UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PAR STERILE PRODUCTS, LLC,	)	
	)	
Plaintiff,	)	
	)	**No. 14 C 3349**
v.	)	
	)	**Judge Jorge L. Alonso**
FRESENIUS KABI USA LLC,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Par Sterile Products, LLC ("Par") alleges in its complaint that defendant Fresenius Kabi USA, LLC ("Fresenius") has violated Section 43(a) of the Lanham Act, the Illinois Deceptive Trade Practices Act, and the Illinois Consumer Fraud and Deceptive Business Practices Act by falsely advertising and promoting its vasopressin injection product. Fresenius has moved to dismiss Par's complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). For the reasons set forth below, the motion is denied in part and granted in part.

BACKGROUND

Both plaintiff and defendant manufacture and market pharmaceuticals, including a vasopressin injection product. Par's vasopressin product, Vasostrict, is FDA-approved. Fresenius's Vasopressin Injection[1] product is not.

In its brief, Par helpfully describes the historical and regulatory backdrop for this dispute. Vasopressin is a natural hormone that has been used in medicine for over one hundred years, since before drugs had to be approved by the Food and Drug Administration ("FDA") or, indeed, before the FDA even existed. In 1938, Congress passed the Food, Drug and Cosmetic Act

[1] Because Fresenius's product has no brand name, the Court will simply refer to it as "Vasopressin Injection," with a capital "V" and "I," as Par does in the complaint.

("FDCA"), which required all "new drugs" to be approved for safety. In 1962 Congress amended the FDCA to require "new drugs" to be approved for effectiveness for a particular use as well. However, grandfather clauses exempted drugs from both requirements if they had been on the market prior to the relevant enactment date and met certain other requirements. (*See* Compl. Ex. 3, Food and Drug Admin., *Guidance for FDA Staff and Industry: Marketed Unapproved Drugs—Compliance Policy Guide* 9-12 (2011).)

The modern prescription drug market is made up of not only FDA-approved drugs but also numerous unapproved drugs. Approved drugs include branded drugs, which have FDA-approved New Drug Applications, and generic versions of branded drugs, which have FDA-approved Abbreviated New Drug Applications. Unapproved drugs include pre-1938 and pre-1962 "grandfathered" drugs and other drugs that are marketed without FDA approval, possibly illegally. (Opp'n to Mot. to Dismiss at 2-3 (citing 21 U.S.C. § 255(b), (j)).) Fresenius does not state whether its product has grandfather status.

In recent years, the FDA has encouraged drug makers to seek FDA approval for their products. In its September 19, 2011 document issued to provide guidance to the drug industry, which Par has attached to its complaint as Exhibit 3, the FDA stated that when a company obtains approval of a product that other companies are marketing without approval, the "FDA is more likely to take enforcement action against remaining unapproved drugs." (Compl. Ex. 3 at 7.) However, the document continued, "we intend to take into account the circumstances once the product is approved in determining how to exercise our enforcement discretion with regard to the unapproved products." (*Id.*) The FDA outlined certain enforcement priorities, with the upshot being, as Par puts it in its brief, "absent overriding safety concerns, the FDA generally

does not take enforcement actions to halt the marketing of unapproved drugs."[2] (Opp'n to Mot. to Dismiss at 4-5.)

Par had previously sold Pitressin, an unapproved vasopressin product like Fresenius's Vasopressin Injection, but on September 26, 2012, in accord with the FDA guidance, Par submitted a New Drug Application ("NDA") to the FDA for a vasopressin injection product called Vasostrict. (Compl. ¶ 17.) Par alleges that it went to considerable expense to establish the product's safety to the satisfaction of the FDA (*Id.* ¶ 30), and Vasostrict was finally approved by the FDA on April 17, 2014 (*Id*. ¶¶ 18, 28). Par filed this suit shortly thereafter.

Par alleges, in short, that Fresenius misrepresents its Vasopressin Injection as safe, effective and FDA-approved, when in fact Par markets the *only* FDA-approved vasopressin injection product on the market. Fresenius allegedly represents to wholesale generic drug purchasers, distributors, group purchasing organizations, and integrated delivery networks that it is in compliance with all applicable laws, which these purchasers take to mean that the Vasopressin Injection is FDA-approved (Compl. ¶¶ 43-46); represents that its product is "generic" in providing drug and pricing information to drug and pricing databases known as "price lists," which buyers believe include only FDA-approved drugs (*Id*. ¶¶ 47-56); and places its drug on the market with the sort of standard labeling and packaging typical of FDA-approved drugs, as if its Vasopressin Injection is FDA-approved (*Id*. ¶¶ 57-65).

ANALYSIS

Fresenius contends in its motion to dismiss that (1) Par has no standing under the Lanham Act, (2) Par's purported Lanham Act claim is really an impermissible private attempt to enforce

[2] Par puts this language in quotation marks and cites to the FDA Guidance attached as Exhibit 3, as if to attribute this statement to the FDA, but this language does not appear in the guidance document. It is apparently Par's own summary of the FDA's enforcement priorities.

the Food, Drug and Cosmetics Act ("FDCA"), and (3) Par's factual allegations are insufficient to state a valid Lanham Act claim.

Section 43(a)(1)(B) of the Lanham Act permits a suit against anyone who "in commercial advertising or promotion, misrepresents the nature, characteristics, qualities or geographic origin of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B). To state a claim under this section, plaintiffs must allege:

> (1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a loss of goodwill associated with its products.

Hot Wax, Inc. v. Turtle Wax, Inc., 191 F.3d 813, 819 (7th Cir.1999).

I. Standing

Fresenius moves to dismiss Par's complaint for lack of Lanham Act standing under Rule 12(b)(1). When considering a Rule 12(b)(1) motion to dismiss, a district court accepts as true all well-pleaded factual allegations and draws reasonable inferences from the allegations in favor of the plaintiff. *Kelley v. Med-1 Solutions, LLC*, 548 F.3d 600, 604 (7th Cir. 2008) (citing *Capitol Leasing Co. v. FDIC*, 999 F.2d 188, 191 (7th Cir. 1993)). The court may also look beyond the allegations of the complaint and consider affidavits and other documentary evidence. *Capitol Leasing*, 999 F.2d at 191.

Fresenius claims that Par has no standing to bring a Lanham Act claim because it has not yet begun to sell Vasostrict. (Mem. in Supp. of Mot. to Dismiss at 4-5.) Fresenius cites cases for the proposition that a Lanham Act claim based on injury to a product that the plaintiff has not yet begun to sell must be dismissed for lack of standing. *See, e.g., ITC Ltd. v. Punchgini, Inc.*,

482 F.3d 135, 170-71 (2d Cir. 2007); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1112 (2d Cir. 1997); *Alphamed Pharms. Corp. v. Arriva Pharms., Inc.*, 391 F. Supp. 2d 1148, 1163 (S.D. Fla. 2005).

Par contends that these cases are distinguishable because the harm alleged in them was remote, speculative and ill-defined. (Opp'n to Mot. to Dismiss at 12-14.) The Court agrees. Unlike the products in the cited cases, Par's product is already FDA-approved, fully developed and ready for sale. In other words, Par has a concrete competing product to compare with Fresenius's Vasopressin Injection. Allegations that sales of Vasostrict are *likely* to suffer due to misrepresentations made by Fresenius in advertising or promoting its Vasopressin Injection are sufficient to satisfy the Lanham Act's standing requirement. *See* 15 U.S.C. 1125(a)(1) (person who uses false advertising "shall be liable in a civil action by any person who believes that he or she is *or is likely to be* damaged") (emphasis added); *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1389-90 (2014) (Lanham Act false advertising cause of action protects against "unfair competition," which is "concerned with injuries to . . . present *and future sales*") (emphasis added); *Hot Wax*, 191 F.3d at 819 (Lanham Act plaintiff must establish that it "has been *or is likely to be* injured as a result of the false statement") (emphasis added); *see also Warner-Lambert Co. v. Breathasure, Inc.*, 204 F.3d 87, 93 (3d Cir. 2000) ("[A] plaintiff must prove that it has a reasonable basis for believing that it is *likely* to suffer injury.") (emphasis added). The allegations of the complaint adequately demonstrate Par's standing.

II. Par's Lanham Act Claims

Fresenius also moves to dismiss Par's complaint under Rule 12(b)(6). "A motion under Rule 12(b)(6) tests whether the complaint states a claim on which relief may be granted." *Richards v. Mitcheff*, 696 F.3d 635, 637 (7th Cir. 2012). Under Rule 8(a)(2), a complaint must

include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The short and plain statement under Rule 8(a)(2) must "give the defendant fair notice of what the claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (ellipsis omitted). Fresenius contends that Par's complaint must also comply with Rule 9(b), which requires a plaintiff alleging fraud to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

Under federal notice-pleading standards, a plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. Stated differently, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S.at 570, 556 (2007)). "In reviewing the sufficiency of a complaint under the plausibility standard, [courts must] accept the well-pleaded facts in the complaint as true, but [they] 'need[ ] not accept as true legal conclusions, or threadbare recitals of the elements of a cause of action, supported by mere conclusory statements.'" *Alam v. Miller Brewing Co.*, 709 F.3d 662, 665–66 (7th Cir. 2013) (quoting *Brooks v. Ross*, 578 F.3d 574, 581 (7th Cir. 2009)).

A. The Lanham Act and the FDCA

Fresenius claims that Par impermissibly attempts to enforce the FDCA via the Lanham Act. In its complaint, Par seeks an order enjoining Fresenius from selling its Vasopressin Injection and ordering it to "recall and remove its misleading, unapproved products from the distribution supply chains." (Compl., Prayer for Relief, ¶¶ A, F.) It is well-settled, as Fresenius

states, that "the FDCA does not create a private right of action," and the authority to enforce the FDCA "rests exclusively with the FDA." (Mem. in Supp. of Mot. to Dismiss at 6 (citing *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharm., Inc.*, 586 F.3d 500, 509 (7th Cir. 2009)).) Further, Fresenius states that "courts have held that plaintiffs may not use Lanham Act claims as an end-run around the FDCA's prohibition on private enforcement," *id.* at 8, and it cites a long line of cases beginning with *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993)), for the proposition that the mere implication, rather than an explicit statement, that its Vasopressin Injection has FDA approval is insufficient to state a Lanham Act claim. (Mem. in Supp. of Mot. to Dismiss at 9-10.)

Par responds that the cases Fresenius cites have been arguably abrogated by *POM Wonderful, LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), which held that the FDCA does not preclude Lanham Act claims pertaining to drugs because the two statutes serve distinct, complementary purposes. Par cites *JHP Pharmaceuticals, LLC v. Hospira, Inc.*, No. CV 13-07460, 2014 WL 4988016, at *5-6 (C.D. Cal. Oct. 7, 2014), in which the court held, applying *POM Wonderful*, that Par's[3] Lanham Act claim that the defendant misrepresented that its product was FDA-approved, in part by describing it as "generic," was not precluded by the FDCA and could withstand a motion to dismiss.

This court agrees with the court in *JHP Pharmaceuticals* that the FDCA does not preclude Lanham Act claims like the one Par asserts here. As in that case, Par asserts the specific, particularized claim that a competitor injuriously misrepresents its product as FDA-approved by offering it for sale in certain marketing channels alongside FDA-approved generic drugs. Whether Fresenius is actually deceiving consumers in violation of the Lanham Act by

[3] Par is also the plaintiff in that case, which involves similar claims against a competitor selling an unapproved epinephrine product.

doing so remains in question at this early stage of the proceedings, but the dispute is of the sort with which the Lanham Act is concerned to the extent it involves deception of consumers as to the fact of whether a product carries the imprimatur of FDA approval, not whether the product is safe and effective enough to be approved by the FDA. *See POM Wonderful*, 134 S. Ct. at 2238; *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 939 (8th Cir. 2005) (rejecting *Mylan Laboratories* and similar cases). As long as there is no allegation that Fresenius must do something that directly conflicts with the FDCA or an FDA regulation, or may not do something that the FDCA or an FDA regulation specifically requires (not merely authorizes), Par's Lanham Act claim is not precluded by the FDCA. *See POM Wonderful*, 134 S. Ct. at 2241.

B. *FDA approval and price lists*

Fresenius replies that *POM Wonderful* has no application to this motion, that *POM Wonderful* does not overrule or abrogate the *Mylan Laboratories* line of cases, and that Fresenius's motion to dismiss is not based on preclusion at all. Rather, Fresenius reiterates its contention that, under *Mylan Laboratories* and its progeny, the mere implication, rather than an explicit statement, that the Vasopressin Injection has FDA approval is insufficient to state a Lanham Act claim. (Reply in Supp. of Mot. to Dismiss at 7.)

The court would be inclined to agree with Fresenius, except that Par does not merely allege that Fresenius has implied that Vasopressin is FDA-approved. Par also alleges that "buyers believe all prescribed drugs identified on the Price Lists are . . . FDA-approved." (Compl. ¶ 54.) Importantly, Par further alleges that, according to some surveys, 91% of pharmacists are actually confused about whether all drugs that appear on industry price lists are FDA-approved. (*Id.*) The court in *JHP Pharmaceuticals* found a claim using similar language, even without the reference to the survey of pharmacists, to be sufficient to survive a motion to

dismiss. 2014 WL 4988016, at **7-8; *see also Morningware, Inc. v. Hearthware Home Prods., Inc.*, 673 F. Supp. 2d 630, 638-39 (N.D. Ill. 2009).

A Lanham Act claim of false advertising may be based on either (1) a statement or representation of fact in advertising that is literally false, or (2) statements or misrepresentations that, even if ambiguous or literally true, were misleading in context, as shown by actual consumer deception. *See Hot Wax, Inc. v. Turtle Wax, Inc.*, 191 F.3d 813, 820 (7th Cir. 1999); *LG Elecs. U.S.A., Inc. v. Whirpool Corp.*, 661 F. Supp. 2d 940, 948 (N.D. Ill. 2009). Fresenius seems to suggest that the second theory of false advertising is unavailable, under the *Mylan Laboratories* line of cases, if the allegedly false advertising concerns whether a product is FDA-approved.[4] The Court fails to see any reason why it should so hold, particularly in light of *POM Wonderful*, which emphasized that both the Lanham Act and the FDCA can typically be enforced in full alongside one another, given their complementary purposes.[5]

Mylan Laboratories and its progeny are frequently cited for the proposition, as stated in *Mylan Laboratories* itself, that the mere act of placing a pharmaceutical product on the market, without more, cannot support a Lanham Act claim. *See Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993). While that may be true, this Court understands Par to be making a slightly different claim. Par is alleging that, by placing a product on the market in a particular marketing channel—namely, the industry price lists—and by making certain representations

[4] It is uncertain whether Par would concede that it is making a claim of implied falsity, not literal falsity. Par contends in its brief that Fresenius represents its Vasopressin Injection as "a 'generic' product, which is literally false." (Opp'n to Mot. to Dismiss at 10.) In any case, it is not necessary to determine at this stage whether Fresenius's advertising is literally false or merely misleading in context; it is enough to determine whether Par states a claim under either theory. *See Morningware, Inc. v. Hearthware Home Prods., Inc.*, 673 F. Supp. 2d 630, 638-39 (N.D. Ill. 2009); *see also LG Elecs.*, 661 F. Supp. 2d at 948 ("Regardless of the theory advanced by the plaintiff, 'whether a claim is either false or misleading is an issue of fact rather than law.'") (quoting *Mead Johnson & Co. v. Abbott Labs.*, 209 F.3d 1032, 1034 (7th Cir. 2000)).

[5] Although *POM Wonderful* appeared to leave open the possibility that a Lanham Act claim might be precluded in certain cases that fall within the exclusive purview of the FDA, *see JHP Pharms.*, 2014 WL 4988016, at *4, whether a product is FDA-approved is a simple, easily verifiable matter, not the sort of complex inquiry that might be beyond the Court's competence or might require the Court to invade the FDA's rule-making authority.

about its products such as that the product is "generic," Fresenius is representing that its product is an FDA-approved generic drug and deceiving consumers, as demonstrated by a consumer survey. This case is distinguishable from the *Mylan Laboratories* cases, which involved no such claim. *See JHP Pharm.*, 2014 WL 4988016, at *7; *Mut. Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d 925, 941-42 (C.D. Cal. 2006) (distinguishing *Mylan Laboratories* where plaintiff alleged that defendant used price lists, "a specialized marketing channel . . . that, through its use, conveys the false implication its drug is approved by the FDA"). The Court rejects Fresenius's contention that Par must allege that Fresenius explicitly stated that its Vasopressin Injection was FDA-approved. Par states a claim by alleging that Fresenius made misleading statements that actually confused and deceived consumers as to whether the Vasopressin Injection was FDA-approved. *See Morningware*, 673 F. Supp. 2d at 638-39.

Fresenius also contends that Par fails to state a claim premised on the price lists because the price lists are not Fresenius's advertising; rather, they are controlled by third parties. (Mem. in Supp. of Mot. to Dismiss at 13-14.) Par correctly responds that the issue of whether Fresenius bears any responsibility for misrepresentations made by the price lists, like the issue of whether the price lists are misleading at all, is a fact issue that may not be decided on a motion to dismiss. (Opp'n to Mot. to Dismiss at 11.) "[L]iability under the Lanham Act has been construed to extend beyond those who actually misrepresent goods or directly place such goods in commerce . . . to any person who knowingly causes a false representation to be used in connection with goods and services in commerce." *Grant Airmass Corp. v. Gaymar Indus., Inc.*, 645 F. Supp. 1507, 1511-12 (S.D.N.Y. 1986) (citing *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 854-55 (1982)). Fresenius can be held liable if Par can prove, as it alleges in the complaint, that "Fresenius knows that buyers believe all prescribed drugs identified on the Price Lists are . . .

FDA approved." (Compl. ¶ 54.) *See Mut. Pharm. Co.*, 459 F. Supp. 2d at 942-43 (pharmaceutical company can be held liable to competitor for third-party internet retailer's misrepresentation that the company's product is FDA-approved if plaintiff can prove that the company knew of the misrepresentations).

Par's allegations as to its claim that is based on Fresenius's advertising of its Vasopressin Injection via price lists are sufficient to state a claim under the Lanham Act. The motion to dismiss is denied as to this claim.

C. Contracts and Compliance with Applicable Laws

Fresenius contends that Par's allegation that Fresenius misrepresented in its contracts with purchasers that its Vasopressin Injection "complies with all relevant state and federal laws, including the FDCA when, in fact, [it does] not" is deficient because any such misrepresentations would not be in "commercial advertising and promotion," as the statute requires. (Mem. in Supp. of Mot. to Dismiss at 9-10 (citing Compl. ¶¶ 43-44).) As Fresenius states, the Seventh Circuit has defined "advertising and promotion" as "promotion to anonymous recipients, as distinguished from face-to-face communication," and explained that an "advertisement read by millions . . . is advertising, while a person-to-person pitch by an account executive is not." *Id.* (citing *First Health Grp. Corp. v. BCE Emergis Corp.*, 269 F.3d 800, 803-04 (7th Cir. 2001)). Fresenius also argues that representations made to a particular purchaser in the context of negotiating or executing a transaction are not "advertising" or "promotion." *Id.* (citing *Solers, Inc. v. Hartford Cas. Ins. Co.*, 36 F. App'x 740, 743 (4th Cir. 2002); *Johnson Controls, Inc. v. Exide Corp.*, 152 F. Supp. 2d 1075, 1081-82 (N.D. Ill. 2001); *C=Holdings B.V. v. Asiarim Corp.*, 992 F. Supp. 2d 223, 243 (S.D.N.Y. 2013)).

Par, citing *Neuros Co. v. KTurbo, Inc.*, 698 F.3d 514, 522 (7th Cir. 2012) and *Lidochem, Inc. v. Stoller Enters., Inc.*, 500 F. App'x 373, 381 (6th Cir. 2012), responds only that misrepresentations to "specialized . . . purchasers" may qualify as "advertising" or "promotion," despite the fact that they are not disseminated to the public at large. The cases Par cites are inapposite. Neither *Neuros* nor *Lidochem* involved misrepresentations made in the course of negotiating or executing a transaction with a particular purchaser; both involved disseminating false information about a competitor's product, albeit to a small "class of consumers," to prevent consumers from trading with the competitor. *See Neuros*, 698 F.3d at 522; *Lidochem*, 500 F. App'x at 379. The false representations Par alleges with regard to Fresenius's contracts are more like the "person-to-person pitch" that the Seventh Circuit expressly excluded from the definition of "advertising" in *First Health Group Corp. v. BCE Emergis Corp.*, 269 F.3d 800, 803-04 (7th Cir. 2001), than the statements in *Neuros* or *Lidochem*. Par has produced no authority squarely supporting its position, and the Court must conclude that Fresenius's statements in its contracts or contract negotiations are not advertising.

Par's claims premised on Fresenius's contracts, unlike Par's claims premised on Fresenius's use of the price lists, amount to no more than claims that Fresenius violated the Lanham Act by putting an unapproved drug on the market, as in *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993), because they do not rest on any statements made in advertising or promotion. Par fails to state a claim based on misrepresentations made in or by Fresenius's contracts. Any claim that Fresenius violated § 43(a) of the Lanham Act by representing in its contracts or contract negotiations that its product is in compliance with applicable laws, or that it implied that its product is FDA-approved by doing so, is dismissed.

D. Misleading Labeling and Packaging

In its complaint, Par makes allegations relating to the labeling of Fresenius' Vasopressin Injection and directed to the safety and effectiveness of the product:

> Fresenius' deficient package insert, labels, advertising, promotion, which (1) include indications that have not been approved as safe and effective by the FDA, and (2) omit specific recommendations to dosing and administration, . . . will cause confusion and lead purchasers to mistakenly conclude that Par's VASOSTRICT product is less effective than Fresenius' unapproved Vasopressin Injection product when in fact the opposite is true." (Compl. ¶ 63.)

Fresenius asserts that this claim "fails for the same reasons it did in *JHP* [*Pharmaceuticals*]." (Reply in Supp. of Mot. to Dismiss at 15.) The court agrees. Just as in *JHP Pharmaceuticals*, Par does not plead any facts to show that the implied message that Vasostrict is less effective than Fresenius's Vasopressin Injection is actually transmitted to consumers, nor does it plead any facts on which the court might base a finding that Vasostrict is *not* less effective than Vasopressin. *See JHP Pharm.*, 2014 WL 4988016, at *10. The Court cannot draw a reasonable inference that Fresenius's statements are misleading based on the allegations Par has made. This claim is dismissed.

E. "Safe" and "Effective"

Par alleges throughout its complaint—not only in connection with the labeling and packaging of the Vasopressin Injection—that Fresenius makes misrepresentations as to whether its product is "safe" and "effective." The court in *JHP Pharmaceuticals* rejected any claims based on these allegations:

> A determination of whether the Defendants' products are "safe" or "effective" might well fall within the primary jurisdiction of the FDA, or even be precluded entirely. However, the Court need not decide these issues today. Par alleges *no* facts to show that Defendants' products are either unsafe or ineffective. The repeated inclusion of such language may well be mere rhetorical excess on Par's part. However, to the extent that any of the Plaintiff's arguments about FDA approval rest on a determination of either safety or effectiveness, such arguments

> suffer a fatal lack of factual sufficiency. Thus, the sole question with respect to the surviving claim against Defendants is whether it [misrepresents] its products as being "FDA-approved," and not any question of safety or effectiveness.

JHP Pharms., 2014 WL 4988016, at *8. Par's allegations in this case suffer from similar deficiencies, and this Court reaches a similar conclusion. Par's complaint does not contain sufficient factual matter for the court to reasonably infer that Fresenius's Vasopressin Injection is not safe or effective. Any claims based on the allegations that Fresenius represents that its product is safe and effective, as distinct from whether it is FDA-approved, must be dismissed as conclusory and potentially precluded.

III. Par's State Law Claims

Par makes additional claims under the Illinois Deceptive Trade Practices Act and the Illinois Consumer Fraud and Deceptive Business Practices Act. (Compl. ¶¶ 74-88.) Fresenius contends that these claims rise or fall with the Lanham Act claims because they are premised on the same assertions and are to be resolved according to the same principles. (Mem. in Supp. of Mot. to Dismiss Compl. at 14-15 (citing *Spex, Inc. v. Joy of Spex, Inc.*, 847 F. Supp. 567, 579 (N.D. Ill. 1994), *Pure Imagination, Inc. v. Pure Imagination Studios, Inc.*, No. 03 C 6070, 2004 WL 2967446, at *13 (N.D. Ill. Nov. 15, 1994).) Par does not contest this assertion or present any authority to the contrary. The state law claims survive to the extent they are based on the allegations that Fresenius's advertising (which does not include statements made in contracts or contract negotiations) misleads consumers to believe that its Vasopressin Injection is FDA-approved. They are otherwise dismissed.

CONCLUSION

For the reasons set forth above, the Court grants in part and denies in part defendant's motion to dismiss [26]. Plaintiff's Lanham Act and corresponding state law claims based on false representations of FDA approval survive. Plaintiff's claims based on false or misleading representations in defendant's contracts are dismissed with prejudice because they do not relate to advertising or promotion. Plaintiff's claims that defendant's product's labeling and packaging deceptively imply that plaintiff's product is less effective than defendant's are dismissed without prejudice. Any claims based on representations that the defendant's product is "safe" or "effective" are dismissed without prejudice.

SO ORDERED.

ENTERED:

March 17, 2015

JORGE L. ALONSO
United States District Judge