UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ASHLEY FRANZ,

Plaintiff,

vs.

BEIERSDORF, INC., et al.,

Defendant.

CASE NO. 14cv2241-LAB (RBB)

ORDER GRANTING BEIERSDORF'S MOTION TO DISMISS, STAYING FRANZ'S UCL CLAIM, AND DENYING BEIERSDORF'S MOTION TO STRIKE AS MOOT

In this putative class action, Ashley Franz challenges representations that Beiersdorf, Inc. makes on bottles of its Nivea CoQ10 Lotion. Beiersdorf has filed a motion to dismiss (Docket no. 22) and a motion to strike Franz's class allegations (Docket no. 23).

I. Factual Background

A. Alleged Misrepresentations

Franz alleges that Nivea CoQ10 Lotion bottles are misleading because: (1) they falsely represent that the product is "proven to firm and tighten skin's surface in as little as two weeks," "improves skin firmness within 2 weeks," and "improves skin firmness in as little as two weeks" (the "skin firming representations"); and (2) they convey the false message that CoQ10 is a key active ingredient. (Docket no. 19 at ¶¶ 1, 2, 14).

Franz alleges the skin firming representations are false because they're not supported by "reliable scientific evidence." (*Id*. at ¶ 16). She contends the "universally accepted" method for determining whether a product provides a health benefit is to demonstrate its

value over a placebo in randomized controlled clinical trials. (*Id*. at ¶ 17–18). Even then, according to Franz, a study isn't sufficient unless it's "subjected to the peer review publication process" and published in "impact peer-reviewed journals." (*Id.*). Franz alleges she can't find any such published reports on Nivea CoQ10 Lotion's ingredients. (*Id*.).

Franz alleges Nivea CoQ10 Lotion bottles create the false impression that CoQ10 is the key ingredient in the product. (*Id*. at ¶ 22). But, she contends, three tests have revealed that the product contains trivial amounts of CoQ10, at most. (*Id*. at ¶¶ 23–26). Franz alleges further that, for purposes of the federal Food, Drug, and Cosmetics Act ("FDCA") and California's Sherman Food, Drug, and Cosmetic Law, Nivea CoQ10 Lotion is a cosmetic drug and, as such, can't be sold without an approved New Drug Application ("NDA"). (*Id*. at ¶¶ 27–36). According to Franz, an NDA must include "substantial evidence" that the drug is effective to treat the conditions suggested on the proposed labeling, but Beiersdorf doesn't have "substantial evidence" to back its representations. (*Id.* at ¶ 36). Franz contends that Beiersdorf sells the product without an approved NDA and has therefore violated the FDCA and California's Sherman Law. (*Id*. at ¶ 38).

B. Franz's Claims

Based on these two alleged misrepresentations, Franz asserts causes of action for violation of the unlawful prong of California's unfair competition law, Cal. Bus. & Prof. Code § 17200 *et seq*. ("UCL"), the Consumer Legal Remedies Act, Cal. Bus. & Prof. Code § 1750 *et seq*. ("CLRA"), and CLRA-like laws from other states. (Docket no. 19 at ¶¶ 58, 67). "Under its 'unlawful' prong, the UCL borrows violations of other laws and makes those unlawful practices actionable under the UCL." *Berryman v. Merit Prop. Mgmt., Inc*., 152 Cal. App. 4th 1544, 1554, 62 Cal. Rptr. 3d 177, 185 (2007) (internal ellipses and quotation marks omitted). Franz's UCL claim is premised on Beiersdorf's alleged violation of the FDCA and California's Sherman Law. (Docket no. 19 at ¶¶ 56–64). Under the CLRA, a defendant is liable if it misrepresents its goods to contain certain characteristics, uses, or benefits that the goods don't have or advertises goods intending not to sell them as advertised. Cal. Civ.

/ / /

Code § 1770(a)(5), (7), (9) and (16). Franz bases her CLRA-related claims on both the skin firming representations and the CoQ10 representation. (Docket no. 19 at ¶¶ 71–73).

Franz alleges that she and the putative class members have been injured because they wouldn't have purchased Nivea CoQ10 Lotion absent Beiersdorf's skin firming representations. (*Id*. at ¶¶ 42–45). She identifies a proposed multi-state class consisting of "[a]ll consumers who, within the applicable statute of limitations period, purchased NIVEA CoQ10 Lotion in California and states with similar laws" and an alternative California-only class of "[a]ll consumers who, within the applicable statute of limitations period, purchased NIVEA CoQ10 Lotion in California." She seeks restitution, disgorgement, injunctive relief, corrective advertising, punitive damages, and attorney's fees and costs. (*Id*. at 20).

II. Motion to Dismiss

Beiersdorf seeks dismissal, arguing: (1) Franz hasn't sufficiently alleged an actionable misleading representation; (2) the UCL claim should be dismissed or stayed because the question of whether Beiersdorf needs an NDA to sell Nivea CoQ10 Lotion lays within the primary jurisdiction of the Food and Drug Administration ("FDA"); and (3) Franz lacks standing. (Docket no. 22).

A. Legal Standard

A 12(b)(6) motion to dismiss for failure to state a claim challenges the legal sufficiency of a complaint. *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). The Court must accept all factual allegations as true and construe them in the light most favorable to Franz. *Cedars Sinai Med. Ctr. v. Nat'l League of Postmasters of U.S.*, 497 F.3d 972, 975 (9th Cir. 2007). To defeat Beiersdorf's motion to dismiss, Franz's factual allegations need not be detailed, but they must be sufficient to "raise a right to relief above the speculative level . . . ." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). While the Court must draw all reasonable inferences in Franz's favor, it need not "necessarily assume the truth of legal conclusions merely because they are cast in the form of factual allegations." *Warren v. Fox Family Worldwide, Inc*., 328 F.3d 1136, 1139 (9th Cir. 2003) (internal quotation marks omitted). In fact, the Court does not need to accept any legal conclusions as true. *Ashcroft v. Iqbal*, 556

U.S. 662, 664 (2009). A complaint does not suffice "if it tenders naked assertions devoid of further factual enhancement." *Id*. at 678 (internal brackets and quotation marks omitted).

B. Sufficiency of Franz's Allegations

Beiersdorf argues that Franz's allegations are insufficient because: (1) the skin firming allegations are uncognizable "lack of substantiation" claims; (2) the absence of published randomized controlled clinical trial reports doesn't mean that Beiersdorf's skin-firming representations are false; and (3) Franz doesn't plausibly allege that the amount of CoQ10 in NIVEA CoQ10 Lotion renders the product ineffective.

1. Lack of Substantiation

Under California law, a private plaintiff may not bring UCL or CLRA claims based on a claim made in advertising that is merely unsubstantiated. *See Bronson v. Johnson & Johnson, Inc.*, 2013 WL 1629191, at *8 (N.D. Cal. Apr.16, 2013) ("Claims that rest on a lack of substantiation, instead of provable falsehood, are not cognizable under the California consumer protection laws. Challenges based on a lack of substantiation are left to the Attorney General and other prosecuting authorities; private plaintiffs, in contrast, have the burden of proving that advertising is actually false or misleading.") "A claim can survive a lack of substantiation challenge by, for example, alleging studies showing that a defendant's statement is false." *Id*. (Internal quotation marks omitted).

Franz doesn't allege studies that contradict the skin firming representations, or make any other nonconclusory allegations that the skin firming representations are false. Instead, she merely contends they lack substantiation. But, it remains Franz's burden to allege facts sufficient to demonstrate Beiersdorf's statements are false or misleading, and she can't shift her burden by merely alleging she can't find substantiation. Beiersdorf's use of the word "proven" doesn't change the analysis. *See Aloudi v. Intramedic Research Grp., LLC*, 2015 WL 4148381, at *4 (N.D. Cal. July 9, 2015); *Kwan v. SanMedica Int'l, LLC*, 2015 WL 848868, at *7 (N.D. Cal. Feb. 25, 2015) (Plaintiffs can't "make an end run around the bar against private substantiation claims" by alleging a reference to the substantiation is misleading). Thus, the skin firming misrepresentation allegations fail to state a cognizable claim.

2. Randomized Controlled Clinical Trial Reports

Franz's skin firming representation allegations are insufficient for another reason—they're based entirely on her inability to find published randomized controlled clinical trial reports. But, even if no published reports exist, it doesn't follow that Beiersdorf's skin firming representations are false. Indeed, while the lack of a published report is consistent with Franz's allegations, it's at least as likely that Beiersdorf has verified its representations through other methods, such as testing that didn't result in a published report. *See Iqbal*, 556 U.S. at 681. And Franz doesn't cite any authority supporting her position that, to avoid UCL and CLRA liability, a defendant must verify its representations through a randomized controlled clinical trial and a published report.

3. Key Ingredient

Franz alleges that, by highlighting the inclusion of CoQ10, Beiersdorf gives the impression that it's a "key ingredient" in Nivea CoQ10 Lotion, but her testing revealed the product "contained just over one part per million of CoQ10." (Docket no. 19 at ¶¶ 22, 23). Franz labels this "on its face, a sub-therapeutic amount," "a trivial and meaningless amount," and "a de minimis amount." (*Id*. at ¶¶ 2, 3, 23). The Court need not accept Franz's conclusory allegation that one part per million is a sub-therapeutic amount of CoQ10. *See Iqbal*, 556 U.S. at 678. That's especially true in light of Franz's prior admission that some studies have reported that CoQ10 has skin firming benefits. (Docket no. 1 at ¶¶ 23); *cf. Harbridge v. Schwarzenegger*, 2011 WL 6960830, at *8 (C.D. Cal. Aug. 31, 2011) (collecting cases and explaining "[w]here allegations in an amended complaint contradict those in a prior complaint, a district court need not accept the new alleged facts as true . . ."). While it's possible that one part per million is insufficient to provide skin firming benefits, Franz hasn't alleged facts sufficient to demonstrate that's the case.

Additionally, under the CLRA and UCL, a plaintiff can only recover if she suffers damage as a result of the alleged misrepresentation. Cal. Civ. Code § 1780(a); *Webb v. Carter's Inc*., 272 F.R.D. 489, 501 (C.D. Cal. 2011); *Pirozzi v. Apple, Inc*., 966 F. Supp. 2d 909, 920 (N.D. Cal. 2013). In her complaint, Franz explains that it was the skin firming

representations that led her and other putative class members to purchase NIVEA CoQ10 Lotion. (Docket no. 19 at ¶¶ 11 ("Plaintiff purchased NIVEA CoQ10 Lotion in reliance on Defendant's skin firming representations."), 42, 71, 74). Nowhere does she allege that her purchase was induced by the prominence of CoQ10 on the product label, or that CoQ10 is a prized ingredient that can induce customers to purchase a product. Thus, her key ingredient allegations also fall short because she doesn't link them to any injury.

C. Primary Jurisdiction

Beiersdorf argues that the UCL claim should be dismissed or stayed because the question of whether it needs an NDA to sell Nivea CoQ10 Lotion lays within the primary jurisdiction of the FDA.

"The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). This doctrine enables a court to determine that "an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch." *Id*. "[I]t is to be used only if a claim requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency, and if protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme." *Id*. (citations and quotation marks omitted). Although there's no fixed formula, the Ninth Circuit has looked at four factors when deciding whether to apply the primary jurisdiction doctrine:

> (1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration.

Syntek Semiconductor Co. v. Microchip Tech. Inc., 307 F.3d 775, 781 (9th Cir. 2002).

Here, all four factors favor application of the primary jurisdiction doctrine. First, there's an issue that needs to be resolved—Franz alleges Beiersdorf acts unlawfully by selling a

drug without an NDA. Second, the FDA has jurisdiction to determine whether a product is a drug and whether an NDA is necessary. 21 U.S.C. § 351 *et seq*.; *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 653 (1973) (Whether a product is a new drug and whether it's grandfathered in "are the kinds of issues peculiarly suited to initial determination by the FDA."). Third, the FDCA subjects the drug industry to a comprehensive regulatory authority. 21 U.S.C. § 301 *et seq*.; *Imagenetix, Inc. v. Frutarom USA, Inc*., 2013 WL 6419674, at *4 (S.D. Cal. Dec. 9, 2013). Fourth, determining whether a product is a drug "involves complex chemical and pharmacological considerations and determination of technical and scientific questions." *Imagenetix*, 2013 WL 6419674, at *4 (collecting cases) (internal quotation marks omitted).

The FDA's informal guidelines illustrate that it makes fine distinctions when evaluating whether a lotion is a drug. *Wrinkle Treatments and Other Anti-Aging Products*, http://www.fda.gov/cosmetics/productsingredients/products/ucm388826.htm (updated May 28, 2015) (explaining "if a product is intended to make lines and wrinkles less noticeable, simply by moisturizing the skin, it's a cosmetic" but "if a product is intended, for example, to remove wrinkles or increase the skin’s production of collagen, it's a drug or a medical device"). Franz doesn't provide any indication regarding how the FDA would view Beiersdorf's skin firming representations. Several courts have applied the primary jurisdiction doctrine where, as here, "a determination of a plaintiff's claim would require a court to decide an issue committed to the FDA's expertise without a clear indication of how the FDA would view the issue." *Figy v. Lifeway Foods, Inc*., 2014 WL 1779251, at *2 (N.D. Cal. May 5, 2014) (collecting cases). The Court does the same here.

The Court's application of the primary jurisdiction doctrine doesn't leave Franz in limbo. FDA regulations expressly provide that an interested person may "petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a); *see also Imagenetix*, 2013 WL 6419674, at *4. The petition may take the form of a citizen's petition under 21 C.F.R. § 10.30. The Commissioner's decision on such a petition, which must be made within

180 days, 21 C.F.R. § 10.30(e)(2), is reviewable in federal court as a final agency action, 21 C.F.R. § 10.45(d), and with the benefit of a developed administrative record, 21 C.F.R. § 10.30(l). *Imagenetix*, 2013 WL 6419674, at *4.

Franz doesn't address whether her UCL claim should be stayed or dismissed. "Typically, if courts conclude that the dispute that forms the basis of the action is within the agency's primary jurisdiction, the case should be dismissed without prejudice." *Id.* at *9. The Court may, however, stay the proceedings pending the outcome of the administrative process if the statute of limitations may prevent the plaintiff from refiling. *Id*. Thus, to avoid statute of limitations concerns, Franz's UCL claim is **STAYED**.

D. Standing

Beiersdorf argues that Franz lacks standing to pursue any form of relief because she hasn't sufficiently alleged injury, and she lacks standing to pursue injunctive relief because she hasn't sufficiently alleged redressability. In response, Franz contends her alleged injury is sufficient, but voluntarily dismisses her claim for injunctive relief. (Docket no. 24 at 22–24, n.15). Franz hasn't alleged a causal link between the CoQ10 representations and an injury, so her CoQ10-based claim falls short of Article III's mandate. *In re iPhone Application Litig*., 6 F. Supp. 3d 1004, 1022 (N.D. Cal. 2013) ("A causal link between a defendant's misrepresentation and a plaintiff's injury is required to establish standing under Article III, the CLRA, and the UCL."). But, if Franz can amend her complaint to allege that the skin firming representations are false or that the prominence of CoQ10 on the product's label is materially misleading, and that the alleged misrepresentations induced her to spend money she otherwise wouldn't have, then the Court will be inclined to find standing.

III. Motion to Strike

Beiersdorf also seeks to strike Franz's class allegations, arguing: (1) Franz hasn't pled that putative class members can be readily identified; (2) her multi-state class definition isn't ascertainable because it doesn't specify which state laws apply, and thereby fails to put Beiersdorf, putative class members, or the Court on notice of which purchasers are in the class or what claims will be asserted; and (3) variations in state laws render Franz's

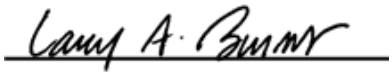
multi-state class unmanageable. (Docket no. 23). Because the Court grants Beiersdorf's motion to dismiss, it **DENIES** the motion to strike as moot.

IV. Conclusion

Beiersdorf's motion to dismiss is **GRANTED** and the motion to strike is **DENIED AS MOOT**. Franz's UCL claim is **STAYED**, but, to avoid needlessly clogging the Court's docket, Franz is **ORDERED** to report to the Court if she declines to pursue the administrative process; begins the process but abandons it; or, if she pursues it, once the administrative process is complete. If Franz thinks she can successfully amend her CLRA-related claims, she must seek leave by *ex parte* motion no later than August 24, 2015. Her proposed amended complaint must be attached as an exhibit to the motion. If she files such a motion, Beiersdorf shall have until September 7, 2015 to oppose it. No reply should be filed unless leave is obtained in advance.

IT IS SO ORDERED.

DATED: August 3, 2015



HONORABLE LARRY ALAN BURNS
United States District Judge