23-642
Jackson-Mau v. Walgreen Co.

IN THE

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2023
Argued: May 2, 2024
Decided: August 16, 2024

No. 23-642

THEDA JACKSON-MAU, on behalf of herself and others similarly situated,

Plaintiff-Appellant,

v.

WALGREEN CO. and INTERNATIONAL VITAMIN CORPORATION,

Defendants-Appellees.

Before: JACOBS, SACK and SULLIVAN, *Circuit Judges*.

A consumer of a glucosamine-based dietary supplement brought a putative class action lawsuit against the supplement's manufacturer (International Vitamin Corporation) and retailer (Walgreen Co.) under New York law. The complaint alleged that the supplement was mislabeled because it contained a different formulation of glucosamine than the one displayed on the

front of the label and disclosed as the main ingredient on the side. The United States District Court for the Eastern District of New York (Block, *J.*) granted summary judgment for the defendant companies on federal preemption grounds, and the consumer appealed. We hold that the consumer's state law mislabeling claims are expressly preempted by the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and we **AFFIRM** the judgment of the district court.

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JEAN-CLAUDE ANDRÉ, Bryan Cave Leighton Paisner LLP, Santa Monica, CA (Annie J. Avery, Mark K. Kanow, Elliot Averett, Bryan Cave Leighton Paisner LLP, Santa Monica, CA; A. Elizabeth Blackwell, Darci F. Madden, Stefani L. Wittenauer, Bryan Cave Leighton Paisner LLP, St. Louis, MO; Courtney J. Peterson, Bryan Cave Leighton Paisner LLP, New York, NY, *on the brief*), *for Defendants-Appellees* Walgreen Co. and International Vitamin Corporation.

DENNIS JACOBS, *Circuit Judge*:

Glucosamine is a natural chemical compound that is widely used as a dietary supplement to alleviate pain caused by osteoarthritis. Plaintiff-Appellant Theda Jackson-Mau is a former consumer of a glucosamine supplement manufactured by International Vitamin Corporation ("IVC") and sold by

Walgreen Co. ("Walgreens") (collectively, "Defendants"). In 2018, Jackson-Mau brought a putative class action lawsuit in the United States District Court for the Eastern District of New York (Block, *J.*), asserting three causes of action under New York law: deceptive business practices, in violation of N.Y. Gen. Bus. Law § 349,[1] breach of contract, and unjust enrichment. The complaint alleged that the dietary supplement that she purchased was mislabeled because it contained a different formulation of glucosamine than the one displayed on the front of the label and disclosed on the label's Supplement Facts panel. The district court granted summary judgment for Defendants on federal preemption grounds and dismissed Jackson-Mau's complaint.

The decisive question is whether Jackson-Mau's state law mislabeling claims are wholly preempted by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., which establishes national standards for the labeling of dietary supplements. We hold that Jackson-Mau's state law claims are preempted, and we **AFFIRM** the judgment of the district court.

[1] N.Y. Gen. Bus. Law § 349(a) "declare[s] unlawful" "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in" New York.

I.

According to Jackson-Mau, glucosamine is commonly sold as a dietary supplement in two chemical forms: "single-crystal" glucosamine and "blended" glucosamine. In the single-crystal form, glucosamine is bound to sulfuric acid to produce glucosamine sulfate; the glucosamine sulfate is then bound to another compound, potassium chloride, to produce a crystal (or "salt") of glucosamine sulfate potassium chloride. In the blended form, glucosamine is bound to hydrochloric acid to produce crystals of glucosamine hydrochloride, which are then physically mixed with crystals of another compound, potassium sulfate. Single-crystal glucosamine is one compound (glucosamine sulfate potassium chloride); blended glucosamine is a mixture of two chemically separate compounds (glucosamine hydrochloride and potassium sulfate). Despite the structural difference, however, both forms, when dissolved in water, dissociate into the same four chemical constituents--glucosamine, sulfate, potassium, and chloride.

Jackson-Mau purchased a bottle of Defendants' Finest Nutrition brand "Glucosamine Sulfate" (the "Product") in 2018. J.A. 19. Allegedly, Jackson-Mau chose the Product because she thought it contained glucosamine sulfate (i.e., single-crystal glucosamine), which she believed is more effective for alleviating

joint pain than glucosamine hydrochloride (i.e., blended glucosamine). J.A. 19-20. The front of the bottle displayed the name "Glucosamine Sulfate," and the Supplement Facts panel on the side of the bottle identified the Product's active dietary ingredient as "Glucosamine Sulfate Potassium Chloride." J.A. 242-47. Acting on the suspicion that the Product might be "fake," she gave some tablets to her lawyer, who sent them to a laboratory for testing by chemist Dr. Neil Spingarn. J.A. 1370. Dr. Spingarn's tests detected the presence of glucosamine hydrochloride and potassium sulfate, but not glucosamine sulfate potassium chloride. J.A. 332. From this, Dr. Spingarn concluded that the Product was mislabeled. J.A. 332.

On behalf of herself and putative classes of "[a]ll persons in the United States who purchased Finest Nutrition Glucosamine Sulfate" from Walgreens and "[a]ll persons in New York who purchased a dietary supplement labeled Glucosamine Sulfate" that was manufactured by IVC, J.A. 21, Jackson-Mau brought suit in federal court asserting state law causes of action for deceptive business practices, breach of contract, and unjust enrichment. The complaint alleged that the Product's label, which displayed the name "Glucosamine Sulfate" and identified the dietary ingredient as "Glucosamine Sulfate Potassium

Chloride," misled Jackson-Mau into believing that the Product contained single-crystal glucosamine when it in fact contained blended glucosamine.[2] J.A. 19. Jackson-Mau claimed that she was damaged because she paid for a product that she would not have purchased had its labeling truthfully disclosed that it contained blended glucosamine. J.A. 20. Jackson-Mau sought class certification, damages, and injunctive relief. J.A. 26.

Defendants moved for summary judgment on the ground that Jackson-Mau's state law mislabeling claims are wholly preempted by the FDCA.[3] The district court agreed and granted summary judgment on January 24, 2023. Jackson-Mau v. Walgreen Co., 652 F. Supp. 3d 349, 353 (E.D.N.Y. 2023). The

[2] During the pendency of Jackson-Mau's lawsuit, Defendants allegedly changed the name of the glucosamine supplement from "Glucosamine Sulfate" to "Glucosamine Sulfate Potassium Chloride." Pl.'s Br. 15 n. 15.

[3] Defendants first raised their preemption argument when they moved to dismiss under Fed. R. Civ. P. 12(b)(6). The district court denied the motion, ruling that Jackson-Mau had plausibly alleged sufficient independent testing results to support the inference that the Product did not contain the glucosamine formulation that was advertised on its labeling. Jackson-Mau v. Walgreen Co., No. 18-cv-4868, 2019 WL 5653757, at *1 (E.D.N.Y. Oct. 31, 2019). The district court also dismissed Jackson-Mau's unjust enrichment claim as duplicative of her other claims. Id. The request for injunctive relief was dismissed during discovery. Jackson-Mau v. Walgreen Co., No. 18-cv-4868, 2022 WL 2541091, at *1 (E.D.N.Y. July 7, 2022).

district court concluded that the FDCA, which comprehensively regulates dietary supplements and contains broad preemption clauses, foreclosed the state law mislabeling claims. Id. at 357-59. Judgment was entered on January 25, 2023, and reconsideration was denied on April 4, 2023. Jackson-Mau v. Walgreen Co., No. 18-cv-4868, 2023 WL 2771635, at *1 (E.D.N.Y. Apr. 4, 2023). Jackson-Mau timely appealed.

II.

We review de novo a grant of summary judgment, Murphy v. Hughson, 82 F.4th 177, 183 (2d Cir. 2023), and the "application of preemption principles," N.Y. SMSA Ltd. P'Ship v. Town of Clarkstown, 612 F.3d 97, 103 (2d Cir. 2010) (per curiam). We will affirm a grant of summary judgment "only if the evidence, when viewed in the light most favorable to the party against whom it was entered, demonstrates that there is no genuine issue as to any material fact and that judgment was warranted as a matter of law." Saleem v. Corp. Transp. Grp., Ltd., 854 F.3d 131, 138 (2d Cir. 2017).

Under the Supremacy Clause, U.S. Const., art. VI, cl. 2, "Congress has the power to preempt state law." Arizona v. United States, 567 U.S. 387, 399 (2012). "The question of whether federal law preempts state law is fundamentally a matter of Congress's intent." In re WTC Disaster Site, 414 F.3d 352, 371 (2d Cir.

2005). "Congress may manifest its intent to preempt state or local law explicitly, through the express language of a federal statute, or implicitly, through the scope, structure, and purpose of the federal law." N.Y. SMSA, 612 F.3d at 104 (citing Altria Grp., Inc. v. Good, 555 U.S. 70, 76-77 (2008)). In either case, because "the existence of preemption turns on Congress's intent, we are to begin as we do in any exercise of statutory construction," with "the provision in question." In re WTC Disaster Site, 414 F.3d at 371 (internal quotation marks and alteration omitted). We do so here with the FDCA, which establishes national standards for the labeling of dietary supplements. See 21 U.S.C. §§ 301 et seq.

Congress enacted the FDCA in 1938 to "prevent the adulteration, misbranding, and false advertising of food," H.R. Rep. No. 75-2139, at 1 (1938), and empowered the Food and Drug Administration ("FDA") to issue regulations enforcing the statute, see 21 U.S.C. § 393(b)(2)(A) (charging the FDA with "protect[ing] the public health" by ensuring that "foods are safe, wholesome, sanitary, and properly labeled"). The FDCA was amended by the Nutrition Labeling and Education Act of 1990 ("NLEA"), Pub. L. No. 101-535, 104 Stat. 2353, which set forth "national standards for the nutritional claims and the required nutrient information" displayed on food labels, H.R. Rep. No. 101-538,

at 12 (1990). The FDCA was again amended by the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417, § 2(15)(B), 108 Stat. 4325, 4236, to create "a rational Federal framework" for the regulation of dietary supplements. The DSHEA added a statutory definition for dietary supplements[4]--and deemed them "to be a food" under the FDCA. DSHEA § 3, 108 Stat. at 4327 (codified at 21 U.S.C. § 321(ff)). It also authorized the FDA to issue dietary supplement-specific labeling regulations, see DSHEA § 7(b), 108 Stat. at 4330 (codified at 21 U.S.C. § 343(q)(5)(F)), which the FDA has done, see, e.g., Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation, 62 Fed. Reg. 49826, 49826 (Sept. 23, 1997) (to be codified at 21 C.F.R. pt. 101) (establishing "requirements for the identification of dietary supplements and for their nutrition labeling and ingredient labeling in response to the [DSHEA]"). This

[4] A "dietary supplement" is a product that is "intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)." DSHEA § 3, 108 Stat. at 4327 (codified at 21 U.S.C. § 321(ff)).

case arises under the comprehensive labeling regime that was created by these acts of Congress and implemented by FDA regulations.

A.

The FDCA prohibits the "misbranding of any food," including dietary supplements, "in interstate commerce." 21 U.S.C. § 331(b). A dietary supplement is "deemed to be misbranded" if it fails to comply with the requirements enumerated in 21 U.S.C. § 343, including: if it is "offered for sale under the name of another" supplement, id. § 343(b); or if its label fails to bear certain "nutrition information," such as a list of dietary ingredients present in the supplement, in a manner specified in FDA regulations, id. § 343(q)(5)(F)(i).

A dietary supplement manufacturer must declare the names of the dietary ingredients that are present in the supplement in the Supplement Facts panel, the familiar black and white box usually found on the side of a product's label. See 21 C.F.R. § 101.36(b), (e).[5] Dietary ingredients for which the FDA has not established a Reference Daily Intake or Daily Reference Value must be declared

[5] "The declaration of nutrition information on the label and in labeling shall contain the following information, using the . . . format specified in paragraph (e) of this subsection." 21 C.F.R. § 101.36(b). Paragraph (e) provides that such "nutrition information shall be enclosed in a box" entitled "Supplements Facts" and presented in a specified format. Id. § 101.36(e)(1)-(3), (e)(11) (presenting "sample labels for the purpose of illustration").

by their "common or usual name[s]." Id. § 101.36(b)(3)(i).[6] The "common or usual name" of a dietary ingredient is determined by testing the ingredient with a validated method of identification. "Compliance with [§ 101.36] will be determined in accordance with § 101.9(g)(1) through (g)(8), (g)(10), and (g)(11)." Id. § 101.36(f)(1). Under section 101.9(g)(2),[7] the FDA analyzes supplements for compliance "by appropriate methods as given in the 'Official Methods of

[6] The FDA established Reference Daily Intakes and Daily Reference Values for dietary ingredients in 21 C.F.R. § 101.9(c). When the FDA gives an ingredient a Reference Daily Intake or Daily Reference Value, it specifies the name of that ingredient and requires the use of that name (and no other) in the Supplement Facts panel. See id. ("[N]utrient information shall be presented using the nutrient names specified."). The ingredients with predetermined names are "total calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, vitamin D, calcium, iron, and potassium." Id. § 101.36(b)(2)(i).

[7] In full, 21 C.F.R. § 101.9(g)(2) states:

> The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot. Unless a particular method of analysis is specified in paragraph (c) of this section, composites shall be analyzed by appropriate methods as given in the "Official Methods of Analysis of the AOAC International," or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures.

Analysis of the AOAC International,' or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures."[8]

"Other reliable and appropriate" methods of identification may be found in compendia, such as the official United States Pharmacopoeia ("USP"), 21 U.S.C. § 321(j), or the European Pharmacopoeia ("EP"), "the European counterpart to the USP," J.A. 331; Hollins v. Walmart Inc., 67 F.4th 1011, 1015 (9th Cir. 2023) ("The [EP] is a compendial standard recognized in the European Union and observed by the United States."). Some compendia like the EP also maintain certified reference materials--samples of dietary ingredients that satisfy the compendium's identity tests for those ingredients--which manufacturers can purchase to ensure the accuracy of their own identity testing. See U.S. Food & Drug Admin., Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products 6, 17, 20 (3d ed. 2019); U.S. Food & Drug Admin., Guidance for Industry: FDA Nutrition Labeling Manual -- A Guide for

[8] The AOAC "is a comprehensive collection of chemical and microbiological methods of analysis" which "have undergone rigorous scientific review and validation to determine the performance characteristics for the intended analytical application and fitness for purpose." Food Labeling: Revision of the Nutrition & Supplemental Facts Labels, 81 Fed. Reg. 33742, 33748-49 (May 27, 2016) (to be codified at 21 C.F.R. pt. 101).

Developing and Using Data Bases (1998), 1998 WL 34327548, at *16 (explaining that assessing the accuracy of a new test method "requires a material or a standard with a certified concentration of the analyte being measured").

Dietary supplement manufacturers are responsible for ensuring that the ingredients used in their products are properly identified on labels. See Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements, 68 Fed. Reg. 12158, 12169 (proposed Mar. 13, 2003) (to be codified at 21 C.F.R. pts. 111 and 112) ("Manufacturers should be responsible for identifying the ingredients that they use in their products and, in addition, for verifying that the dietary ingredients or dietary supplements they make contain the identity, purity, quality, strength, and composition that the manufacturer intends the product to have."). The FDA has instructed manufacturers that, in identifying and labeling dietary ingredients, they "are free to use whatever methodology they believe will give results consistent with methods used by [the] FDA." Food Labeling; General Requirements for Nutrition Labeling for Dietary Supplements of Vitamins, Minerals, Herbs, or Other Similar Nutritional Substances, 59 Fed. Reg. 354, 369 (Jan. 4, 1994) (to be codified 21 C.F.R. pt. 101). But as the FDA has observed: "To the extent that

another dietary ingredient is covered by an official compendium, [the] FDA would expect that the dietary ingredient's common or usual name to be drawn from that source." Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements, 60 Fed. Reg. 67194, 67201 (proposed Dec. 28, 1995) (to be codified at 21 C.F.R. pt. 101). And the FDA requires the use of compendial over non-compendial methods of identification for its own enforcement efforts. See U.S. Food & Drug Admin., Compliance Program Guidance Manual, Program 7321.008: Dietary Supplements--Foreign and Domestic Inspections, Sampling, and Imports 25 (2020) ("Use of methods contained in [the AOAC, USP, or National Formulary] must take precedence over use of other methods. If [such] methods are not available, then use of an appropriate validated method from the scientific literature or from in-house work is appropriate. Compendial methods must be considered before non-compendial methods are considered.").

B.

To preserve the uniformity of federal labeling standards, the FDCA has expansive express preemption clauses:

> [N]o State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce-- . . .

> (3) any requirement for the labeling of food of the type required by *section 343(b)* . . . of this title that is *not identical to* the requirement of such section, . . . [or]
>
> (4) any requirement for nutrition labeling of food that is *not identical to* the requirement of *section 343(q)* of this title . . . .

21 U.S.C. § 343-1(a)(3), (a)(4) (emphasis added). A state labeling requirement is "not identical to" a federal labeling requirement if "the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food" that "[a]re not imposed by or contained in," or that "[d]iffer from those specifically imposed by or contained in," the FDCA and its implementing regulations. 21 C.F.R. § 100.1(c)(4); see Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982) ("Federal regulations have no less pre[]emptive effect than federal statutes."). In other words, the FDCA preempts "*any* state law that provides for labeling requirements that are not *exactly the same* as those set forth in the FDCA and its regulations." Critcher v. L'Oreal USA, Inc., 959 F.3d 31, 35-36 (2d Cir. 2020).

Although the FDCA provides no private right of action, see 21 U.S.C. § 337(a); POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 109 (2014), plaintiffs may nevertheless bring misbranding claims under state law, but only "to enforce violations of *state laws* imposing requirements identical to those

contained in the FDCA," Kroessler v. CVS Health Corp., 977 F.3d 803, 808, 814 (9th Cir. 2020) (internal quotation marks and citation omitted). If a dietary supplement satisfies the section 343 labeling requirements that have preemptive effect, "consumers may not attack" the supplement's labeling under similar state law mislabeling theories. Ferrari v. Vitamin Shoppe Indus. LLC, 70 F.4th 64, 68 (1st Cir. 2023).

III.

Defendants are entitled to judgment as a matter of law if there is no genuine dispute that Jackson-Mau's claims are preempted--i.e., if they seek to impose labeling requirements that are "not identical to" those that are imposed by federal law and given express preemptive effect, such as sections 343(b) and 343(q). See 21 U.S.C. § 343-1(a)(3), (a)(4). To determine whether Jackson-Mau's state law claims are preempted by the FDCA, we consider the theories underlying her claims. See Critcher, 959 F.3d at 36. The complaint advances two theories of mislabeling: (1) the Product used the wrong name for its glucosamine-based dietary ingredient in the Supplement Facts panel; and (2) the Product used the wrong name for the supplement itself on the front of the label. We hold that Jackson-Mau's state law claims are expressly preempted under both theories.

A.

We begin with the Supplement Facts panel because whether the Product's dietary ingredient is properly identified bears on whether the Product is properly named on the front of its label. The dietary ingredient in the Product's Supplement Facts panel is "Glucosamine Sulfate Potassium Chloride." Defendants argue that Jackson-Mau's claims are preempted because the Product's dietary ingredient satisfies FDA-endorsed compendial identity tests for an ingredient of that name, and thus complies with the "common or usual name" requirement under section 343(q). Jackson-Mau contends that those compendial methods are inappropriate because they cannot distinguish between single-crystal and blended glucosamine, and that "glucosamine sulfate potassium chloride" is not the "common or usual name" for blended glucosamine according to the non-compendial methods of her own expert witness.

Jackson-Mau's mislabeling theory as to the Supplement Facts panel is expressly foreclosed by 21 U.S.C. § 343-1(a)(4), which preempts "*any* [state] requirement for nutrition labeling of food that is *not identical to* the [common or usual name] requirement of section 343(q)." Id. (emphasis added). Because the FDA has not established Reference Daily Intakes or Daily Reference Values for glucosamine-based dietary ingredients, see 21 C.F.R. § 101.9(c), the Product is

properly branded under section 343(q) if "Glucosamine Sulfate Potassium Chloride" is the "common or usual name," as determined by an AOAC method or, if none is available, by other "reliable and appropriate" methods, 21 U.S.C. § 343(q)(5)(F); 21 C.F.R. §§ 101.9(g)(2), 101.36(b)(3).

Here, there is no AOAC method for identifying a dietary ingredient called "glucosamine sulfate potassium chloride." The AOAC does provide a method--AOAC Official Method 2005.01--for determining the amount of glucosamine base in "finished products and dietary supplements containing glucosamine sulfate and/or glucosamine hydrochloride." J.A. 60-62. While that method can validate a label's accuracy as to the quantity of glucosamine sulfate in a supplement, it does not purport to define or detect the single-crystal formulation identified in the Product's Supplement Facts panel. But the absence of an applicable AOAC method is of no moment, since there is no genuine dispute that the Product's glucosamine-based dietary ingredient conforms to the specifications of "glucosamine sulfate potassium chloride" according to the "reliable and appropriate" methods provided in the United States Pharmacopoeia and European Pharmacopoeia. 21 C.F.R. § 101.1(g)(2). Jackson-Mau acknowledges that, ordinarily, the FDA allows dietary supplement manufacturers to rely on

methods in these compendia to identify ingredients on labels, and she does not dispute that each compendium contains definitions of and identity tests for a dietary ingredient called "glucosamine sulfate potassium chloride" (as set forth in the margin[9]). J.A. 1376.

Defendants have shown that the Product's glucosamine-based dietary ingredient passes those compendial identity tests. After Jackson-Mau filed her complaint, IVC and its suppliers tested the raw materials of the ingredient using the USP's methods of identification. Each set of tests showed that the raw materials conformed to the USP's specifications for "glucosamine sulfate potassium chloride." Jackson-Mau's own expert, Dr. Spingarn, found that the Product's ingredient matched the EP's certified reference standard for "glucosamine sulfate potassium chloride." Jackson-Mau does not dispute any of these results, nor could she. Dr. Spingarn testified in his deposition that the dietary ingredient "passed the USP monograph's identity test for glucosamine

[9] The USP defines "Glucosamine Sulfate Potassium Chloride" as "NLT 98.0% and NMT 102.0% of glucosamine sulfate potassium chloride [$(C_6H_{14}NO_5)_2SO_4 \cdot 2KCl$], calculated on the dried basis" and provides several tests to identify the ingredient by that definition. J.A. 177-78. The EP's identity tests mirror the USP's, and the EP sells a certified reference standard for "glucosamine sulfate potassium chloride" that satisfies those tests. J.A. 331-32.

sulfate potassium chloride." J.A. 121-22. Indeed, he conceded that both single-crystal glucosamine (i.e., what Jackson-Mau thought she bought) and blended glucosamine (i.e., what Jackson-Mau actually bought) "will pass" the USP's and EP's identity tests for "glucosamine sulfate potassium chloride."[10] J.A. 122, 331-33.

According to Jackson-Mau, the USP and EP methods of identification are inappropriate in this case because neither distinguishes between blended and single-crystal glucosamine. She insists that the Product "exploits" a "blind spot" in these compendial methods in order to "defraud the consumer," the blind spot being an "inability to identify" or "distinguish between different forms of glucosamine." Pl.'s Br. 35-39; J.A. 1376-86. However, that argument does not preserve her state law mislabeling claims. The FDA gives manufacturers the ability to choose among methods that "they believe will give results consistent with methods used by [the] FDA." 59 Fed. Reg. at 369. The FDA prefers compendial over non-compendial methods for determining the accuracy of

[10] Dr. Spingarn contacted the scientist responsible for developing the USP identity tests for glucosamine sulfate potassium chloride "[t]o clarify how USP could promulgate a method incapable of distinguishing between" blended and single-crystal glucosamine. J.A. 331. The scientist simply confirmed that the USP tests do not differentiate.

ingredient labeling. See 60 Fed. Reg. at 67201; Compliance Program Guidance Manual at 24. And manufacturers are not required to use one method of identification over another. See 68 Fed. Reg. at 12169 (stating that "no single approach or test method may be appropriate for every dietary ingredient").

Defendants have shown that "glucosamine sulfate potassium chloride" is the "common or usual name" for the Product's dietary ingredient according to the methods in two compendia, one of which is explicitly endorsed in the FDCA and FDA guidance. See 21 U.S.C. § 321(j) (defining "official compendium" to include the USP); Compliance Program Guidance Manual at 24 (referencing the USP). Jackson-Mau's state law claims as to the Supplement Facts panel would thus impose under state law a labeling requirement for blended and single-crystal glucosamine that is "not identical to" the "common or usual name" requirement imposed by 21 U.S.C. § 343(q) and implemented by 21 C.F.R. §§ 101.36(b)(3), 101.9(g)(2). "This is exactly what the FDCA does not permit." Critcher, 959 F.3d at 36; cf. Turek v. Gen. Mills, Inc., 662 F.3d 423, 427 (7th Cir. 2011) (explaining that even when additional disclaimers on packaging would be "a good thing" for consumers, they are barred if they are not identical to those imposed by federal law). Jackson-Mau's claims as to the name of the dietary

ingredient in the Supplement Facts panel are therefore expressly preempted by the FDCA. 21 U.S.C. § 343-1(a)(4).

The Ninth Circuit is the other Court of Appeals to have addressed this FDCA preemption issue.[11] In Hollins v. Walmart Inc.--a case involving the same two glucosamine formulations at issue here, the same compendial test methods, and the same expert witness (Dr. Spingarn)--the Ninth Circuit came to the same conclusion: the claim that the defendant's glucosamine supplement was mislabeled "due to being a blend" would allow a state to impose a different labeling requirement on the supplement than what is imposed under federal law. 67 F.4th at 1019. The Ninth Circuit emphasized that Dr. Spingarn's non-compendial testing had not been endorsed by the FDA for use in determining a label's compliance with the "common or usual name" requirement, and that his tests confirmed that the supplement met the EP's certified reference standard for "glucosamine sulfate potassium chloride." Id. at 1018-19. The Ninth Circuit also

[11] Other lawsuits under various state consumer laws have been resolved in favor of the defendants at the district court level. See, e.g., Parker v. Wal-Mart Stores, Inc., 367 F. Supp. 3d 979, 984 (E.D. Mo. 2019) (dismissing the complaint for failure to state a claim on preemption grounds); Amavizca v. Nutra Mfg., LLC, No. 20-cv-01324, 2021 WL 4945242, at *4 (C.D. Cal. June 15, 2021) (decertifying the plaintiff's two classes on grounds unrelated to preemption).

rejected the plaintiff's assertion that the compendial methods were inappropriate because that assertion "is irrelevant for purposes of determining what federal law requires." Id. at 1019.

This result is consistent with this Court's holding in an analogous FDCA preemption case. In Critcher, consumers brought mislabeling claims under state consumer protection statutes, alleging that the labels of various cosmetics products omitted the information that skin creams could not be fully dispensed from their containers. 959 F.3d at 36. The issue was whether those state law claims were foreclosed by the FDCA's express preemption provision for cosmetics products under 21 U.S.C. § 379s(a).[12] Id. at 34. We held that the FDCA foreclosed the state law claims because, to avoid liability under the consumers' mislabeling theory, the defendant would have to make packaging disclosures "in

[12] That express preemption provision provides:

> [N]o State or political subdivision of a State may establish or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under this chapter, the Poison Prevention (15 U.S.C. [§] 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. [§] 1451 et seq.).

21 U.S.C. § 379s(a).

addition to" the requirements already imposed by the FDCA and its regulations. Id. at 36-37. Jackson-Mau's claims as to the Supplement Facts panel are foreclosed for the same reason.

B.

Jackson-Mau's second mislabeling theory is that the wrong name is displayed on the front of the label. In Jackson-Mau's view, a supplement containing blended glucosamine cannot be offered for sale under the name "glucosamine sulfate" or "glucosamine sulfate potassium chloride" because it contains neither of those compounds. Jackson-Mau argues that the Product is mislabeled on the front even if its dietary ingredient satisfies the "common or usual name" requirement because the testing regime underlying that requirement applies only to the Supplement Facts panel. Whether the Product's name is misleading, she contends, is therefore a "question[] of fact" that should be resolved without looking to identity tests. See Pl.'s Br. 20. We disagree.

Jackson-Mau's mislabeling theory as to the Product's name on the front of the label is foreclosed by 21 U.S.C. § 343-1(a)(3), which expressly preempts "*any* [state] requirement for the labeling of food *of the type* required by *section 343(b)* . . . that is *not identical to* the requirement of [section 343(b)]." Id. (emphasis added). A dietary supplement is misbranded under section 343(b) if it

is sold under the name of another supplement. See 21 U.S.C. § 343(b). The FDA has not issued regulations to implement this requirement, but it has spoken by example: a food is sold under the name of another food if it is advertised as red snapper but contains rockfish, "an economically inferior species," Proposal To Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products, 59 Fed. Reg. 4142, 4176 (proposed Jan. 28, 1994) (to be codified at 21 C.F.R. pts. 123 and 1240); or if it is labeled as "frozen cherry pie" but contains no cherries, Frozen Cherry Pie; Revocation of a Standard of Identity and a Standard of Quality, 89 Fed. Reg. 18784, 18788 (proposed Mar. 15, 2024) (to be codified at 21 C.F.R. pt. 152); or if it is corn syrup masquerading as maple syrup, see Seizure, 94-50 FDA Enf. Rep. 13, 1994 WL 697738 (Dec. 14, 1994).

The Product here was not offered for sale under the name of a different dietary supplement. The Product was offered for sale under the name "Glucosamine Sulfate." We concluded supra that "glucosamine sulfate potassium chloride" is an acceptable "common or usual name" for the Product's dietary ingredient in the Supplement Facts panel under section 343(q) and its regulations. We decline to say that a name constitutes misbranding on the front of the label when the same name is not misbranding on the side. "Logically,

using the 'common or usual' name of a product to identify the product on the label does not constitute offering that product for sale 'under the name of another food,' in violation of § 343(b)." Hollins, 67 F.4th at 1020 (rejecting the same mislabeling argument).

While the district court held that Jackson-Mau's state law claims as to the Product's name are *impliedly* preempted by the FDCA's structure, see Jackson-Mau, 652 F. Supp. 3d at 359 ("Allowing state law claims that seek to mandate the use of an ingredient name not included on the [S]upplement [F]acts panel would violate [section] 343(s)(2)(B)."), we reach the same result on the ground that those claims are preempted *expressly* by the statute's plain text. Jackson-Mau's mislabeling theory would require Defendants to name their supplement "glucosamine hydrochloride and potassium sulfate." See Pl.'s Br. 22 n. 17. But because Congress included the sweeping preemption clause at 21 U.S.C. § 343-1(a)(3) governing the name under which a supplement may be offered for sale, state law cannot be used to impose a "different" or "additional" naming requirement. Jackson-Mau's state law claims as to the Product's name on the front of the label are therefore preempted by the FDCA. Id.

IV.

State requirements for the labeling of dietary supplements are preempted by the FDCA to the extent that they are "not identical to" those that are imposed by federal law and given express preemptive effect. See 21 U.S.C. § 343-1(a). Jackson-Mau's state law mislabeling claims would permit a state to impose requirements for the name of a dietary supplement on the front of the label and the name of a dietary ingredient in the Supplement Facts panel that are "not identical to" the requirements imposed by sections 343(b) and 343(q) and FDA regulations. See 21 U.S.C. § 343-1(a)(3), (a)(4). Accordingly, Jackson-Mau's claims are preempted, and Defendants are entitled to judgment as a matter of law. The judgment of the district court is **AFFIRMED**.