IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

KRYSTAL LOPEZ,

Plaintiff,

v.

ZARBEE'S, INC.,

Defendant.

Case No. 22-cv-04465-CRB

ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS

Plaintiff Krystal Lopez brings this putative class action against Defendant Zarbee's, Inc. in connection with Zarbee's melatonin supplements.[1] Lopez alleges that Zarbee's products include significantly more melatonin than the label asserts, and therefore violate state consumer protection laws. Zarbee's moves to dismiss, arguing that all of the claims are completely preempted, and that Lopez lacks standing as to some claims. See MTD (dkt. 26). The Court found this matter suitable for resolution without oral argument, and therefore vacated the motion hearing. See Civil Local R. 7-1(b). Because Zarbee's arguments largely fail at this stage, the Court grants in part and denies in part the motion.

I. BACKGROUND[2]

A. The Parties

Zarbee's, a Delaware corporation, sells melatonin supplements nationwide at retailers like Walmart and Target. FAC (dkt. 24) ¶¶ 3, 8. Lopez lives in California, and purchased a Zarbee's melatonin product in California. Id. ¶ 6.

[1] This is one of several melatonin suits brought by this law firm. Murphy v. Olly Public Benefit Corp., 22-cv-3760-CRB, is also before this Court.

[2] These background facts are drawn from the complaint and accepted as true for the

B. FDA Regulations for Dietary Supplements

Melatonin is a neurohormone that regulates sleep. Id. ¶ 1. Millions of consumers take over-the-counter melatonin supplements to help them sleep. Id. ¶ 14. Federal law imposes a comprehensive regulatory scheme for dietary supplements, including melatonin supplements. See generally FDCA, 21 U.S.C. § 301 et seq.; 21 C.F.R. Part 100 et seq. Under applicable FDA regulations, melatonin qualifies as an "other dietary ingredient," meaning that the quantity of melatonin in a supplement must be listed on the product label. 21 C.F.R. § 101.36(b)(3)(i). The declared quantity of melatonin must be established by a specific FDA-mandated test "consisting of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot." See 21 C.F.R. § 101.9(g)(2); 21 C.F.R. § 101.36(f)(1) (applying this testing method to "other dietary ingredients").

The FDA forbids supplement labels that overstate quantities. FDA regulations require that the quantity of melatonin "be at least equal to the value . . . declared on the label" for the product's full shelf life. See 21 C.F.R. § 101.9(g)(4)(i). A product that has less melatonin than is listed on the label is "misbranded." See 62 Fed. Reg. 49826-01 at 49839 (Sept. 23, 1997).

The FDA treats supplement labels that understate quantities differently. The FDA recognizes that some supplements, like melatonin, degrade over time, "such that a product that contains a certain amount of a supplement when it gets put on the shelves might have less of that supplement at expiration." FAC ¶ 22. The FDA further recognizes that some manufacturers formulate their supplements with overages to ensure "that the finished product can meet the label declaration for that dietary ingredient throughout the product's shelf life." 68 Fed. Reg. 12158, 12203 (Mar. 13, 2003). Accordingly, there is a safe harbor: "[r]easonable excesses over labeled amounts are acceptable within current good manufacturing practice." 21 C.F.R. § 101.36(f)(1). Current good manufacturing practice requires manufacturers to keep track of "any intentional overage amount of a dietary

ingredient." 21 C.F.R. § 111.210(e).[3]

Although the FDA allows for overages, it does not intend "to allow a manufacturer to add excess dietary ingredients in unspecified amounts that would be in excess of the amount actually needed to meet the label declaration." 68 Fed. Reg. 12158, 12203; see also 72 Fed. Reg. at 34884 ("the amount of overage should be limited to the amount needed to meet the amounts listed in accordance with final § 111.210(d)."). The FDA has declined to adopt a specific cap on overages. See, e.g., 60 Fed. Reg. 67194-01 at 67207 (Dec. 28, 1995) (declining proposed 20% overage cap).

C. This Litigation

In June of 2022, Lopez purchased a bottle of Zarbee's Children's Sleep with Melatonin Gummies from a Walmart store in Salinas, California. FAC ¶ 50. The gummies were for her 8-year-old child. Id. Lopez "relied on the fact that Zarbee's dosages were well-controlled" and "read and relied on the accuracy of the melatonin content on the label." Id. She chose the 1mg dose per gummy "because she did not want to give her child more melatonin, due to increased concerns about side effects and safety." Id. She gave him the gummies and noticed that they sometimes "would have a very strong tranquilizing effect that concerned her, and then the next day he would be unusually subdued." Id.

Lopez did a liquid chromatograph-mass spectrometry analysis on three gummies from each of two bottles of gummies, including the bottle she purchased. Id. ¶ 36. The gummy from Lopez's bottle had more than twice the amount of melatonin than what Zarbee's stated on the label (2.16mg instead of 1mg). Id. A gummy from a bottle that was one month away from expiring still had 222% of the claimed melatonin content (2.23mg instead of 1mg). Id.

Lopez initially brought suit in August of 2022, arguing that the product "was not accurately dosed or labeled." See Compl. (dkt. 1) ¶ 33. Zarbee's moved to dismiss the

original complaint, arguing that the FDA allows for overages and that Lopez's testing methodology was inadequate. See First MTD (dkt. 21) at 7–11. Lopez amended. FAC. The FAC now alleges that "[b]ecause the excess is materially more than reasonably necessary to ensure that the melatonin meets the amount specified on the product label throughout the product's shelf life, Zarbee's Melatonin is unreasonably overdosed." Id. ¶ 38. It includes claims for violation of: (1) California, Connecticut, Illinois, Maryland, Missouri, and New York consumer protection acts; (2) California's Unfair Competition Law (UCL); (3) California's False Advertising Law (FAL); (4) California's Consumers Legal Remedies Act (CLRA); as well as: (5) breach of express warranty; and (6) unjust enrichment/quasi-contract. Id. ¶¶ 67–110. Zarbee's again moves to dismiss. See MTD.

II. LEGAL STANDARD

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, the Court may dismiss a complaint for failure to state a claim upon which relief may be granted. The Court may base dismissal on either "the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." Godecke v. Kinetic Concepts, Inc., 937 F.3d 1201, 1208 (9th Cir. 2019) (cleaned up).

A complaint must plead "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (cleaned up). A claim is plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to survive a 12(b)(6) motion. Id. (citing Bell Atlantic v. Twombly, 550 U.S. 544, 555 (2007)). When evaluating a motion to dismiss, the Court "must presume all factual allegations of the complaint to be true and draw all reasonable inferences in favor of the nonmoving party." Usher v. City of Los Angeles, 828 F.2d 556, 561 (9th Cir. 1987). "Courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a

court may take judicial notice." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007).

If a court dismisses a complaint for failure to state a claim, it should "freely give leave" to amend "when justice so requires." Fed. R. Civ. P. 15(a)(2). A court may deny leave to amend due to "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendment previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of amendment." Leadsinger, Inc. v. BMG Music Pub., 512 F.3d 522, 532 (9th Cir. 2008).

III. DISCUSSION

Zarbee's argues that the FAC should be dismissed with prejudice because (A) all of the claims are completely preempted by the FDA, and (B) Lopez lacks standing.

A. Express Preemption

The FDA expressly preempts state law claims that seek to impose manufacturing and labeling requirements for dietary supplements that are "not identical to" federal requirements of the same type. 21 U.S.C. § 343-1(a)(1); see also 21 C.F.R. § 100.1(c)(4) ("not identical to" means "that the State requirement directly or indirectly imposes obligations . . . concerning the composition or labeling of food" that are "not imposed by or contained in the applicable [federal statute or regulation]" or "[d]iffer from those specifically imposed by or contained in the applicable [federal statute or regulation]"); 21 U.S.C. § 321(ff) (dietary supplements are "a food" within the meaning of the FDCA). Zarbee's argues that the FDA expressly preempts Lopez's claims because (1) she is complaining about FDA-permitted overages; and (2) the testing method Lopez uses to support her claims deviates from the FDA-mandated testing method. MTD at 8–14. "Preemption is an affirmative defense," so the burden is on Zarbee's to prove it. See Cohen v. ConAgra Brands, Inc., 16 F.4th 1283, 1289 (9th Cir. 2021).

1. Overages

Stressing that the FDA allows manufacturers to include overages in nutritional supplements, Zarbee's contends that Lopez's claims, all based on overages in Zarbee's

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