NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ENDO PHARMACEUTICALS, INC., **Plaintiff,** **v.** **ACTAVIS, INC. and ACTAVIS SOUTH ATLANTIC LLC,** **Defendants.**	Civ. No. 12-cv-7591 (KM) **MEMORANDUM OPINION**

KEVIN MCNULTY, U.S.D.J.:

Plaintiff, Endo Pharmaceuticals, Inc. ("Endo") brought this action against Defendants Actavis, Inc. and Actavis South Atlantic LLC (collectively, "Actavis") alleging that Actavis falsely marketed a generic form of oxymorphone hydrochloride extended-release tablets. Endo has asserted violations of the Lanham Act, 15 U.S.C. § 1125(a); the New Jersey Fair Trade Act, N.J. Stat. Ann. 56:4-1 et seq.; and the New Jersey Consumer Fraud Act, N.J. Stat. Ann. 56:8-1 et seq. Now before the Court is Actavis's renewed motion to dismiss the complaint on the grounds that it fails to state a claim under Fed. R. Civ. P. 12(b)(6). (Dkt. No. 44)

Because I write for the parties, I write briefly and assume familiarity with the case. For the reasons set forth below, the motion is denied as to claims under the Lanham Act and the New Jersey Fair Trade Act, although the theories will require narrowing. Dismissal is granted as to the claim under the New Jersey Consumer Fraud Act.

BACKGROUND

Endo is a pharmaceutical company which researches, develops, sells and markets prescription pharmaceuticals used to treat and manage pain. (Dkt. No.

1 ("Compl.") ¶ 10) Endo obtained approval from the FDA on June 22, 2006, for an extended release oxymorphone hydrochloride pain reliever under the brand name Opana® ER. (*Id.* ¶ 26) Endo began selling Opana® ER in July of 2006. (*Id.* ¶ 27)

Actavis manufactures and sells generic drugs. (*Id.* ¶ 11) In February of 2008, Actavis sought approval to produce a generic form of the original, then-current formulation of Opana® ER. (*Id.* ¶ 52) The FDA approved Actavis's application in December 2010. (Certification of Samuel Spital in Support of Motion to Dismiss, dated March 31, 2015, Dkt. No. 45 ("Spital Cert."), Ex. B p. 2) Actavis' generic is AB rated to the drug known as Opana® ER, meaning that the product is therapeutically equivalent to Opana® ER. Actavis began selling generic tablets in July 2011. (*Id.*)

Concerned about the potential for abuse of the drug, including the possibility that persons would crush the pills and snort or inject the powder, Endo developed a crush-resistant version of Opana® ER. (*Id.* ¶ 33) Endo submitted this new formulation to the FDA for approval on July 7, 2010, and was granted approval on December 9, 2011. (*Id.* ¶¶ 35, 40)

Endo ceased manufacturing the old formulation, but did not recall the tablets that had already been produced and distributed. (*Id.* ¶¶ 41-42) Instead, Endo sought to bring the new formulation to market as quickly as possible while allowing the supply of the old formulation to work its way through the distribution pipeline. (*Id.* ¶ 42) Endo began shipping the new formulation in February 2012. (*Id.* ¶ 43) This new crush-resistant formulation was bioequivalent to the original formulation of Opana® ER and was sold by Endo under the same brand name. Endo sought to distinguish it in the consumer's mind, however, by referring to it as "Opana® ER with Intac." Actavis does not have approval for a generic version of that new, crush-resistant formulation of Opana® ER. (*Id.* ¶ 51)

(For simplicity, I will from now on refer to the two formulations as "Old Opana® ER" and "Opana® ER with Intac".)

In August of 2012, Endo filed a Citizen Petition with the FDA, seeking to have the FDA (1) determine that the old formulation of Opana® ER was discontinued for reasons of safety, (2) refuse to approve any pending generic approvals for the old formulation, and (3) suspend and withdraw approval for generic versions of the old formulation. (Spital Cert. Ex. B p. 1) Several months later, before the FDA could address the petition, Endo filed suit against the FDA in the United States District Court for the District of Columbia seeking to compel immediate action on its petition.

On December 11, 2012, Endo filed this action against Actavis. (Dkt. No. 1) Endo alleges that Actavis's marketing of "Generic Oxymorphone ER Tablets" as "AB Rated to Opana® ER™ became misleading after May 2012, once Endo had stopped selling Old Opana® ER in favor of Opana® ER with Intac. (*Id.* ¶ 58)

Endo moved to dismiss the complaint on January 22, 2013. (Dkt. No. 8) This Court (the action was then assigned to District Judge Dennis M. Cavanaugh, since retired) dismissed the complaint. (Dkt. No. 33) Judge Cavanaugh's decision cited the primary jurisdiction doctrine. The issues surrounding Actavis's generic, he reasoned, were properly the subject of pending proceedings before the FDA. Endo appealed Judge Cavanaugh's dismissal to the Third Circuit.

Meanwhile, on May 10, 2013, the FDA denied—I do not say crushed—Endo's Petition. The FDA determined that Old Opana® ER would *not* be withdrawn from sale for safety or effectiveness reasons, because the data did not support the claim that Opana® ER with Intac was superior; ruled that the agency would *not* stop approving generic applications for the old formulation so long as they met all necessary requirements; and ruled that it would *not* suspend or withdraw its approval of generic versions of Old Opana® ER. (Spital Cert., Ex. B) Once the FDA had made its decision, the basis of Judge Cavanaugh's decision (deferral to the FDA under the primary jurisdiction

doctrine) became moot. The Third Circuit therefore vacated Judge Cavanaugh's order and remanded to this Court for further proceedings.

On March 31, 2015, Actavis moved to dismiss the now-restored complaint, citing the same grounds it had asserted originally. (Dkt. No. 44) On April 10, 2015, the case was reassigned to me. (Dkt. No. 47) Endo filed its opposition to Actavis's motion May 18, 2015. (Dkt. No. 52) Actavis filed a reply on June 1, 2015. (Dkt. No. 55) Endo was granted leave to file a surreply, which it did on February 12, 2016. (Dkt. No. 62) Actavis was granted leave to file an opposition to that surreply, which it did on February 22, 2016. (Dkt. No. 63)

LEGAL STANDARD

Actavis has moved to dismiss the Complaint for failure to state a claim, pursuant to Fed. R. Civ. P. 12(b)(6). Rule 12(b)(6) provides for the dismissal of a complaint, in whole or in part, if it fails to state a claim upon which relief can be granted. The defendant, as the moving party, bears the burden of showing that no claim has been stated. *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). In deciding a Rule 12(b)(6) motion, a court must take the allegations of the complaint as true and draw reasonable inferences in the light most favorable to the plaintiff. *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (traditional "reasonable inferences" principle not undermined by *Twombly*, *see infra*).

Federal Rule of Civil Procedure 8(a) does not require that a complaint contain detailed factual allegations. Nevertheless, "a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Thus, the complaint's factual allegations must be sufficient to raise a plaintiff's right to relief above a speculative level, so that a claim is "plausible on its face." *Id.* at 570; *see also Umland v. PLANCO Fin. Serv., Inc.*, 542 F.3d 59, 64 (3d Cir. 2008). That facial-plausibility standard is met "when the plaintiff pleads factual

content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). While "[t]he plausibility standard is not akin to a 'probability requirement' . . . it asks for more than a sheer possibility." *Iqbal*, 556 U.S. at 678.

DISCUSSION

A. Lanham Act and New Jersey Fair Trade Act

The parties do not differ as to the essential elements of a Lanham Act claim, and I do not repeat them here. *See Groupe SEB United States, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 198 (3d Cir. 2014). An advertisement may be literally false, in which case the plaintiff does not have to prove actual consumer deception. Or the advertisement may be literally true but misleading to the consumer, in which case the plaintiff must prove actual deception of the consumer by a preponderance of the evidence. *See Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 943 (3d Cir. 1993). (Here, the "consumer" may be a prescribing physician, and an "advertisement" may include many forms of communication.) Endo claims literal falsity, but also states that its complaint is broad enough to encompass a claim of misleading.

Actavis continues to urge that the Complaint must be dismissed, not only because Endo's claim raised matters committed to the FDA, but because the FDA has now rejected Endo's position. It is true (not at the time of the Complaint, but now) that the FDA has declined to revoke its approval of Actavis's generic drug as AB rated to Old Opana® ER, and has rejected the safety/abuse claims of Endo. Actavis may believe that Endo, in effect, is asking the Court to contradict that ruling, or to rule that generic equivalents of Old Opana® ER should no longer be marketed. Or Actavis may believe that Endo is asking the Court to find that Actavis's generic is not AB rated to Opana® ER with Intac (a claim that Actavis does not make, and that the FDA has not ruled

on). Any of these would allegedly entangle the court in the administrative process.

Endo, citing *Pom Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), replies that there is room for a Lanham Act claim that does not implicate FDA decision making. And perhaps there is—just. Endo accepts, as it must, the premise that Actavis's drug was AB rated to Old Opana® ER. What is misleading about Actavis's advertising, says Endo, is that *the consumer* could *now* mistakenly infer (as the consumer could not have before) that Actavis's drug is AB rated to Opana® ER with Intac.

The claim poses interpretive, even philosophical, difficulties about the relation between the name and the thing.[1] Actavis's contentions put in play the notion that a brand name manufacturer, by its own post-generic-approval branding decisions (or even, I suppose, a change of brand name), may *render* the generic manufacturer's true advertising misleading and then sue on that basis.[2] Actavis also notes that Endo itself simultaneously marketed the two versions of the drug for some months, but of course does not accuse itself of

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[1] One is reminded of the conundrums, if not the legal issues, posed by that old law school chestnut, the contracts case of *Raffles v. Wichelhaus,* EWHC Exch. J19, (1864) 2 Hurl. & C. 906. There, the parties contracted (or attempted to contract) for shipment of goods by a ship ironically named the *Peerless*. There turned out to be two ships of that name, sailing from Bombay to Liverpool at different times, and the court seemingly could find no basis for reconciling the parties' accounts of which one they meant.

[2] Here, the advertisement states that Actavis's generic is AB rated to Opana® ER. On its face, the statement appears unambiguous; Actavis is asserting that the FDA had approved its generic drug as therapeutically equivalent to the brand name drug Opana® ER. That is correct, and it has now been reaffirmed in response to Endo's petition. That FDA approval was for a generic version of something called—called *by plaintiff Endo*—Opana® ER. But since then, says Endo, there has been another formulation of Opana® ER. They have the same name (sort of; it seems that Endo refers to the later formulation publicly as "Opana® ER with Intac"); it follows that "Opana® ER" may signify two different things (but not too different; that would have jeopardized FDA approval for the crush-resistant version). Because Endo has stopped manufacturing one of them, it says, "Opana® ER" would now be taken to mean only the newer, "with Intac" version.

confusing physicians.[3] Also relevant may be the extent to which Endo has been scrupulous about distinguishing between the two versions (*e.g.*, by referring to the second as "Opana® ER with Intac" or otherwise marking the distinction). There may be answers to these contentions, but they implicate issues of fact unsuitable for disposition on a motion to dismiss.

The Third Circuit observed rightly that this Court (then Judge Cavanaugh, now me) "would be interested in the continued effectiveness of an AB rating to the original, discontinued Opana ER®.... 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®." *Endo Pharmaceuticals Inc., v. Actavis Inc.*, No. 13-4096, slip op. at 5 (3d Cir. Dec. 5, 2014).

I do consider the FDA's rulings. While not absolutely dispositive of a Lanham Act claim, they do, as the Third Circuit suggested, bear on Endo's Lanham Act theory. Endo's complaint of Course did not cite the FDA's rejection of its Petition, which then lay in the future. Rather, the Complaint alleges that Actavis's statements that its drug is "AB rated to Opana® ER" are false, because its drug is not so rated to the *current* version "with Intac." That, says

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[3] The theory of the complaint appears to be that a physician will now be falsely told, or at least misled into thinking, that there is just one version of the drug on the market, whereas there are actually two: one crush resistant and one not. Such issues must ordinarily be explored with a factual context. *See Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co.*, 290 F.3d 578, 588 (3d Cir. 2002). Part of that factual context must include of Endo's own conduct. According to the complaint, Endo did not recall the Old Opana® ER on December 9, 2011, when it received FDA approval for the new formulation; rather, Endo let that supply of the old formulation dwindle while it ramped up production of the new formulation. (Compl. ¶¶ 40-44) Endo began shipping the new formulation in February of 2012, but it was not until after May 31, 2012, that the old inventory cleared the pipeline, and Endo ceased marketing Old Opana® ER. By Endo's own pleading, from February through May it was simultaneously selling both the old and the new formulations. The FDA apparently found this highly significant in rejecting Endo's petition. And Endo in this action will face the question of how it could keep the two drugs straight in physicians' minds then, but can no longer do so now.

Endo, is not a challenge to regulatory rulings of the FDA, but an allegation that Actavis is making false statements *about* those regulatory rulings. In so claiming, Endo is threading the needle under *Pom Wonderful.* But the FDA has said a lot of things since the Complaint was filed.

Among those things are rulings that there were *not* safety concerns about Old Opana® ER, and that generic versions of Old Opana® ER may validly remain on the market. To the extent Endo was alleging falsity with respect to these regulatory matters, current or anticipated, its theory cannot survive. Indeed, the FDA's rulings tend to undercut even the materiality of the alleged misleading statements. The Complaint alleges, for example, that Actavis has implicitly "acknowledged the dangers" of its version of the drug by virtue of having submitted a new ANDA (No. 20390) seeking approval for a generic crush-resistant version. But the FDA has now explicitly rejected those safety concerns.[4] Safety as such, or whether doctors *should* be prescribing the more crushable version of Opana® ER, is not a Lanham Act issue. And such issues are properly directed to the FDA.

Other issues, factual in nature, loom.

For example, Actavis suggests that it no longer advertises that its product is AB rated to Opana® ER. Endo's complaint provides two examples of Actavis's advertisements, both of which date from 2011. (Compl. ¶ 56, Exs. A, B) The Complaint alleges more generally that Actavis "continues to market" its generic as AB rated to Opana® ER, and that consumers "are likely to rely on and have relied on Actavis's misrepresentations in distributing, prescribing, dispensing and purchasing" Actavis's generic. Actavis denies this, and that poses a factual issue. In an action which seeks injunctive relief, however, it is

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[4] The FDA ruled that the data did not support Endo's claim that Opana® ER with Intac had any safety advantage over Old Opana® ER. (Spital Cert., Ex. B p. 6) It rejected Endo's contention that it had safety advantages similar to those of reformulated OxyContin. (*Id.* at 8) The FDA continued to list, and declined to withdraw approval of, generic versions of Old Opana® ER. In short, Endo's safety concerns about Old Opana® ER (which seemed to have crested shortly after it sold off the last of its inventory) have not been borne out. So the claim that any misleading advertising has a regulatory dimension has become very problematic.

an issue (potentially jurisdictional, but relevant even if not) that should be addressed, and soon.

To take another example, it has been suggested that Actavis is or was seeking approval for a generic version of crush-resistant Opana® ER. The status of that ANDA is unknown to the Court, and is not discernible from the face of the Complaint. But that fact, too, may bear on the viability of claims (and may change during the pendency of this action).

I have taken the trouble to speak of these issues in an attempt to guide further litigation of this case. All of the above factors radically change the environment in which Endo's claims are asserted, and require that, if they are to go forward, they must be carefully defined and limited to remain within the scope of what is actionable under the Lanham Act. The more I analyze them, the more I find myself needing to perform surgery on the complaint to conform it to subsequent developments.

Nevertheless I cannot, within the four corners of the complaint, find that a Lanham Act claim is ruled out as a matter of law. False or misleading advertising has a consumer focus, not a regulatory focus. It deals with false statements about matters the consumer is likely to care about in making a purchasing choice.

I will therefore deny the motion to dismiss the Lanham Act claim. The elements of unfair competition under the New Jersey Fair Trade Act, N.J. Stat. Ann. § 56:4, are the same as those under Section 43(a) of the Lanham Act, saving the jurisdictional interstate commerce element. *See SK & F Co. v. Premo Pharm. Laboratories, Inc.*, 625 F.2d 1055, 1066 (3d Cir. 1980). Accordingly, my ruling as to unfair competition under the New Jersey Fair Trade Act is the same.

This matter may be well suited for targeted discovery and an early motion for summary judgment, however. I will permit contention interrogatories so that Endo may redefine or narrow its theory in light of the intervening rulings of the FDA. Endo may also wish to move to amend its complaint. I will permit interrogatories, and further discovery if appropriate, as

to what advertising by Actavis, if any, is current or threatened in a way that makes it an appropriate target of injunctive relief. Counsel shall confer with each other and with the Magistrate Judge, as necessary, to work out a discovery plan.

B. NJ Consumer Fraud Act

Endo asserts an additional cause of action under the New Jersey Consumer Fraud Act. Although it is not specifically addressed in this round of briefing, Actavis originally moved to dismiss that claim as well. Although it was not necessary for Judge Cavanaugh to address this particular issue, I believe it is appropriately addressed on remand.

The New Jersey Consumer Fraud Act ("NJCFA"), N.J. Stat. Ann. 56:8-1 et seq., proscribes as an "unlawful practice"

> [t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise.

N.J. Stat. Ann. § 56:8-2. The NJCFA authorizes a private cause of action for "[a]ny person who suffers any ascertainable loss of moneys or property, real or personal, as a result" of a violation of the NJCFA. *Id.* at 56:8-19. Although broadly stated, the NJCFA "is not intended to cover every transaction that occurs in the marketplace" but is rather limited to "consumer transactions." *Trans USA Prods., Inc. v. Howard Berger Co., Inc.*, 2008 WL 3154753, at *6 (D.N.J. Aug. 4, 2008) (citing *Arc Networks, Inc. v. Gold Phone Card Co.*, 756 A.2d 636, 638 (N.J. Super. Ct. Law Div. 2000)). Thus, to have standing to pursue a claim under the NJCFA, the plaintiff must be a "consumer." *Id.* ("[T]he NJCFA is not intended to protect competitors...that do not suffer a consumer-like injury.")

Endo is not a consumer of Actavis's product, but a competitor of Actavis. Accordingly, Endo cannot bring a claim under the NJCFA. As to the NJCFA claim, the motion to dismiss is granted.

CONCLUSION

For the reasons set forth above, Defendant Actavis's motion to dismiss the complaint is denied as to claims under the Lanham Act and the New Jersey Fair Trade Act. It is granted as to the claim under the NJCFA.

Dated: March 21, 2016

KEVIN MCNULTY
United States District Judge