UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

GENUS LIFESCIENCES INC.,

Plaintiff,

v.

LANNETT COMPANY, INC., et al.,

Defendants.

Case No. 18-cv-07603-WHO

ORDER GRANTING LANNETT COMPANY, INC.'S AND CODY LABORATORIES, INC.'S MOTION TO DISMISS IN PART AND DENYING IN PART; GRANTING FIRST DATABANK, INC.'S MOTION TO DISMISS

Re: Dkt. Nos. 29, 30

Genus Lifesciences Inc. ("Genus") is a competitor of Lannett Company Inc. and Cody Laboratories, Inc., Lannett's wholly owned subsidiary, in the market for cocaine hydrochloride nasal spray. It is suing Lannett and Cody for false advertising and maintaining a monopoly related to Lannett's production of C-Topical® ("C-Topical"), a cocaine hydrochloride solution that competes with Genus' own cocaine hydrochloride solution, GOPRELTO® ("Goprelto").[1] It also sues First Databank, Inc. a pricing list company that compares drug products and their prices so that wholesalers and customers can see all the alternatives available for a particular medication, for false advertising and contributory false advertising. Some of Genus's claims against Lannett and Cody are plausibly stated, but none against First Databank is because First Databank's challenged statement in the pricing list was not "commercial speech" and First Databank did not influence Lannett's conduct about which Genus complains. Accordingly, First Databank's motion to dismiss is granted and Lannett and Cody's motion to dismiss is granted in part and denied in part.

[1] Genus's apparent attempt to add a sheen of criminality by calling C-Topical "Lannett's Cocaine Drug" is not well taken. Referring to Lannett's product as C-Topical will do.

BACKGROUND[2]

Genus claims that Lannett and Cody falsely advertise, market, and promote C-Topical as approved when it has not been approved by the U.S. Food and Drug Administration ("FDA"). Complaint at ¶¶ 1-5 [Dkt. No. 1]. It also asserts claims against Lannett and Cody for engaging in anticompetitive conduct aimed at maintaining a monopoly and preventing Genus from occupying a place in the market. *Id.* at ¶ 1.

Otolaryngologists (commonly known as ear, nose and throat specialists, or ENTs) use Lannett's product, Goprelto, while performing intranasal medical procedures. *Id.* at ¶ 3. On December 14, 2017, the FDA granted approval of Goprelto's New Drug Application 209963. *Id.* at ¶ 2. To gain approval, Genus performed five clinical trials and ten non-clinical trials involving over 700 human subjects. *Id.* at ¶ 29. The FDA approved Goprelto "for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults." *Id.* at ¶ 30. The FDA determined that Goprelto's route of administration is "nasal." *Id.* The drug's packaging, label, and package insert are regulated and approved by the FDA. *Id.* at ¶ 34. As the first FDA approved cocaine product, Goprelto was awarded new chemical exclusivity, which bars any third-party applicant from seeking FDA approval until December 14, 2022. *Id.* at ¶ 135.

C-Topical and Goprelto have the same active ingredient, the same strength, and the same dosage form, making them commercially equivalent. *Id.* at ¶ 127. Both drugs are interchangeable for certain medical uses, including Goprelto's approved indicated use. *Id.*

Unapproved Marketed Drugs and FDA Procedures

Today, most prescription drugs marketed in the United States must have FDA approval. *Id.* at ¶ 36. To legally market a drug, a company has several options. It may obtain approval of a new drug application ("NDA") or approval of an abbreviated new drug application ("ANDA") for generic drugs. *Id.* at ¶ 67. A drug may also be exempt from the NDA requirement. *Id.* Exempt drugs include "grandfathered" drugs, drugs subject to an ongoing drug efficacy study

[2] I accept Genus's allegations in the complaint as true for purposes of this motion.

implementation proceeding, drugs that are generally recognized as safe and effective, and drugs marketed in accordance with a final or tentative over-the-counter drug monograph. *Id.* at ¶ 68.

In 1984, after about 40 infants died after taking unapproved vitamin intravenous injections, the FDA created a program called the "Prescription Drug Wrap-Up" to identify the universe of unapproved drugs in the United States. *Id.* at ¶ 40. The FDA identified approximately 5,150 unapproved, marketed products. *Id.* According to the FDA, each of these drugs is illegally marketed unless the manufacturer establishes that the drug is "grandfathered." *Id.* A drug is grandfathered if, among other requirements, its composition and labelling have not changed since the October 10, 1962 enactment date of an amendment to the Food, Drug, and Cosmetic Act. *Id.* at ¶ 39.

In 2006 and 2011, the FDA published "guidances"—nonbinding recommendations—to encourage makers of unapproved drugs to seek formal NDA approval for their products. *Id.* at ¶ 41. The stated goals of the 2006 guidance were to "(1) clarify to FDA personnel and the regulated industry how we intend to exercise our enforcement discretion regarding unapproved drugs and (2) emphasize that illegally marketed drugs must obtain FDA approval." *Id.*

The FDA's 2006 guidance also stated that in cases where one drug was approved but had unapproved competitors, there would generally be a grace period of one year before the FDA initiated enforcement action against the unapproved drug. Guidance for FDA Staff and Industry: Marketed Unapproved Drugs—Compliance Policy Guide (2006) at 6, attached as Exhibit 6 to Compliant [Dkt. No. 1-1]. Although C-Topical's grace period would have ended in December 2018, the FDA does not appear to have taken any action against Lannett or Cody.

The FDA has Not Approved C-Topical

Lannett commercially launched C-Topical at least as early as 2008. *Id.* at ¶ 47. Lannett was the sole supplier of cocaine hydrochloride solution products to ENTs from 2012 until Genus's launch of Goprelto in 2017. *Id.* at ¶ 48. C-Topical had a monopoly on the market after Lannett's only competitor at the time withdrew from the marketplace. *Id.* Genus claims that Lannett falsely advertises C-Topical as "grandfathered," as a "preliminary new drug application" product, as FDA approved, as a generic of Goprelto, or as a branded drug pursuant to a NDA. *Id.*

On November 12, 2015, the FDA rejected Lannett's request that C-Topical be grandfathered. *Id.* at ¶¶ 58-60; Exhibit 15 ("FDA Rejection Decision") attached to Compl [Dkt. No. 1-1]. The FDA found that the evidence provided by Lannett was inadequate to support a conclusion that either cocaine hydrochloride products in general, or Lannett's drug in particular, met the requirements of the grandfather clause. Compl. at ¶ 59; FDA Rejection Decision at 16. Nevertheless, Lannett claimed that C-Topical was grandfathered in a number of Securities and Exchange Commission ("SEC") filings and investor calls in between December 2017 and September 2018. Compl. at ¶¶ 51-54; Exhibits 10-14 attached to Compl. [Dkt. No. 1-1].

Genus also claims that Lannett has advertised C-Topical as being legally marketed under a "preliminary new drug application" in a number of SEC filings. Compl. at ¶¶ 63-66; Exhibits 2, 13, 14 attached to Compl. [Dkt. No. 1-1]. It argues that the FDA does not permit production or marketing of prescription drug products under a "preliminary new drug application" and that the phrase is a fictitious regulatory category fabricated by Lannett. Compl. at ¶ 70.

Genus points out that Lannett's meta description for its C-Topical webpage is misleading: it states, "Learn more about the facts and characteristics of the generic pharmaceutical C-Topical® Solution CII." *Id.* at ¶ 74. A meta description is the one or two sentences that appear underneath the blue clickable links in a search engine results page. *Id.* at ¶ 76. Meta descriptions come from HTML code written by the owner of the webpage. *Id.* at ¶ 78. But C-Topical is not a generic pharmaceutical product because it does not have an approved ANDA. *Id.* at ¶ 79. At the time the complaint was filed, the FDA had not approved any ANDAs for any cocaine hydrochloride products. *Id.*

Genus also accuses Lannett and Cody of intentionally misleading customers into falsely believing that C-Topical is FDA approved by making the product packaging look like an approved FDA drug, maintaining a website with the package insert information, and registering a trademark for C-Topical. *Id.* at ¶¶ 81-88. For example, the C-Topical bottle label contains what Genus describes as the hallmarks of an FDA approved label: storage conditions, prescribing information, national drug codes, controlled substance marks, lot numbers, expiration dates, the date when the bottle label was last revised, the "Rx Only" symbol, strength of the dosage form, bar code,

"Lannett" as the labeler, and "Cody Laboratories, Inc." as the manufacturer. *Id.* at ¶ 82. Genus points out that C-Topical's packaging and packaging insert do the same. *Id.* at ¶¶ 83-84. Lannett also has maintained a website for C-Topical that displays similar sections as the package insert for an FDA approved product. *Id.* at ¶ 85.

In addition, Genus complains that Lannett and Cody maintain misleading general websites. Lannett's website identifies it as a generic pharmaceutical manufacturer whose leadership is committed to adherence to FDA standards and compliance with regulatory requirements. *Id.* at 89-91. Similarly, Cody's website states that "Cody Laboratories is committed to compliance with all Local, State, and Federal requirements and regulations governing [its] business, especially FDA, DEA," that Cody's "active pharmaceutical ingredients are used in FDA approved commercial drug products," and that Cody is "actively engaged in continuous improvement of [its] quality systems in accordance with current FDA guidance." *Id.* at ¶ 92. Genus contends that this is misleading because the FDA has not approved C-Topical but the drug is listed as a product on both websites. *Id.* ¶ 93.

Lannett Advertises C-Topical as Appropriate for Oral, Laryngeal, or Nasal Topical Administration

Lannett advertises C-Topical as a "topical solution . . . indicated for the introduction of local (topical) anesthesia of accessible mucous membranes of the oral, laryngeal, and nasal cavities." *Id.* at ¶ 107. Genus claims that this falsely implies that a cocaine hydrochloride solution product has been approved by FDA for oral or laryngeal uses, when no such product has ever been approved in that way. *Id.* at ¶ 111. By advertising C-Topical for oral and laryngeal use, Lannett misleads customers into believing that C-Topical has more uses than Goprelto, making it a more desirable and better product because Goprelto is only approved as an intranasal product. *Id.* at ¶¶ 112-113

The Role of Third Party Intermediaries

Genus further contends that Lannett provides incomplete or false information to third party intermediaries in the supply chain of pharmaceutical products, including wholesalers, group purchasing organizations ("GPOs"), integrated delivery networks ("IDNs"), and third party

managed price lists. *Id.* at ¶ 95. In the pharmaceutical industry, customers (pharmacists, hospitals, and doctors) often purchase prescription drugs from wholesalers. *Id.* at ¶ 96. Manufacturers contract with wholesalers to provide a certain amount of a product and the wholesaler advertises the product to customers through proprietary databases. *Id.* Wholesalers collect information about the product directly from the manufacturer. *Id.* For instance, Lannett sells C-Topical to McKesson Corp., a wholesaler who distributes in California. *Id.* McKesson's website indicates that C-Topical is generic and does not state that it is unapproved by the FDA. *Id.* As an alternative to wholesalers, some hospitals and hospital pharmacies form GPOs and IDNs to negotiate discounts with manufacturers and wholesalers in exchange for ordering a greater volume of products. *Id.* at ¶ 97. They also collect information about particular products directly from the manufacturer. *Id.*

Wholesalers, GPOs, and IDNs also rely on companies that aggregate third-party drug pricing information ("price lists"), including defendant First Databank. *Id.* at ¶ 98. Price lists provide pricing information for drugs and their pharmaceutical equivalents by maintaining databases that compare drugs and their prices so wholesalers and customers can see the available alternatives to a particular product. *Id.* These companies, including First Databank, assign unique identifying codes for each drug, allowing for price comparisons of equivalent products. *Id.* For example, a customer can search for "cocaine hydrochloride" and pull up all available cocaine hydrochloride products and their associated prices. *Id.* Price list companies also collect information about a particular product directly from the manufacturer. *Id.*

Genus accuses Lannett of providing incomplete or incorrect information to wholesalers, GPOs, IDNs, and price lists. *Id*. at ¶ 99. It states that Lannett does not identify C-Topical as unapproved to these third party intermediaries, and as a result, they are unable to accurately describe C-Topical as unapproved and customers are unable to differentiate Goprelto and C-Topical. *Id.* at ¶ 100. It argues that this results in a material misrepresentation to customers because FDA approval status carries with it an assurance as to the quality of the product. *Id.* at ¶ 101. It also cites a study that states that in a nationwide survey of pharmacists, 91% thought all products pharmacists dispense are FDA approved. *Id.* at ¶ 102. Taken together, Genus argues that

customers are misled to believe that C-Topical is FDA approved and choose to purchase C-Topical over Goprelto on that basis. *Id.* at ¶ 103.

First Databank's Listing Practices

First Databank assigns a unique clinical formulation ID ("CFI") to drugs based on ingredients, strength, dosage form, and route of administration. *Id.* at ¶ 116. Drugs with the same attributes are assigned the same CFI and "linked" so that when a customer searches for one product on First Databank's database, the other will appear as a substantive alternative. *Id.* Genus complains that since C-Topical's route of administration is listed as "topical" and Goprelto's is listed as "intranasal," the two drugs are given different CFI numbers. *Id.* at ¶ 117. As a result, third parties and customers searching for, or reordering, C-Topical may not see Goprelto listed as an alternative and will be misled into believing that C-Topical is the only cocaine hydrochloride drug available on the market. *Id.* at ¶¶ 118-120. Genus further states that First Databank knowingly contributes to Lannett's false advertising because it notified First Databank about the allegedly misleading advertisement of C-Topical no later than October 2, 2018. *Id.* at ¶¶ 122-123.

Lannett and Cody's Anticompetitive Conduct

Even after the launch of Goprelto, Lannett and Cody have maintained more than 99% of the market of cocaine hydrochloride in the United States. *Id.* at ¶ 125. Genus alleges that the relevant market to determine if Lannett and Cody engaged in anticompetitive conduct is the market for cocaine hydrochloride solution, including both FDA approved and unapproved versions. *Id.* at ¶ 126. Cocaine hydrochloride solution is unique because it is the only nasal product that is both a vasoconstrictor and local anesthetic. *Id.* at ¶ 128. No other drugs on the market, besides Goprelto and C-Topical, combine these two characteristics. *Id.* Genus alleges that a small, but significant, non-transitory price increase would not induce customers to shift their purchases to an alternative drug or combination of drugs. *Id.*

Genus accuses Lannett and Cody of devising an anticompetitive scheme to interfere with Genus's access to potential customers and exclude it from the market by manipulating First Databank's product categorization processes. Since the route of administration listed for C-Topical is different, C-Topical would have a different CFI number than Goprelto and customers

would not find Goprelto, as discussed above. *Id.* at ¶¶ 136-144. Genus believes that if both products were assigned the same CFI number, they would compete for customers on the basis of price. *Id.* at ¶ 142. But because the CFI numbers are different, and C-Topical had a monopoly on the market for a number of years, customers are generally not aware that Goprelto exists and will not find it when searching for or reordering C-Topical. *Id.* at ¶ 143. As a result, between June 2018 and September 2018, Genus sold only 544 bottles of Goprelto while Lannett sold over 45,000 bottles of C-Topical. *Id.* at ¶ 145. This difference is even starker given that Goprelto is sold for a lower price than C-Topical. *Id.* at ¶ 146.

Genus's Claims

Genus brings claims for false advertising and unfair competition under the Lanham Act, California's false advertising law, California's unfair competition law, and monopolization under the Sherman Act against Lannett and Cody. *Id.* at ¶¶ 150-177, 213-219. It asserts claims for contributory false advertising against Cody and First Databank under the Lanham Act. *Id.* at ¶¶ 178-188, 200-212. And it sues First Databank for false advertising under the Lanham Act. *Id.* at ¶¶ 189-199.

LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(6), a district court must dismiss a complaint if it fails to state a claim upon which relief can be granted. To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible when the plaintiff pleads facts that "allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). There must be "more than a sheer possibility that a defendant has acted unlawfully." *Id.* While courts do not require "heightened fact pleading of specifics," a plaintiff must allege facts sufficient to "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555, 570.

In deciding whether the plaintiff has stated a claim upon which relief can be granted, the court accepts the plaintiff's allegations as true and draws all reasonable inferences in favor of the plaintiff. *Usher v. City of Los Angeles*, 828 F.2d 556, 561 (9th Cir. 1987). However, the court is

not required to accept as true "allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008). If the court dismisses the complaint, it "should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000).

DISCUSSION

I. THE LANHAM ACT CLAIMS

Lannett moves to dismiss Genus's Lanham Act claims because simply selling an unapproved drug is not actionable under the Lanham Act absent an affirmative representation of approval, and Lannett has not made an affirmative representation of approval.[3] Defendants Lannett Co. Inc. & Cody Laboratories, Inc.'s Motion to Dismiss the Complaint at 6-8 ("Lannett MTD") [Dkt. No. 30]. Lannett argues that none of the materials Genus relies upon supports a claim under the Lanham Act. Lannett MTD at 8-16.

The Lanham Act creates a private right of action for competitors to bring claims for false or misleading advertising, even if the challenged products are regulated by the FDCA. *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2233 (2014). Section 43(a) of the Lanham Act allows "any person who believes that he or she is or is likely to be damaged" by a "commercial advertising or promotion [that] misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities" to bring suit. 15 U.S.C. § 1125(a).

"Courts can evaluate Lanham Act claims that do not require specialized knowledge or interpretation of the FDCA's requirements." *Belcher Pharm., LLC v. Hospira, Inc.*, No. 17-cv-2353, 2018 WL 4643292, at *4 (M.D. Fla. Apr. 9, 2018). "For example, courts can review a claim that a competitor falsely represented its product as FDA approved." *Id.* (*citing Innovative Health Sols., Inc. v. DyAnsys, Inc.*, Case No. 14-cv-05207-SI, 2015 WL 2398931, at *8 (N.D. Cal. May

[3] Genus does not contend that selling an unapproved drug is illegal. Plaintiff Genus Lifesciences, Inc.'s Brief in Opposition to Lannett Company, Inc. and Cody Laboratories, Inc.'s Motion to Dismiss at 7 ("Lannett Oppo.") [Dkt. No. 36].

19, 2015)). "And claims that involve whether a product's advertising misleads consumers also fall within a court's jurisdiction." *Id.* (*citing Church & Dwight Co. Inc. v. SPD Swiss Precision Diagnostics*, 104 F. Supp. 3d 348, 362 (S.D.N.Y. 2015).

To state a false advertisement claim under the Lanham Act, a plaintiff 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 lessening of the goodwill associated with its products." *Wells Fargo & Co. v. ABD Ins. & Fin. Servs., Inc.*, 758 F.3d 1069, 1071–72 (9th Cir. 2014) (*citing Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997)). Plaintiffs must allege all five elements of the test in order to state a false advertising claim. *Id.* "When the alleged representation is not an overt false statement, but merely misleading in context, the evidentiary showing required to sustain a Lanham claim is higher" and "proof that the advertising actually conveyed the implied message and thereby deceived a significant portion of the recipients becomes critical." *JHP Pharm., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 1002-03 (C.D. Cal. 2014) (*citing William H. Morris Co. v. Grp. W, Inc.*, 66 F.3d 255, 258 (9th Cir. 1995)).

A. Are Allegations of Affirmative Misstatements Required?

Lannett's core argument is that absent an affirmative representation of approval, marketing an unapproved drug is not actionable under the Lanham Act. Lannett MTD at 6-8. It cites *Mylan Labs., Inc. v. Matkari* for the proposition that "the very act of placing a drug on the market, with standard package inserts often used for FDA-approved drugs, somehow implies (falsely) that the drug had been 'properly approved by the FDA'" is "quite simply, too great a stretch under the Lanham Act." 7 F.3d 1130, 1139 (4th Cir. 1993). The Fourth Circuit in *Mylan* held that "to state a proper claim for relief under § 43(a) of the Lanham Act, Mylan was required to point to *some* claim or representation that is reasonably clear from the face of the defendants' advertising or package inserts." *Id.* (emphasis in original). Lannett argues that *POM Wonderful* did not abrogate

the principle established in *Mylan*. Lannett MTD at 7 n.4.

Genus responds that Lannett does not need to make affirmative, literally false statements about its product to be liable, and that false advertising can be based on statements or misrepresentations that, although not literally false, mislead, confuse, or deceive the consuming public. Lannett Oppo. at 7-8 (*citing Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1140 (9th Cir. 1997) ("Even if an advertisement is not literally false, relief is available under Lanham Act § 43(a) if it can be shown that the advertisement has misled, confused, or deceived the consuming public."); *TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820, 828 (9th Cir. 2011) ("plaintiff must show that a statement made in a commercial advertisement or promotion is false or misleading")). It points to *Par Sterile Prod., LLC v. Fresenius Kabi USA LLC*, No. 14-cv-3349, 2015 WL 1263041, at *4 (N.D. Ill. Mar. 17, 2015), where although the court held that mere implication that a drug was approved by the FDA was insufficient to state a Lanham Act claim, it also found that the implication that a drug was approved by the FDA was enough to state a false advertising claim when combined with allegations that (i) buyers believe all prescribed drugs identified on the Price Lists are FDA approved and (ii) that in some surveys 91% of pharmacists are actually confused about whether all drugs that appear on industry price lists are approved. *Par*, 2015 WL 1263041, at *4.

Genus's complaint contains essentially the same allegations as described in *Par*. It asserts that Lannett lists C-Topical on price lists and appears to cite to the same studies as in *Par*. *See* Compl. at ¶¶ 99, 102 ("On information and belief, despite customers' preference for FDA approved prescription drugs, customers are misled to purchase and dispense Lannett's C-Topical because they believe that all prescription drugs are FDA approved. For example, a nationwide survey of 500 pharmacists found that 91% thought all products pharmacists dispense are FDA approved."). Whether the survey data referred to in the complaint will be sufficient for Genus to survive summary judgment is unclear. But at the motion to dismiss stage, it is sufficient to show that Genus is not proceeding purely on a theory of implication.

Additionally, allegations about the survey data meet the standard articulated in *JHP Pharm.* 52 F. Supp. 3d at 1002-03. Genus alleges that by placing C-topical on price lists, Lannett

conveyed the implied message that it was approved, generic, or grandfathered and deceived a significant portion of recipients as shown by the survey data. *Id.* Lannett's reliance on *Mylan* and its argument on this point is not persuasive.

B. Statements in SEC Filings and Investor Calls that C-Topical is "Grandfathered" or Sold Under a "Preliminary New Drug Application" Status

For purposes of a false advertising claim, statements constitute commercial advertising if they are: "(1) commercial speech; (2) by a defendant who is in commercial competition with plaintiff; (3) for the purpose of influencing consumers to buy defendant's goods or services. While the representations need not be made in a 'classic advertising campaign,' but may consist instead of more informal types of 'promotion,' the representations (4) must be disseminated sufficiently to the relevant purchasing public to constitute 'advertising' or 'promotion' within that industry." *Rice v. Fox Broadcasting Co.*, 330 F.3d at 1170, 1181 (9th Cir. 2003) (*quoting Coastal Abstract Serv. v. First Am. Title Ins. Co.*, 173 F.3d 725, 735 (9th Cir. 1999)).

Lannett asserts that the only statements where it has described C-Topical as "grandfathered" or under a "preliminary new drug application" are contained in either investor earnings calls or securities fillings. Lannett MTD at 10. It argues that these statements do not fall under the Lanham Act because they were directed to actual and potential investors, not purchasers of C-Topical. *Id.* Genus responds that Lannett's cited authority does not refer to SEC filings but instead to other investor material and therefore should not be persuasive in this case. Lannett Oppo. at 9-11.

As an initial matter, I am not persuaded that the distinction between statements in materials disseminated to investors and statements contained in SEC filings is material. Other courts have found that SEC filings cannot form the basis of a Lanham Act false advertising claim. *See C=Holdings B.V. v. Asiarim Corp.*, 992 F. Supp. 2d 223, 243-44 (S.D.N.Y. 2013).

Further, Lannett cites three cases that I find persuasive. In *RPost Holdings, Inc. v. Trustifi Corp.*, the court, in ruling on a motion for summary judgment, found that the defendant's statements to potential investors via email were not actionable under the Lanham Act because they were not made for the purpose of influencing consumers to buy its goods or services. No. 10-cv-

1416, 2012 WL 12952728, at *7 (C.D. Cal. May 11, 2012). It also found that the statements were not "disseminated sufficiently to the relevant purchasing public to constitute advertising or promotion." *Id.* (internal citations and quotation marks omitted). Although the procedural posture in *RPost* is different, Genus has failed to allege (rather than prove as in *RPost*) that the SEC statements and investor calls were made for the purpose of influencing consumers to buy its goods or services, or that they were disseminated sufficiently to pharmacists, doctors, and hospital groups.

In *Tercica, Inc. v. Insmed Inc.*, the court found that statements communicated in webcasts to potential investors and in press releases on the "Investor Relations" section of the defendant's website failed to state a Lanham Act false advertising claim because there were "no allegations . . . that any actual or potential consumer attended any of these conferences or participated in any investor conference calls." No. 05-cv-5027-SBA, 2006 WL 1626930, at *18 (N.D. Cal. June 9, 2006). It also found that the plaintiff failed to allege sufficient facts to show that these communications were made for the purpose of influencing consumers to buy defendant's goods or services or that any consumers specifically associated the alleged false statements with the actual product at issue. *Id.* The complaint here is similarly deficient of such allegations.

In Lannett's third case, *Sigma Dynamics, Inc. v. E. Piphany, Inc.*, the plaintiffs failed to state a Lanham Act false advertising claim based on statements made in investor conference calls. No. 04-cv-0569-MJJ, 2004 WL 2648370, at *3 (N.D. Cal. June 25, 2004). The court held that in order for statements on the investor calls to be actionable, plaintiffs would need to allege that consumers attended the investor conference calls and that the purpose of the investor calls was to influence customers to buy defendant's goods or services. *Id.* That the calls might have an incidental effect of promoting goods to customers did not put them within reach of the Lanham Act. *Id.*

Genus rightly points out that the court in *Sigma* found that statements on websites and in press releases available to the public at large satisfy the commercial speech requirement for purposes of a motion to dismiss. *Id.* But I disagree with the reasoning in *Sigma* on this point. To be sure, statements contained in SEC filings, such as the 10-K or 10-Q forms cited by Genus,

could form the basis of a Lanham Act false advertising claim. But in order to be actionable, the statements must be accompanied by specific allegations that they were made for the purpose of influencing the customers of cocaine hydrochloride solutions to buy C-Topical, or were disseminated sufficiently to the relevant purchasing public (pharmacists, hospitals, and doctors) to constitute "advertising" or "promotion" within the pharmaceutical industry. *Rice*, 330 F.3d at 1181.

I find that the allegations contained in the SEC filings and investor calls stating that C-Topical is "grandfathered" or under a "preliminary new drug application" cannot, without more, state a claim for Lanham Act false advertising because they do not rest on any statements made in advertising or promotion.[4] Argument related to Lannett's contention that, when read in context, these statements explicitly and consistently refer to C-Topical as "unapproved" is premature. Lannett MTD at 10-11.

C. C-Topical's Indication for Oral, Laryngeal, or Nasal Topical Administration

Lannett claims that absent allegations demonstrating that Lannett's label is inaccurate, the mere fact that its label is broader than Genus's label is not actionable. Lannett MTD at 15-16. It also asserts that Genus fails to identify false statements by Lannett comparing C-Topical to Goprelto and that the allegation that consumers would believe C-Topical is superior to Goprelto is conclusory. *Id.*; Reply at 6-7. It argues that Genus has failed to allege facts that purchasers might view C-Topical as superior by virtue of Lannett's use of the word "topical." *Id.*

Genus counters with the FDA's Data Standards Manual for Route of Administration, which states that a "topical" route is "[a]dministration to a particular spot on the outer surface of the body[.]" Oppo. at 16-17*Id.*; Compl. at ¶¶ 107-109. Lannett's label states that C-Topical is "indicated for the introduction of local (topical) anesthesia of accessible mucous membranes of the oral, laryngeal and nasal cavities." Genus points out that mucous membranes are not the outer

[4] Should Genus amend its complaint, it should be aware that Lanham Act false advertising claims must meet the Rule 9(b) particularity pleading requirements. *Openwave Messaging, Inc. v. Open-Xchange, Inc.*, No. 16-cv-00253-WHO, 2016 WL 2621872, at *5 (N.D. Cal. May 9, 2016) (*citing Stahl Law Firm v. Judicate W.*, No. 13-cv-1668-TEH, 2013 WL 4873065, at *7 (N.D. Cal. Sept. 12, 2013) (applying 9(b) to Lanham Act claim); *SKEDKO, Inc. v. ARC Products, LLC*, No. 13-cv-00696-HA, 2014 WL 585379, at *3 (D. Or. Feb. 13, 2014) (same)).

surface of the skin and therefore that Lannett's label contains an affirmative misrepresentation. *Id.* According to Genus, this affirmative misrepresentation harms it by inducing customers to believe that C-Topical is different and superior to Goprelto because of its additional routes of administration. *Id.*

Taking Genus's allegations as true for the purposes of this motion, the inside of the nose, mouth, and larynx are not "particular spots on the outer surface of the body" and C-Topical's route of administration cannot accurately be described as "topical" under the FDA's definitions. Compl. at ¶¶107-109. Lannett's cited authority is distinguishable. In *Par* the plaintiff made allegations directed to the safety and effectiveness of the product. 2015 WL 1263041, at *4. The court found that any claims based on allegations that the defendant represented its product as safe and effective, rather than as FDA-approved, were dismissed as conclusory and potentially precluded. *Id.* at *7. Here, Genus does not seek a determination of whether C-Topical is safe or effective (i.e., something which may be potentially precluded as under the FDA's expertise). Instead, this is like asking a court to determine whether that drug is mislabeled as FDA approved when it is not. *See JHP Pharms.*, 52 F. Supp. 3d at 1001 ("it takes no special expertise to determine whether the FDA has granted approval or not."). It takes no special expertise to determine that the inside of the nose, mouth, and larynx are not on the outside of the body. Genus has sufficiently alleged that C-Topical's label route of administration is false.

D. Lannett's Failure to Affirmatively Identify C-Topical as "Unapproved" to Third Party Intermediaries and Customers

Lannett argues that it does not violate the Lanham Act by failing to affirmatively identify C-Topical as unapproved to third party intermediaries because there is no affirmative duty of disclosure under the Lanham Act. Lannett MTD at 11-12. It also states that the materials it sent to the third party intermediaries explicitly state that C-Topical lacks FDA approval and that the product information on First Databank and other price lists make it that clear C-Topical is unapproved. *Id.*

Genus has several responses. It states that: (1) Lannett can be found to liable for false advertising without making affirmative misrepresentations; (2) wholesaler McKesson "reports

Genus's FDA-approved Goprelto® product and Lannett's unapproved C-Topical using descriptions that do not indicate FDA approval status;" (3) Lannett's description of its product as topical to third parties is false; and (4) even where price lists state that C-Topical is unapproved, that information is buried. Oppo. at 15-16.

As discussed above, because C-Topical is featured on price lists, and Genus has alleged that customers believe all drugs on price lists are approved, Genus is able to state a claim for false advertising to customers. *Supra* section I. A. This rationale does not extend to false advertising to price lists and other third party intermediaries because there are no other supporting allegations, such as the surveys Genus cites with relation to its customers. That McKesson's description for C-Topical does not state that it is unapproved would not weigh in favor of, nor against, a finding that Lannett has misled McKesson.

As to the price lists, that the lists have C-Topical's unapproved status "buried" would support a finding that Lannett has correctly informed the price lists concerning C-Topical's status as an unapproved drug. But Lannett's description of C-Topical to the price lists as "topical" has been sufficiently alleged to be a false statement, as discussed earlier.

E. Statements on Lannett's Website

1. The Meta Description

According to Lannett, the meta description on its C-Topical website describing the drug as generic is not misleading because it must be read in context with Lannett's landing page that states that the FDA has not approved C-Topical. Lannett MTD at 12-13. Genus says that Lannett has misrepresented where it states that C-Topical is unapproved. Instead of on the landing page itself, one must click to a "package insert" link, which then takes the user to a version of C-Topical's package insert from the U.S. National Library of Medicine that states that C-Topical is not approved by the FDA.[5] Lannett Oppo. at 12-13. *Id.* Genus claims that this is even worse, because the final link is not even to a statement by Lannett, but rather of one by the government.

[5] In its reply, Lannett writes that it did not mislead the court because the landing page does not state that C-Topical is generic, and the package insert link on the landing page explicitly states that C-Topical is not approved. Defendants Lannett Co. Inc. & Cody Laboratories, Inc.'s Reply in Support of Their Motion to Dismiss the Complaint at 10 ("Lannett Reply") [Dkt. No. 42].

Id.

Lannett cites *Novation Ventures, LLC v. J.G. Wentworth Co.*, LLC, No. 15-CV-00954, 2015 WL 12765467, at *7 (C.D. Cal. Sept. 21, 2015) and *Toyota Motor Sales, U.S.A., Inc. v. Tabari*, 610 F.3d 1171, 1179 (9th Cir. 2010) for the proposition that consumers "fully expect to find some sites that aren't what they imagine based on a glance at the domain name or search engine summary. . . . [C]onsumers don't form any firm expectations . . . until they've seen the landing page—if then. This is sensible agnosticism, not consumer confusion." Lannett MTD at 13. These cases are unhelpful to Lannett. Its landing page would not disabuse a consumer of the notion that C-Topical is generic based on the meta description. It is relevant that consumers would have to click on yet another link to be informed that C-Topical has not completed the ANDA approval process required for generic drugs. Lannett's statement in its website's meta description states a claim for false advertising under the Lanham Act.

2. General Statements on Lannett's Website Related to Compliance with FDA Requirements

Lannett claims argues that the statements on its website regarding its compliance with FDA regulatory requirements are not associated with, or made in reference to, C-Topical, and that they cannot constitute false advertising when the C-Topical page explicitly states that it is not approved by the FDA. Lannett MTD at 13. Lannett also argues that the question of whether it complies with the FDA's regulatory requirements is squarely within the primary jurisdiction of the FDA. *Id.*

Genus counters that Lannett's website makes no carveout for C-Topical and that the actual C-Topical landing page does not state that the drug is unapproved. Oppo. at 14-15. It also states that because the FDA denied Lannett's application to "grandfather" C-Topical, Lannett's statement that its products comply with the law is false. *Id.*

Genus's argument stretches the FDA's denial of Lannett's grandfathering petition too far. The conclusion in the FDA's denial letter states:

> The evidence you have provided through the Citizen Petition process is inadequate to support a conclusion either that cocaine HCl products in general, or Lannett's cocaine HCl, 40 mg/mL, or cocaine HCl, 100

> mg/mL, topical solutions in particular, meet the requirements of the 1938 grandfather clause. Accordingly, your requests that the Agency affirm the "grandfather" status of cocaine HCl products in general, and Lannett's Cocaine HCl Products in particular, are denied.
>
> In addition, we deny your request that we acknowledge these products may be legally marketed based on their "grandfather" status and that, therefore, the new drug requirements, including premarket approval and prescription drug user fees, are not applicable. Therefore, your request that FDA acknowledge that the new drug requirements, including premarket approval and user fees, are not applicable to Lannett's Cocaine HCl Products is also denied.

FDA Rejection Decision at 16-17. The FDA does not state that C-Topical cannot be sold, but only that it cannot be represented to customers as "grandfathered." In order for the statements on the websites to be actionable, they would need to state that either C-Topical was "grandfathered" or that it was sold with FDA approval. Genus does not allege that either statement is found on Lannett's website.

According to the complaint, Lannett's website states that its "leadership is committed to quality, adherence to FDA standards, and compliance with regulatory requirements to ensure patient safety." Compl. at ¶ 89. It also asserts that "[a]s generic pharmaceuticals manufacturers, we serve an important need for the population: making pharmaceutical products affordable[ ]" and that "[i]t's important to remember that generic medicines are made to meet the same standards, as provided by FDA, as brand name medicines. Customers may rest assured that generic pharmaceuticals are produced with the same active ingredients and attention to quality as branded versions." *Id.* at ¶ 90. None of these statements qualify as false, but may be misleading in context. Genus must plausibly allege that the statements actually conveyed the implied message that C-Topical was grandfathered or sold with FDA approval, and deceived a significant portion of recipients. *JHP Pharm*, 52 F. Supp. 3d at 1002–03. It has not done so yet.

3. General Statements on Cody's Website Related to Compliance with FDA Requirements

With regards to Cody's website, Genus identifies the following statements as false or misleading: "Cody Laboratories is committed to compliance with all Local, State, and Federal requirements and regulations governing our business, especially FDA, DEA . . ."; Cody's "active pharmaceutical ingredients are used in FDA approved commercial drug products;" and that

Cody's website then identifies "Cocaine Hydrochloride USP" as one of its active pharmaceutical ingredients. Compl. ¶¶ 92-93. Lannett contends that allegations based on the statements identified on Cody's website, without more, fail to allege that either (i) any customer was misled or likely to be misled as to Cody's statements regarding active pharmaceutical ingredients (not the marketed product itself) that do not identify C-Topical, or (ii) that statements regarding active pharmaceutical ingredients materially influence customers purchasing decisions. *Id.* at 16. Genus responds that at this stage of the proceeding, Genus need not prove its case and it is more than plausible that a consumer, taking the above statements together, would identify Cody as the manufacturer of the C-Topical, would visit Cody's website, and would be misled by Cody's statements. *Id.*

Unlike with Lannett's website, Cody's website has an affirmatively false statement (that its active pharmaceutical ingredients are used in FDA approved commercial drug products and that cocaine hydrochloride is one of Cody's active pharmaceutical ingredients). *Id.* This is false because it affirmatively suggests that C-Topical is approved by the FDA. It would have a tendency to deceive a substantial segment of visitors to Cody's website. Genus has sufficiently alleged that the statement is material, stating that the "FDA approval status of a prescription drug is material to customers because approved drugs provide customers assurance as to the quality of the product not afforded to unapproved prescription drugs." Compl. at ¶ 101. Genus has sufficiently stated a claim for false advertising and contributory false advertising based on the statements contained on Cody's website.

F. The Appearance and Content of the C-Topical's Labeling and Packaging

Lannett moves to dismiss Genus's claims based on the allegedly misleading similarities between C-Topical's labeling and packaging and the labeling and packaging of an FDA approved drug. Lannett MTD at 14-15. It argues that Genus's allegations are conclusory and that Genus has failed to allege facts tending to show that C-Topical's packaging and labelling actually conveyed the message that "C-Topical is FDA-approved" to customers. *Id.* It contends that if C-Topical's packaging and labelling merely implies that it is approved, it is not actionable under the Lanham Act. *Id.*

Genus responds that it has sufficiently alleged that a customer looking at the label and packaging of C-Topical would never be able to determine that it is unapproved. Lannett Oppo. at 13-15. Combined with the way in which Lannett and Cody hold themselves out as complying with FDA requirements on their websites (as discussed above), Genus argues that the packaging and labelling will mislead consumers into thinking that C-Topical is approved by the FDA. *Id.*

I agree with Lannett. Although Genus cites *Merck Eprova AG v. Brookstone Pharm., LLC*, 920 F. Supp. 2d 404, 420 (S.D.N.Y. 2013), it is distinguishable. *Id.* at 14. In *Merck*, following a bench trial, the court found that the plaintiff was entitled to a presumption of consumer deception because it had demonstrated that the defendant intentionally set out to deceive its consumer base. 920 F. Supp. 2d at 420. The plaintiff was able to show egregious conduct on the part of the defendant who, despite knowing of two chemically distinct substances, one pure and one mixed, purposefully sought out the mixture and labelled it as identical to the pure substance. *Id.* No such showing or allegation exists here.

As discussed in *JHP Pharm.*, when the alleged representation is not an overt false statement but is merely misleading in context as it is here, the pleading standard is higher and allegations that the advertising actually conveyed the implied message and deceived a significant portion of recipients is required. 52 F. Supp. 3d at 1002-03. Genus has not met this standard. It makes only conclusory statements such as, "On information and belief, Lannett's and Cody's packaging and packaging insert deceives, or has the **capacity** to deceive, a substantial segment of customers, including pharmacists, into believing that Lannett's and Cody's C-Topical has FDA approval." Compl. at ¶ 88 (emphasis added). More specific allegations are required in the absence of an affirmative misstatement.

II. THE SHERMAN ACT CLAIMS

Lannett argues that Genus has failed to state a monopolization claim under the Sherman Act for either Lannett's false advertising or how C-Topical is listed on price lists, such as the one maintained by First Databank. Lannett MTD at 17-22. I agree.

"There are three essential elements to a successful claim of Section 2 monopolization: (a) the possession of monopoly power in the relevant market; (b) the willful acquisition or

maintenance of that power; and (c) causal 'antitrust' injury." *Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 998 (9th Cir. 2010). Genus has successfully alleged the first and third elements of the test. It meets the first element by stating that Lannett and Cody maintain more than 99% of the cocaine hydrochloride market in the United States. Compl. at ¶¶ 125, 129-132, 145. It meets the third element by alleging that Lannett's conduct has maintained the price of C-Topical and the market price of cocaine hydrochloride solution above the competitive level and that Genus has been directly harmed in the form of lost sales and the extensive resources it spent to obtain FDA approval. Compl. at ¶¶ 148-149.

To violate the second element, a defendant must use its monopoly power "to foreclose competition, to gain a competitive advantage, or to destroy a competitor." *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 482-83 (1992) (citation omitted). Accordingly, to be actionable under Section 2 a monopolist's conduct "must have an 'anticompetitive effect.' That is, it must harm the competitive process and thereby harm consumers. In contrast, harm to one or more competitors will not suffice." *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001) (emphasis in original) (citations omitted); *see also Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209 (1993) ("Even an act of pure malice by one business competitor against another does not, without more, state a claim under the federal antitrust laws . . . .").

In addition, to be actionable under section 2, a monopolist's conduct must "foreclose competition in a substantial share of the line of commerce affected." *Kolon Indus. Inc. v. E.I. DuPont de Nemours & Co.*, 748 F.3d 160, 175 (4th Cir. 2014) (*quoting Tampa Elec*, 365 U.S. at 328, 81 S.Ct. 623). Establishing that a substantial share of the relevant market is foreclosed is necessary because, for the monopolist's conduct to adversely affect competition, "the opportunities for other traders to enter into or remain in that market must be significantly limited." *Id.* (*quoting Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 328 (1961)). The Supreme Court has explained that:

> To determine substantiality in a given case, it is necessary to weigh the probable effect of the contract on the relevant area of effective competition, taking into account the relative strength of the parties,

> the proportionate volume of commerce involved in relation to the total volume of commerce in the relevant market area, and the probable immediate and future effects which pre-emption of that share of the market might have on effective competition therein.

Tampa Elec., 365 U.S. at 329.

A. Monopolization Claim for False Advertising

Lannett argues that Genus has failed to state a monopolization claim based on false advertising because it has failed to overcome the presumption that Lannett's advertising had a *de minimis* effect on competition. Lannett MTD at 18-19. Specifically, Lannett contends that Genus has not plausibly alleged that Lannett's statements about C-Topical were "clearly false," that Genus has failed to plead that any of the false statements were clearly likely to induce reasonable reliance or made to buyers without knowledge of the subject matter, and that any purportedly false statement made by Lannett are not "readily susceptible of neutralization or other offset" by Genus. *Id.*

To plausibly allege that false and misleading advertising constituted exclusionary conduct and overcome a presumption that the effect on competition was *de minimis*, a plaintiff must allege cumulative facts that would prove the statements were (1) clearly false, (2) clearly material, (3) clearly likely to induce reasonable reliance, (4) made to buyers without knowledge of the subject matter, (5) continued for prolonged periods, and (6) not readily susceptible to neutralization or other offset by rivals. *Am. Prof'l Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publications, Inc.*, 108 F.3d 1147, 1152 (9th Cir. 1997) (citation omitted). Genus must satisfy all six elements to overcome *de minimis* presumption. *Id.*

Genus has adequately alleged the first four elements: the statements on Cody's website and Lannett's meta description are clearly false, as described above;[6] the statements are clearly material based on its allegations as to customer's preferences for approved drugs, Compl. at ¶ 101; the statements fool customers who would not purchase C-Topical or distribute it to patients if they knew it was unapproved, *Id.* at ¶ 104; and Genus's survey data alleges facts to show that

[6] Genus argues that the SEC statements and investor calls could form the basis of a false statement in the antitrust context, even if they cannot in the Lanham Act context. Oppo. at 23. I disagree, as those statements are not made to buyers with the intent of increasing Lannett's customer base.

customers for cocaine hydrochloride are not knowledgeable about the FDA approval status of prescription drugs. *Id.* at ¶ 102.

As to the fifth element, Genus has alleged that Lannett has been selling C-Topical since 2008. But it has not alleged how long Lannett's meta description and the challenged statements on Cody's website have been online or how long Lannett has described C-Topical as having a "topical" route of administration.

More significantly, Genus fails to satisfy the sixth element by alleging that these statements are not readily susceptible to neutralization of other offset by rivals. Genus points to its allegations that "Lannett makes it prohibitively difficult for customers to find a competing product," and that "customers" tend to repeat their last order or search directly for [C-Topical]," making it difficult to rebut the false promotions. *Id.* ¶¶ 134, 143. It also alleges that "[w]holesalers, GPOs, and IDNs use, or rely upon, First Databank's CFI codes to compare products" implicitly recognizing that other marketing methods may not be successful. *Id.*

But these allegations do not show why other efforts to promote its product, other than its attempt to get First Databank to change C-Topical's CFI number, have failed or would not be successful. "In the marketplace of ideas, there is competition and competing information. It is all too easy for losers in the rough-and-tumble of commerce to accuse competitors of spreading false information." *Tate v. Pac. Gas & Elec. Co.*, 230 F. Supp. 2d 1072, 1080 (N.D. Cal. 2002) (Alsup, J.). For instance, Genus has failed to allege why an advertising campaign touting Goprelto as the only FDA approved cocaine hydrochloride product would not be successful, or why any efforts to tell its customers that C-Topical is unapproved or that its route of administration is misleading would fail. Genus has not sufficiently alleged why it is incapable of pushing back on Lannett's listing practices through other means. Genus has failed to plead more than *de minimis* effect on competition from Lannett's false statements.

B. Monopolization Claim for Listing Practices

Genus states that Lannett's mischaracterization of C-Topical's route of administration as "topical" is not merely an advertisement meant to market the drug to potential purchasers. Oppo. at 19-20. It is part of a concerted effort to redefine the market to exclude all competitors whose

route of administration is properly nasal from even being considered in the first place. *Id.*

Lannett argues that Genus's monopolization claim for its listing practices must be dismissed because Genus has failed to allege that Lannett did anything improper to "manipulate" First Databank's classification of C-Topical because the drug's label describing its route of administration is not false. Lannett MTD at 20. It also contends that Genus has failed to allege that its conduct foreclosed Genus from competing for three reasons. *Id.* First, Genus's allegations relate to Lannett's conduct with respect to only a single price list in a single promotional channel; there are many price lists, and price lists are only one channel among many that promote pharmaceutical products. *Id.* at 21. Second, Genus does not, and cannot, allege that Lannett denied Genus access to First Databank. *Id.* Genus promotes its product on First Databank, but with a different CFI number. *Id.* At most, this would suggest that only the narrow subset of customers who search for C-Topical specifically by name or CFI code will not be notified of Goprelto; any allegation that this creates a material barrier to entry is conclusory. *Id.* Third, Genus's complaint is really that it is not being allowed to free-ride on C-Topical's acceptance in the market for customers that repeatedly reorder C-Topical or directly seek out C-Topical. *Id.* at 21-22. Lannett argues that it is not required to take affirmative steps to make such free-riding easier for Genus. *Id.*

As discussed above, Genus has sufficiently alleged that describing C-Topical as "topical" is a false statement. Given First Databank's alleged method of assigning CFI codes to drug products based on ingredient, strength, dosage form, and route of administration, misstating C-Topical's route of administration as topical would create a misleading CFI code. Compl. at ¶ 116. But Lannett's allegations related to Genus's efforts on only a single promotional channel cannot give rise to a monopolization claim because "[i]f competitors can reach the ultimate consumers of the product by employing existing or potential alternative channels of distribution, it is unclear whether such restrictions foreclose from competition any part of the relevant market." *Omega Envtl., Inc. v. Gilbarco, Inc.*, 127 F.3d 1157, 1163 (9th Cir. 1997). Even if Genus is able to prove its allegations about Lannett's marketing practices on First Databank's pricing list, that does not establish that it has been substantially foreclosed from entire the cocaine hydrochloride market.

Lannett's motion to dismiss Genus's monopolization claim based on its listing practices is granted.

III. THE STATE LAW CLAIMS

Lannett moves to dismiss Genus's claims under California's False Advertising Law, Cal. Bus. & Prof. Code § 17500 et seq., and California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 et seq., because they are premised on the same allegations of false advertising as Genus's Lanham Act claims. Lannett MTD. At 22-23. As I have found that Genus has stated a claim for a Lanham Act violation, I deny Lannett's motion to dismiss Genus's state law claims.

IV. THE CLAIMS AGAINST FIRST DATABANK

Genus brings two claims against First Databank. Genus's first claim is for false advertising under the Lanham Act, based on First Databank's allegedly false and misleading advertisement of C-Topical in its price list as having a "topical" route of administration. Compl. at ¶¶ 189-199. Genus alleges that First Databank fools customers into believing that C-Topical is the only cocaine hydrochloride 4% solution on the market. *Id.* Genus's second claim for contributory false advertising is based on the same conduct as its first claim. *Id.* at 200-212.

A. The False Advertising Claim

First Databank argues that Genus has failed to show that its challenged statement was made in "commercial advertising or promotion" because its price list is not meant to influence purchasers to buy First Databank's commercial offering. Defendant First Databank Inc.'s Motion to Dismiss ("FD MTD") at 6-10 [Dkt. No. 29]. Instead, First Databank is only a reference database to which others can subscribe for their own purposes. Because statements on it are available only to paid subscribers, the statements are not for the purpose of influencing new purchasers to subscribe. *Id.*

First Databank cites the factors outlined in *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 735 (9th Cir. 1995): "The statements must be: (i) commercial speech; (ii) by a defendant who is in commercial competition with plaintiff; (iii) for the purpose of influencing consumers to buy defendant's goods or services; and (iv) . . . the representations must be disseminated sufficiently to the relevant purchasing public to constitute 'advertising' or

'promotion' within that industry." It argues that it is an independent publisher with no financial stake in the pharmaceutical products themselves, and so the speech at issue, namely its categorization of C-Topical in its database of descriptive information about pharmaceutical products (the pricing list), does not constitute commercial speech under the Lanham Act. FD MTD at 6-9. It states that Genus has failed to allege any non-conclusory factual allegations to support a conclusion that its pricing list constitutes commercial speech and that the pricing list is not commercial as a matter of law. *Id.*

Genus argues, without support, that the test in *Coastal Abstract* is no longer controlling after *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014). Plaintiff Genus Lifesciences, Inc.'s Opposition to First Databank, Inc.'s Motion to Dismiss at 17 ("FD Oppo.") [Dkt. No. 37]. The Ninth Circuit has not overruled *Coastal Abstract* and courts in this district and circuit regularly apply it after *Lexmark*. *See GOLO, LLC v. Higher Health Network, LLC*, No. 18-cv-2434, 2019 WL 446251, at *8 (S.D. Cal. Feb. 5, 2019); *Prager Univ. v. Google LLC*, No. 17-cv-06064-LHK, 2018 WL 1471939, at *9 (N.D. Cal. Mar. 26, 2018); *Ariix, LLC v. NutriSearch Corp.*, No. 17-cv-320, 2018 WL 1456928, at *4 (S.D. Cal. Mar. 23, 2018) ("After Lexmark, the second element is likely in need of revision . . . [b]ut the first and fourth elements were not implicated by *Lexmark's* holding, and remain good law."); *Kische USA LLC v. Simsek*, No. 16-cv-0168, 2016 WL 7212534, at *11 (W.D. Wash. Dec. 13, 2016). Courts outside of the Ninth Circuit have continued to apply it as well, though the Fourth and Sixth Circuits no longer apply the second element. *Handsome Brook Farm, LLC v. Humane Farm Animal Care, Inc.*, 700 F. App'x 251, 256 (4th Cir. 2017) ("But following the Sixth Circuit, we do not adopt the second factor requiring a competitive relationship."); *In re McCormick & Co., Inc., Pepper Prod. Mktg. & Sales Practices Litig.*, 215 F. Supp. 3d 51, 59 (D.D.C. 2016) (applying all four factors). But it is somewhat unclear whether the second *Coastal Abstract* factor continues to apply after *Lexmark*, so I will analyze the sufficiency of Genus' claims under the other three factors.

Genus contends that First Databank is not a "mere reference database" because it derives millions of dollars from licensees to access the pricing list and that First Databank fails to identify any statements of public importance that would make the pricing list non-commercial speech. FD

Oppo. at 17-23. It claims that pricing lists play a unique role in facilitating commercial transactions because customers rely on pricing lists to compare products and prices. *Id.*; Compl. at ¶¶ 98, 117–19, 193–94. Therefore, it argues that the statements in First Databank's pricing list are provided to relevant consumers for their use in buying cocaine hydrochloride. *Id.*

"The core notion of commercial speech is 'speech which does no more than propose a commercial transaction.' " *Rice v, Fox Broad. Co.*, 330 F.3d 1170, 1181 (9th Cir. 2003) (*quoting City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 422 (1993)). The Supreme Court has relied on three factors to determine whether statements amounted to commercial speech: (i) whether they were in an advertising format, (ii) whether they referred to a specific product, and (iii) economic motivation for publication. *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66-68 (1983); *Assoc. of Nat'l Advertisers, Inc. v. Lungren*, 44 F.3d 726, 728 (9th Cir. 1994) (outlining the *Bolger* factors). No single factor, even an economic motive, is enough to render speech commercial. *Bolger*, 463 U.S. at 67. A determination of whether speech is commercial should rest on "the commonsense distinction between speech proposing a commercial transaction . . . and other varieties of speech." *Id.* at 64 (internal quotation marks omitted). Courts have repeatedly cautioned that commercial speech "not be defined too broadly lest speech deserving of greater constitutional protection be inadvertently suppressed." *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 579 (1980) (Stevens, J., concurring); *Dex Media W., Inc. v. City of Seattle*, 696 F.3d 952, 961 (9th Cir. 2012) (quoting concurrence).

First Databank's pricing list does not propose a commercial transaction between First Databank and customers of cocaine hydrochloride. Genus does not allege that the information contained in First Databank's pricing list is for the purpose of inducing Genus (or Lannett's) customers to enter into a commercial transaction with First Databank. Further, Genus does not contend that First Databank will be more successful or have a monetary interest in whether customers of cocaine hydrochloride choose to buy C-Topical, rather than Goprelto. The complaint does not assert that there is some particular quid-pro-quo relationship between Lannett and First Databank, where First Databank gets a kickback from sales of C-Topical that it would not receive from sales of Goprelto. Genus argues that "First Databank's business involves a quid pro quo in

which information is provided to First Databank in exchange for First Databank utilizing the data, including assigning its own CFI codes, and targeting and distributing it to the relevant consumers." Oppo. at 19. But this would be true for every drug listed on the pricing database, including Goprelto, and cannot reasonably be characterized as a quid pro quo relationship for the purposes of this case. Rather, the allegations suggest that First Databank's interest is in having a comprehensive list of pharmaceutical products, not that any particular pharmaceutical product should be more successful than another.

Genus also argues that First Databank has an economic motivation to make representations about specific drugs in order to maintain its market position in the pharmaceutical supply chain. First Databank Oppo. at 21. But this only supports an inference that First Databank wants to be thorough in its representations, not that it has a profit motive in any particular representation. Genus claims that discovery will show that First Databank promotes itself as used by nine of the top ten pharmacy benefit managers representing over 95% of the total prescription volume in the U.S. and the top three major drug product wholesalers controlling 85% of the market. *Id.* But this is irrelevant to whether First Databank's representations relating to C-Topical's routes of administration proposes a commercial transaction between First Databank and consumers of cocaine hydrochloride. Genus may be ultimately be correct that First Databank's characterization of itself as only a "reference database" is false, but it has not alleged any facts at this stage to plausibly suggest otherwise.

First Databank cites two cases that are instructive, *Ariix, LLC v. NutriSearch Corp.*, No. 17-cv320, 2018 WL 1456928, at *5 (S.D. Cal. Mar. 23, 2018) and *Acella Pharm., LLC v. First DataBank, Inc.*, No. 17-cv-5013, 2018 WL 7199992, at *12 (N.D. Ga. June 4, 2018), vacated, No. 17-cv-5013, 2018 WL 7199807 (N.D. Ga. Oct. 4, 2018). In *Ariix*, the plaintiff was a producer of nutritional supplements and the defendant published a guide to nutritional supplements that reviewed various companies' products and awarded a "Gold Medal of Achievement." *Ariix*, 2018 WL 1456928, at *1. The *Ariix* plaintiff sued the publisher under the Lanham Act after it made a vigorous, though unsuccessful, effort to qualify for the gold medal of achievement. *Id.* The plaintiff alleged that the guide's staff was biased because some members of the staff had

previously worked for one of the plaintiff's rivals. *Id.* at *6. The court found that these suggestions of bias were insufficient as the guide did not sell any of the nutritional products it reviewed, the defendant did not have an ownership interest in the companies that produced the supplements, and that the defendant did not solicit or accept paid advertisements from the plaintiff's rival. *Id.* at *5. The court held that to the extent that the lawsuit was based on the publisher's reviews, they were non-actionable. *Id.* at *7. It reasoned that given the sheer number of products mentioned, the fact that the guide otherwise mentioned plaintiff's products did not weigh in favor of finding the guide to be commercial speech. *Id.*

Acella is not a Lanham Act case and it was ultimately dismissed pursuant to a stipulation, but it has a close factual relationship to this case. There, the plaintiff sued First Databank, arguing that its proposed reclassification of a prenatal vitamin as no longer requiring a prescription in response to a review of FDA guidance documents was unlawful. 2018 WL 7199992 at *12. In denying a motion for a preliminary injunction, the court found that the information in First Databank's database was not commercial speech. *Id.* at *11-14. With regards to the first *Bolger* factor, the court found the fact that First Databank sought to sell subscriptions to its database did not turn the database itself into commercial speech. *Id.* at *12. The court reasoned that as a publisher of databases that provide information about drug products and dietary supplements to the healthcare industry for purposes of decision-making, pricing, and negotiated reimbursement rates, First Databank was not alleged to have engaged in the development, marketing, or sale of items listed in its database, nor was it alleged to profit from the sale of those items. *Id.* The *Acella* court found no facts to distinguish the guide from information found in general reference materials, such as directories or encyclopedias. *Id.*

Genus cites *Exeltis USA Inc. v. First Databank, Inc.*, No. 17-cv-04810-HSG, 2017 WL 6539909, at *14 (N.D. Cal. Dec. 21, 2017), where the plaintiff sought a preliminary injunction against First Databank for false advertising under the Lanham Act for proposing to change the characterization of the plaintiff's product to indicate that it did not require a prescription when the drug's previous code indicated a prescription was required. The court found that this would constitute a prior restraint on First Databank's speech, which carries a heavy presumption of

constitutional invalidity, and denied the plaintiffs request for a preliminary injunction. *Id.* at *4-5, 7. But the court also denied First Databank's motion to dismiss, finding that under the more lenient standard for a motion to dismiss, the court could not resolve contested facts or address the substantive merits of the plaintiff's case. *Id.* at *14.

Exeltis is of no help to Genus. While I agree that at the motion to dismiss stage it is inappropriate to resolve contested facts or address the substantive merits of Genus's case, Genus has not plausibly pleaded that First Databank's price list constitutes commercial speech. Its false advertising claim against First Databank is dismissed.[7]

C. Contributory False Advertising

First Databank argues that contributory liability under the Lanham Act arises when a party intentionally induces another to directly violate the Lanham Act and that it did not induce anyone to violate the Lanham Act here. First Databank MTD at 11-12. Genus responds that First Databank has contributed to Lannett's alleged false advertising by knowingly and materially participating in it. FD Oppo. at 9-13. Its complaint alleges :

> First Databank not only directly misleads customers through its characterization of C-Topical as "topical," First Databank also knowingly and materially participates in Lannett's false advertising of C-Topical. Genus notified First Databank about the misleading advertisement of Lannett's C-Topical no later than October 2, 2018. On information and belief, First Databank continues to falsely assign C-Topical a different CFI than GOPRELTO® or its authorized generic.

Id. (*citing* Compl. at ¶¶ 122-123).

It is unclear in this Circuit if contributory false advertising can apply to non-commercial speech in any context because the Lanham Act, as a whole, applies only to commercial speech. *Farah v. Esquire Magazine*, 736 F.3d 528, 541 (D.C. Cir. 2013) (*citing Bosley Med. Inst., Inc. v. Kremer*, 403 F.3d 672 (9th Cir. 2005) (holding that there was no liability where an unsatisfied hair transplant customer had used Bosley's mark for purposes of criticism, because the customer's "use

[7] The parties also dispute whether Genus has standing to bring a false advertising claim against Databank and if a false advertising claim must concern statements about the speaker's own products or services, or those of a competitor. FD MTD at 5-6; FD Oppo. at 14-17. Because Genus has not plausibly alleged that the price list constitutes commercial speech, I do not reach these arguments.

of the Bosley mark [was] not in connection with a sale of goods or services—it [was] in connection with the expression of his opinion about Bosley's goods and services"). I do not see why it would be okay to assert a claim for contributory false advertising regarding non-commercial speech but not for false advertising. As discussed above, Genus has not pleaded a false advertising claim against First Databank because it has not alleged facts to suggest that First Databank's pricing list constitutes commercial speech. For the same reason, I find that Genus's contributory false advertising claim fails as well. But out of an abundance of caution, I will analyze Genus's theory that First Databank can be liable under a theory of contributory false advertising for non-commercial statements.

1. The Eleventh Circuit's Contributory False Advertising Rule in *Duty Free*

Because the Ninth Circuit has yet to articulate a legal standard for contributory false advertising, Genus asks that I apply the standard articulated by the Eleventh Circuit in *Duty Free Ams., Inc. v. Estée Lauder Cos.*, 797 F.3d 1248, 1275 (11th Cir. 2015). FD Oppo. at 10-12. In *Duty Free* the Eleventh Circuit held that:

> First, the plaintiff must show that a third party in fact directly engaged in false advertising that injured the plaintiff. Second, the plaintiff must allege that the defendant contributed to that conduct either by knowingly inducing or causing the conduct, or by materially participating in it.

797 F.3d at 1277. Applying this standard, Genus satisfies the first element, alleging that Lannett directly engaged in false advertising that injured Genus. *Id.* It does not, however, allege that First Databank contributed to that conduct either by knowingly inducing or causing the conduct, or by materially participating in it. *Id.* It is apparent from the pleading that First Databank did not knowingly induced or cause Lannett to engage in false advertising. As for "materially participating," the Eleventh Circuit gave the following examples:

> Analogies from trademark infringement, in which contributory liability is more developed, can be instructive. Thus, for example, a plaintiff may be able to make out the participation prong of a contributory false advertising claim by alleging that the defendant directly controlled or monitored the third party's false advertising. *See Perfect 10, Inc. v. Visa Int'l Serv. Ass'n*, 494 F.3d 788, 807 (9th Cir. 2007). It is also conceivable that there could be circumstances under which the provision of a necessary product or service, without which the false advertising would not be possible, could support a

> theory of contributory liability. *See* [*Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 854-55 (1982).] In determining whether a plaintiff has adequately alleged facts to support such a claim, we look to whether the complaint suggests a plausible inference of knowing or intentional participation, examining "the nature and extent of the communication" between the third party and the defendant regarding the false advertising; "whether or not the [defendant] explicitly or implicitly encouraged" the false advertising; whether the false advertising "is serious and widespread," making it more likely that the defendant "kn[ew] about and condone[d] the acts"; and whether the defendant engaged in "bad faith refusal to exercise a clear contractual power to halt" the false advertising. *See* [*Mini Maid Servs. Co. v. Maid Brigade Sys., Inc.*, 967 F.2d 1516, 1522 (11th Cir. 1992)].

Duty Free, 797 F.3d at 1277-78.

Contrary to these examples, Genus does not allege that First Databank directly controlled Lannett's false advertising, was a dispositive factor in enabling Lannett's false advertising, explicitly or implicitly encouraged Lannett's false advertising, or refused to halt Lannett's false advertising in bad faith. The allegations in the complaint do not suggest that First Databank's conduct was persuasive in inducing Lannett to do what it did. No court in the Ninth Circuit has applied the *Duty Free* test, but if it applies, Genus has failed to state a claim for contributory false advertising against First Databank.

2. **The Test in *ADT Sec. Services, Inc.***

First Databank asks instead that I apply the test articulated in *ADT Sec. Servs., Inc. v. Sec. One Int'l, Inc.*, No. 11-cv-05149-YGR, 2012 WL 4068632, at *1 (N.D. Cal. Sept. 14, 2012). First Databank MTD at 11-12. There, the Hon. Yvonne Gonzalez Rogers held that in order to state a claim for contributory false advertising, a plaintiff must allege that the defendant: "(1) intentionally induced the primary Lanham Act violation; or (2) continued to supply an infringing product to an infringer with knowledge that the infringer is mislabeling the particular product supplied." *Id.* at *3 (*citing Perfect 10, Inc. v. Visa Intern. Serv. Ass'n*, 494 F.3d 788, 807 (9th Cir. 2007). *ADT Sec. Servs.* appears to be the only contributory false advertising case in this district and one of very few contributory false advertising cases in any of the courts embraced by the Ninth Circuit. *See e.g. BioCell Tech. LLC v. Arthro-7,* No. 12-cv-00516, 2012 WL 12892937, at *12 (C.D. Cal. Nov. 19, 2012) (applying the *ADT Sec. Servs.* test).

Under this test, Genus's claims fail as well because it has not alleged that First Databank

intentionally induced the primary Lanham Act violation by Lannett, or that First Databank continued to supply an infringing product to Lannett. Although the tests in *Duty Free* and *ADT. Sec. Servs.* are different, the same theory animates both: the party accused of contributorily infringing essentially drives the infringing party's conduct. Here, Genus's theory is the opposite. It cannot state a claim for contributory false advertising under its preferred test or under First Databank's preferred test. Genus's contributory false advertising claim against First Databank is dismissed with prejudice.

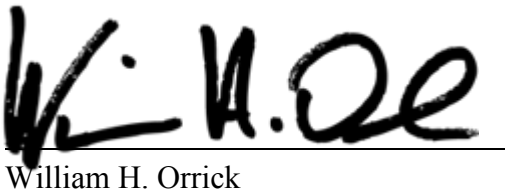
CONCLUSION

Lannett's motion to dismiss is granted in part and denied in part. Genus's claims based on its statements contained in SEC forms or made during investor calls, its alleged misstatements to third party intermediaries, the statements on Lannett's own website, the label and package of C-Topical, and on its Sherman Act claims are dismissed with leave to amend. It is denied in all other respects.

First Databank's motion to dismiss is granted. Genus's false advertising claim is dismissed with leave to amend. Its contributory false advertising claim is dismissed with prejudice.

IT IS SO ORDERED.

Dated: May 3, 2019



William H. Orrick
United States District Judge

United States District Court
Northern District of California