United States Court of Appeals
For the First Circuit

No. 21-1492

AZURITY PHARMACEUTICALS, INC.,

Plaintiff, Appellant,

v.

EDGE PHARMA, LLC,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Rya W. Zobel, U.S. District Judge]

Before

Barron, Chief Judge,
Howard and Thompson, Circuit Judges.

James H. Hulme, with whom Nadia A. Patel, Valerie C. Samuels, and Arent Fox LLP were on brief, for appellant.

Robert J. Fluskey, Jr., with whom Linda L. Morkan, William J. Egan, Julianna M. Charpentier, Robinson & Cole LLP, and Hodgson Russ LLP were on brief, for appellee.

August 12, 2022

BARRON, Chief Judge. Azurity Pharmaceuticals, Inc. ("Azurity") is a specialty pharmaceutical company. It markets a hydrochloride vancomycin drug that received pre-market approval from the United States Food and Drug Administration ("FDA"). Edge Pharma, LLC ("Edge") is a drug compounding company. It markets a hydrochloride vancomycin drug that competes with Azurity's but has not been given pre-market FDA approval.

In 2020, Azurity filed suit in the United States District Court for the District of Massachusetts against Edge under both the Lanham Act and a Massachusetts consumer protection law, Mass. Gen. Laws. ch. 93A ("Chapter 93A"), based on statements that Edge allegedly made on its website. The suit alleges that a number of these statements represent or convey the impression that Edge is not in violation of section 503B of the Food, Drug, and Cosmetic Act ("FDCA"), which authorizes drug compounders who meet certain conditions to market their compounded drugs without first obtaining FDA approval. The suit alleges that these statements are literally false and/or misleading. The suit further alleges that another one of Edge's statements on its website is false and/or misleading because it holds out Edge's vancomycin drug as being superior to Azurity's.

Edge moved to dismiss Azurity's claims for, among other things, failure to state a claim on which relief could be granted under Federal Rule of Civil Procedure ("Rule") 12(b)(6). The

District Court granted Edge's Rule 12(b)(6) motion as to Azurity's Lanham Act claim on the ground that the FDCA precluded Azurity's claim. The District Court based this ruling on the determination that the claim would require a court to interpret the meaning of section 503B in a way that would interfere with the FDA's authority to administer and enforce the FDCA. Azurity Pharms., Inc. v. Edge Pharma, LLC, 540 F. Supp. 3d 141, 144 (D. Mass. 2021). The District Court also ruled that, because the FDCA precluded Azurity's Lanham Act claim, Azurity's Chapter 93A claim "likewise fails as it is premised on the same allegations" as Azurity's Lanham Act claim.[1] Id. (citing Reed v. Zipcar, Inc., 883 F. Supp. 2d 329, 334–35 (D. Mass. 2012)).[2] We affirm in part (albeit on an alternative ground) and vacate in part.

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[1] Azurity's complaint contains two counts, one for violation of the Lanham Act and another for unfair and deceptive trade practices under Chapter 93A. The District Court treated Azurity as having made one "claim" under each statute. See Azurity, 540 F. Supp. 3d at 144. On appeal, Azurity frames its complaint has having stated four distinct claims under the Lanham Act. Following the District Court, we use the singular "claim" to encompass all of the theories that Azurity argues for finding Edge to have violated the Lanham Act, and we do the same with respect to Chapter 93A.

[2] In granting Edge's motion to dismiss, the District Court also denied Azurity's motion for a preliminary injunction as moot. Azurity, 540 F. Supp. 3d. at 145. Azurity referred to this denial in its notice of appeal, but it makes no mention of it in its briefing to us so any challenge to that ruling is waived. See United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990).

I.

Because this appeal is from the grant of a motion to dismiss Azurity's complaint for failure to state a claim under Rule 12(b)(6), we accept all well-pleaded facts in Azurity's operative complaint as true. See Clorox Co. P.R. v. Proctor & Gamble Com. Co., 228 F.3d 24, 30 (1st Cir. 2000). We also draw all reasonable inferences in Azurity's favor. Id.

A.

The FDCA requires the FDA's pre-approval to market any drug. However, the FDCA exempts "compounded" drugs -- which are drugs that are produced by "combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering . . . a drug or bulk drug substance," 21 U.S.C. § 353b(d)(1) -- from the FDCA's pre-approval requirements in some circumstances.

The circumstances are set forth in section 503B of the FDCA, 21 U.S.C. § 353b. That section provides that certain pre-approval requirements "shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the . . . conditions [set forth in section 503B] is met." 21 U.S.C. § 353b(a). The FDCA defines an "outsourcing facility" as a facility that "is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies

with all of the requirements of [section 503B of the FDCA]." Id. § 353b(d)(4)(A)(i)-(iii).

In specifying the conditions that an outsourcing facility must meet, section 503B provides that an "outsourcing facility" may not compound a drug that is "essentially a copy of one or more approved drugs." Id. § 353b(a)(5). Section 503B defines "essentially a copy" to mean:

> (A) a drug that is identical or nearly identical to an approved drug . . . unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing; or
>
> (B) a drug, a component of which is a bulk drug substance that is a component of an approved drug . . . , unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Id. § 353b(d)(2).

Another portion of section 503B concerns the use by "outsourcing facilities" of a "bulk drug substance." Id. § 353b(a)(2). That provision requires, as a "condition" for an "outsourcing facility" to market a compounded drug without prior FDA approval, that:

> The drug is compounded in an outsourcing facility that does not compound using bulk drug substances . . ., unless--

> (A)(i) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by--
>
> > (I) publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;
> >
> > (II) providing a period of not less than 60 calendar days for comment on the notice; and
> >
> > (III) publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or
>
> (ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing . . . .

Id.

B.

The vancomycin hydrochloride drug that Azurity markets is called FIRVANQ. FIRVANQ is "indicated for treatment of Clostridium difficile-associated diarrhea and enterocolitis caused by Staphylococcus aureus, including methicillin-resistant strains." Azurity does not purport to be an "outsourcing facility," but it has received FDA pre-approval to market FIRVANQ.

Edge "produces and markets an oral vancomycin solution that competes directly with Azurity's FIRVANQ." Edge markets the drug under the generic name "Vancomycin Oral Solution." Unlike

Azurity, Edge has not received FDA pre-approval to market this drug. Edge is registered, however, as an "outsourcing facility".

Prior to this suit, Edge made the following statements about its operations, each of which appeared on Edge's website:

> a. "Edge Pharma is a pharmaceutical sterile and non-sterile 503B Outsourcing Facility offering high quality, innovative solutions for the health care community."
>
> b. "As your compliance partner, we are dedicated to providing turnkey 503B outsourcing with the highest level of quality, easy ordering, simple logistics, and excellent customer support."
>
> c. "Edge Pharma is an FDA-registered and state-licensed, 503B Outsourcing Facility providing service to hospital pharmacies, outpatient surgery Centers, and clinics."
>
> d. "Our facility is compliant with the following state, local, and federal regulations and guidelines:
>
> USP 795, USP 797, USP 800[,]
> Occupational Safety and Health Administration (OSHA)[,]
> Food and Drug Administration (FDA)[,]
> US Pharmacopeia (USP)[,]
> Applicable Good Manufacturing Practice (GMP) Guidelines."
>
> e. "Edge Pharma is a USP 797 and cGMP compliant FDA-Registered 503B Outsourcing Facility that specializes in a wide array of sterile and non-sterile compounded medications."
>
> f. "As an FDA registered and inspected 503B Outsourcing facility, Edge has the ability to react quickly to customer requirements and deliver cost effective solutions."

In addition, "Edge . . . claim[ed] to be a 'Registered and Inspected FDA Outsourcing Facility'" in its marketing materials. Edge also stated on its website: "commercially available options are not ideal for use in the hospital setting."

We will refer to the statements that refer to Edge's "compliance" with the law as the "Compliance Statements." We will refer to the statements that refer to Edge being a "registered" and "inspected" "Outsourcing Facility" as the "Registration Statements." We will refer to the statement that "commercially available options are not ideal for use in the hospital setting" as the "Superiority Statement."

C.

On February 12, 2020, Azurity sued Edge in the District Court for the District of Massachusetts based on the statements just described. One count of Azurity's two-count complaint alleges that the Compliance and Registration Statements, as well as the Superiority Statement, constitute unfair competition and false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a). The other count alleges that the Compliance and Registration Statements, as well as the Superiority Statement, constitute unfair or deceptive acts or practices under Chapter 93A, Mass. Gen. Laws. ch. 93A, § 2(a).

To prove a Lanham Act claim for unfair competition and false advertising, a plaintiff must demonstrate that

> (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another's product; (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.

Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave., 284 F.3d 302, 310-11 (1st Cir. 2002).

A description or representation of fact in an advertisement may be either literally false or "true or ambiguous yet misleading." Id. at 311. Literal falsity and misleadingness represent two "independent" theories of recovery under the Lanham Act. Clorox, 228 F.3d at 36.

In assessing a Lanham Act claim for unfair competition and false advertising, a determination first must be made as to what the statement by the defendant that grounds the claim communicates. Id. at 34. A determination then must be made about whether that statement, given what it communicates, is either false and/or misleading. See id. at 34, 36. The Lanham Act prohibits only "false or misleading description[s] of fact." 15 U.S.C. § 1125(a)(1) (emphasis added).

The plaintiff bears the burden of proving that the statement at issue is false and/or misleading. Clorox, 228 F.3d at 33. That question is typically for the factfinder to determine. Id. at 34, 37.

If the statement is alleged to be literally false, "a violation [of the Lanham Act] may be established without evidence of consumer deception." Cashmere & Camel Hair Mfrs. Inst., 284 F.3d at 311. If the statement is alleged to be only misleading, rather than literally false, there is generally "an additional burden . . . placed upon the plaintiff to show that the advertisement . . . conveys a misleading message to the viewing public."[3] Id. (second alteration in original) (quoting Clorox, 228 F.3d at 33).

"[F]actfinders usually base literal falsity determinations upon the explicit claims made by an advertisement." Clorox, 228 F.3d at 34-35. However, "they may also consider any claims the advertisement conveys by 'necessary implication.'" Id. at 35 (quoting Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1139 (9th Cir. 1997)). We have explained that "[a] claim is conveyed by necessary implication when, considering the

[3] "[A] plaintiff alleging an implied falsity claim, however, is relieved of the burden of demonstrating consumer deception when there is evidence that defendants intentionally deceived the consuming public." Cashmere & Camel Hair Mfrs. Inst., 284 F.3d at 311 n.8. No such argument is made here.

advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated." Id.

When the Lanham Act claim is predicated on finding the advertisement to be misleading, the question is whether "the advertisement, though explicitly true, nonetheless conveys a misleading message to the viewing public." Id. at 33. In other words, in that circumstance, the question is whether the advertisement, though "literally true or ambiguous," nonetheless is "likely to mislead and confuse consumers" into believing a "false . . . representation of fact." Id. 33 & n.6. Moreover, when the plaintiff is pursuing a claim based on a statement's misleadingness, "the plaintiff must show how consumers have actually reacted to the challenged advertisement, rather than merely demonstrating how they could have reacted." Id. at 33.

Chapter 93A provides that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." Mass. Gen. Laws ch. 93A, § 2(a). The elements of a Chapter 93A claim "overlap[]" with those of a Lanham Act false advertising claim. See Cashmere & Camel Hair Mfrs. Inst., 284 F.3d at 320.

D.

Edge moved to dismiss Azurity's complaint on March 20, 2020, pursuant to Rule 12(b)(6) and Rule 12(b)(1). Edge gave the following grounds for dismissal.

First, Edge contended that Azurity had not plausibly alleged a claim under the Lanham Act based on any of the statements described above because the complaint plausibly alleges no more than that each of the statements contains "non-actionable puffery, opinion, and generalized comments about compliance with administrative law." Edge asserted in support of that contention that Azurity's complaint lacked the factual allegations necessary to plausibly allege a Lanham Act claim for either literal falsity or misleadingness, insofar as the claim relies on the Compliance or Registration Statements.

Edge contended in the alternative that, under the analysis set forth in POM Wonderful, the FDCA precludes Azurity's Lanham Act claim in any of its variants. Thus, Edge contended, Azurity's Lanham Act claim must be dismissed even if the complaint plausibly alleges that any or all of the statements at issue are literally false or misleading.

Relatedly, Edge contended that Azurity's Lanham Act claim -- again, even if based on plausible allegations of literal falsity or misleadingness, and no matter on which of the statements that claim is based -- must be dismissed under the doctrine of primary jurisdiction. That doctrine requires a federal court presented with an issue that falls within the primary jurisdiction of a regulatory agency to "defer any decision in the action before it until the agency has addressed the issue that is within its

primary jurisdiction." Ass'n of Int'l Auto. Mfrs., Inc. v. Comm'r, Mass. Dep't of Env't Prot., 196 F.3d 302, 304 (1st Cir. 1999) (quoting 2 Kenneth Culp Davis & Richard J. Pierce, Jr., Administrative Law Treatise 271 (3d ed. 1994)).

Finally, Edge asserted that Azurity's Chapter 93A claims must be dismissed. That was so, according to Edge, "because the allegedly false statements cited by Azurity are not actionable" under the Lanham Act, Cashmere & Camel Hair Mfrs. Inst., 284 F.3d at 320 (explaining there that if "plaintiffs were unable to satisfy the requirements of a Lanham Act claim, they would not be able to prove their state law claims, as the two have overlapping requirements"), and because "to the extent that Azurity's state law claims mirror its Lanham Act claims, they are preempted by the FDCA."

Azurity filed an opposition to the motion to dismiss. The opposition addressed each of Edge's asserted grounds for dismissal.

E.

The District Court granted Edge's motion and dismissed the complaint per Rule 12(b)(6) on May 18, 2021. Azurity, 540 F. Supp. 3d at 145. The District Court began by explaining its ruling as to the Lanham Act claim. The District Court relied solely on FDCA preclusion to dismiss the Lanham Act claim.

In POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102 (2014), the Supreme Court of the United States rejected the defendant's contention that the FDCA precluded a Lanham Act claim that involved a challenge to a statement that had been made in a label on a food item that was regulated by FDA pursuant to its authority to administer the FDCA's food labeling provisions. POM Wonderful, 573 U.S. at 121.

In so deciding, the Court reversed the Ninth Circuit's holding that the claim was precluded by the FDCA. See POM Wonderful LLC v. Coca-Cola Co. ("POM I"), 679 F.3d 1170 (9th Cir. 2012), rev'd, 573 U.S. 102 (2014). The Ninth Circuit had found the claim precluded based on its own precedent establishing that "a Lanham Act claim may not be pursued if the claim would require litigating whether [the underlying] conduct [to which the alleged misstatement refers] violates the FDCA" when the FDA itself has not determined a violation occurred. See id. at 1176-78 (citing PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 924 (9th Cir. 2010)). This was so, the Ninth explained in that prior case, because "the FDCA may be enforced only by the [federal government]," id. at 1175 (citing 21 U.S.C. § 337(a)), and "allowing such a suit would undermine" that exclusive enforcement authority, id. at 1176.

The Supreme Court thought differently. In POM Wonderful, the Court reasoned that "the centralization of FDCA enforcement authority in the Federal Government does not indicate

that Congress intended to foreclose private enforcement of other federal statutes." POM Wonderful, 573 U.S. at 117. Thus, because the plaintiff there sought to "enforce the Lanham Act, not the FDCA or its regulations," the FDA's exclusive enforcement authority did not itself warrant preclusion of the plaintiff's Lanham Act claim. Id.

In so concluding, the Court did not rule out the possibility that the FDCA might preclude a Lanham Act claim in some circumstances, id. at 118, and it specifically noted that the case before it did not involve a claim of preclusion regarding a statement about a drug, id. at 109, 116 ("Unlike other types of labels regulated by the FDA, such as drug labels, it would appear the FDA does not preapprove food and beverage labels under its regulations and instead relies on enforcement actions, warning letters, and other measures." (internal citation omitted)). But, the Court did not purport to identify any circumstance in which the FDCA would preclude a Lanham Act claim, and it noted that "the FDCA and the Lanham Act complement each other in the federal regulation of misleading food and beverage labels." Id. at 106.

None of the statements at issue in this case appear on any label that must be approved by the FDA. The statements are all ones that Edge allegedly made on its website. Nonetheless, the District Court concluded that the FDCA precluded Azurity's Lanham Act claim -- seemingly in all its variants -- on the ground

that the evaluation of the merits of the claim necessarily "would require the court to determine whether defendant is violating the FDCA and the FDA's interim policies." Azurity, 540 F. Supp. 3d at 143-44. The District Court explained that the FDA had not itself made those determinations and that "[e]nforcement of the FDCA and the detailed prescriptions of its implementing regulations is largely committed to the FDA," id. at 144 (quoting POM Wonderful, 573 U.S. at 115), such that "[i]t would be inappropriate . . . to resolve plaintiff's Lanham Act claim, which necessitates resolution of 'thorny questions that may require the FDA's expertise,'" id. (quoting Allergan USA Inc. v. Imprimis Pharms., Inc., No. 17-1551, 2017 WL 10526121, at *7 (C.D. Cal. Nov. 14, 2017)); see also id. ("Because the FDCA forbids private rights of action . . . [a] Lanham Act [claim] may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation where the FDA has not itself concluded that there was such a violation." (quoting PhotoMedex, Inc., 601 F.3d at 924)). The District Court went on to explain that, because the FDCA precluded the Lanham Act claim, Azurity's Chapter 93A claim had to be dismissed as well. Id.

Azurity timely filed this appeal. We review de novo the District Court's grant of Edge's Rule 12(b)(6) motion to dismiss Azurity's Lanham Act and Chapter 93A claims. See Clorox, 228 F.3d at 30.

II.

We start with Azurity's challenge to the District Court's dismissal of the variant of Azurity's Lanham Act claim that alleges that Edge's Compliance and Registration Statements communicate the message that Edge is not "in violation of" section 503B of the FDCA. Azurity contends that its complaint plausibly alleges in this variant of its Lanham Act claim that Edge has engaged in conduct that is barred by the portion of section 503B that restricts the marketing of compounded drugs that are "essentially a copy" of approved drugs, 21 U.S.C. § 353b(a)(5). Accordingly, Azurity contends, it has plausibly alleged that the Compliance Statements are literally false and the Registration Statements are misleading due to the messages that those statements communicate concerning Edge's purported compliance with the "essentially a copy" portion of section 503B and what conditions that portion of that section of the FDCA sets forth. Azurity further contends that, given that this variant of its Lanham Act claim is otherwise actionable, the District Court erred in dismissing it, because the FDCA does not preclude it.

We reject Azurity's challenge to the District Court order of dismissal as to this variant of Azurity's Lanham Act claim. We do not do so, however, based on FDCA preclusion, even though Edge urges us to affirm the ruling below on that basis. We do so because, as we will explain, we are persuaded by the

alternative ground that Edge advances to us on appeal for affirming the District Court's order of dismissal for this variant of Azurity's Lanham Act claim. See Lin v. TipRanks, Ltd., 19 F.4th 28, 36 (1st Cir. 2021) ("We, of course, may affirm the District Court's ruling on any ground manifest in the record.").

A.

We begin with Edge's assertion that, FDCA preclusion aside, Azurity fails to state a claim on which relief can be granted in the variant of its Lanham Act claim that alleges that the Compliance Statements, insofar as they communicate that Edge is not in violation of the "essentially a copy" provision of section 503B, make a literally false representation of fact.[4] In advancing this non-preclusion-based ground for dismissal, Edge relies chiefly on two out-of-circuit precedents that set forth a framework for assessing when a statement that concerns whether an entity is in violation of a law is actionable under the Lanham Act. The two precedents are Coastal Abstract Service, Inc. v.

[4] Azurity mentions in passing that the Compliance Statements "mislead health care providers and other customers into believing that Edge's vancomycin product complies with state and federal law, and that it is safe, effective, and legal." But, Azurity develops no argument as to whether, or why, the Compliance Statements are misleading as to the "safe[ty], effective[ness], and legal[ity]" of Edge's vancomycin product if the assertion that Edge is not in violation of section 503B is not literally false. Thus, any such argument is waived for lack of development. See Zannino, 895 F.2d at 17.

First American Title Insurance Co., 173 F.3d 725 (9th Cir. 1999), and Dial A Car, Inc. v. Transportation, Inc., 82 F.3d 484 (D.C. Cir. 1996).[5]

In Coastal Abstract, the Ninth Circuit considered whether a plaintiff could state a Lanham Act claim based on a defendant's statement that the plaintiff "was not licensed in California as an escrow company," 173 F.3d at 729, and the fact that the defendant "stated or clearly implied" that such a license was "required [by California law] . . . for [the plaintiff's] activities in connection with refinancing California property," id. at 731. The Ninth Circuit concluded that, "[a]bsent a clear and unambiguous ruling from a court or agency of competent jurisdiction, statements by laypersons that purport to interpret the meaning of a statute or regulation are opinion statements, and not statements of fact," and, as such, are "not generally actionable under the Lanham Act." Id. The Ninth Circuit ruled on

[5] In its briefing to us, Edge also cites to a district court case that presented a similar situation to Dial A Car, in which that court adopted the reasoning of the D.C. Circuit in that case, Greenwich Taxi, Inc. v. Uber Techs., Inc., 123 F. Supp. 3d 327, 335-36 (D. Conn. 2015), as well as several other cases in which the district courts there concluded that a legal opinion could not form the basis of a Lanham Act claim, see Metro. Reg'l Info. Sys., Inc. v. Am. Home Realty Network, Inc., 948 F. Supp. 2d 538, 554 (D. Md. 2013); Language Line Servs., Inc. v. Language Servs. Assocs., LLC, No. 10-02605, 2011 WL 5024281, *11 (N.D. Cal. Oct. 13, 2011). These cases accord with our understanding that Edge is asking us to apply the analytic framework that Dial A Car and Coastal Abstract adopt.

that basis that the plaintiff had not sufficiently plead that the statement at issue was false or misleading in violation of the Lanham Act, because "the correct application of [the statutory licensing requirement] was not knowable to the parties at the time that [the defendant] made the licensure statement." Id. at 732.

In Dial A Car, the D.C. Circuit considered a plaintiff's contention that the defendants "violat[ed] the Lanham Act by misrepresenting to [the plaintiff]'s actual and potential . . . customers that [the defendants'] taxicabs can legally provide within [Washington, D.C.]" point-to-point transportation to corporate clients using taxicabs licensed in Virginia or Maryland, but not D.C. 82 F.3d at 486. The plaintiff argued there that an order by the D.C. Taxicab Commission Office prohibited the defendants' taxicabs from providing the service in question to or from D.C. unless their passengers' origin or destination was in the county of the taxicabs' licensure. Id. The D.C. Circuit held that the defendants' representations at issue were not actionable under the Lanham Act, because "there must be a clear and unambiguous statement from the Taxicab Commission regarding [the defendants'] status before a Lanham Act claim can be entertained" based on the defendants' statements "that they lawfully may perform" a particular service and there was none in that case. Id. at 485, 489 (emphasis in original).

The D.C. Circuit did acknowledge that it was possible that "a regulation might conceivably be drafted that would be so clear on its face that no good faith doubt concerning its interpretation would be possible, even without an explicit statement from the [relevant regulatory entity]." Id. at 489 n.3. In such a circumstance, the court posited, the meaning of the regulation in question could be "so clear as to be a fact for Lanham Act purposes," id., such that a representation concerning the meaning of that law in advertising -- as a representation as to whether the defendant was violating a law would necessarily make -- might be actionable as a "false or misleading representation of fact," 15 U.S.C. § 1125(a)(1). But, the D.C. Circuit explained, the regulation at issue in that case was not of that sort. Dial A Car, 82 F.3d at 489 n.3. It thus held the Lanham Act claim there could not go forward on that basis. Id.

Azurity does not take issue with the framework for analysis that Coastal Abstract and Dial A Car set forth. Azurity also makes no argument that the framework is inapplicable here. It contends instead that, even under that framework, it has plausibly alleged an actionable Lanham Act claim based on the literally false representation or description of fact that it contends that the Compliance Statements make in communicating a message regarding the relationship between Edge's conduct and the "essentially a copy" provision of section 503B. Azurity contends

that is so because "the section 503B requirements," unlike the regulation involved in Dial A Car, "are explicit in the statute, and the FDA has issued clear and unambiguous guidance on how to apply those requirements."

Azurity refers here to a document cited in its complaint that the FDA issued in January 2018. See Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503b of the Federal Food, Drug, and Cosmetic Act Guidance For Industry, 2018 WL 953053 (Jan. 2018) [hereinafter "Essentially a Copy Guidance"]. That document purports to provide non-binding guidance about how the FDA "intends to consider" a "compounded drug" with respect to whether it is "identical or nearly identical to an approved drug" pursuant to the "essentially a copy" provision of section 503B, see 21 U.S.C. § 353b(d)(2).

The document states that the

> FDA intends to consider a compounded drug product to be identical or nearly identical to an approved drug if the compounded drug product and the FDA-approved drug have the same:
>
> - active ingredient(s),
> - route of administration,
> - dosage form,
> - dosage strength, and
> - excipients.

Essentially a Copy Guidance, 2018 WL 953053, at *5.

Azurity asserts that, in light of this document, its complaint plausibly alleges that "FIRVANQ and Edge's vancomycin

product satisfy each of the applicable factors" for making a compounded drug "identical or nearly identical" to an approved one under section 503B's "essentially a copy" provision. And, that is so, according to Azurity, because its complaint plausibly alleges that its vancomycin drug and Edge's each has the same active ingredient, is administered orally, and is liquid.[6]

Azurity acknowledges that its complaint does not allege that Vancomycin Oral Solution has the same "excipients" as FIRVANQ. But, Azurity points out that its complaint plausibly alleges that information about the "excipients" in FIRVANQ is not publicly available. Thus, Azurity contends, the absence of any allegation in its complaint about the two drugs sharing the same excipients is of no concern, given that the FDA's Essentially a Copy Guidance expressly states that when information about the approved drug's excipients is not publicly available the agency "does not intend to consider whether the compounded drug has the same excipients that the approved drug is labeled to contain in determining whether a compounded drug is identical or nearly identical to an approved drug." Id. at *5 n.15.

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[6] Azurity's complaint does not allege that the two products' dosage strengths are the same, but Azurity did argue to the District Court that its product is administered in the same dosage strength as Edge's. Additionally, Edge argues that the products have different "dosage form[s]" because FIRVANQ is made and sold as "powder and diluent" for oral administration, whereas "Edge's product is a single-dose syringe of oral solution."

Azurity does not deny, however, that it is premising this variant of its Lanham Act claim on the complaint plausibly alleging that, in the Compliance Statements, Edge made a false representation or description of fact about the meaning of the "essentially a copy" provision of section 503B. And yet, to support the contention that the complaint does plausibly so allege, Azurity is not relying on any ruling by the FDA, or any court, that Edge has in fact violated section 503B by engaging in conduct barred by the "essentially a copy" provision. See Coastal Abstract Serv., 173 F.3d at 731. Nor is Azurity relying even on a binding ruling by an agency or a court about the meaning of the "essentially a copy" provision itself with respect to what the "applicable factors" are for determining whether two drugs are identical or nearly identical under that provision of section 503B. Instead, Azurity is relying solely on a guidance document from the FDA that the FDA itself describes as "only recommendations" that are non-binding, see Essentially a Copy Guidance, 2018 WL 953053, at *1, and that states only that the FDA "intends to consider" a compounded drug to be "identical or nearly identical" within the meaning of the "essentially a copy" portion of section 503B to an approved drug when the five-factor test set forth above is satisfied, id. at *5 & n.15.

Moreover, Azurity is relying solely on that non-binding guidance document to support the contention that it has plausibly

alleged that, in the Compliance Statements, Edge has made a literally false representation or description of fact about the meaning of the "essentially a copy" provision of section 503B even though the text of section 503B does not itself make clear, on its face, that two drugs can be "identical or nearly identical" even if they have divergent "excipients." Indeed, the relevant statutory text does not refer to any of the five factors set forth in the FDA's non-binding guidance document, see 21 U.S.C. § 353b(d)(2) -- let alone suggest that fewer than all of them need to be satisfied for a compounded drug to be "essentially a copy" of an FDA-approved one for purposes of section 503B.

Thus, Azurity does not explain how there is the kind of "clear and unambiguous ruling" from a court or agency -- either that Edge specifically is in violation of the relevant provisions of law, or that interprets the "essentially a copy" provision of section 503B -- that could ground the variant of the claim that is at issue under the framework for determining whether this variant of the claim is actionable that Azurity accepts applies. See Coastal Abstract Serv., 173 F.3d at 731; Dial A Car, 82 F.3d at 489 & n.3; cf. Metro. Reg'l Info. Sys., Inc. v. Am. Home Realty Network, Inc., 948 F. Supp. 2d 538, 554 (D. Md. 2013) ("any statements made by [the counterclaim-defendants] regarding the copyrightability of [particular information] were nonverifiable legal opinions that are not actionable under the Lanham Act");

Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 230 (3d Cir. 1990) (rejecting a Lanham Act false labeling claim -- premised on the argument that FDA regulations required a label that the defendant's product lacked -- on the grounds that the plaintiff "has not proved that [the defendant's] labeling is false" because "interpretation of FDA regulations, absent direct guidance from the promulgating agency, is not as simple as [the plaintiff] proposes" and therefore did not compel the conclusion that the defendant's labeling was false). Nor can Azurity argue that the text of section 503B, given what that text sets forth, is clear enough on its face to make up for the absence of there being any such ruling. Cf. Dial A Car, 82 F.3d at 489 n.3. Thus, we agree with Edge that this variant of Azurity's Lanham Act claim cannot survive the motion to dismiss under Rule 12(b)(6) because it fails plausibly to allege that Edge made any literally false description or representation of fact.

We recognize that Azurity does attempt to fend off Edge's non-preclusion-based ground for affirming the District Court's dismissal of this variant of the Lanham Act claim by directing our attention to a different portion of the "essentially a copy" provision of section 503B from the "identical or nearly identical" one that has been our concern thus far. That portion of section 503B reads:

> The term 'essentially a copy of an approved drug' means . . . a drug, a component of which is a bulk drug substance that is a component of an approved drug . . ., unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

21 U.S.C. § 353b(d)(2)(B).

Azurity contends that the Compliance Statements are literally false because they communicate that Edge is not engaging in conduct barred by section 503B based on this "prescribing practitioner" portion of it. Azurity points as support for that contention to a different portion of the FDA's non-binding Essentially a Copy Guidance:

> If an outsourcing facility compounds a drug, the component of which is a bulk drug substance that is a component of an approved drug, there must be a change that produces a clinical difference for an individual patient as determined by the prescribing practitioner. If an outsourcing facility intends to rely on such a determination to establish that a compounded drug is not essentially a copy of an approved drug, the outsourcing facility should ensure that the determination is noted on the prescription or order (which may be a patient-specific prescription or a non-patient specific order) for the compounded drug.
>
> FDA is aware that a health care practitioner who orders a compounded drug from an outsourcing facility for office stock will not know the identity of the individual patients who will receive the compounded drug at the time of the order. In that case, the outsourcing facility should obtain a statement

> from the practitioner that specifies the change between the compounded drug and the comparable approved drug and indicates that the compounded drug will be administered or dispensed only to a patient for whom the change produces a clinical difference, as determined by the prescribing practitioner for that patient. Such assurances should be provided by the health care practitioner or a person able to make the representation for the health care practitioner.

2018 WL 953053, at *7 (emphasis added).

Azurity's complaint, however, is bereft of allegations that support the prescriber documentation theory for permitting its Lanham Act claim based on the literal falsity of the Compliance Statements to go forward that Azurity now presses on appeal. Its complaint alleges that "the vancomycin [Edge] sells is essentially a copy of an FDA-approved drug," but the complaint refers in doing so only to facts and statutory language that bear on the "identical or nearly identical" portion of that provision of section 503B. Indeed, Azurity conceded at oral argument to us that no allegations in its complaint bore on its prescriber documentation theory specifically. Accordingly, we agree with Edge that Azurity has not pleaded its "prescribing practitioner" theory of noncompliance with the "essentially a copy" provision, such that the Compliance Statements are plausibly alleged to violate the Lanham Act.[7]

[7] Azurity argues in the alternative that if its complaint cannot support its prescriber documentation theory, it should be

B.

We turn, then, to Azurity's challenge to the District Court's dismissal of the Lanham Act claim insofar it rests on the allegation that the Registration Statements "are materially misleading to health care providers." Azurity's theory is that while Edge's representations that it is a "registered" outsourcing facility may be literally true, such representations give health care providers the false impression "that Edge complies with state and federal law," including "[section] 503B." And that is so, according to Azurity, because despite those statements conveying

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entitled to amend its complaint. We leave that determination to the discretion of the District Court on remand. See Fed. R. Civ. P. 15(a)(2); cf. Nikitine v. Wilmington Tr. Co., 715 F.3d 388, 389 (1st Cir. 2013) ("We review a district court's denial of leave to amend for abuse of discretion.").

In so doing, we recognize that we leave unaddressed the question of whether a Lanham Act claim predicated on the prescriber documentation theory would be precluded by the FDCA, and if such a claim were precluded, that would render any such amendment futile. But, given that the preclusion analysis depends in large part on the precise nature of the claim brought, and Azurity has not represented to us the precise contours of its proposed amendment, we do not attempt to address the preclusion of any such amended claim here. See PDK Lab'ys Inc. v. DEA, 362 F.3d 786, 799 (D.C. Cir. 2004) (Roberts, J., concurring in part) ("[I]f it is not necessary to decide more, it is necessary not to decide more."). We do not mean in any way to suggest, by opting for this restrained approach at this juncture, what we would decide as to preclusion or that the argument for preclusion would be any stronger with respect to such an amended claim than we conclude that it is for the version of Azurity's Lanham Act claim predicated on the Compliance Statements and Section 503A's bulk drug substance provision. See infra at Part IV.

that impression, its complaint plausibly alleges that Edge is in violation of the "essentially a copy" provision of section 503B due to the shared characteristics of FIRVANQ and Vancomycin Oral Solution.[8]

Edge responds to this argument in part by disputing that Azurity has plausibly alleged that the Registration Statements convey the implicit message that Edge is not "in violation of" section 503B for having engaged in conduct prohibited by the "essentially a copy" provision of that statute. Edge contends that the Registration Statements merely convey true and undisputed facts about its status: that it is registered and inspected. But, even if we were to conclude otherwise, the question remains as to whether that implicit message is one that Azurity has plausibly alleged makes a "misleading representation of fact," 15 U.S.C. § 1125(a) (emphasis added), under Dial A Car and Coastal Abstract, see Coastal Abstract Serv., 173 F.3d at 731; Dial A Car, 82 F.3d at 489 & n.3. Yet, as to that question, Azurity merely makes the same arguments based on the non-binding FDA guidance document that

[8] Azurity also asserts that the Registration Statements give the false impression "that the FDA has approved the drugs or given its seal of approval to Edge's drugs, and therefore the compounded drugs are safe and effective." However, it develops no argument as to whether, or why, that message would be false or misleading if Edge had not violated section 503B by engaging in conduct prohibited by its "essentially a copy" provision. Thus, we deem any such argument waived. See Zannino, 895 F.2d at 17.

we found wanting in connection with its "essentially a copy" argument with respect to the Compliance Statements. As a result, we reject Azurity's challenge to the District Court's dismissal of this variant of the Lanham Act claim as well, because we agree with Edge that Azurity does not plausibly allege that the Registration Statements, insofar as they implicitly convey a message about Edge's compliance with the "essentially a copy" provision of section 503B, make a misleading representation of fact.

III.

We now turn to Azurity's challenge to the District Court's dismissal of the variant of the Lanham Act claim that rests on allegations about the way that Edge's Compliance and Registration Statements implicate a different provision of section 503B -- namely, the "bulk drug substance" provision, 21 U.S.C. § 353b(a)(2)(A). That provision "conditions" the ability of an "outsourcing facility" to market a drug without prior FDA approval on the facility "not compound[ing] using bulk drug substances . . . unless" the substance in question appears on a list of "bulk drug substances for which there is a clinical need" promulgated by the FDA or the compounded drug appears on the drug shortage list. Id. (emphasis added).

The District Court dismissed this variant of Azurity's Lanham Act claim -- just as it dismissed all variants of it -- on

the ground that it was precluded by the FDCA. Azurity argues on appeal that the District Court was wrong to do so. But, before we take up that argument, we first must address Edge's contention that, even if the FDCA does not preclude this variant of Azurity's Lanham Act claim, it still must be dismissed because Azurity's complaint fails plausibly to allege that the Compliance and Registration Statements are false and/or misleading. See TipRanks, 19 F.4th at 36.

A.

We start with Edge's contention that the viability of this "bulk drug substance"-based variant of Azurity's Lanham Act claim fails under the analytic framework set forth in Coastal Abstract and Dial A Car insofar as the claim is premised on the allegation that the Compliance Statements are literally false. For, Edge contends, Azurity does not allege that there has been any ruling that Edge has violated section 503B by failing to conform to the requirements in the "bulk drug substance" provision of that section of the FDCA, or any binding ruling from the FDA or a court that interprets the FDCA to impose a requirement that Edge's alleged use of bulk drug substances would violate. See Coastal Abstract Serv., 173 F.3d at 731 ("Absent a clear and unambiguous ruling from a court or agency of competent jurisdiction, statements by laypersons that purport to interpret the meaning of a statute or regulation are opinion statements, and

not statements of fact. Statements of opinion are not generally actionable under the Lanham Act." (internal citations omitted)); Dial A Car, 82 F.3d at 489.

Azurity responds as follows. It contends that the text of the provision of law at issue -- namely, the "bulk drug substance" provision of section 503B -- clearly prohibits the use of bulk drug substances in compounding where the bulk drug substance used does not appear on the FDA's official list of "bulk drug substances for which there is a clinical need," or on the operative drug shortage list. See 21 U.S.C. § 353b(a)(2)(A). It further contends that FDA guidance confirms that same understanding of the meaning of this statutory provision. And, finally, Azurity argues it has plausibly alleged that Edge is using a bulk drug substance that is not on either the bulk drug substance list or the drug shortage list to which the "bulk drug substance" provision of section 503B refers. Thus, Azurity contends, this case is factually distinguishable from Dial A Car, such that this variant of Azurity's Lanham Act claim is actionable even under the analytic framework that precedent sets forth. And, we note, that same contention, if it holds up, also would suffice to distinguish this case, factually, from Coastal Abstract.

We are persuaded by Azurity's response to Edge's argument that this variant of the Lanham Act claim must be dismissed even if the FDCA does not preclude it. Recall that

section 503B provides that an outsourcing facility cannot market a compounded drug without prior FDA approval "unless" the substance in question appears on a list of "bulk drug substances for which there is a clinical need" promulgated by the FDA or the compounded drug appears on the drug shortage list. Id. § 353b(a)(2)(A) (emphasis added). Given that text, there is no interpretation necessary to determine whether section 503B, through the "bulk drug substance" provision, sets as a condition for the sale of a compounded drug that is made using a bulk drug substance that the bulk substance be on either of the lists that the statutory provision specifies. Section 503B plainly does.

That is significant. Dial A Car itself recognized the possibility that a law or regulation could be "so clear on its face that no good faith doubt concerning its interpretation would be possible, even without an explicit statement from the [relevant regulatory entity]," such that it is "so clear as to be a fact for Lanham Act purposes," 82 F.3d at 489 n.3. Nor are we aware of any precedent that holds to the contrary. Cf. Dial A Car, Inc. v. Transp., Inc., 884 F. Supp. 584, 592 (D.D.C. 1995) ("[The d]efendants were expressing an opinion on an inconclusive question of law and were not making representations of verifiable or 'hard definable facts.'" (emphasis added) (quoting Licata & Co. Inc. v. Goldberg, 812 F. Supp. 403, 408 (S.D.N.Y. 1993))), aff'd, 82 F.3d 484 (D.C. Cir. 1996). And, the statutory provision at issue is of

a kind that is unusually susceptible of being clear enough on its face as to what condition it establishes for the scope of the condition to be a fact. The provision at issue specifies exactly which substances cannot be used unless they are on readily identifiable lists. Yet, one of these lists does not yet even exist, while there is no dispute that Azurity has plausibly alleged that the other list does not include the bulk drug substance in question.

This case is also not one in which the administering agency has purported to give the statutory provision at issue a different construction from the one that its plain text appears to demand. Rather, here, the FDA has merely stated its intention -- in, we add, a non-binding guidance document -- with respect to the "action" it "intends to take" on the event the condition at issue is not met. Nothing in that statement suggests that section 503B does not impose the condition that it plainly imposes with respect to the use of "bulk drug substances." Indeed, to the extent that the FDA's interim guidance makes a representation about what section 503B's bulk substance provision means, which is the operative question under the framework set forth in Coastal Abstract and Dial A Car, that guidance acknowledges both that vancomycin hydrochloride is not on the "503B Bulks List" and that an "outsourcing facility" that compounds a "drug product from a bulk drug substance" that is not on the list "does not meet the

conditions of section 503B(a)(2)," see Interim Policy On Compounding Using Bulk Drug Substances Under Section 503b of the Federal Food, Drug, and Cosmetic Act Guidance For Industry, 2017 WL 345598 at *4, *7 (Jan. 2017) [hereinafter "Interim Bulk Drug Policy"], and identifies vancomycin hydrochloride as being among them. Id. at *4, *7.

In sum, Edge appears to accept -- and certainly develops no argument to the contrary -- that the statements that reference Edge's "compliance" with section 503B are, plausibly, understood to make representations about the meaning of section 503B's "bulk drug substance" provision and not merely representations about what enforcement action the FDA will or will not take against the company in the event the condition that is set forth in the "bulk substance" provision is not satisfied. And, for the reasons we have given, Azurity has plausibly alleged that, in the Compliance Statements, Edge represents, in effect, that section 503B does not say what it plainly says, given that there is no dispute that Azurity plausibly alleges that the bulk drug substance used by Edge in compounding -- vancomycin hydrochloride -- is not on either the bulk drug substance list or the drug shortage list. Thus, we cannot agree with Edge that we may affirm the District Court's ruling dismissing this variant of Azurity's Lanham Act claim -- namely, the variant rooted in the Compliance Statements as they

relate to the "bulk drug substance" provision -- on the non-preclusion-based ground that Edge advances.[9]

B.

We next address Edge's non-preclusion-based ground for affirming the dismissal of Azurity's Lanham Act claim with respect to the variant of that claim that alleges that the Registration Statements are misleading in light of the "bulk drug substance" provision of section 503B. Here, Azurity alleges that the statements that Edge is a "registered" outsourcing facility, while literally true, are misleading because they convey the message that Edge is not in violation of section 503B, even though Edge is using a bulk drug substance in a circumstance that is barred by that provision.

Edge emphasizes that when a plaintiff alleges that an advertisement is misleading, but not literally false, it bears an "additional burden . . . to show that the advertisement . . . conveys a misleading message to the viewing public." Cashmere & Camel Hair Mfrs. Inst., 284 F.3d at 311 (quoting Clorox, 228 F.3d

[9] We note that in finding this version of Azurity's Lanham Act claim viable, we do not mean to foreclose the possibility that a factfinder may conclude that Edge's Compliance Statements represented that Edge was in compliance with the FDCA as the FDA said it was going to enforce it. See Clorox, 228 F.3d at 34 ("Whether an advertisement is literally false is typically an issue of fact. . . . [A] factfinder must determine the claim conveyed by the advertisement.").

at 33) (second omission in original). And, Edge then contends that Azurity has not met this burden because Azurity "pleads no facts to satisfy this burden" with respect to this variant of its Lanham Act claim and instead sets forth conclusory allegations "that the statements could give a misleading impression." We agree.

Azurity's complaint contains only the allegations that Edge's statements "are materially misleading to health care providers and are intended to induce health care providers into believing that Edge complies with state and federal law," and the conclusory assertion that "[Edge]'s false and misleading statements actually deceive and have the tendency to deceive a substantial segment of the intended audience." Azurity makes no allegations that explain how, or why, the Registration Statements could mislead an audience about Edge's conduct with respect to the "bulk drug substance" provision specifically.

Azurity does cite as support to McGrath & Co., LLC v. PCM Consulting, Inc., No. 11-10930, 2012 WL 503629 (D. Mass. Feb. 15, 2012). But, the complaint in that case alleged a specific misimpression that the statements at issue communicated -- that the statements "give the incorrect impression that . . . 'PCM is a larger company than it actually is,'" id. at *2, *5. Here, by contrast, Azurity's complaint alleges only that the statements "are materially misleading and are intended to induce health care

providers into believing that Edge complies with state and federal law." The complaint makes no allegations that the Registration Statements actually misled their audience into believing that Edge does not violate the "bulk drug substance" provision of section 503B specifically.

Clorox Co. Puerto Rico v. Proctor & Gamble Com. Co., 228 F.3d 24 (1st Cir. 2000), accords with our conclusion. The complaint there laid out in detail the nature of the misleading impression the statements at issue conveyed. By contrast, Azurity's complaint lacks any specific explanation as to how the Registration Statements could mislead an audience as to Edge's conduct related to the "bulk drug substance" provision in particular. See id. at 36-37.

Azurity's complaint does state that the Registration Statements "are intended to induce health care providers into believing that Edge complies with state and federal law" (emphasis added). But, Azurity does not argue to us that it has plausibly pleaded that Edge made those statements with the intention of deceiving its consumers. See Cashmere & Camel Hair Mfrs. Inst., 284 F.3d at 311 n.8 ("[A] plaintiff alleging an implied falsity claim, however, is relieved of the burden of demonstrating consumer deception when there is evidence that defendants intentionally deceived the consuming public."). Thus, any such argument is waived. See Zannino, 895 F.2d at 17.

Accordingly, for reasons independent of possible FDCA preclusion, we agree with Edge that this variant of Azurity's Lanham Act claim fails plausibly to allege a statement that is actionably "misleading."[10] Accordingly, we affirm the dismissal of the claim on that basis. See Intermountain Stroke Ctr., Inc. v. Intermountain Health Care, Inc., 638 F. App'x 778, 793 (10th Cir. 2016) (affirming dismissal of Lanham Act claim in part because "at no point during these proceedings have Plaintiffs explained how consumers might infer" the misleading representation of fact that the plaintiff asserted had been made).

IV.

Although we have put the preclusion issue aside up to this point, we do need to return to it. For, Edge does also contend that the District Court was right to dismiss the "bulk drug substance"-based variant of Azurity's Lanham Act claim based

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[10] Similarly, insofar as Azurity has alleged and argued that the Compliance Statements are misleading -- rather than literally false -- because of what they communicate concerning Edge's conduct under the "bulk drug substance" provision of section 503B, that allegation, too, fails plausibly to state a claim under the Lanham Act.

Azurity also asserts that the Registration Statements give the false impression "that the FDA has approved the drugs or given its seal of approval to Edge's drugs, and therefore the compounded drugs are safe and effective." But, here too, Azurity has failed to develop any argument as to why that message would be false or misleading if Edge had not been in violation of section 503B's "bulk drug substance" provision at the time the Registration Statements were made. Any such argument is therefore waived. See Zannino, 895 F.2d at 17.

on FDCA preclusion (insofar as Azurity's complaint alleges with respect to this variant of its Lanham Act claim that the Compliance Statements are literally false) because the adjudication of that claim "would undoubtedly interfere with an FDA policy judgment."

In support of that contention, Edge seizes upon the enforcement priorities stated in the FDA's Interim Bulk Drug Policy. Based on them, it argues that, because the FDA has indicated that it does not intend to take action against outsourcing facilities compounding drugs by using vancomycin hydrochloride, the FDCA precludes the claim at issue. Interim Bulk Drug Policy, 2017 WL 345598, at *7.

Edge contends that this conclusion follows from POM Wonderful, which it contends establishes that the FDCA precludes Lanham Act claims that would "directly conflict[] with the agency's policy choice" or otherwise "undermin[e] an agency judgment," 573 U.S. at 120. But, insofar as POM Wonderful could be read to imply that FDCA preclusion could be warranted under some circumstances, we find no basis for dismissing this variant of Azurity's Lanham Act claim on the ground that the FDCA precludes it.

First, like in POM Wonderful, which found no preclusion, the FDA did not preapprove the statements by Edge that Azurity alleges were made in violation of the Lanham Act. Thus, this case is not one in which a finding that the statement is actionable

under the Lanham Act calls into question the lawfulness of a statement that the FDA has deemed proper.

Second, POM Wonderful found no preclusion even where an FDA regulation governed some aspects of the challenged label. See 573 U.S. at 108. Here, the case for finding no preclusion would only seem to be stronger. After all, the parties have identified no FDA regulation that governs the statements that outsourcing facilities may make in advertising -- let alone a regulation that would risk subjecting Edge to inconsistent obligations if its Compliance Statements could be the basis of Lanham Act claims.

Third, and relatedly, like in Pom Wonderful, this is not a case in which a plaintiff is attempting to enforce the FDCA indirectly. True, the FDCA does not furnish a private right of action. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4 (2001); 21 U.S.C. § 337(a). But, we fail to see the import of that observation here. For, while Edge does argue that "Azurity seeks to enforce a 'bulk drug substance' provision of the FDCA under circumstances in which the FDA has expressly declined to take any enforcement action," Azurity "seeks to enforce the Lanham Act, not the FDCA or its regulations," POM Wonderful, 573 U.S. at 117.

Section 503B does regulate how compounded drugs may be labeled. See 21 U.S.C. § 353b(a)(10). But, neither party suggests that section 503B or any other provision of the FDCA regulates the

statements that outsourcing facilities may make in advertising. So, rather than enforcing the FDCA, Azurity is merely pursuing a private right of action under the Lanham Act. See id. at 120 (noting that "the FDA does not have authority to enforce the Lanham Act" and finding it insufficient to preclude a Lanham Act claim that the FDA "enacted regulations that touch on similar subject matter but do not purport to displace that remedy or even implement the statute that is its source").

Edge's only remaining argument for preclusion is that Azurity's claim should be precluded because it depends on the meaning of a law that the FDA administers. Such an argument may be better understood to rest on the doctrine of primary jurisdiction, rather than preclusion. See Pejepscot Indus. Park, Inc. v. Me. Cen. R.R. Co., 215 F.3d 195, 205 (1st Cir. 2000) (setting forth three factors that inform the decision to refer an issue to an agency under the doctrine of primary jurisdiction: "(1) whether the agency determination l[ies] at the heart of the task assigned the agency by Congress; (2) whether agency expertise [i]s required to unravel intricate, technical facts; and (3) whether, though perhaps not determinative, the agency determination would materially aid the court" (alterations in original) (quoting Massachusetts v. Blackstone Valley Elec. Co., 67 F.3d 981, 992 (1st Cir. 1995))). But, whatever the proper label, the argument does not persuade us here.

Edge relies on the Federal Circuit's holding that

> a complainant fails to state a cognizable claim under [section 337 of the Tariff Act, 19 U.S.C. § 1337, based on alleged violations of the Lanham Act] where that claim is based on proving violations of the FDCA and where the FDA has not taken the position that the articles at issue do, indeed, violate the FDCA. Such claims are precluded by the FDCA.

Amarin Pharma, Inc. v. Int'l Trade Comm'n, 923 F.3d 959, 968 (Fed. Cir. 2019). The plaintiff's argument in Amarin was that a competitor had falsely or misleadingly labeled its dietary supplement products because "labeling the products as 'dietary supplements' is literally false because the products 'cannot meet the definition of "dietary supplement" in Section 201(ff) of the FDCA.' . . . [T]he [competitor's] products 'are actually unapproved "new drugs" under the FDCA.'" Id. at 967 (quoting the plaintiff's complaint). But, despite the broad language of the excerpt that Edge quotes, Amarin was in fact concerned with a lack of guidance from the FDA about an unclear statutory question, the resolution of which implicated the FDA's expertise: whether synthetically produced omega-3 products were "new drugs" as defined in the FDCA, which would trigger a requirement that the FDA approve them for sale and use in the United States. See id. at 961. Indeed, the Federal Circuit explicitly stated that it was not making the "broader ruling -- that all such claims are

precluded regardless of whether the FDA has provided guidance." Id. at 968.

Here, by contrast, the "bulk drug substance" provision of section 503B is clear in the relevant respects, and that clear statutory text is reinforced by the FDA's interim guidance. The adjudication of Azurity's "bulk drug substance" claim thus does not require a court to make a determination that "l[ies] at the heart of the task assigned the agency by Congress" or requires "agency expertise . . . to unravel intricate, technical facts." Pejepscot Indus. Park, Inc., 215 F.3d at 205 (quoting Blackstone Valley Elec. Co., 67 F.3d at 992 (alteration in original)). Instead, the adjudication of this claim simply requires a court to ascertain whether a particular drug appears on either the list of "bulk drug substances for which there is a clinical need," or on the drug shortage list. 21 U.S.C. § 353b(a)(2)(A); see also Alpharma, Inc. v. Pennfield Oil Co., 411 F.3d 934, 936, 939 (8th Cir. 2005) ("The question of whether [the defendant's product] has been approved as safe and effective is much different from the question of whether [the defendant's product] should be approved as safe and effective, and it is only the latter that requires the FDA's scientific expertise.").

Thus, even if we were to assume that the FDCA precludes Lanham Act claims that "directly conflict with" the FDA's "policy choice[s]" or "undermin[e] an agency judgment," see POM Wonderful,

573 U.S. at 117, Azurity's bulk drug claim is not of that kind. The plain text of the relevant portion of section 503B is clear: one of the statutory "conditions" for "outsourcing facilit[ies]" is that the "facility . . . does not compound using bulk drug substances . . . unless" the substance in question appears on a list the FDA has not yet promulgated in the manner prescribed by statute. 21 U.S.C. § 353b(a)(2). Nothing in the FDA's guidance suggests otherwise. See Belcher Pharms., LLC v. Hospira, Inc., 1 F.4th 1374, 1381 (11th Cir. 2021) (holding a Lanham Act claim not precluded by the FDCA because the plaintiff "is . . . not asking us to contradict any regulatory conclusion reached by the FDA" or "to make any original determination that only the FDA could make—such as whether the indications for use are safe or effective, or whether [defendant]'s drug is approved or grandfathered"). Indeed, the FDA's interim bulk drug policy states that bulk drug substances like vancomycin hydrochloride "[are] not on the 503B bulks list," Interim Bulk Drug Policy, 2017 WL 345598, at *7.

That is not to deny that the FDA has made a statement regarding the way it intends to exercise its enforcement discretion. But, the FDA's choice not to enforce the terms of this provision against outsourcing facilities that use such bulk drug substances does not mean that the terms of the provision are less than perfectly clear. See Allergan, 2017 WL 10526121, at *8 ("[T]he FDA's decision to decline enforcement of certain

. . . 503B requirements does not help [the defendant]. As an executive agency, the FDA has discretion to enforce the law, but the lack of enforcement does not make [the defendant's] actions legal."). And, the Lanham Act claim at issue merely asks a court -- with respect to the meaning of that provision -- to find that the terms of the provision are as clear as they plainly are. Thus, we perceive no basis for finding the kind of conflict between Lanham Act enforcement and FDA policy discretion that Edge contends could supply the basis for finding a Lanham Act claim to be precluded by the FDCA.[11]

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[11] Edge does also contend, more broadly, that Azurity's "Lanham Act claims are precluded because they require litigation of alleged FDCA violations." And, Edge further argues, relying on the Ninth Circuit's pre-POM Wonderful decision in PhotoMedex, "[a] Lanham Act claim may not be pursued if the claim would require litigating whether [the underlying] conduct violates the FDCA," PhotoMedex, Inc., 601 F.3d at 924. But, while Edge is right that Azurity can only succeed on its Lanham Act claims if it can prove that Edge was not in compliance with the relevant provision of section 503B at the time the statements were made, the Supreme Court rejected in POM Wonderful the argument that because only the FDA can enforce the FDCA, Lanham Act claims based on a statement also regulated by the FDCA are categorically precluded. POM Wonderful, 573 U.S. at 117; see also ThermoLife Int'l, LLC v. Gaspari Nutrition Inc., 648 F. App'x 609, 612 n.1 (9th Cir. 2016) (acknowledging that POM Wonderful, by "explain[ing] that the FDCA's exclusive enforcement authority 'does not indicate that Congress intended to foreclose private enforcement of other federal statutes,'" rejected the core rationale underlying the Ninth Circuit's precedent that held that a Lanham Act claim may not be pursued if the claim would require litigating whether the underlying conduct violates the FDCA); JHP Pharms., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 999 (C.D. Cal. 2014) ("PhotoMedex was the primary case relied on by the lower courts in POM Wonderful,

v.

That brings us to Azurity's contention that the District Court erred in dismissing its challenge to the dismissal of the variant of its Lanham Act claim that is premised on the Superiority Statement. That statement, once present on a page of Edge's website describing its Vancomycin Oral Solution, stated that "commercially available options are not ideal for use in the hospital setting."

Azurity argues that this statement by Edge constituted "a literally false statement about vancomycin hydrochloride" in violation of the Lanham Act. Edge responds that its statement is "non-actionable puffery" and that we should affirm the District Court's dismissal of this version of Azurity's Lanham Act claim on that basis. We agree with Edge.

Azurity correctly notes that the District Court did not specifically address the Superiority Statement-based theory in granting Edge's motion to dismiss. We may also assume that Azurity

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and although it was not specifically overruled, its precedential value may be limited."); Innovative Health Solutions, Inc. v. DyAnsys, Inc., No. 14-CV-05207, 2015 WL 2398931, at *7 n.4 (N.D. Cal. May 19, 2015) (same); Surgical Instrument Serv. Co., Inc. v. Intuitive Surgical, Inc., 571 F. Supp. 3d 1133, 1142 (N.D. Cal. 2021) ("PhotoMedex is no longer good law. . . . The 'reasoning and theory' of PhotoMedex is [] 'clearly irreconcilable with the reasoning and theory' of POM Wonderful, making PhotoMedex 'effectively overruled.'" (cleaned up, internal citations omitted)). Accordingly, we are not persuaded by Edge's broader argument.

is right that the preclusion rationale upon which the District Court grounded its decision does not dictate the resolution of this version of Azurity's Lanham Act claim, because evaluating the falsity of the Superiority Statement does not require construing the FDCA. And, that is so because we may affirm a district court's judgment on any ground manifest in the record, see TipRanks, 19 F.4th at 36, and we conclude that Edge's statement is nonactionable puffery.

"Advertising claims that fall in the category of 'puffing' are considered not to constitute false advertising and are not in violation of the Lanham Act." 5 McCarthy on Trademarks and Unfair Competition § 27:38 (5th ed.). McCarthy's treatise recognizes two varieties of puffery: (1) "grossly exaggerated advertising claims . . . [that] no reasonable buyer would believe was true," and (2) "a general claim of superiority over a comparative product that is so vague and indeterminate that it will be understood as a mere expression of opinion. . . . Advertising claims that a product or service is 'better' and 'superior' fall into this category." Id. But, "[a] specific and measurable advertisement claim of product superiority . . . is not puffery." Clorox, 228 F.3d at 38 (alteration in original) (quoting Southland Sod Farms, 108 F.3d at 1145).

In Clorox, for example, we held that two statements in advertisements for laundry detergent -- "Compare with your

detergent . . . Whiter is not possible" and "Whiter is not possible" -- were specific and measurable claims of superiority, rather than puffery, id. at 38–39. The challenged statements, we explained, "invite[] consumers to compare [the defendant's detergent]'s whitening power against either other detergents acting alone or detergents used with chlorine bleach," id. at 39, in part because the tag line appeared in commercials that featured "consumers who normally used bleach to achieve white clothes . . . who [were] favorably impressed by the results obtained from using [the defendant's product] alone," id. at 35.

Other circuits have concluded similarly. In Pizza Hut, Inc. v. Papa John's International, Inc., 227 F.3d 489 (5th Cir. 2000), for example, the Fifth Circuit concluded that the slogan "Better Ingredients, Better Pizza" standing alone constituted nonactionable puffery under the Lanham Act, because "[t]he word 'better,' when used in this context is unquantifiable" "without further description," id. at 498-99. But, when that slogan was accompanied by ads that compared specific ingredients, such as the tomatoes and the water that went into the dough, the slogan was given "quantifiable, and fact-specific meaning" such that it no longer constituted puffery. Id. at 500.

Likewise, in Castrol Inc. v. Pennzoil Co., 987 F.2d 939 (3d Cir. 1993), the Third Circuit upheld a trial court's determination that the defendant's statement that its motor oil

product "outperforms any leading motor oil against viscosity breakdown" was not puffery, because "[v]iscosity breakdown" is a specific attribute of motor oil that is measured and graded by performance on "an industry-recognized laboratory test that measures the 'kinematic viscosity' of motor oils." Castrol Inc. v. Pennzoil Co., 799 F. Supp. 424, 429 (D.N.J. 1992), aff'd, 987 F.2d 939 (3d Cir. 1993). And, while the statement did not explicitly mention any of the defendant's competitors, the fact that the statement represented that the product was "superior to other brands" invited the consumer to make that comparison by necessary implication. Castrol, 987 F.2d at 946.

Azurity argues that Edge's Superiority Statement represents a false "claim[] that [Edge's] product was 'ideal' for use in a hospital setting, implying that products such as FIRVANQ are not, or was otherwise superior to FDA-approved drugs such as FIRVANQ." But, Azurity further argues, FIRVANQ is ideal for use in hospitals because it is FDA approved, and, "[b]y its inherent nature, an FDA-approved product is presumed to be safer and superior to a compounded formulation using the same active ingredient." Therefore, Azurity contends, Edge's Superiority Statement is not nonactionable puffery, because it is "a specific and measurable advertisement claim of product superiority" that can form the basis of a Lanham Act claim.

But, even if we assume that the challenged statement by Edge does in fact necessarily imply that Edge's product is "ideal for use in the hospital setting" and competing products such as FIRVANQ are not, Azurity's argument rests on the premise that when Edge represents its product to be "ideal for use in the hospital setting," a "reasonable consumer" of these drugs would measure the "ideal-ness" of each drug for use in the hospital setting by whether the drugs were FDA-approved or not. Pizza Hut, 227 F.3d at 501. But, Azurity provides no explanation why that is so. Nor does the Superiority Statement itself invite the consumer to compare the drugs along that dimension.[12] See, e.g., Clorox, 228 F.3d at 38 (inviting the consumer to compare the "whiteness" of their laundry when they use the defendant's product versus when

[12] Nor does the word's definition indicate that, insofar as it can be measured at all, the quality of being "ideal" is anything other than "vague or subjective." Clorox, 228 F.3d at 38. The Oxford English Dictionary defines "ideal" as, "[c]onceived or regarded as perfect or supremely excellent in its kind; answering to one's highest conception." Ideal, Oxford English Dictionary Online (Dec. 2021 update); see also ideal, Merriam-Webster's Unabridged Dictionary ("of or relating to an ideal or to perfection of kind : existing as a perfect exemplar : embodying or symbolizing an ideal").

Additionally, we note that the source that Azurity cites to support its claim that FDA approval serves as proof that a drug is "ideal" in fact belies the contention. Azurity cites the following language from the FDA: "FDA approval of a drug means that data on the drug's effects have been reviewed . . . and the drug is determined to provide benefits that outweigh its known and potential risks for the intended population." A determination that a drug's benefits outweigh its risks is a far cry from a determination that the drug is "ideal."

they use bleach); Pizza Hut, 227 F.3d at 501 ("[A] reasonable consumer would understand the slogan[, 'Better Ingredients, Better Pizza,'] when considered in the context of the comparison ads, as conveying the following message: Papa John's uses 'better ingredients,' which produces 'better pizza' because Papa John's uses 'fresh-pack' tomatoes, fresh dough, and filtered water." (emphasis in original)). Because there are, perhaps, many other factors that go into whether a drug is "ideal for use in the hospital setting," such as ease of administration or reliable supply of the drug in large quantities, that FDA approval itself may not have a bearing on, we see no reason why FDA approval is the only measure by which a consumer of these drugs would measure the "ideal-ness" of them. See Impact Applications, Inc. v. Concussion Mgmt., LLC, No. 19-3108, 2021 WL 978823, *7 (D. Md. March 16, 2021) (rejecting the argument that a statement that implied that the defendant's product was superior to that of the plaintiff's was not nonactionable puffery on the ground that a claim of superiority need not equate to a representation of FDA approval, as "[i]t is unclear, if not unlikely, . . . that a device that is not approved by the FDA can never be superior in any respect to an FDA-approved device").

The claim allegedly being made in the Superiority Statement, moreover, is not like a claim concerning a specifically measurable attribute like motor oil viscosity (or its capability

to prolong engine life), see Castrol, 799 F. Supp. at 427–28, or a claim in which the advertiser suggests that an attribute, if not measurable, is comparable, see Ferring Pharms., Inc. v. Braintree Lab'ys, Inc., 38 F. Supp. 3d 169, 178 (D. Mass. 2014) (finding that a claim that a drug had a "'superior cleansing efficacy,' [when] backed up by study results, [was] not mere 'puffery'"). It is a claim about a product being "not ideal" is not susceptible to specific measurement. But, we discern no objective way to measure the quintessentially "vague [and] subjective," Clorox, 228 F.3d at 38, attribute of "ideal-ness" and compare it across products, and Azurity does not supply us with any guidance.

Thus, we agree with Edge that Edge's statement is nonactionable puffery. See Catilina Nominees Proprietary Ltd. v. Stericycle, Inc., No. 15-CV-10734, 2021 WL 1165087, at *6 (N.D. Ill. Mar. 26, 2021) (concluding, on a motion to dismiss, that defendant's statement that its products are "ideal for patient rooms and treatment areas where security and convenience are critical" "employ[ed] . . . vague buzzwords" and constituted "puffery"). We therefore affirm on this ground the District Court's grant of Edge's motion to dismiss the variant of Azurity's Lanham Act that is premised on Edge's statement that "commercially available options are not ideal for use in the hospital setting."

VI.

Azurity also brings a claim under Chapter 93A, the Massachusetts state consumer protection law, based on Edge's Compliance and Registration Statements, as well as its Superiority Statement. The District Court held that Azurity's "Chapter 93A claim . . . fails as it is premised on the same allegations" as its Lanham Act claim. Azurity, 540 F. Supp. 3d at 144 (citing Reed, 883 F. Supp. 2d at 334–35).

On appeal, Azurity focuses on its Lanham Act claim; it develops no argument that its Chapter 93A claim can survive if it has not plausibly alleged Lanham Act violations. On the other hand, Edge develops no argument for affirming the District Court's dismissal of Azurity's Chapter 93A claim insofar as any variant of Azurity's Lanham Act claim can survive. And, as we have explained, one such variant of that claim can: the "bulk drug substance"-based one that alleges the Compliance Statements are literally false. Thus, to the same extent, and for the same reasons, that we vacate the District Court's dismissal of Azurity's Lanham Act claim in and affirm that dismissal in part, we vacate and affirm in part the District Court's dismissal of Azurity's Chapter 93A claim.[13]

[13] We do note that FDCA preemption rather preclusion would appear to be the operative doctrine to assess whether the FDCA

VII.

For the foregoing reasons, we affirm in part and vacate in part the District Court's grant of Edge's motion to dismiss Azurity's lawsuit, and remand for further proceedings. The parties shall bear their own costs.

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bars a Chapter 93A claim, given that it is a state law claim. But, no such preemption argument has been advanced, and Edge does not explain how preclusion could bar a Chapter 93A claim predicated on the allegations underlying the "bulk substance"-based variant of Azurity's Lanham Act claim that is the only variant that we conclude states a claim.