UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

STACIE SOMERS, individually and on behalf of others similarly situated, Plaintiff, vs. BEIERSDORF, INC., a Delaware corporation, Defendant.	CASE NO. 14cv2241-LAB (AGS) **ORDER GRANTING MOTION FOR SUMMARY JUDGMENT [Dkt. 103]**

Four years ago, Plaintiff Stacie Somers purchased a twin-pack of Nivea CoQ10 Lotion online. Three motions to dismiss and one appeal later, Somers is left with a single claim: that Defendant Beiersdorf's sale of the lotion was "unlawful" under California's Unfair Competition Law ("UCL") because the lotion is a "drug" sold without the approval of the Food and Drug Administration ("FDA"). Beiersdorf now moves for summary judgment, arguing that the Federal Food, Drug and Cosmetics Act ("FDCA") preempts Plaintiff's state-law claim. In the alternative, Beiersdorf urges the Court to find that (as a matter of law) the lotion is a cosmetic, not a drug. The Court agrees with Beiersdorf that Plaintiff's claims are preempted under the FDCA and therefore **GRANTS** the motion for summary judgment.

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BACKGROUND

The relevant facts are not in dispute. In November 2016, Plaintiff Stacie Somers[1] purchased two bottles of Nivea CoQ10 Lotion from Amazon.com. That lotion is manufactured and sold by Defendant Beiersdorf. Among the various claims on the lotion's label are that it "provides skin firming hydration," "improves skin's firmness in as little as 2 weeks," and is "proven to firm and tighten skin's surface in as little as two weeks." See Joint Statement of Undisputed Facts ("SUF"), Dkt. 103-3, at ¶ 2-3. The central—and at this point only—allegation in Somers's Complaint is that these claims on the label suggest the lotion is intended to "affect the structure of the body," which renders it a drug under the language of the FDCA. And because the "drug" was sold without first obtaining approval from the FDA, Somers argues, Beiersdorf's decision to sell the lotion was necessarily "unlawful" under California's UCL. See Cal. Bus. & Prof. Code § 17200 (creating a private right of action for "any unlawful, unfair or fraudulent business act or practice."). Somers brings the suit on behalf of herself and all others who purchased Nivea CoQ10 Lotion in California.

In May 2019, the Court denied Beiersdorf's most recent motion to dismiss, finding that Somers had plausibly alleged the lotion was a drug. See Dkt. 70. Given the relatively straightforward nature of the dispute, however, the Court suggested that this might be the "rare case in which a motion for summary judgment would be appropriate before addressing class certification." Id. at 5. Taking the Court up on its suggestion, Beiersdorf now moves for summary judgment, albeit on different grounds than the Court anticipated.

DISCUSSION

Beiersdorf moves for summary judgment on two grounds. First, it argues that Somers's attempt to "privately enforce the federal drug pre-market approval process is

[1] This suit was originally brought by Ashley Franz, who purchased the same Nivea CoQ10 Lotion at a San Diego CVS store in 2012. Late last year, Plaintiff's counsel substituted Somers as lead plaintiff due to concerns over Franz's health. The two Plaintiffs' claims are otherwise identical.

preempted" by the FDCA. Second, assuming that Somers's claim is not preempted, Beiersdorf argues that the undisputed material facts show that the company intended the lotion to be used as a cosmetic (not a drug), meaning Somers's UCL "unlawful" claim fails as a matter of law. The Court agrees that Somers's claims are preempted under the FDCA and that summary judgment is warranted.[2] Because it disposes of the motion on preemption grounds, the Court does not—and indeed cannot—reach the question of whether the lotion is a drug or a cosmetic.[3]

The FDCA defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beautifying, promoting attractiveness, or altering the appearance." 21 U.S.C. § 321(i). Drugs, by contrast, are articles "intended to affect the structure or any function of the body of man." Id. § 321(g)(1). If a product qualifies as a drug under the FDCA, the seller must first seek approval from the FDA before selling that product. See id. § 355. There is no such requirement if the product is a cosmetic.

Recognizing that the distinction between drugs and cosmetics is a difficult one, Congress gave the FDA the sole authority to police violations of the FDCA. 21 U.S.C. § 337(a) implicitly preempts any private right of action to enforce the FDCA, providing in relevant part, "proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States." The FDCA provides the agency with a range of enforcement mechanisms, such as injunction proceedings, civil and criminal penalties, and seizure. 21 U.S.C. §§ 332–34, 372. Although citizens may petition the FDA to take

[2] The Court and the parties are familiar with the summary judgment standard, and the Court doesn't repeat it here. Indeed, because the relevant facts are not in dispute and because the resolution of this motion largely turns on a question of law, a motion to dismiss would have been the better procedural vehicle for resolving this issue.

[3] The parties' requests for judicial notice, which reference documents only relevant to this second argument, are **DENIED AS MOOT**. Dkts. 103-6, 109.

administrative action, 21 C.F.R. §§ 10.25(a) & 10.30, private enforcement of the statute is barred. Perez v. Nidek Co., Ltd., 711 F.3d 1109, 1119 (9th Cir. 2013).

The leading case on implied preemption under the FDCA[4] is Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001). In Buckman, the plaintiffs premised defendant's liability on its allegedly fraudulent statements to the FDA, which resulted in approval of a medical device that ultimately injured the plaintiffs. Id. at 343. In finding plaintiffs' "fraud on the FDA" claims impliedly preempted under the FDCA, the Supreme Court explained that the "conflict stem[med] from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." Id. at 348. Under the FDCA, the FDA may investigate suspected fraud, and may respond by using a variety of legal measures. Id. at 349 (explaining the FDA may respond by seeking injunctive relief, seizing the medical device, or pursuing criminal prosecutions). This flexibility of enforcement mechanisms, the Supreme Court reasoned, allowed the FDA "to make a measured response to suspected fraud upon the Administration[,]" and was a "critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." Id. In light of this, the Supreme Court held that the plaintiffs' claims were impliedly preempted because state-law fraud-on-the-FDA claims would "exert an extraneous pull on the scheme established by Congress." Id. at 353.

The Ninth Circuit faced a similar issue in Perez, 711 F.3d 1109. In that case, the plaintiff brought a state law fraud-by-omission claim, alleging defendants had misled the class "by failing to disclose that [a medical laser] was not FDA approved for hyperopic

[4] The FDCA also contains an express preemption provision. See 21 U.S.C. § 360k(a). That provision is not at issue here because the relevant state laws do not impose duties "different from, or in addition to" those imposed by the FDCA. Riegel v. Medtronic, Inc., 552 U.S. 312, 321–22 (2008). Instead, the issue here is whether Plaintiff is attempting to privately enforce the FDCA through a state-law analog, and therefore whether her claims are impliedly preempted.

surgeries." Id. at 1117. The court found that Perez's claims, like those in Buckman, existed only because of the FDA approval system for medical devices. Id. at 1119. Importantly, "[t]he FDA knew about the allegations that the Laser was being used for unapproved hyperopic use and took steps to address the allegations by issuing warning letters and an Import Alert, but it did not take final action against the defendants." Id. at 1120. Whether the defendants' use of the laser violated the FDCA depended on, "among other things, the scope of the [pre-market approvals], whether the lasers were modified . . . under . . . the FDCA, whether defendants were engaged in a permissible 'off-label' use of the laser, and whether re-certification of the device was required under [the relevant FDA regulation]. All of these matters rest within the enforcement authority of the FDA, not this Court." Id. (quoting the district court's opinion).

Buckman and Perez stand for the proposition that claims seeking to enforce the FDCA must thread a "narrow gap" to escape preemption. "The plaintiff must be suing for conduct that violates the FDCA (or else [the] claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman)." Perez, 711 F.3d at 1120 (quoting In re Medtronic, Inc., 623 F.3d 1200, 1204 (8th Cir. 2010)).

Plaintiff's claims do not thread that narrow gap here. Plaintiff's Third Amended Complaint ("TAC")—which repeatedly references provisions of the FDCA—makes clear that she is suing Beiersdorf because its decision to sell the Nivea CoQ10 Lotion violated the FDCA. See TAC, Dkt. 87., at ¶¶ 11-13, 18, 31 (citing 21 U.S.C. §§ 301, 321, 355, 359). She alleges, for example, that "Defendant engaged in illegal conduct by unlawfully making skin firming representations about its Nivea CoQ10 Lotion that resulted in its being deemed a drug under FDA regulations, but did so without obtaining required FDA approval through the FDA NDA [New Drug Approval] process." Id. at ¶ 31. There is no reasonable way to construe this allegation except as an attempt to privately enforce the FDCA, enforcement that has been committed by law to the FDA. As Defendants correctly

point out, Plaintiff does not raise any separate or distinct state law drug process that should have been followed; she refers only to the FDA NDA process.

That Plaintiff's claims are preempted is made even more apparent by the FDA's actions in this very case. In 2015, the Court, relying on the "primary jurisdiction doctrine," stayed the case and gave Plaintiff an opportunity to seek relief directly from the FDA. See Order Granting Motion to Dismiss, Dkt. 34, at 6-8. Plaintiff's counsel filed a "Citizen Petition" with the FDA asking it to (1) take action by sending a warning letter to Beiersdorf that the Lotion is an unapproved new drug, or (2) inform Plaintiff that it did not intend to take any action regarding the lotion. See Status Report, Dkt. 37, Ex. A. The agency chose the latter, stating that it did "not intend to take action regarding Nivea CoQ10." Id. That letter stated that while Citizen Petitions are helpful in identifying possible violations, enforcement is decided on a case-by-case basis and is within the agency's discretion. Id.

The FDA's non-enforcement decision here resembles the facts in Perez. In that case, the FDA knew of the allegations that the medical device at issue was being used for unapproved purposes, and the agency "took steps to address the allegations by issuing warning letters . . . ." Perez, 711 F.3d at 1120. Recognizing that whether the device violated the FDCA turned on issues related to pre-market approval and certification of the device—all matters that "rest within the enforcement authority of the FDA, not this Court"—the Ninth Circuit found plaintiff's claims preempted. Id. The same is true here. Whether the Nivea CoQ10 Lotion is being sold unlawfully depends on whether it is subject to the NDA process in the first instance, and that is a determination that "rest[s] within the enforcement authority of the FDA, not this Court." Id. Indeed, if the Perez's claims are preempted, there is even more reason to think that Somers's claims are. After all, in Perez the FDA acknowledged allegations of improper use and issued warning letters to the device's manufacturer. By contrast, the FDA here flatly refused to take action against Beiersdorf, which counsels against a court finding to the contrary. In sum, the Court finds that Plaintiff's claims are impliedly preempted under the FDCA.

Plaintiff offers a handful of responses, which the Court addresses in turn. First, Somers argues that she isn't suing because Beiersdorf has violated the FDCA, but rather because Beiersdorf has violated the Sherman Act, a state statute whose language tracks the FDCA's. Specifically, her TAC relies on California Health & Safety Code § 111550, which prohibits the sale of "any new drug" unless that drug has "been approved . . . under . . . the federal act." But, of course, this argument is largely circular: a drug can only be unlawful under the California statute if it violates the FDCA, and determining whether the California statute has been violated requires first determining whether the article is a drug under the FDCA. Although Somers argues her state-law claim would remain "even if the FDA ceased to exist," she is incorrect. Opposition at 8. The New Drug Approval process, adopted by reference in the the Sherman Act, exists solely by virtue of the FDCA. Because the FDA is tasked with administering the New Drug Approval process, her claim depends on the existence of the FDA and would disappear if the "FDA ceased to exist."

In support of her argument that the Sherman Act creates a "parallel obligation" distinct from the FDCA, Somers points to a handful cases, all of which arise from the food labeling context and none of which are on point here. Chief among these is Farm Raised Salmon Cases, a California Supreme Court case holding that state food labeling laws are not preempted to the extent they "do not seek to enforce the FDCA." Farm Raised Salmon Cases, 42 Cal. 4th 1077, 1093 (2008). Several federal court cases have followed the same line of reasoning. See, e.g, Vassigh v. Bai Brands LLC, 2015 WL 4238886, *4-5 (N.D. Cal. 2015) (UCL claims related to antioxidant labeling not preempted); In re Trader Joe's Tuna Litig., 289 F.Supp.3d 1074, 1084-85 (C.D. Cal. 2017) (UCL claims related to under-filled tuna cans not preempted).

There are two problems with the "parallel obligation" argument in this context. First, although food labeling is undoubtedly "within the states' historic police powers," Farm Raised Salmon Cases, 42 Cal. 4th at 1083, the same cannot be said for new drug approval, a process that is uniquely federal. See Wyeth v. Levine, 555 U.S. 555, 566 (2009) ("The FDCA's most substantial innovation was its provision for premarket approval

of new drugs."). Indeed, cases holding that a plaintiff's food labeling claims are not preempted routinely recognize that the outcome would be different if the plaintiff were bringing claims related to a drug or medical device, both of which require premarket approval by the FDA. See, e.g., Gustavson v. Wrigley Sales Co., 961 F.Supp.2d 1100, 1118 (N.D. Cal. 2013) ("The parties here do not assert that the dangers arising out of food mislabeling are even remotely equivalent to the 'unreasonable risk of illness or injury' presented by Class III medical devices [in Buckman], nor do they allege that food labeling is subjected to a comparably rigorous review process that requires premarket approval."). Further, the FDCA's enforcement provisions—which generally permit only the FDA to bring an enforcement action—implicitly acknowledge these differences by specifically allowing states to bring suits related to food labeling. See 21 U.S.C. § 337(b)(1) (permitting states to bring suits for civil enforcement of sections 341 (food standards), 343(b)-(i) (food labeling), 343(k) (food flavorings), 343(q)-(r) (nutrition information)). But unlike the FDCA's food and labeling provisions, the FDCA's premarket approval process, which requires individualized determinations by the FDA, does not afford space for non-federal enforcement.

Second, even accepting Farm Raised Salmon's conclusion that state food labeling laws are not preempted to the extent they "do not seek to enforce the FDCA," Somers is seeking to "enforce the FDCA." Without belaboring the point, this is the reason she originally went the FDA, not a California regulatory body, when she filed her Citizen Petition in 2015.

Somers next attempts to differentiate this case from Borchenko, a recent case from the Central District of California. Like the current case, the plaintiff in Borchenko alleged that several skin-care products distributed by L'Oreal were "drugs" that had not gone through the NDA process. Relying on Buckman and Perez, the court in Borchenko held that plaintiff's UCL claim was preempted because it "exists solely by virtue of the FDCA and [state] law which references the FDCA." *Borchenko v. L'Oreal USA, Inc.*, 389 F.Supp.3d 769, 774 (C.D. Cal. 2019). Sensing that this Court would likely reach the same

result, Somers argues that the plaintiff in Borchenko sought injunctive relief, which she does not seek here. Fair enough. But the Court can find nothing in the Borchenko opinion that suggests the presence of injunctive relief was determinative. Indeed, as Beiersdorf correctly points out, if Borchenko's claims were viable but for the injunctive relief, the court could have dismissed only the claim for injunctive relief rather than dismissing the entire case; it did not.

In short, no matter how Plaintiff couches her argument, her complaint is an attempt to privately enforce the FDCA. Because Congress has given the FDA a monopoly on FDCA enforcement in the New Drug Approval context, her claims are preempted. As other courts have recognized, "the [FDCA's] public enforcement mechanism is thwarted if savvy plaintiffs can label as arising under a state law for which there exists a private enforcement mechanism a claim that in substance seeks to enforce the FDCA." Loreto v. Procter & Gamble Co., 515 F. App'x 576, 579 (6th Cir. 2013); see also Borchenko, 389 F.Supp.3d at 773 ("Moreover, because the Sherman Law references and incorporates the FDCA, this Court cannot grant any relief to Plaintiff without referring to and applying provisions of the FDCA."). Beiersdorf is therefore entitled to summary judgment.

CONCLUSION

Federal law preempts plaintiff's only remaining claim.[5] Defendant's Motion for Summary Judgment is **GRANTED**. The clerk is directed to enter judgment in favor of Beiersdorf and close the case.

IT IS SO ORDERED.

Dated: April 15, 2020

HONORABLE LARRY ALAN BURNS
Chief United States District Judge

[5] Plaintiff's TAC makes passing reference to Beiersdorf's violation of 21 C.F.R. § 201.66, which sets labeling standards for drugs. This claims rises and falls with Somers's larger claim that the Nivea CoQ10 Lotion is a drug, so it must necessarily be dismissed as well. In any event, by failing to address this argument in opposition, Somers has waived any argument that this portion of her UCL claim survives.