UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

MICHAEL MUIR, individually and on behalf of all others similarly situated,))
Plaintiff,)
v .)) No. 15 C 9835
NBTY, INC., REXALL SUNDOWN, INC., NATURE'S ORIGIN, LLC, NATURE'S BOUNTY, INC., VITAMIN WORLD, INC., and PURITAN'S PRIDE, INC.,) Judge Rebecca R. Pallmeyer)))
Defendants.)

MEMORANDUM OPINION AND ORDER

Plaintiff Michael Muir purchased a bottle of the dietary supplement St. John's Wort from a Walgreens store in Illinois in 2015. The label states that the product is "[s]tandardized to contain 0.3% Hypericin, 0.9 mg." Muir claims the product actually contains a far lower amount of hypericin, purportedly the active ingredient in St. John's Wort. Muir filed this action on behalf of a nationwide class of persons who purchased St. John's Wort Standardized Extract from any of five different manufacturers. Defendants move to dismiss the complaint for lack of standing and failure to state a claim. For the reasons explained here, the motion is granted in part and denied in part. Muir has leave to file an amended complaint against the manufacturer of the supplement he himself purchased.

BACKGROUND

On November 3, 2014, Muir filed this class action on behalf of all persons in the United States "who purchased the dietary supplements St. John's Wort Standardized Extract" from Defendants, five manufacturers of nutritional supplements, and their joint corporate parent. (Compl. [1] ¶¶ 1, 46.) Plaintiff alleges that the dietary supplements sold by Defendants "did not contain consistent amounts of the sole active ingredient Standardized Extract Hypericin listed on their labels" and that Defendants' advertising and distribution of the products was false, misleading, and deceptive. (*Id.* ¶¶ 5, 6.) Muir himself, a resident of Lake Zurich, Illinois,

purchased the product from a retailer, Walgreens, in July 2015. (*Id.* ¶ 13.) Defendants are allegedly "licensed" in Delaware and have their principal places of business in New York. (*Id.* ¶¶ 14-20.) Defendant NBTY, Inc. is the parent company of the other five Defendants. (*Id.* ¶ 14.)

Plaintiff alleges that there is no legal or regulatory definition of the term "standardized," but that a standardized extract is understood to have "one or more components present in a specific, guaranteed amount, usually expressed as a percentage," and that the "intention behind standardization of herbs is to guarantee that the consumer is getting a product in which the chemistry is consistent from batch to batch." (*Id.* ¶¶ 23, 24.) He asserts that when purchasers shop for a St. John's Wort Product, they expect to receive the "guaranteed" amount on the label. (*Id.* ¶ 26.) Included in the complaint are images of the labels of the products distributed by Defendants, each of them bearing the figure "300 mg.," and stating that the product is "[s]tandardized to contain 0.3% Hypericin, 0.9 mg." (*Id.* ¶¶ 27-28.) In fact, however, the products actually contain different amounts of hypericin, all far less than the amount listed on the label. (*Id.* ¶ 29.) Attached to the complaint as Exhibits A through E are test results of the products distributed by the Defendant manufacturers. For the five products tested, the total amount of hypericin per serving ranged from as little as 0.166 milligrams to 0.615 milligrams. None contained an amount close to 0.9 milligrams. (Test Results, Exs. A-E to Compl.).

St. John's Wort is "promoted as an anti-depressant herb" that has "shown benefits" in the dosage amount of 0.9 milligrams per day—the "exact amount" that the packaging touts as present in Defendants' products. (*Id.* ¶¶ 31, 32.) In fact, as Defendants knew, the products "contain less of the standardized extract than claimed." (*Id.* ¶ 32.) Plaintiff alleges that he and other class members purchased and consumed the products in reliance on the misleading labeling, and would not have done so had they realized that the products contained less of the standardized extract than the products (*Id.* ¶ 36.) The difference between what the labels stated and what was actually delivered in the products is "significant," Plaintiff alleges, and has

"real impacts on the benefits provided to consumers." (Id. ¶ 38.) He contends that the false statements in Defendants' labeling violate federal and state laws which prohibit "misbranding" of food and nutritional supplement with labels that contain a statement "false or misleading in any particular." (*Id.* ¶¶ 39-42 (citing 21 U.S.C. § 343(a)(1); 410 ILCS 620/11, 620/21).)¹

Plaintiff brings this case on behalf of himself and all persons in the United States who purchased the products. He also seeks to assert consumer fraud claims on behalf of all purchasers in the states of California, Florida, Illinois, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, and Washington, referred to as the "multi-state class." (*Id.* ¶ 46.) The complaint alleges four counts: A claim of violation of state consumer fraud acts on behalf of the multi-state class (Count I); a claim of violation of the Illinois Consumer Fraud Act, 815 ILCS 505/1, *et seq.*, on behalf of Illinois purchasers (Count II); a claim of unjust enrichment on behalf of the nationwide class (Count IV). He claims each member of the class has been damaged "in the amount of the purchase price of the products and any consequential damages resulting from the purchases." (*Id.* ¶ 81.)

Defendants have moved to dismiss the complaint in its entirety. They raise several arguments: First, they contend the court has no jurisdiction over this case because Plaintiff has not alleged any harm resulting from the hypericin level in any product he bought, and therefore lacks standing. Second, Defendants assert that none of them are subject to personal jurisdiction in this court. Defendants' third argument is that the complaint fails as a matter of law because federal law expressly preempts his claims and because the sampling method on which the complaint rests is inadequate. Moreover, Defendant urges, federal law allows for "natural

¹ For obvious reasons, both parties in this case assume that St. John's Wort has therapeutic value, and that hypericin is the source of the treatment effect. That assumption could be questioned. As early as 2002, the National Institutes of Health reported that a randomized, double-blind trial compared the use of a standardized extract of St. John's Wort to a placebo, and found the extract no more effective than placebo in treating major depression of moderate severity. Press Release, Nat'l Insts. of Health, Study Shows St. John's Wort Ineffective for Major Depression of Moderate Severity (Apr. 9, 2002), https://nccih.nih.gov/ news/2002/stjohnswort/pressrelease.htm.

variability" in the nutrient content of foods, and the allegations do not establish that the nutrient level of any of Defendants' products falls outside the range of natural variability. Plaintiff has misinterpreted the term "standardized," Defendants assert. They argue, further, that because Plaintiff did not purchase any product directly from any Defendant, and because he did not notify Defendants before suing them, as required by Illinois law, the court must dismiss the breach-of-warranty claim. The flaws in Plaintiff's consumer claim requires dismissal of his unjust-enrichment claim, as well, they assert. Finally, Defendants argue that Plaintiff has not pleaded fraud with particularity, as required by federal pleading standards, and has not established any right to injunctive relief. The court concludes that several of these arguments have merit. The complaint in its current form will be dismissed without prejudice, for the reasons explained here.

I. Standing

A. Plaintiff has standing to sue for the product he purchased

Defendants' threshold argument is that Plaintiff lacks standing because he has not identified an "injury in fact" that is both concrete and particularized. In support, Defendants note that Plaintiff has not specified which of their products he purchased and cannot allege that the one he did purchase in July 2015 was in fact low in hypericin or that it was of no benefit to him.

Defendants are correct that Plaintiff has not identified which of the products he took, but he did allege that he and other class members "purchased and consumed" the products in reliance on labels that assured them the products contained particular quantities of the desired ingredient. (Compl. ¶ 33.) Plaintiff's failure to identify any physical harm that he may have suffered, or even to allege that the product did not "work" is not fatal to his claim. He has alleged a financial loss—specifically, that he and the class members would not have purchased the products at issue, had they known that the quantity of hypericin in those products was "significantly lower" than what was stated on the label. The Seventh Circuit has recognized that one who has allegedly paid more for a product in reliance on misrepresentations about the product's quality has standing to sue for recovery of the financial loss. In *Aqua Dots Prods. Liability Litig.*, 654 F.3d 748 (7th Cir. 2011), plaintiffs alleged that a children's toy consisted of beads that resembled candy but were harmful if swallowed. The Seventh Circuit concluded that parents of children who had not been physically injured nevertheless had standing because, having paid more for the toys than they would have, had they known of the hazard, the parents had suffered financial injury. "A financial injury creates standing," the court observed. 654 F.3d at 749. Judge Feinerman of this court followed *Aqua Dots* in *Muir v. Playtex Prods., LLC*, 983 F. Supp. 2d 980, 983 (N.D. III. 2013), where plaintiff and a class he sought to represent had purchased defendant's "Diaper Genie" product at a premium price, in reliance on the defendant's claim—defeated by independent testing--that the product had been "Proven #1 in Odor Control." And in *Askin v. Quaker Oats Co.*, 818 F. Supp. 2d 1081, 1084 (N.D. III. 2011), Judge Kim agreed with plaintiffs that they had standing to pursue a claim that defendant had falsely touted its oatmeal and granola products as being "wholesome" and "heart healthy" when those products in fact contained trans fats.

Defendants contend that the Seventh Circuit has walked back a bit from this thinking. They cite *Remijas v. Neiman Marcus Group, LLC*, 794 F.3d 688, 694 (7th Cir. 2015), where the court recognized that credit card holders had a claim only for amounts they paid to protect themselves from the consequences of a retailer's data breach. In reaching that conclusion, the court also considered plaintiffs' alternative argument that the data breach resulted in their overpaying for products; the court was "dubious" that the overpayment injury was one that would establish standing. Significantly, however, the *Remijas* court explicitly distinguished the data breach situation from the circumstances in *Chicago Faucet Shoppe, Inc. v. Nestle Waters North America, Inc.*, 24 F. Supp. 3d 750 (N.D. Ill. 2014). Plaintiff there had claimed it overpaid for bottled water it purchased from defendant in reliance on false statements on defendant's website that the water was "100% natural spring water." Judge Tharp of this court dismissed that complaint on other grounds, but was satisfied that plaintiff's alleged overpayment was

sufficient to establish "injury and causation for purposes of Article III standing." *Id.* at 756. The *Remijas* court's effort to distinguish *Chicago Faucet Shoppe* suggests that overpayment for products is a viable theory of harm. Plaintiff here has standing to recover for the amounts he overpaid for the St. John's Wort product he purchased.

B. Plaintiff lacks standing for products he did not purchase

As Defendants observe, however, Plaintiff has not bothered to reveal what product that is. Thus, Defendants urge, even if Plaintiff has standing to sue one of the five distributors of St. John's Wort, he has no standing to sue the remaining four. Both parties cite Payton v. City of Kane, 308 F.3d 673, 682 (7th Cir. 2002), where six named plaintiffs filed a class action against 19 Illinois counties that had charged arrestees a "bond fee" as a condition of their being released, a practice permitted by Illinois statute. Despite the fact that the named plaintiffs resided in just two of the 19 counties, the Court of Appeals concluded that the district court erred in refusing to consider "whether these named plaintiffs may represent a class that includes people from the other 17 named counties." Id. at 680. The court was willing to address the propriety of class certification first and then assess the standing issue "with reference to the class as a whole, not simply with reference to the individual named plaintiffs." Id. Plaintiff believes this rationale supports the conclusion that he may proceed here against all Defendants who made what he believes to be the same misrepresentations. The court is less certain. In Payton, the named plaintiffs were challenging a bail fee practice authorized, in their home counties and several others, by a single state law: "These putative representatives were personally injured by the operation of the very same statute that caused the injuries to all other members of the proposed class." Id. at 682 (emphasis added).

This case differs. Plaintiff alleges that the various St. John's Wort distributors made identical representations about the hypericin concentration, but he has not alleged that their actual formulations are identical or that the discrepancy between the stated amounts and actual amounts of hypericin was the product of a single decision or policy. The fact that Plaintiff has

named the distributors' joint corporate parent does not cure this defect.² In pursuing a claim on behalf of purchasers of products he never himself purchased, Plaintiff appears to be attempting to "acquire [standing] through the back door of a class action." *Payton*, 308 F.3d at 682. In similar circumstances, other courts in this district have refused to recognize standing to assert a consumer fraud claim for a product that the plaintiff himself did not purchase. *Gubala v. Allmax Nutrition, Inc.*, No. 14 C 9299, 2015 WL 6460086 (N.D. III. Oct. 26, 2015); *Pearson v. Target Corp.*, No. 11 C 7972, 2012 WL 7761986 (N.D. III. Nov. 9, 2012); *Padilla v. Costco Wholesale Corp.*, No. 11 C 7686, 2012 WL 2397012 (N.D. III. June 21, 2012); *but see Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 541-42 (S.D.N.Y. 2013) (collecting and discussing cases, and citing, with approval *Brown v. Hain Celestial Grp., Inc.*, 913 F. Supp. 2d 881, 890 (N.D. Cal. 2012) for the proposition that "a plaintiff may have standing to assert claims for unnamed class members based on products he or she did not purchase so long as the products and alleged misrepresentations are substantially similar.") Purchasers of St. John's Wart from other manufacturers may choose to become part of this case. Plaintiff Muir's claim is limited to the product he himself purchased.

II. Personal Jurisdiction

Defendants, all located in New York and Delaware, contend the court lacks personal jurisdiction over them. They contend, correctly, that general personal jurisdiction requires a showing that the corporation's "affiliations with [Illinois] are so 'continuous and systematic' as to render [it] essentially at home" here. *Daimler AG v. Bauman*, 134 S. Ct. 746, 761 (2014). A corporation is ordinarily "at home" in its state of incorporation and the state where it has its principal place of business. *Kipp v. Ski Enterprise Corp.*, 783 F. 3d 695, 698 (7th Cir. 2015).

² And, though Defendant NBTY, Inc., has not separately argued the matter, the court notes that in the absence of an allegation that it directed or controlled the pricing or formulation of its subsidiaries' products, Plaintiff has offered no basis for imposing liability on the corporate parent of the source of the product he purchased. *See Esmark Inc. v. N.L.R.B.*, 887 F.2d 739, 753 (7th Cir. 1989) ("[A] parent corporation may not be held to account for the liabilities of a subsidiary unless the legal separateness of parent and subsidiary has been disregarded in a wide range of corporate matters.")

Disappointingly, in response, Plaintiff cites no case that post-dates *Daimler*, though it is well recognized that *Daimler* "raised the bar" for a claim of general personal jurisdiction. *Kipp*, 783 F. 3d at 698. Instead, he argues that the court can exercise specific jurisdiction over Defendants because they "formulated, manufactured, warranted, advertised, and sold the Products" in Illinois (Compl. ¶ 4); and "regularly conduct business" here (*id.* ¶ 58); and because Plaintiff and the class he seeks to represent purchased products in Illinois (*id.* ¶ 59). The court has specific jurisdiction "if the defendant has 'purposefully directed' his activities at residents of the forum, and the litigation results from alleged injuries that 'arise out of or relate to' those activities." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472, (1985) (citations omitted). Contacts relevant to specific jurisdiction are those contacts with the forum state that are both related to the lawsuit and created by the defendant. *Walden v. Fiore*, 134 S. Ct. 1115, 1121-22 (2014).

The claim of specific jurisdiction fails, Defendants contend, because Plaintiff did not make such a claim in his complaint, instead emphasizing that Defendants "conduct substantial business in the State of Illinois." (Defs.' Mem. [21] at 6; Compl. ¶ 10.) But Plaintiff also alleged that Defendants have "significant continuous and pervasive contacts" with this state (Compl. ¶ 10), a factor relevant to specific jurisdiction as well. See Daimler, 134 S. Ct. at 761 (confirming that the "continuous and systematic" standard relates to specific jurisdiction). Defendants' only other objection is the more general concern that one Defendant is a parent corporation and that, of the remaining five, four of those did not make any product Plaintiff bought. The court has concluded that Plaintiff has standing only to challenge the mislabeling of the product he actually purchased. Once he has identified that product, the court will be in a position to determine whether its manufacturer had systematic contacts with this state such that the court can exercise personal jurisdiction over that manufacturer for a claim arising out of Plaintiff's purchase.

III. Failure to State a Consumer Fraud Claim (Counts I and II)

Defendants' most complicated challenge to the complaint goes to the sufficiency of the allegations. Defendants allege that Plaintiffs have not stated a claim. As Plaintiff concedes, the federal Food, Drug, and Cosmetics Act expressly preempts any state law claims for false or misleading product labeling, if that claim seeks to impose requirements that are not identical to those imposed by the federal law. 21 U.S.C. § 343-1(a)(1)-(5). As Defendants understand this principle, it means that Plaintiff must allege he has complied with the testing standards that federal regulators adhere to in determining whether a food product's label accurately states the product's nutrient content. Further, Defendants urge, Plaintiff has ignored the fact that federal regulations allow for some variation in nutrient content, and has misinterpreted the word "standardized" on the products' labels to mean "guaranteed."

A. Product Sampling

The court begins with the product sampling requirements. Defendants cite federal regulations directing that nutrient content is determined by averaging test results from a representative sample of products in the marketplace. Specifically, for food products, "[t]he sample for nutrient analysis shall consist of a composite of 12 subsamples (customer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot." 21 C.F.R. § 101.9(g)(2). For nutritional supplements, the regulations similarly call for testing of "a composite of 12 subsamples" or "10 percent of the number of packages" in a single inspection lot. 21 C.F.R. § 101.36(f)(1). The objective of the sampling technique "is to determine whether the average, within a given lot . . . meets label claims." Nutrition Labeling, 38 Fed. Reg. 2125, 2162. Because federal regulations require only that the average nutrient levels, in an entire lot of product, meet label requirements, Defendants assert, "every court to consider the question has held that a state law claim attacking the veracity of a food label's nutrient content claim **must** allege tests of a proper sample of 12 consumer products from a single lot, one each taken from 12 randomly chosen shipping cases." (Defs.' Mem. at 8

(emphasis in original).) Plaintiff has not alleged tests of a "proper sample of 12 consumer products," Defendants urge; the test results attached to the complaint reveal testing of only one or two samples of each of the five Defendants' products, meaning that the complaint must be dismissed.

Plaintiff effectively concedes he has not performed the 12-product sampling Defendants insist is required. Indeed, the court is uncertain how a plaintiff, prior to discovery, would have access to "randomly chosen shipping cases" from which he could have selected 12 consumer samples that he could be sure had come "from a single lot." ³ In any event, the law is not as unequivocal as Defendants suggest. No controlling authority addresses the question of whether chapter-and-verse compliance with FDA testing is a pleading requirement, though some district courts have so held. *See Salazar v. Honest Tea, Inc.*, 74 F. Supp. 3d 1304, 1310 (E.D. Cal. 2014) (failure to allege compliance with FDA testing protocols requires dismissal of plaintiff's claims as preempted); *Mee v. I A Nutrition Inc.*, No. 14-cv-05006-MMC, 2015 WL 2251303, at *3 (N.D. Cal. May 13, 2015) (same); *Dougherty v. Source Naturals, Inc.*, 148 F. Supp. 3d 831, 836 (E.D. Mo. 2015) (same); *Burke v. Weight Watchers Int'l, Inc.*, 983 F. Supp. 2d 476 (D.N.J. 2013) (same).

But there is contrary authority, as well. In *Clay v. Cytosport, Inc.*, No. 15-cv-165 L (DHB), 2015 WL 5007884 (S.D. Cal. Aug. 19, 2015), the court considered allegations that defendant misrepresented the ingredients and characteristics of its "Muscle Milk" product, specifically alleging that the product provided less protein than advertised on the product label. Defendant moved to dismiss the complaint as preempted, noting the absence of any allegations that the sample plaintiffs had tested "consisted of a composite of twelve subsamples taken from each of twelve different randomly chosen shipping cases." *Id.* at *3. The court acknowledged that this is the appropriate standard, but disagreed that plaintiffs' failure to allege testing in

³ In their reply memorandum, Defendants suggest that Plaintiff has overstated the difficulty of obtaining the appropriate samples at the pleading stage. (Defs.' Reply [27] at 9.) Yet the language Defendants call out as an overstatement ("randomly chosen shipping cases") appears in Defendants' own opening memorandum. (Defs.' Mem. at 8.).

accordance the FDA methodology required dismissal. The simple allegation that the product violates federal law by providing less of the nutrient than advertised was sufficient to give notice of plaintiffs' claim. *Id.* at *3-4. Similarly, in *Smith v. Allmax Nutrition*, No. 15-cv-007454-SAB, 2015 WL 9434768, at *7 (E.D. Cal. Dec. 24, 2015), another mislabeling case, the court concluded that laboratory reports showing testing of just one sample were sufficient to support a plausible inference that the more comprehensive 12-sample test would support plaintiff's claims.

More recently, two judges of this court have reached similar conclusions. First, in Gubala v. CVS Pharmacy, Inc., No. 14 C 9039, 2016 WL 1019794 (N.D. III. Mar. 15, 2016), Judge Durkin considered allegations that defendant made false and misleading statements in the label of its protein power supplement-statements that suggested the product contained more whey protein than was actually present. Defendant argued that this claim was preempted, but the court recognized that a state-law claim survives so long as it enforces requirements identical to those imposed by the FDCA. Id. at *4. That meant, in defendant's view, that plaintiff was required to allege that he had tested the protein content of the product in the manner prescribed by FDCA regulations, using a "composite of 12 subsamples . . . 1 from each of 12 different randomly chosen cases, to be representative of a lot." Id. at *7 (quoting 21 C.F.R. § 101.9(g)(2)). The plaintiff in Gubala had not done so. Instead, he attached to his complaint the result of a single test on a single product sample. Id. In a comprehensive and thoughtful opinion, Judge Durkin acknowledged that other courts have concluded that compliance with the 12-sample test is a pleading requirement, but he noted that the apparent origin of that doctrine is a district court case, Vital v. One World Co., LLC, No. SACV 12-00314-CJC(MLGx), 2012 U.S. Dist. LEXIS 186203 (C.D. Cal. Nov. 30, 2012), that was decided not on a motion to dismiss, but on summary judgment, after an opportunity for discovery. At the 12(b)(6) stage, the complaint need only overcome two "easy-to-clear hurdles": describing the claim "in sufficient detail to give defendant fair notice," and "plausibly suggest[ing] that the plaintiff has a right to relief" Gubala, 2016 WL 1019794, at * 8 (citing Tamayo v. Blagojevich, 526 F.3d 1074,

1084 (7th Cir. 2008)). Gubala's complaint met that test, the court concluded. Plaintiff was not required to prove his case at the pleading stage, and the test results he attached to his complaint were sufficient to "nudge his claims . . . 'across the line from conceivable to plausible." *Id.* *8 (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Still more recently, the same plaintiff brought another mislabeling case against the seller of another protein supplement. Adhering to the same rationale, Judge Ellis of this court concluded that plaintiffs were not required to plead compliance with the 12-sample testing protocol and that their allegations, supported by the results of tests performed by a third party, were sufficient to "plausibly claim" that the label was false. *Gubala v. HBS Intern. Corp.*, No. 14 C 9299, 2016 WL 2344583, at *4 (N.D. III. May 4, 2016).

Neither of the *Gubala* decisions had been rendered at the time of the briefing in this case, but Plaintiff brought both to the court's attention by way of Notices of Supplemental Authority [29], [34]. Defendants did not respond at all to the second Notice, and their effort to distinguish *Gubala v. CVS*, at least on the matter of testing compliance, is unsuccessful. First, they urge that the testing regulation relevant to the nutrition supplements they manufacture is not 21 C.F.R. § 101.9(g)(2) but 21 C.F.R. § 101.35(f)(1). (Response to Plaintiff's Notice of Supplemental Authority [30] at 2.) But Defendants' opening memorandum referred to the two regulations as "very similar," and faulted Plaintiff for failing to allege that he has performed a test of a "composite of 12 consumer packages or 10 percent of the number of packages in the inspection lot, whichever is smaller." (Defs.' Mem. at 8, 9.) Second, Defendants emphasize that "a private plaintiff's proof of a violation of the regulations must be based on the 12-sample method." Like its colleagues, this court declines to decide what Plaintiff will need to prove in order to establish its claims,⁴ merely holding here that compliance with the 12-sample testing

⁴ See Gubala v. CVS, 2016 WL 1019794, at *9 ("whether § 101.9(g)92) is in fact a substantive requirement that Plaintiff would have to meet to establish liability on the part of CV is simply not clear to the Court at this point in time."); Gubala v. HBS, 2016 WL 2344583, *4 n.5 ("At this time the Court is not ruling on whether Plaintiffs are ultimately required to conduct testing compliant with § 101.9(g)(2) in order to prevail.") Compare Smith v. Allmax, 2015 WL

protocol is not a requirement at the pleading stage.

B. Allowance for Test Variability

Even if 12-sample testing is not a pleading requirement, Defendants urge that Plaintiff's claim is preempted because it does not acknowledge what Defendants refer to as the "80% rule" and Plaintiff calls the "safe harbor provision" of 21 C.F.R. § 101.9(g)(4)(ii). The regulations distinguish between "Class I nutrients," which are nutrients added to "fortified or fabricated" food products, and "Class II nutrients," which occur naturally as the result of differences in season, soil, weather, and "processing that a food undergoes." 21 C.F.R. § 101.9(g)(3)(i), (ii); 58 Fed. Reg. at 2161. For Class II nutrients, federal regulations require that the nutrient content of a labeled food product must be at least 80% of "the value for that nutrient declared on the label." § 101.9(g)(4)(ii).

It is undisputed that hypericin occurs naturally in the St. John's Wort plant. Plaintiff nevertheless insists the safe harbor does not apply here because the hypericin in Defendants' products is not a Class II nutrient. This is because the manufacturing process does not simply package the chemical composition of the plant in its natural state. Instead, Plaintiff asserts, in the manufacturing process, hypericin is extracted from the plant and then "pushed back into the finished products so Defendants can add a higher level of the extract than occurs naturally." (Pl.'s Resp. [24] at 12.) Hypericin is therefore properly categorized as a Class I nutrient, Plaintiff contends, thus subject to the requirement that the nutrient content "must be formulated to be at least equal to the value for that nutrient declared on the label." § 101.9(g)(4)(i).

Defendants' reply memorandum suggests, at most, that there may be a factual dispute about the manufacturing process. Defendants note that the complaint does not allege how St. John's Wort tablets are manufactured, meaning that there is no basis in the record for Plaintiff's claim that extra hypericin is added to those tablets. (Defs.' Reply at 10.) But Defendants do not

^{9434768,} at *8 n.1 ("The parties are advised that while the Court finds that pleading the 12sample methodology is not required to survive a motion to dismiss, any adjudication of the claims on the merits other than by the 120-sample methodology as set forth in section 101.9(g) would be preempted ty the FDA.")

deny Plaintiff's account of the manufacturing process, instead noting that the regulations themselves recognize that nutrients may be present in varying amounts as a result of "processing that a food undergoes." The court is uncertain what that phrase means, and there is apparently no case law addressing the question of whether a process that fortifies an herb supplement with additional amounts of the active ingredient removes it from Class II status.

Plaintiff's contention that this is indeed the manufacturing process is a plausible one. If Defendants are doing nothing more than converting the St. John's Wort plant to tablet form, it is not clear what is meant by the words "standardized extract." Rexall Sundown, Inc. v. Perrigom, 651 F. Supp. 2d 9, 14 (E.D.N.Y. 2009) arose in a completely different context, and involves an unrelated product, but as Plaintiff notes, in that case brought by Rexall Sundown (a Defendant in this case), the court used the word "standardized" in a way suggesting that standardization means increasing the amount of an ingredient that would naturally occur at lower levels. The court here presumes that "standardized" means that the amount of hypericin in the tablets is adjusted in some fashion as to make the active ingredient at least roughly equal across the production process.⁵ For purposes of this ruling, however, the court need not resolve the question of whether the 80% rule applies. Even if it does, the test results attached to Plaintiff's complaint show that Defendants' products did not even contain 80% of the nutrient levels shown on the product labels. The largest tested amount of hypericin-0.615 milligrams-is just 68% of the .9 milligrams called for by the label. And the court declines Defendants' invitation to water down the 80% standard still further to account for a further "error or variance rate," as there is no basis for determining what that "error rate" might be. (Defs.' Mem. at 10-11.) Defendants' motion to dismiss this complaint under the "safe harbor" regulations is denied.

⁵ As explained on the National Institute of Health website, "[s]tandardization is a process that manufacturers may use to ensure batch-to-batch consistency of their products," but "no legal or regulatory definition exists in the United States for standardization as it applies to dietary supplements." Nat'l Insts. of Health, Dietary Supplements, https://ods.od.nih.gov/factsheets/DietarySupplements-HealthProfessional/ (last visited September 21, 2016).

C. Pleading Fraud with Particularity

A consumer fraud claim is governed by the ordinary fraud pleading standards. See *Gallagher Corp. v. Mass. Mut. Life Ins. Co.*, 940 F. Supp. 176, 180 (N.D. III. 1996) (citing Illinois cases requiring that Consumer Fraud Act claims be pleaded with particularity). Specifically, plaintiffs must state "the identity of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated." *Schiffels v. Kemper Fin. Servs., Inc.*, 978 F.2d 344, 352 (7th Cir.1992) (quoting *Bankers Trust Co. v. Old Republic Ins. Co.*, 959 F.2d 677, 683 (7th Cir. 1992)). Defendants urge that much of this information is missing from the complaint, but for the most part, the court is less mystified. Plaintiff has identified the "who and what" of his claim by providing images of each of the manufacturers' products, each bearing labels prominently assuring the consumer of the products' hypericin content. The "when and where" questions are arguably answered, as well: the allegedly misleading statements were made at the point of sale of the product, when consumers purchased bottles of St. John's Wort in reliance on claims appearing on the labels.

That leaves the issue of "how" Plaintiff was misled—or even, in this case, whether he was misled at all. Defendants point out that the testing records Plaintiff has attached all include disclaimers, warning that the test results related solely to the individual tested sample. (Defs.' Mem. at 4.) Most significantly, Defendants point out, the tests were ordered in May and June 2015, well before Plaintiff made his purchase in July 2015. For what purpose was the test performed? If Plaintiff purchased his product in July 2015 with full knowledge of the test results, he was either very foolish or attempting to purchase a lawsuit. In either event, there would be no basis for the conclusion that Plaintiff was reasonably misled. For purposes of this motion, the court assumes Plaintiff Muir was unaware of the alleged inadequacy of the product at the time he purchased it. Should this prove untrue, it may be a basis for summary judgment.

IV. Failure to State an Unjust Enrichment Claim (Count III)

Defendants' challenge to Plaintiff's unjust enrichment claim is presented in a total of five

sentences—three in the opening memorandum and two in the reply—and a single case citation. (Defs.' Mem. at 13; Defs.' Reply at 14.) In the case Defendants rely on, *Cleary v. Philip Morris, Inc.*, 656 F.3d 511, 516 (7th Cir. 2011), the court addressed a question that has generated substantial litigation: whether unjust enrichment is an independent claim for relief that can "stand untethered from any underlying claim." Without answering that question definitively, the Seventh Circuit explained:

Unjust enrichment is a common-law theory of recovery or restitution that arises when the defendant is retaining a benefit to the plaintiff's detriment, and this retention is unjust. What makes the retention of the benefit unjust is often due to some improper conduct by the defendant. And usually this improper conduct will form the basis of another claim against the defendant in tort, contract, or statute. So, if an unjust enrichment claim rests on the same improper conduct alleged in another claim, then the unjust enrichment claim will be tied to this related claim and, of course, unjust enrichment will stand or fall with the related claim.

Id. at 517. *Cleary* was a consumer fraud claim alleging that defendant tobacco companies had conspired to conceal the truth about the dangers of cigarette smoking. The court noted as "crucial" the fact that plaintiffs did not allege that they had been harmed, that they had relied on defendants' marketing, or that they would have behaved differently had defendants told the truth. *Id.* at 518. This doomed their effort to allege unjust enrichment, the court concluded, whether or not it can stand alone as an independent cause of action. Plaintiffs here have alleged all of these things—harm, reliance on defendant's statements, and conduct in reliance on those statements.

This court is uncertain that *Cleary* establishes what Defendants say it does: that when an unjust enrichment claim rests on the same facts alleged in support of a consumer fraud action, dismissal of the consumer fraud claim dooms the unjust enrichment claim, as well. Again, however, the court need not answer the question. The court is not prepared to dismiss Plaintiffs' consumer fraud claims on the merits. There may be other bases for dismissal of the unjust enrichment claim, but Defendants have not raised them. The motion to dismiss Count III is denied.

V. Breach of Warranty (Count IV)

Plaintiff alleges that he (and the other consumers he seeks to represent) purchased a "standardized" St. John's Wort product; reviewed the label before dong so; and made the purchase in reliance on the claims made on the label. These allegations, Plaintiff urges, state a claim for breach of express warranty against all of the Defendant manufacturers and their corporate parent. Defendants object to Plaintiff's breach of warranty claim for two reasons—lack of privity and a failure to give pre-suit notice. Both of these objections appear to have merit.

First, Plaintiff himself has alleged a single purchase of St. John's Wort, from a Walgreens store in July 2015. He did not purchase the product directly from any of the Defendants, and for all but one, he did not purchase the product at all. Defendants could not have warranted the quality or chemistry of a product that Plaintiff never purchased or used. And had Plaintiff's complaint identified the particular product he himself purchased, his breach-ofwarranty claim against that manufacturer would fail for another reason: In order to recover under a claim for breach of express or implied warranty under Illinois law, a plaintiff must establish that she provided defendant with notice of the alleged breach "within a reasonable time after she discover[ed] or should have discovered [it]." See Connick v. Suzuki Motor Co., Ltd., 174 III. 2d 482, 494, 675 N.E.2d 584, 591-92 (III. 1996) (citing 810 ILCS 5/2-607(3)(a)); There are two exceptions to the notice requirement. Direct notice is not required when: (1) the defendant had "actual knowledge" of the product's defect, or (2) where the plaintiff suffered personal injury. Ibarrola v. Kind, LLC, 83 F. Supp. 3d 751, 760 (N.D. III. 2015) (citing Connick, 174 III. 2d at 494, 675 N.E.2d at 591). Neither exception to the notice requirement applies in this case. Plaintiff has not alleged any physical injury as a result of his purchase. He contends that the notice requirement is inapplicable here because the manufacturer knew of the defect at the time of the sale. (Compl. ¶¶ 13, 32-33.) Plaintiff cites three district court cases that appear to excuse the pre-suit notice requirement where the manufacturer is alleged to have had actual

knowledge of the design flaws or dangerous nature of a product line. *Stella v. LVMH Perfumes & Cosmetics USA, Inc.,* 564 F. Supp. 2d 833, 837 (N.D. III. 2008); *Mednick v. Precor, Inc.*, No. 14 C 4231, 2014 WL 6474915, at *6 (N.D. III. Nov. 13, 2014); *Hedges v. Earth, Inc.,* No. 14 C 9858, 2015 WL 1843029 (N.D. III. Apr. 21, 2015). Respectfully, this court notes language from the Illinois Supreme Court holding that this kind of generalized knowledge is not sufficient to excuse the pre-suit notice requirement. In *Connick, the Illinois Supreme Court* noted that even if a manufacturer "is aware of problems with a particular product line," a purchaser must provide pre-suit notice of a breach of warranty claim unless the manufacturer is "somehow apprised of the trouble with the particular product purchased by a particular buyer." 174 III. 2d at 494, 675 N.E.2d at 591-92.

Plaintiff has alleged that each of the Defendants was aware of the defective nature of the St. John's Wort product, but he offers no specific information that would support this conclusion. No allegations at all suggest any Defendant had knowledge of any specific problem with the bottle Plaintiff himself purchased. Plaintiff has not identified the manufacturer or that bottle, and has not alleged that the bottle he purchased was itself ever tested. His breach of warranty claim is dismissed.

VI. Injunctive Relief

In addition to damages, Plaintiff seeks injunctive relief funder the ICFA. (Compl. ¶ 54.) Defendants argue, however, that injunctive relief would be inappropriate here, citing *Camasta v. Jos. A. Bank Clothiers*, 761 F.3d 732, 741 (7th Cir. 2014): "Since [plaintiff] is now aware of [defendant's] sales practices, he is not likely to be harmed by the practices in the future. Without more than the speculative claim that he will again be harmed by [defendant], [plaintiff] is not entitled to injunctive relief." (Defs.' Mem. at 15.) This is essentially an argument that Plaintiff lacks standing to pursue injunctive relief. But Defendants overstate the holding of *Camasta*. For one thing,

the *Camasta* court merely repeated the well-accepted rule that the standing inquiry for the purpose of injunctive relief is probabilistic, i.e., is there "likelihood" that some harm will be suffered by the plaintiff in the future? Interpreting the *Camasta* court's dicta to instead announce a broad rule that strips a prospective plaintiff of standing to seek an injunction solely because they are aware of a past wrong overreads that court's language and leads to anomalous results. For example, just because someone is aware that the police have acted brutally in the past does not automatically deprive that person of standing to enjoin brutal police activity so long as they can show such brutality is likely to harm him/her in the future. *Cf. Schirmer v. Nagode*, 621 F.3d 581, 588 (7th Cir. 2010) (highlighting that, in such a case, official action conducted pursuant to a policy and/or procedure may be sufficient to establish Article III standing).

Le v. Kohls Dep't Stores, Inc., 160 F. Supp. 3d 1096, 1111 (E.D. Wis. 2016).

Just as importantly, the complaint in *Camasta* included a single allegation related to the likelihood the plaintiff would suffer future harm, namely, that "there is a substantial danger that [the defendant's] wrongful retail practices will continue." *Camasta v. Jos. A. Bank, Clothiers, Inc.*, No. 12-CV-7782, 2013 WL 474509, at *6 (N.D. III. Feb. 7, 2013). The complaint in this case, meanwhile, alleges that "Defendants continue to advertise, distribute, label, manufacture, market, and sell the Products in a false, misleading, unfair, and deceptive manner." (Compl. ¶ 6.) This is enough to establish, at this stage in the proceedings, that Plaintiff has standing to seek injunctive relief. *See, e.g., Le*, 160 F. Supp. 3d at 1111 (denying motion to dismiss a claim for injunctive relief on standing grounds where the complaint contained similar allegations).

CONCLUSION

For the reasons explained here, Defendants' motion to dismiss [20] is granted in part and denied in part. All claims against the corporate parent, NBTY, Inc., are dismissed. Plaintiff has standing to sue the single Defendant manufacturer from whom he purchased the product. His claims of consumer fraud and unjust enrichment against that single manufacturer survive this motion. His breach-of-warranty claim is dismissed. Leave is granted to file an amended complaint within 21 days. ENTER:

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REBECCA R. PALLMEYER United States District Judge

Dated: September 22, 2016