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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ALEXANDER FOROUZESH, on behalf of himself and all others similarly situated,

Plaintiff,

v.

CVS PHARMACY, INC., a foreign business corporation; and DOES 1–25 inclusive

Defendants.

Case № 2:18-CV-04090-ODW (AFMx)

ORDER GRANTING DEFENDANT'S MOTION TO DISMISS [22]

I. INTRODUCTION

Plaintiff Alexander Forouzesh brings this putative class action against Defendant CVS Pharmacy, Inc., claiming CVS's labeling of its SPF 100+ sunscreens is false and misleading. CVS now moves to dismiss Forouzesh's First Amended Complaint ("FAC"). (Mot. to Dismiss ("Mot."), ECF No. 22.) For the reasons below, the Court **GRANTS CVS's Motion with leave to amend**.[1]

[1] After carefully considering the papers filed in support of and in opposition to the Motion, the Court deemed the matter appropriate for decision without oral argument. Fed. R. Civ. P. 78; C.D. Cal. L.R. 7-15.

II. FACTUAL BACKGROUND[2]

In or around November 2016, Forouzesh purchased a bottle of "CVS Sport SPF 100+ Sunscreen Spray" in reliance on its SPF 100+ label. (FAC ¶¶ 9, 17, ECF No. 20.) Forouzesh purchased the product "on the assumption that [it] contained the advertised SPF level of protection." (*Id.* ¶ 24.) However, Forouzesh had a CVS Sport SPF 100+ product ("the Product") tested using FDA-compliant testing protocols, and the testing report ("Report") revealed an SPF of only 29. (*Id.* ¶¶ 3, 22; Decl. of Justin Farahi ("Farahi Decl."), Ex. 1 (Report), ECF No. 20-2.) As a result, Forouzesh alleges, the SPF 100+ label on all CVS Sport SPF 100+ products and CVS's implied message of superior UVB protection are false and misleading. (FAC ¶¶ 7, 16.) Forouzesh would not have purchased the products had he known the truth about the lower SPF value. (*Id.* ¶ 24.)

Forouzesh filed his initial Complaint on behalf of a putative nationwide class. (Compl., ECF No. 1.) CVS moved to dismiss and Forouzesh amended his complaint. (*See* FAC.) Accordingly, the Court denied CVS's first motion to dismiss as moot. (Order Denying Mot. to Dismiss, ECF No. 28.) Based on the allegations above, Forouzesh asserts four causes of action through his FAC, including (1) violation of California Business and Professions Code ("B&P") section 17200 *et seq.* (Unfair Competition Law ("UCL")), (2) violation of B&P section 17500 *et seq.* (False Advertising Law ("FAL"), (3) violation of California Civil Code section 1750 *et seq.* (Consumers Legal Remedy Act ("CLRA")), and (4) breach of express warranty. (FAC 1.) Forouzesh asserts that "all of [his] causes of action are . . . predicated on the fact that [CVS's] sunscreen is inaccurately labeled as SPF 100+ since product testing following FDA protocol revealed an SPF level of 29." (Opp'n to Mot. ("Opp'n") 5–6, ECF No. 29.) Through his FAC, Forouzesh seeks damages and an order that CVS relabel all its CVS Sport SPF 100+ sunscreen products as SPF 29 per his independent

[2] The facts derive from Forouzesh's FAC and are taken as true for the purposes of this Motion. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

testing and conduct a corrective advertising campaign to inform consumers of its deceptive labeling. (FAC ¶ 8; *id.* at 20–21.)

CVS moves to dismiss Forouzesh's FAC, arguing that Forouzesh's claims are preempted, should be dismissed under the primary jurisdiction doctrine, and are otherwise improper. (Mot. 3–4.)[3]

III. LEGAL STANDARD

A court may dismiss a complaint under Rule 12(b)(6) for lack of a cognizable legal theory or insufficient facts pleaded to support an otherwise cognizable legal theory. *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988). A claim has facial plausibility, and thus survives a motion to dismiss, when the pleaded factual content allows "the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a plaintiff must plead facts sufficient to "state a claim to relief that is plausible on its face." *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The factual "allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

The determination of whether a complaint satisfies the plausibility standard is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. A court must construe all "factual allegations set forth in the complaint . . . as true and . . . in the light most favorable" to the plaintiff. *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001) (internal quotation marks omitted). However, a court need not accept conclusory allegations, "allegations that contradict exhibits attached to the complaint or matters properly subject to judicial notice," "unwarranted deductions of fact, or

[3] Although Forouzesh filed his opposition late, CVS does not challenge his opposition as untimely, possibly because CVS noticed the motion for an improper motion day. (*See* Mot.; Reply, ECF No. 30; Notification, ECF No. 23.) Despite the untimeliness, the Court still considers Forouzesh's opposition in full. The Court again advises the parties that future failure to comply with this Court's rules and deadlines may result in rejection of filings or sanctions.

unreasonable inferences." *Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010).

A court is generally limited to the pleadings in ruling on a Rule 12(b)(6) motion, but may consider documents attached to the complaint or properly subject to judicial notice without converting a motion to dismiss into one for summary judgment. *See Lee*, 250 F.3d at 688–89. Where a claim includes allegations of fraud, Rule 9(b) requires a party to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9.

IV. REQUEST FOR JUDICIAL NOTICE

CVS requests that the Court take judicial notice of several excerpts from the Federal Register (Request for Judicial Notice ("RJN"), Exs. 1–6, ECF No. 22-1) as well as the complaint in *Gisvold v. Merck & Co., Inc.*, 62 F. Supp. 3d 1198 (S.D. Cal. 2014) (No. 14-cv-1371 DMS (JLB)) (RJN, Ex. 7). Forouzesh did not oppose CVS's RJN.

The contents of the Federal Register are judicially noticeable as a matter of law. *See* 44 U.S.C. § 1507; *Bayview Hunters Point Cmty. Advocates v. Metro. Transp. Comm'n*, 366 F.3d 692, 702 n.5 (9th Cir. 2004) (granting request for judicial notice of a proposed rulemaking published in the Federal Register). Accordingly, the Court takes judicial notice of Exhibits 1–6, excerpts of the Federal Register.

As to the *Gisvold* complaint, courts regularly take judicial notice of proceedings in other courts and facts that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2); *see also Montantes v. Inventure Foods*, No. 14-cv-1128-MWF (RZx), 2014 WL 3305578, at *2 (C.D. Cal. July 2, 2014) (stating that courts "take judicial notice of 'proceedings in other courts . . . if those proceedings have a direct relation to matters at issue'") (quoting *United States v. Borneo, Inc.*, 971 F.2d 244, 248 (9th Cir. 1992)). Accordingly, the Court takes judicial notice of Exhibit 7, the *Gisvold* complaint, but not the truth of the facts contained therein. *Lee*, 250 F.3d at 690 (stating that judicial

notice of public records is limited to the existence of the documents, not the truth of their contents).

V. DISCUSSION

CVS expends a great portion of its Motion arguing that Forouzesh's claims are expressly and impliedly preempted by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). (*See* Mot. 4–11.)

A. Preemption

Pursuant to the Supremacy Clause, U.S. Const. art. VI, cl. 2, federal law preempts state law when "(1) Congress enacts a statute that explicitly preempts state law; (2) state law actually conflicts with federal law; or (3) federal law occupies a legislative field to such an extent that it is reasonable to conclude that Congress left no room for state regulation in that field." *Chae v. SLM Corp.*, 593 F.3d 936, 941 (9th Cir. 2010). Regardless of the type of preemption the "purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (internal quotation marks omitted).

The FDCA includes an unambiguous express preemption clause with respect to sunscreen labeling. It provides "no State or political subdivision of a State may establish or continue in effect any requirement . . . that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter." 21 U.S.C. § 379r(a)(2). State common law causes of action are considered state "requirements" subject to preemption. *Reigel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008); *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1282 (C.D. Cal. 2008). "The touchstone of preemption under § 379r is the *effect* that a finding of liability on a particular claim would have on the Defendants, and not the particular common law or state law theory upon which that claim was brought." *Carter*, 582 F. Supp. 2d at 1283.

The FDCA regulates over-the-counter ("OTC") drugs including non-prescription sunscreens like the one at issue here. *See* 21 C.F.R. § 201.327. "The

current regulations establish labeling requirements, provide for effectiveness testing upon which the labeling relies, and identify false and misleading claims that render a product misbranded." *Gisvold*, 62 F. Supp. 3d at 1202 (citing 76 Fed. Reg. 35620–21 (Jun. 17, 2011) (*Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-the-Counter Human Use*) ("Final Rule")); *see also* 21 C.F.R. § 201.327.

B. Plaintiff's Claims

CVS first argues that Forouzesh's claims are preempted because they are based on the assertion that the product's SPF label misrepresents that it provides "proportionally greater UVB protection than comparable, lower SPF valued products." (*See* Mot. 4 (quoting FAC ¶ 85).) CVS argues this claim is preempted because CVS cannot label its Product in any other way and still comply with FDA regulations. (*Id.* at 6.) However, Forouzesh expressly disavows claims not specifically predicated on the accuracy of the SPF value. (*See* Opp'n 5–6.) Thus, the claims concern whether CVS accurately labeled its CVS Sport SPF 100+ labels *in compliance with* FDA regulations.

CVS also argues that Forouzesh's claims are expressly preempted because they would effectively impose labeling requirements different from or in addition to those required by FDA regulations and that allegations regarding Forouzesh's independent FDA-compliant testing are simply not plausible. (Mot. 7–11.) Forouzesh responds that he "does not claim to impose a different state requirement regarding labeling of SPF 100+ nor does he seek directly or indirectly to impose liability for conduct sanctioned by the FDA." (Opp'n 7.) He contends the essential issue is whether CVS's Product is mislabeled according to FDA-compliant testing. (*Id.*)

1. Methodology

The federal regulations promulgated by the Final Rule mandate that OTC sunscreens be labeled according to the lengthy, detailed scientific and technical testing procedures laid-out in the regulation. *See* 21 C.F.R. § 201.327(a)(1)(i), (ii) (requiring OTC sunscreen to be labeled: "SPF [insert numerical SPF value resulting from testing

under paragraph (i) of this section].") Paragraph (i) in turn sets out the extensive testing requirements, including detailed requirements for the solar simulator; number of test subjects and valid test results; determination of subjects' skin types; method for testing, including application, waiting times, and size of test areas; the method and formula for calculating the SPF from the results; and when and why to reject test data. *See id.* § 201.327(i)(1)–(6). "[W]here, as here, an FDA regulation provides that the question of compliance must be determined using the method specified therein, a state law claim that seeks to establish a violation of the regulation by a different methodology is preempted." *Mee v. I.A. Nutrition, Inc.*, No. C-14-5006-MMC, 2015 WL 2251303, at *4 (N.D. Cal. May 13, 2015) (citing *Salazar v. Honest Tea, Inc.*, 74 F. Supp. 3d 1304, 1313 (E.D. Cal. 2014)).

Thus, a claim seeking to enforce SPF labeling according to FDA-compliant testing would be "identical to" FDA requirements and not preempted, while a claim seeking to enforce SPF labeling according to non-FDA-compliant testing would be "different from" that mandate and preempted.

2. Allegations of FDA-Compliant Testing

The Court finds Forouzesh's allegations of independent FDA-compliant testing conclusory and fail to support a plausible conclusion that his testing was done in compliance with FDA regulations. Forouzesh alleges only that his "independent testing following FDA protocol revealed that the product provides an SPF 29 protection." (FAC ¶¶ 3; *see also id.* ¶¶ 16, 25, 42, 46.) He fails to allege the product tested is one he purchased. He fails to identify the specific product tested. And he fails to provide any factual support as to how his testing complied with FDA regulations. As just one example, Forouzesh alleges the product he purchased is a "Sunscreen Spray." (FAC ¶ 9.) Yet he does not explain how the spray was applied according to FDA requirements, where protocol requires application with a "finger cot . . . to spread the product as evenly as possible." 21 C.F.R. § 201.327(4)(iii).

Without more, Forouzesh fails to plausibly allege that his independent testing is FDA-compliant. *See Mee*, 2015 WL 2251303, at *4; *Anglin v. Edgewell Pers. Care Co.*, No. 4:18-CV-00639-NCC, 2018 WL 6434424, at *7 (E.D. Mo. Dec. 7, 2018) ("The *substance* of the allegations is particularly important in determining the *sufficiency* of those allegations in situations where, as here, the governing FDA regulation imposes a specific, lengthy, and very detailed methodology for testing the products, including the specific number of subjects to be tested, timelines for testing, etc."); *Curran v. Bayer Healthcare LLC*, No. 17 C 7930, 2018 WL 2431981, at *3 (N.D. Ill. May 30, 2018) ("[P]laintiff needs to include some facts about his testing procedure in order to make it plausible that defendant's label was not in compliance with the requirements of 21 C.F.R. § 201.327. . . . He needs to include at least some facts about his testing.").

3. The Report

Some courts have found minimal allegations sufficient at the pleading stage when supported by a report of product testing. *See Muir v. NBTY, Inc.*, No. 15-C-9835, 2016 WL 5234596, at *6 (N.D. Ill. Sept. 22, 2016) (finding "chapter-and-verse compliance with FDA testing" was not a pleading requirement). Here, Forouzesh attached a copy of his product-testing Report to his Complaint. However, rather than support the plausibility of his conclusory allegations, the Report contradicts them. *See Daniels–Hall*, 629 F.3d at 998 (discussing that a court need not accept conclusory allegations or allegations contradicted by exhibits attached to the complaint); *see also Mee*, 2015 WL 2251303, at *4 (concluding that plaintiffs who attached lab reports showing non-FDA-compliant testing "pleaded facts demonstrating preemption").

First, it is unclear what product was tested and whether it was the product Forouzesh purchased. The Report shows that the product tested was "SPF 100+ Broad Spectrum Sunscreen," Lot #: 6381316B, while the product Forouzesh purchased was "CVS Sport SPF 100+ Sunscreen Spray." (Report 1; FAC ¶ 9); *see also* 76 Fed. Reg. 35620-01, at 35624–25, 35627 (differentiating "Broad Spectrum"

sunscreens); 21 C.F.R. § 201.372(j) (requiring additional testing for "Broad Spectrum" sunscreens). Additionally, Forouzesh's counsel declares that "One lot of CVS Sport SPF 100+ material was tested." (Farahi Decl. ¶ 4.) Yet he fails to clarify whether the "material" was the Sunscreen Spray Forouzesh purchased or some other CVS Sport SPF 100+ "material." This is particularly significant because Forouzesh's vague allegations broadly encompass the entire CVS Sport SPF 100+ product line without identifying any factual similarities across those products beyond the SPF value. (*See* FAC ¶ 15 ("the CVS Sport SPF 100+ product, a line of sunscreen products labeled with SPF of 100+.").) Forouzesh does not allege that the product tested is the product he purchased or otherwise connect the two.

Also, even assuming the product purchased was the product tested, the testing appears not to comply with FDA regulations. FDA regulations require that testing return ten valid results, with a maximum of three rejected subjects. *See* 21 C.F.R. § 210.372(i)(3). Forouzesh acknowledges this requirement. (*See* Farahi Decl. ¶ 5 ("To determine actual SPF level of a product, a full 10-person panel must be tested with valid results.").) Yet, the Report shows only eight valid test results, with five subjects being rejected or returning invalid results. (*See* Report 4, 5 ("Subjects 06 and 11 were disqualified"; "Data for subject 10 were rejected"; "Subjects 03 and 12 did not yield evaluable SPF data.") Forouzesh's counsel states only that the testing was completed as to ten subjects, but not that testing returned ten valid results. (*See* Farahi Decl. ¶ 5.) Absent explanation as to how the test results comply with the regulations in the face of these obvious deficiencies, the Report only undermines Forouzesh's allegations of FDA-compliant testing.

Courts disagree regarding whether specific compliance with FDA testing is a pleading requirement at the motion to dismiss stage. *Compare Salazar*, 74 F. Supp. 3d at 1313 (failure to allege compliance with FDA testing protocols required dismissal as preempted); *Mee*, 2015 WL 2251303, at *3–4 (same); *with Smith v. Allmax Nutrition*, No. 1:15-cv-00744-SAB, 2015 WL 9434768, at *7 (E.D. Cal. Dec. 24,

2015) (allegations of precise testing methodology were not required at the pleading stage); *Clay v. Cytosport, Inc.*, No. 15-cv-165 L (DHB), 2015 WL 5007884, at *4 (S.D. Cal. Aug. 19, 2015) (same). Here, the Court finds that requiring at least some facts to support a plausible inference of FDA-compliant testing is proper. The substance of the allegations is particularly important here because the question of compliance must be determined using a precise and specific methodology; Forouzesh's claims implicate the particularity pleading standard of Rule 9; and rather than providing support, the Report contradicts Forouzesh's conclusory allegations.

Even courts that do not require factual support for FDA-compliant testing agree that a claim seeking to use a methodology other than that required by the FDA would be preempted. *See Smith*, 2015 WL 9434768, at *7 (finding allegations of precise testing methodology not required at the pleading stage where "Plaintiff has not pled a different methodology . . . than those set forth by the FDA"). Here, the Court cannot conclude that Forouzesh's testing was conducted in compliance with FDA regulations. As the FAC seeks to require CVS to apply this methodology, which is different from or not identical with SPF testing required by FDA regulation, the Court finds Forouzesh's claims, as pleaded, are preempted.

Accordingly, the Court **GRANTS** CVS's motion to dismiss Forouzesh's FAC.[4]

C. Leave to Amend

Generally, leave to amend shall be freely given when justice so requires. *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1051 (9th Cir. 2003). ''This policy is 'to be applied with extreme liberality.''' *Id.* (quoting *Owens v. Kaiser Found. Health Plan, Inc.*, 244 F.3d 708, 712 (9th Cir. 2001)). "Dismissal . . . without leave to amend is not appropriate unless it is clear . . . the complaint could not be saved by amendment." *Eminence*, 316 F.3d at 1052. To the extent Forouzesh can amend his Complaint in good faith to allege that independent testing of the product he

[4] In light of the Court's ruling as to preemption, the Court need not address CVS's additional arguments in support of dismissal.

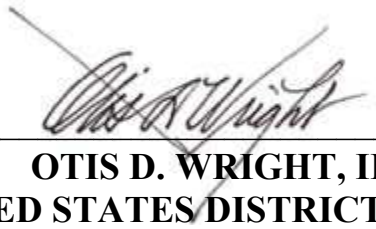
purchased complied with the FDA regulations for SPF testing, Forouzesh may amend his FAC within 21 days of this Order.

VI. CONCLUSION

For the reasons discussed above, the Court **GRANTS** CVS's Motion to Dismiss. (ECF No. 22.) Forouzesh may **AMEND his FAC within 21 days of the date of this Order**, only as to the FDA-compliant SPF testing of the product he purchased. Should Forouzesh not file an amended complaint within 21 days, this dismissal will convert to one with prejudice.

IT IS SO ORDERED.

February 15, 2019



OTIS D. WRIGHT, II
UNITED STATES DISTRICT JUDGE