data, the Agency may add a note to Section 1.8 [Description of Special Situations], or, in rare cases, may even change the therapeutic equivalence rating.

A72.

Similarly, FDA regulations make clear that it is for the FDA to determine whether a voluntarily discontinued RLD was withdrawn for reasons of safety or effectiveness. *See* 21 C.F.R. § 314.161(a), (c). As the FDA's rejection of Endo's Citizen Petition makes clear, the manufacturer's stated reasons for withdrawal are not determinative. If the FDA determines that a drug was withdrawn for reasons of safety or efficacy, the RLD will be removed from the Orange Book's list of approved drugs entirely, and the FDA will initiate proceedings to suspend approved generics. *See id*. § 314.161(d), (e). By contrast, if the FDA determines

that the RLD was not discontinued for reasons of safety or effectiveness, the drug remains listed in the Discontinued Section of the Orange Book; the FDA does not suspend the approval of generics; and the FDA may approve additional generics that have already submitted ANDAs referencing the discontinued drug. *See* A81 (Orange Book); 78 Fed. Reg. 38053-01.

Here, the FDA approved Actavis's product as AB rated to Opana ER. The only change since then has been that Endo voluntarily discontinued marketing Opana ER in favor of a bioequivalent product it calls Opana ER with Intac. In Endo's view, that means Actavis is no longer AB rated to Opana ER. But the FDA has not adopted Endo's interpretation of the FDA's rules, which means that Endo's Lanham Act claim fails. *See Sandoz*, 902 F.2d at 230-32.

Indeed, the FDA has at least implicitly rejected Endo's interpretation. Specifically, when it denied Endo's Citizen Petition, the FDA determined that the original formulation of Opana ER was "discontinued from marketing for reasons other than safety or effectiveness." 78 Fed. Reg. 38053-01. As a result, the FDA concluded that it "will not begin procedures to withdraw approval of ANDAs that refer to" the original formulation Opana ER, and that more ANDAs using Opana ER as the RLD could still be approved. *Id.*[6]

[6] As noted, the FDA denied Endo's Citizen Petition after the parties completed their briefing below, but before the district court issued its ruling. Actavis submits that, where a case was pending *sub judice* in the district court at the (cont'd…)

Consistent with this decision, the FDA even more recently approved an ANDA submitted by Mallinckrodt Inc., referring to the original formulation of Opana ER as the RLD, and the FDA assigned Mallinckrodt's product an AB rating.[7] Stated simply, the FDA even now continues to approve generics as AB rated to the original formulation of Opana ER.

4. Endo's Remaining Arguments Are Unavailing

Endo makes three other arguments for reversal, Blue Br. at 25-27, none of which has merit.

(…cont'd) time an agency issued a decision, this Court may take judicial notice of the agency's decision without violating the general rule against considering materials that were available but not presented to the district court. *See United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 303 (3d Cir. 2011) ("Although a court of appeals may take judicial notice of a matter of public record not presented to the district court when reviewing the disposition of a motion to dismiss under Rule 12(b)(6), we think that ordinarily a court of appeals should not take judicial notice of documents on an appeal which were available before the district court decided the case but nevertheless were not tendered to that court. . . .") (citations omitted). In any event, Endo's suit fails for the reasons stated above and below, regardless of whether this Court considers the FDA's decision.

[7] *See* http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=202946&TABLE1=OB_Rx (noting June 27, 2014 approval) (last accessed July 28, 2014). Because the Orange Book does not list any of the other generics as an RLD, it is clear that the FDA approved Mallinckrodt's generic as AB rated to the original formulation of Opana ER. *See* http://www.accessdata.fda.gov/scripts/cder/ob/docs/queryai.cfm (last accessed July 28, 2014) (type "oxymorphone" into the "Search by Active Ingredient" box).

First, without citation to the record or any legal authority, Endo asserts that Actavis's advertisements are false because it is "self-evident that . . . any statements that Tablets are 'AB rated to Opana® ER'" would be understood to refer to Opana ER with Intac rather than Opana ER. *Id*. at 25. There is nothing self-evident about Endo's *ipse dixit*. The FDA approved Actavis's tablets as AB rated to Opana ER, and Actavis's advertisements accurately report that fact. They do not say that the tablets were approved as AB rated to Opana ER with Intac (the purportedly crush-resistant new formulation). To the contrary, because the advertisements are dated from mid-2011, they could not possibly have referred to Opana ER with Intac, a product that was not approved until December 2011.[8]

But even if Endo's spin on the advertisements were plausible, its suit would still be barred by *Sandoz*. Under those circumstances, a court would defer to the FDA to determine if Actavis's product is AB rated to Opana ER with Intac. *See* A5 (district court's opinion). Indeed, Actavis's generic tablets and Opana ER with Intac were both approved as bioequivalent to Opana ER. A87; A99, A102.

[8] Because of the procedural posture below, the characteristics of "consumers" to whom the ads were directed were not developed. It is clear, however, that the "consumer" here is not the patient filling a prescription, but sophisticated medical, pharmacy, and industry personnel who are fully capable of investigating the regulatory nuances if they consider them material.

Endo asserts that the Orange Book says there are no therapeutic equivalents for Opana ER with Intac, *see* Blue Br. at 11-12, but that is incorrect. The source cited by Endo is an unofficial portion of the FDA's website, Drugs@FDA, which the FDA cautions "is not intended to replace the *Orange Book*." A558; *cf.* 21 C.F.R. § 314.3(b) (making clear, under the definition of "Listed drug," that the Orange Book is an official publication). Endo cannot rely on statements on an unofficial part of the FDA's website to overcome *Sandoz*. *See generally Schering-Plough*, 586 F.3d at 505, 508 (rejecting Lanham Act suit even though the FDA's Director of the Office of Generic Drugs had written the generic sellers, stating that their products were mislabeled, because those letters were not final agency action).

Endo also claims that Actavis conceded that its tablets are not AB rated to Opana ER with Intac. *See* Blue Br. at 15-16; *see also id*. at 12, 25. That is both incorrect and irrelevant. Below, Actavis simply did not dispute Endo's statement that Actavis's products have not "been listed by FDA in the Orange Book as AB rated to the CRF version of Opana ER." A597. That is because (i) Actavis's product was approved as bioequivalent to the original formulation of Opana ER, and (ii) there was no claim by Endo that Actavis ever advertised that its product was approved based on Opana ER with Intac (which it was not).

Endo's second argument—that Endo is entitled to an opportunity to prove that the Actavis ads were misleading, *see* Blue Br. at 26—is precluded because

Endo did not make it below. *See Tri–M Grp., LLC v. Sharp*, 638 F.3d 406, 416 (3d Cir. 2011) ("It is axiomatic that arguments asserted for the first time on appeal are deemed to be waived and consequently are not susceptible to review in this Court absent exceptional circumstances.") (citations and internal quotation marks omitted). In response to Actavis's motion to dismiss, Endo argued only that Actavis's ads were literally false. *See* A514-A516 (arguments under the header "Actavis's Advertisements are Literally False"). Endo never requested an opportunity to prove that Actavis's advertisements were misleading to consumers.[9]

Endo's argument would fail even if it were properly before this Court. Regardless of whether the claim is that the advertisements were "literally false" or only "misleading" to some as-yet-unidentified "consumers," Endo's Lanham Act suit impermissibly usurps the FDA's authority. "[W]ords must, as nearly as possible, be accorded an objectively reasonable meaning if law is to have any fair claim as an instrument of justice." *Pernod Ricard USA, LLC v. Bacardi U.S.A, Inc.*, 653 F.3d 241, 250 (3d Cir. 2011). Therefore, if an advertisement would not be misleading to a reasonable consumer, it is not misleading within the meaning of

[9] Aside from quoting the Lanham Act and the elements of a claim under that Act, Endo only mentioned the word "misleading" once, in the context of a conclusory assertion that Actavis's advertising was "false and misleading." A515; *see also* A331 (Endo's memorandum of law in support of its application for order to show cause) (stating that, "because Actavis's advertising is literally false, Endo need not demonstrate that the advertisement has actually deceived consumers"); Blue Br. at 6 (noting that Endo opposed Actavis's motion to dismiss and moved for partial summary judgment on the ground that Actavis's advertising was literally false).

the Lanham Act regardless of the outcomes of consumer surveys. *See id*. at 250-52 (discussing *Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883, 886 (7th Cir. 2000)).

Whether any reasonable consumer would be misled by Actavis's advertisements cannot be determined without interpreting the term AB rating, and the effect on a generic's AB rating when the manufacturer voluntarily discontinues the RLD and replaces it with a bioequivalent formulation. These are matters that must be resolved by the FDA. *See PhotoMedex*, 601 F.3d at 628 (explaining that, if the FDA disagreed with the plaintiff's interpretation of its regulations, then the defendants' advertisements "were not false or misleading"); *Dial A Car*, 82 F.3d at 488-89 (rejecting plaintiff's Lanham Act claim because, absent further guidance from the relevant agency, the defendants' advertisements were neither false nor misleading).

Endo's third and final argument is that, even if the statement in Actavis's advertisements refers to the original formulation of Opana ER, it is false because the Orange Book shows—without the need for any further guidance from the FDA—that Actavis's tablets are no longer AB rated to the original formulation of Opana ER. *See* Blue Br. at 26. But Endo does not meaningfully explain that argument, instead referring in a footnote to an affidavit Endo submitted below. *See id*. at n.6 (citing A782-A789). Endo has therefore waived this argument. *See*

Ethypharm, 707 F.3d at 231 n.13 ("'[A]rguments raised in passing (such as, in a footnote), but not squarely argued, are considered waived.'") (quoting *John Wyeth & Bro. Ltd. v. CIGNA Int'l Corp.*, 119 F.3d 1070, 1076 (3d Cir.1997)) (alteration in *Ethypharm*). Moreover, Endo's affidavit cannot be considered for the independent reason that it was first submitted with Endo's reply brief in support of its motion for summary judgment, *see* A755; thus, it is not cognizable in analyzing the district court's grant of Actavis's motion to dismiss.

In any event, the substance of the affidavit does not help Endo overcome *Sandoz*. In the affidavit, Endo's affiant presents a convoluted analysis based on inferences he draws by juxtaposing various editions of the Orange Book. *See* A783, A786-A787. At bottom, his argument is that, when the FDA moves an RLD to the Discontinued Drug List, generics automatically lose their AB rating to the RLD. *See id*. Endo's affiant makes no effort to explain how his interpretation is consistent with: (a) the Orange Book's definition of AB coding as signifying bioequivalence; (b) the fact that generics do not lose their AB coding simply because an RLD is moved to the Discontinued Drug List; or (c) FDA rules making clear that ANDAs referencing a discontinued drug as the RLD can continue to be approved so long as the RLD was not discontinued for reasons of safety or efficacy. It is for the FDA, not Endo's affiant, to interpret the Orange Book.

C. Endo's Lanham Act Claim Fails Because Actavis's Advertisements Are Not False

Because adjudicating Endo's Lanham Act suit is bound-up with matters under the FDA's authority and expertise, the district court correctly held that *Sandoz* requires dismissal. In the alternative, Endo's claim fails because Actavis's advertisements are not false.

The statement in Actavis's advertisements challenged by Endo is that Actavis's tablets are "AB rated to Opana ER." That statement is true. As discussed, the FDA approved Actavis's tablets as AB rated to Opana ER. *See* A87 ("The Division of Bioequivalence has determined your Oxymorphone Hydrochloride Extended-release Tablets 7.5 mg, and 15 mg, to be bioequivalent and, therefore, therapeutically equivalent to the RLD . . . Endo's Opana ER Tablets, 7.5 mg, and 15 mg."). Despite Endo's efforts, the FDA has not revoked the approval of Actavis's generic or changed its therapeutic equivalence rating.

Endo insists that Actavis's advertisements are false because Actavis's product is not AB rated to Opana ER with Intac. But the advertisements say that Actavis's tablets are AB rated to "Opana ER," not to "Opana ER with Intac" or to the "crush-resistant formulation of Opana ER." And, even after it stopped marketing the original formulation, Endo itself used the term "Opana ER" to refer to the original formulation of Opana ER while calling the new version "Opana ER

with Intac" or "Opana ER CRF." A155 (Endo's website); A191-A197 (Endo's Citizen Petition).

To the degree the term "Opana ER" may be ambiguous, that is a problem of Endo's own making. It chose to keep the proprietary name "Opana ER" to refer to Opana ER with Intac. And, in any event, the fact that Actavis's advertisements might be misunderstood would not be sufficient even to state a claim for misleading advertising under the Lanham Act. *See Mead Johnson*, 201 F.3d at 886 ("A 'misunderstood' statement is not the same as one designed to mislead."). It certainly is not sufficient to state a claim for false advertising, which is the only issue Endo raised in the district court and the only issue properly before this Court on appeal.

Simply put, Actavis's advertisements are truthful. They certainly are not unambiguously false, which is necessary for a plaintiff to demonstrate literal falsity under the Lanham Act. *See Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 587 (3d Cir. 2002) ("[O]nly an unambiguous message can be literally false.") (emphasis in original). Just as "Sandoz [could not] prevail on its labeling claim because it has not proved that Vicks's labeling is false," *Sandoz*, 902 F.2d at 930, Endo cannot prevail here.

II. Actavis Is Entitled to Judgment Even Under Endo's Theory of the Case Because Endo Failed to Adequately Allege, or Present any Admissible Evidence, that Actavis Made the Complained-of Statements After May 2012

According to Endo, the statement that Actavis's tablets are "AB rated to Opana ER" was false as of June 2012, after Endo stopped marketing the original formulation of Opana ER. *See* A34 ¶ 58 (complaint); Blue Br. at 16, 20. For the reasons stated above, Endo is wrong. But even if Endo were correct, its suit would be barred because it failed to make a plausible allegation that Actavis made this statement after May 2012. In the alternative, Endo failed to present admissible evidence creating a genuine issue of material fact on this point, such that Actavis is entitled to summary judgment.

A. Standard of Review

While the district court did not address the timing of Actavis's advertisements either in the context of Actavis's motion to dismiss or in its cross-motion for summary judgment, this Court may affirm on any ground supported by the record. *See Wiest*, 710 F.3d at 134-35. And, as discussed, a complaint is subject to dismissal under Rule 12(b)(6) if, *inter alia*, it "tenders 'naked assertions' devoid of further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557) (alteration omitted). A plaintiff may also "'plead himself out of court by attaching documents to the complaint that indicate that he or she is not entitled to judgment.'" *N. Ind. Gun & Outdoor Shows, Inc. v. City of*

South Bend, 163 F.3d 449, 455 (7th Cir. 1998) (citation omitted); *see also ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 n.8 (3d Cir. 1994) ("Where there is a disparity between a written instrument annexed to a pleading and an allegation in the pleading based thereon, the written instrument will control.").

Further, when both parties had sufficient opportunity to present evidence beyond the pleadings in the district court, the Court of Appeals "has the authority to convert a motion to dismiss under Rule 12(b)(6) to a grant of summary judgment under Federal Rule of Civil Procedure 56 and affirm the judgment of the District Court." *TermoRio S.A.E. S.P. v. Electranta S.P.*, 487 F.3d 928, 940-41 (D.C. Cir. 2007). Similarly, if the plaintiff's motion to dismiss requested summary judgment in the alternative, the Court of Appeals may convert a district court's Rule 12(b)(6) dismissal to a grant of summary judgment. *See Kingman Park Civic Ass'n v. Williams*, 348 F.3d 1033, 1041 (D.C. Cir. 2003). Summary judgment is properly granted "if there is no genuine issue of material fact and if, viewing the facts in the light most favorable to the non-moving party, the moving party is entitled to judgment as a matter of law." *Beers-Capitol v. Whetzel*, 256 F.3d 120, 130 n.6 (3d Cir. 2001).

B. Endo's Complaint Fails to Make a Plausible Allegation that Actavis Used the Challenged Advertisements After May 2012

Endo's suit depends upon the following allegations in its complaint: "Actavis has been marketing and continues to market the Generic Oxymorphone

ER Tablets as 'AB Rated to Opana® ER.' Examples of advertisements containing such statements are attached hereto as Exhibits A and B." A34 (¶ 56). According to Endo, the statement that Actavis's tablets are AB rated to Opana ER became false as of June 2012, because Endo voluntarily discontinued marketing the original formulation of Opana ER at the end of May 2012. *Id*. (¶ 58); *see also* Blue Br. at 16, 20.

But the advertisements Endo attached as Exhibits A and B are dated June and July 2011, almost a year before Endo claims it became false for Actavis to say that its tablets are AB rated to Opana ER. A43-A46. Indeed, in the summer of 2011, the original formulation of Opana ER was the only formulation on the market, and the FDA had not yet approved Opana ER with Intac. *See* A28, A30 (complaint). And it is the contents of the attached advertisements, not the allegations in Endo's complaint, which are controlling as to any disparity between them. *ALA*, 29 F.3d at 859 n.8. In sum, by "'attaching documents to the complaint that indicate [it] is not entitled to judgment,'" Endo has "'plead[ed itself] out of court.'" *N. Ind. Gun & Outdoor Shows*, 163 F.3d at 455 (citation omitted).

Nor would Endo have done any better by omitting the attached advertisements. Under those circumstances, Endo would have been left with its allegation: "Actavis has been marketing and continues to market the Generic Oxymorphone ER Tablets as 'AB Rated to Opana® ER.'" A34. Such "'naked

assertions' devoid of further factual enhancement,'" are insufficient to survive a motion to dismiss. *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557) (alteration omitted).

C. Endo Failed to Present Competent Evidence Establishing a Genuine Issue of Material Fact As to Whether Actavis Used the Challenged Advertisements After May 2012

In the alternative, Actavis is entitled to summary judgment because Endo failed to present any admissible evidence demonstrating that Actavis made the challenged statement after May 2012.

In cross-moving for summary judgment, Actavis pointed out the absence of any evidence that Actavis used marketing materials stating its product was AB rated to Opana ER after the date Endo claims that statement became false. A571, A578-A580. This was sufficient to meet Actavis's initial burden to show the absence of a genuine issue of material fact. *See, e.g.*, *Singletary v. Pa. Dep't of Corr.*, 266 F.3d 186, 192 n.2 (3d Cir. 2001) ('"[T]he burden on the moving party may be discharged by "showing"—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case' when the nonmoving party bears the ultimate burden of proof.") (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986)).

The burden then shifted to Endo to "'go beyond the pleadings and by [its] own affidavits, or by the "depositions, answers to interrogatories, and admissions

on file," designate "specific facts showing that there is a genuine issue for trial."'" *Guidotti v. Legal Helpers Debt Resolution, L.L.C.*, 716 F.3d 764, 773 (3d Cir. 2013) (quoting *Celotex*, 477 U.S. at 324) (additional citation omitted). In other words, Endo had to present sufficient evidence to permit a reasonable factfinder to find in its favor at trial. *G-I Holdings, Inc. v. Reliance Ins. Co.*, 586 F.3d 247, 253 (3d Cir. 2009). Endo failed to meet its burden.

In opposing Actavis's motion, Endo relied on a declaration of one of its sales representatives, Danielle Overly. A779. Ms. Overly did not state that Actavis made any statement about its tablets being AB rated to Opana ER after May 2012 to her. Instead, she stated that she visited the medical office of one Dr. Michael Platto in Washington, Pennsylvania on November 8, 2012, where she obtained copies of the promotional materials attached to Endo's complaint. A780; *see also* A43-A46; A486-A489 (advertisements in question). Ms. Overly also reported Dr. Platto's hearsay statement that he had received those advertisements the day before from an Actavis sales representative. A780.[10]

[10] In a separate declaration filed with Endo's initial motion for summary judgment, Endo's Vice President of Marketing Marvin Kelly stated that Endo also obtained the advertisements at issue from "CD Promo, a web-based service offered by DTW Market Research, Inc. to monitor competitive promotional resources, including brochures designed for health care professionals." A482. This declaration said nothing about when Endo obtained the advertisements from CD Promo, much less when those advertisements were made. Nor, in any event, is Mr. Kelly's declaration on this point competent summary judgment evidence: Mr. Kelly stated that "Endo has obtained copies" of the advertisements from CD Promo, (cont'd…)

Ms. Overly's declaration fails to create a genuine issue of material fact for trial. All she can say based on her personal knowledge is that she obtained the Actavis promotional materials from a doctor's office in November 2012. This, of course, proves nothing about when the doctor's office received the materials, and therefore does not support Endo's assertion that Actavis disseminated such materials in commerce after May 2012.

And the statement attributed to Dr. Platto does not help Endo because, as hearsay, it would be inadmissible at trial. "Hearsay statements that would be inadmissible at trial may not be considered for purposes of summary judgment." *Smith v. City of Allentown*, 589 F.3d 684, 693 (3d Cir. 2009); Fed. R. Civ. P. 56(c)(4) ("An affidavit or declaration used to support or oppose a motion must . . . set out facts that would be admissible in evidence[.]").

In the district court, Endo attempted to overcome this dispositive problem by arguing that Ms. Overly's statement recounting what Dr. Platto told her is admissible under the residual hearsay exception now codified at Federal Rule of Evidence 807. A864-A865. But Rule 807 does not permit the type of garden-variety hearsay Endo seeks to introduce here; if it did, the prohibition against hearsay would become the exception rather than the rule.

(…cont'd) A482, but he did not state this information was based on his personal knowledge. *See* Fed. R. Civ. P. 56(c)(4).

To qualify for admission under Rule 807, a hearsay statement must meet the following four requirements: (1) the statement must have "equivalent circumstantial guarantees of trustworthiness" as statements admissible under specific hearsay exceptions in Rules 803 or 804; (2) it must be offered as evidence of a material fact; (3) it must be "more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts"; and (4) admitting the statement must "best serve the purposes of these rules and the interests of justice." Fed. R. Evid. 807(a). Rule 807 is "'to be used only rarely, and in exceptional circumstances' and 'applies only when certain exceptional guarantees of trustworthiness exist and when high degrees of probativeness and necessity are present.'" *United States v. Wright*, 363 F.3d 237, 245 (3d Cir. 2004) (Alito, J.) (quoting *United States v. Bailey*, 581 F.2d 341, 347 (3d Cir. 1978)) (alteration omitted).

The statement at issue here fails the necessity and trustworthiness prongs of this test, which means its admission also would not serve the purposes of the rules of evidence and the interests of justice. *See* Fed. R. Evid. 807(a)(1), (3), (4). With respect to necessity, Endo did not argue, much less offer evidence, that Dr. Platto was unavailable to provide direct testimony about when and how he received the advertisements in question. As a result, Ms. Overly's declaration is not "more

probative than . . . any other evidence that [Endo] can obtain through reasonable efforts." Fed. R. Evid. 807(a)(3).

Nor does the statement of a doctor to a salesperson possess the "'exceptional guarantees of trustworthiness,'" required by Rule 807. *Wright*, 363 F.3d at 245 (citation omitted). The statement is classic hearsay, which is presumptively unreliable because the speaker was not under oath and there is no opportunity for cross-examination. Rules 803 and 804 identify exceptions to that presumption for statements that have special circumstantial guarantees of trustworthiness—for example excited utterances, business records, and prior testimony of an unavailable witness against a party who had an opportunity and similar motive to develop that testimony. *See* Fed. R. Evid. 803(2), (6); 804(b)(1). The statement Ms. Overly's declaration attributes to Dr. Platto does not contain such a special guarantee of trustworthiness, and it is therefore inadmissible under Rule 807. *See* Fed. R. Evid. 807(a)(1).

In sum, Endo failed to present admissible evidence to permit a reasonable factfinder to conclude that Actavis made the complained-of statement after May 2012. And, because Endo does not argue that the statement was false until after that date, Actavis is entitled to judgment as a matter of law.

III. Endo's Case Should Be Dismissed with Prejudice

A. Standard of Review

The district court's dismissal of Endo's complaint without prejudice, rather than with prejudice, is reviewed for abuse of discretion. *See United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 302, 314 (3d Cir. 2011). "[A] court 'abuses its discretion when its ruling is founded on an error of law or a misapplication of law to the facts.'" *Montrose Medical Group Participating Savings Plan v. Bulger*, 243 F.3d 773, 780 (3d Cir. 2011) (quoting *In re O'Brien*, 188 F.3d 116, 122 (3d Cir. 1999)).

B. The Possibility of Further Action by the FDA Does Not Justify a Without-Prejudice Dismissal

The district court apparently granted Actavis's motion to dismiss "without prejudice" so that Endo could refile its suit if the FDA granted Endo's Citizen Petition. *See* A5. The FDA has now denied Endo's Citizen Petition, so under that logic, there is no basis for maintaining the without-prejudice dismissal.

But even if Endo's Citizen Petition were still pending, it would not justify a without-prejudice dismissal because, no matter what action the FDA took in response to Endo's petition, it could not have established that the statement in Actavis's advertisements was false at the time it was made.

The D.C. Circuit made a similar point in affirming the district court's with-prejudice dismissal of the plaintiff's Lanham Act claim in *Dial A Car*, explaining

that, even if the plaintiff persuaded the Taxicab Commission that a Commission order prohibited defendants from providing the services they advertised,

> this would still not show that the law was clear at the time [defendants] made the alleged misstatements. In other words, appellant cannot pursue this lawsuit with a simple assertion that current D.C. law is seen to be clear and unambiguous, based on an interpretation by the D.C. Taxicab Commission that was issued subsequent to [defendants'] statements. Rather, the proper inquiry is whether the law was unambiguous at the time [defendants'] alleged misstatements were made.

82 F.3d at 489 (emphases in original); *see also* 884 F. Supp. 584, 593 (D.D.C. 1995) (district court decision).[11]

Thus, this case is different from those where the plaintiff has failed to exhaust a required administrative remedy or where a court decides to refer an issue to an agency under the primary jurisdiction doctrine. A plaintiff that failed to exhaust may have stated a substantive claim for relief, but the complaint is premature absent the agency's having an opportunity to address it. Therefore, a dismissal without prejudice is appropriate. *See Spence v. Straw*, 54 F.3d 196, 202 (3d Cir. 1995). Similarly, the doctrine of primary jurisdiction is "applicable to claims properly cognizable in court that contain some issue within the special

[11] A without-prejudice dismissal is not necessary to keep the door open for Endo to file a new suit if: (a) it ever succeeds in convincing the FDA to adopt its interpretation of FDA rules; and (b) after such action by the FDA, Actavis made new statements like the one challenged by Endo here. "*[R]es judicata* does not bar claims that are predicated on events that postdate the filing of the initial complaint." *Morgan v. Covington Township*, 648 F.3d 172, 178 (3d Cir. 2011).

competence of an administrative agency." *Reiter v. Cooper*, 507 U.S. 258, 268 (1993). When a court applies the primary jurisdiction doctrine, it effectively stays the case while giving the parties a reasonable opportunity to seek an administrative ruling; the court may either retain jurisdiction or dismiss the case without prejudice if the parties would not be unfairly prejudiced. *See id*. at 268-69.

The problem with Endo's false advertising complaint is not that it is premature, but that it fails to state a cognizable claim for relief. Endo's suit would require a court to infringe upon FDA's authority and expertise, which means it is barred by *Sandoz*. *See supra* pp. 21-39. As Endo recognizes, when *Sandoz* applies, a plaintiff's Lanham Act claim is "not cognizable." *See* Blue Br. at 20. Endo's suit is also deficient because, unless and until the FDA adopts Endo's preferred interpretation of FDA regulations, the statement at issue in Actavis's advertisements is not false. *See supra* pp. 40-41.

Because Endo's Lanham Act claim is substantively deficient, rather than premature, it should be dismissed with prejudice.

C. In the Alternative, Endo's Failure to Support Its Own Theory of the Case Concerning the Timing of Actavis's Advertisements Requires Dismissal with Prejudice

By Endo's own account, the advertisements in question were not false prior to the end of May 2012, when Endo stopped marketing the original formulation of Opana ER. But the advertisements Endo attached to its complaint are from the

summer of 2011, and Endo failed to present any admissible evidence that Actavis used the advertisements after May 2012. *See supra* pp. 42-49. Endo's Lanham Act claim therefore fails on its own terms regardless of anything the FDA could say in response to Endo's Citizen Petition or any future Citizen Petition. This is an independent reason why this Court should convert the district court's without-prejudice dismissal into a with-prejudice dismissal.

CONCLUSION

The district court correctly dismissed Endo's complaint. Its without-prejudice dismissal should be converted into a dismissal with prejudice.

Dated: July 30, 2014

Respectfully submitted,

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CERTIFICATIONS

I.

CERTIFICATION OF BAR MEMBERSHIP

I hereby certify that I, Charles A. Weiss, am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

II.

CERTIFICATION OF WORD COUNT

This brief complies with the type-volume limitation of Fed. R. App. P. 28.1(e)(2)(B)(i) because it contains 12,858 words excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and typestyle requirements of Fed. R. App. P. 32(a)(6) because the brief has been prepared in a proportionally spaced typeface using Microsoft Word 2007, in 14-point Times New Roman.

III.

CERTIFICATION OF IDENTICAL COMPLIANCE OF BRIEF

I hereby certify that the electronic and hard copies of the foregoing Brief in the instant matter contain identical text.

IV.

CERTIFICATION OF VIRUS CHECK

I hereby certify that a virus check of the electronic .PDF version of the foregoing Brief was performed using McAfee AntiVirus, and the .PDF filed was found to be virus free.

Dated: July 30, 2014

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CERTIFICATE OF SERVICE

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I also certify that the ten (10) copies of the foregoing Brief have been filed with the Clerk of the United States Court of Appeals for the Third Circuit via UPS overnight delivery, properly addressed as follows:

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The necessary filing and service were performed in accordance with the instructions given to me by counsel in this case.

Dated: July 30, 2014

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