23-642-cv

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

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

Plaintiff-Appellant,

v.

WALGREEN CO. and INTERNATIONAL VITAMIN CORP.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK
No. 18-CV-4868 (Block, J.)

FINAL OPENING BRIEF OF PLAINTIFF-APPELLANT

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JURISDICTIONAL STATEMENT

This is an appeal taken pursuant to Fed. R. App. P. 3 from final orders and judgment of the United States District Court for the Eastern District of New York ("District Court") entered January 24, 2023 (SA-13-34)[1] (154); January 25, 2023 (SA-35) (155); and April 4, 2023 (SA-36-40) (161).

The District Court had subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1332(d)(2) and 1367 because the Plaintiff/Appellant is diverse from at least one of the Defendants/Appellees and the amount in controversy exceeds $5 million. A-16 (62 ¶ 11). This Court has jurisdiction over this appeal pursuant to 28 U.S.C. § 1291 because the appeal is from final Orders of the District Court: on January 24, 2023, the District Court (Block, J.) issued an order denying partial summary judgment to Plaintiff and granting summary judgment to Defendants (SA-13-34) (154, the "Op."); on January 25, 2023, the District Court entered judgment in favor of Defendants (SA-35) (155); and on April 4, 2023, the District Court denied reconsideration of its summary judgment order (SA-36-40) (161). Plaintiff's appeal is timely pursuant to Fed. R. App. P. 4(a)(1)(A) because the Notice of Appeal was

[1] Citations to the deferred joint appendix are abbreviated "A-__." Citations to the special appendix, containing the District Court's opinions and important statutory text, are abbreviated "SA-__." Unless otherwise indicated, all emphasis is added and all citations are omitted.

filed on April 17, 2023, within 30 days of the District Court's denial of Plaintiff's timely motion for reconsideration.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

1. Did the District Court err when it held that Plaintiff's mislabeling claims regarding Defendants' "Glucosamine Sulfate" dietary supplement are preempted under the federal Food, Drug, and Cosmetic Act ("FDCA"), even though Plaintiff's claims are consistent with the FDCA's requirements?

2. Did the District Court err in granting summary judgment on the merits of Plaintiff's N.Y. G.B.L. § 349 claim?

STATEMENT OF THE CASE

I. NATURE OF CLAIMS

Plaintiff-Appellant Theda Jackson-Mau ("Plaintiff"), on behalf of herself and a putative class of similarly situated consumers, alleges that Defendants-Appellees International Vitamin Corp. ("IVC") and Walgreen Co. ("Walgreens") (collectively "Defendants") are respectively producing and selling mislabeled dietary supplements. While the products at issue are called "Glucosamine Sulfate" or "Glucosamine Sulfate Potassium Chloride" (collectively the "Product"), they do not, in fact, contain either of these versions of the chemical glucosamine sulfate. Instead, the Product contains a blend of two different chemicals—glucosamine

hydrochloride and potassium sulfate—neither of which is mentioned on the Product's label.

This mislabeling is material to a reasonable consumer. Only glucosamine sulfate is endorsed for the treatment of osteoarthritis by publicly available medical literature; glucosamine hydrochloride is not. Additionally, potassium sulfate, the chemical mixed with glucosamine hydrochloride in Defendants' Product, is most commonly used as a plant fertilizer and is not found in any dietary supplements. Thus, consumers think they are buying an effective form of glucosamine, but are instead receiving an inferior form of glucosamine mixed with fertilizer. This is consumer fraud.

Plaintiff alleges that Defendants' mislabeling violates N.Y. G.B.L. § 349, which prohibits deceptive consumer-oriented conduct, and constitutes a breach of contract between putative class members and the Product's retailer (Walgreens). *See generally* A-14-27 (62) (operative Amended Complaint). Plaintiff seeks an injunction prohibiting Defendants' mislabeling, as well as actual and/or statutory damages, on behalf of herself and the putative class. *See id.*

The District Court dismissed Plaintiff's claims primarily because it found they were preempted by the FDCA. As explained herein, this holding was erroneous because the FDCA simply does not allow dietary supplements to be sold under the

wrong name. Thus, Plaintiff's claim that the Product is mislabeled is fully consistent with the requirements of federal law.

II. BACKGROUND

A. FDCA Regulation of Dietary Supplements

Dietary supplements are considered "food" under the FDCA. 21 U.S.C. § 321(ff). The agency responsible for enforcing the FDCA—the Food and Drug Administration ("FDA")—"does not have the authority to approve dietary supplements before they are marketed," does not "routinely analyze the content of dietary supplements," and "does not test dietary supplements before they are sold to consumers."[2] It is the FDCA's "stated purpose of promoting public policy by retaining parallel avenues for private and public enforcement actions against false or misleading statements" on dietary supplements. *Kroessler v. CVS Health Corp.*, 977 F.3d 803, 814 (9th Cir. 2020).

B. Forms of Glucosamine

The central issue in the case concerns determining whether Defendants misled consumers in violation of N.Y. G.B.L § 349, and whether Walgreens breached a contract with consumers, by representing that the Product was the version of glucosamine that was fit to treat joint pain, when in fact it was not. The District

[2] https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements (last accessed September 1, 2023) [https://perma.cc/FS8J-HSDU].

Court correctly summarized the evidence on the different forms of glucosamine as follows:

> Glucosamine is a chemical compound marketed to alleviate symptoms of osteoarthritis, namely joint pain. To stabilize glucosamine for sale in dietary supplements, it can be bound to hydrochloric acid to form glucosamine hydrochloride or sulfuric acid to form glucosamine sulfate. Glucosamine sulfate can be further crystalized with potassium chloride to form glucosamine sulfate potassium chloride as a single crystal ("single-crystal glucosamine"). On the other hand, glucosamine hydrochloride crystals can also be blended with potassium sulfate crystals (the "glucosamine blend"). The glucosamine blend is a blend of two crystalized chemical compounds that are chemically separate and are not bound in a single crystal, unlike single-crystal glucosamine, in which the same four ions are joined in one crystal. Single-crystal glucosamine and the glucosamine blend contain the same four chemical ions in the same ratios.

SA-16 (Op._4). Thus, there is a chemical difference between single-crystal glucosamine sulfate and the glucosamine hydrochloride/potassium sulfate blend. *See id.* Importantly, the blend (which was found in Defendants' Product) is ***not*** glucosamine sulfate.[3]

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[3] More precisely, glucosamine sulfate potassium chloride is defined as a "complex" with all its constituent elements bound together in a single crystal, as represented by the chemical formula $(C_6H_{14}NO_5)_2SO_4 \cdot 2KCl$. By contrast, glucosamine hydrochloride blended with potassium sulfate (as testing demonstrates is what is contained in the Product) is a physical mixture of two separate materials represented by the chemical formula $(C_6H_{14}NO_5)Cl + K_2SO_4$. This glucosamine blend ***can*** have the same ions in the same ratio as single-crystal glucosamine sulfate, but ***only*** if it is intentionally blended in a 2:1 ratio of glucosamine hydrochloride to potassium sulfate. Even so, the blend will not ***be*** glucosamine sulfate because it will not feature glucosamine chemically bound to sulfate in a single crystal. *See* A-176-78 (137-28_1); A-325 (141-1_¶ 2.1.6); A-518 (141-2_ ¶ 1.2); A-853 (141-14_48:9-25); A-569-72 (141-3_21:9-24:25); A-579 (141-4_34:7-21); A-633-34 (141-5_14:5-

The difference between these various chemicals is a material issue to consumers.[4] This is so for two reasons. ***First***, the difference between the forms of glucosamine is relevant to consumers. Both the National Library of Medicine and the Mayo Clinic distinguish between glucosamine hydrochloride and glucosamine sulfate in their webpages about glucosamine. For example, the National Library of Medicine's MedlinePLUS webpage states that "Glucosamine supplements are sold as glucosamine sulfate, glucosamine hydrochloride, and N-acetyl glucosamine."[5] The Mayo Clinic publishes similar information, stating that "[t]here are several forms of glucosamine, including glucosamine sulfate, glucosamine hydrochloride and N-acetyl glucosamine. ***These supplements aren't considered interchangeable.***"[6] As the MedlinePLUS page also says, "[t]aking glucosamine

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15:20); A-734-35, A-738-39 (141-8_23:5-24:7, 54:6-55:8); A-756, A-763-64 (141-9_6, 13-14); A-254 (139-17_99:2-4); A-31 (104_4 n.6 (citing https://pubchem.ncbi.nlm.nih.gov/compound/Glucosamine-sulfate-potassium-chloride (last accessed January 28, 2022)); A-324-327 (141-1_¶¶ 2-3); A-756, A-763-64 (141-9_6, 13-14); A-744-45 (141-8_60:7-61:18); A-252-55 (139-17_97:1-100:7); A-955, A-960 (141-16_1, 6); A-521 (141-2_ ¶ 1.7); A-330 (141-1_¶ 6.2).

[4] Plaintiff moved for judicial notice of sources demonstrating the material difference between glucosamine hydrochloride and glucosamine sulfate (A-28-35) (104), which the Court denied as moot in light of its preemption order (*see* SA-13-34) (154). The following citations are to sources included in that motion.

[5] A-29-30 (104_2-3) (citing https://medlineplus.gov/druginfo/natural/807.html (last accessed January 28, 2022)).

[6] A-32-33 (104_5-6 (citing https://www.mayoclinic.org/drugs-supplements-glucosamine/art-20362874 (last accessed July 7, 2022)).

sulfate by mouth for at least 4 weeks can provide some pain relief and improve function for people with knee osteoarthritis," and that "[p]roducts that contain glucosamine hydrochloride do not seem to work as well unless they are taken in combination with other ingredients."[7] This information is confirmed by a meta-analysis conducted by Dr. Olivier Bruyère at the University of Liège in Belgium, which concluded that glucosamine sulfate had demonstrated clinical efficacy, while glucosamine hydrochloride had not. *See* A-1039-41 (141-23_1-3). Dr. Bruyère's work is cited multiple times on the MedlinePLUS page.[8] The Mayo Clinic also says that "glucosamine sulfate might be worth a try," but does not say the same about glucosamine hydrochloride.[9] And both the MedlinePLUS page and WebMD see fit to advise consumers that "some glucosamine products aren't labeled correctly" because "[s]ome products have contained glucosamine hydrochloride when glucosamine sulfate was listed on the label," further supporting that there is a material difference between the two substances.[10] In short, consumers have good

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[7] A-29-30 (104_2-3) (citing https://medlineplus.gov/druginfo/natural/807.html (last accessed July 7, 2022)).

[8] A-29-30 (104_2-3 (citing https://medlineplus.gov/druginfo/natural/807.html (references in footnotes 7, 29, 121, 144, 159)).

[9] A-32-33 (104_5-6 (citing https://www.mayoclinic.org/drugs-supplements-glucosamine/art-20362874 (last accessed July 7, 2022)).

[10] A-29-30 (104_2-3 (citing https://medlineplus.gov/druginfo/natural/807.html (last accessed July 7, 2022)); A-33 (104_6 (citing https://www.webmd.com/vitamins/ai/ingredientmono-807/glucosamine (last accessed July 7, 2022)).

reason to think that glucosamine sulfate is effective, while glucosamine hydrochloride is not.

Second, the presence of undisclosed potassium sulfate is also material to a reasonable consumer. Potassium sulfate is primarily used as fertilizer and it is also commonly used as a laxative for colonoscopy preparation.[11] Indeed, Webster's dictionary defines "potassium sulfate" as "white crystalline compound K_2SO_4 used especially as a fertilizer."[12] There is no dispute that potassium sulfate cannot be found on the label of any dietary supplements. A-270 (139-18_¶ 14).

C. Plaintiff's Purchase of Defendants' "Glucosamine Sulfate" Product

Plaintiff is a consumer who, like many other consumers, sought to buy a glucosamine sulfate dietary supplement to help with aches and pains in her joints. *See* A-1295-1302 (141-24_11:23-18:10). She purchased a bottle of Finest Nutrition Glucosamine Sulfate at Walgreens. *See id.* The label looked like this:

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[11] A-30 (104_3 (citing https://medlineplus.gov/druginfo/meds/a619013.html (last accessed January 28, 2022)); A-32-33 (104_5-6 (citing https://www.mayoclinic.org/drugs-supplements/sodium-sulfate-potassium-sulfate-and-magnesium-sulfate-oral-route/description/drg-20405981 (last accessed January 28, 2022)).

[12] A-34 (104_7 (citing https://www.merriam-webster.com/dictionary/potassium%20sulfate (last accessed January 28, 2022)).

See ECF 141-21 (Ex. U, label image, sealed); A-241-47 (139-12) (images of bottle purchased by Plaintiff). Upon learning that the product she bought may have been a "fake," she sent pills from the bottle she purchased to be analyzed by a laboratory, which found that it did not contain glucosamine sulfate, but instead contained glucosamine hydrochloride mixed with potassium sulfate. *See* A-1295-1302 (141-24_11:23-18:10); *see also* A-327 (141-1_¶ 4).

Plaintiff brought this case on behalf of herself and a proposed class of purchasers of the Finest Nutrition Glucosamine Sulfate dietary supplement. A-14-27 (62). Through the litigation, Plaintiff learned that this Product was made by IVC and sold by Walgreens under Walgreens' private-label Finest Nutrition brand. *See* ECF 141-21 (Ex. U, label image, sealed); A-259-61 (139-18_¶ 8).

D. Testing of Defendants' Product

Plaintiff subjected Defendants' Product to three laboratory tests: Fourier Transform Infrared Spectroscopy ("FTIR"), X-Ray Diffraction ("XRD"), and

Scanning Electron Microscopy with Energy-Dispersive X-Ray Analysis ("SEM-EDX"), all of which were performed at the direction of Dr. Neil Spingarn of S&N Labs in Santa Ana, California. *See generally* A-321-515 (141-1). The testing methodologies and results were independently reviewed by Dr. Glen Jackson, professor of chemistry at West Virginia University, who agreed that the testing validly identified the Product as glucosamine hydrochloride mixed with potassium sulfate, and excluded the possibility that the Product was any version of glucosamine sulfate. *See generally* A-516-63 (141-2). Defendants' ***own expert***, Dr. Derek Beauchamp of Avomeen Analytical Services in Ann Arbor, Michigan, also tested the Product using XRD and agreed that the data matched database references for glucosamine hydrochloride and potassium sulfate. A-582-83, A-606-10, A-625-26 (141-4_44:18-45:6, 68:16-72:13, 87:21-88:3).

Faced with these test results, Defendants produced unauthenticated and unspecific third-party testing records that had purportedly been performed on the Product. Defendants relied on the argument that their Product was not mislabeled because it ***would*** pass the identity test for glucosamine sulfate potassium chloride in the United States Pharmacopeia ("USP"). USP is a nonprofit organization that "develops and publishes standards for drug substances, drug products, excipients,

and dietary supplements in the United States Pharmacopeia–National Formulary (USP–NF)."[13]

USP does not provide controlling standards for dietary supplements, as its own website states: "The existence of a monograph for a dietary supplement does not provide independent evidence that a particular product may be lawfully marketed in the United States under the FD&C Act and its implementing regulations. It is the ultimate responsibility of dietary supplement manufacturers and distributors to ensure that their products are legally marketed in the United States." *Id.* Furthermore, a "dietary supplement must be represented as conforming to a USP–NF dietary supplement monograph in order for the compendial standards to apply," and Defendants' product does not make this representation. *Id.*; ECF 141-21 (Ex. U, label image, sealed).

Plaintiffs' experts, Dr. Spingarn and Professor Jackson, explained that the Product could pass the USP test applicable to glucosamine sulfate potassium chloride, but only because that particular USP test has a blind spot whereby a blend of the wrong chemicals in a specific ratio (2:1 glucosamine hydrochloride to potassium sulfate) will result in a false positive for glucosamine sulfate potassium chloride. A-521 (141-2_¶ 1.7); A-330 (141-1_¶ 6.2). Defendants' expert, Dr.

[13] https://www.usp.org/about/legal-recognition/standard-categories (last accessed August 31, 2023) [https://perma.cc/E5ML-Q7HW].

Alexander Klibanov, agreed in prior litigation that the USP test had this deficiency and that it could be exploited by a manufacturer seeking to "defraud the consumer." A-744-45 (141-8_60:7-61:18); A-252-55 (139-17_97:1-100:7).[14]

Similarly, Defendants asserted that the Product was not mislabeled because it matched the reference material for glucosamine sulfate potassium chloride supplied by the European Pharmacopoeia ("EP"). EP is a compendium of drug information used within the European Union that, similar to USP, also does not provide controlling standards for dietary supplements in the United States (as explained further below). The EP reference material for glucosamine sulfate potassium chloride is a bottle of powder, provided by the private company MilliporeSigma, that is meant to pass the EP's test for that material. *See* A-856-57 (141-14_51:20-52:12); A-582-83 (141-4_44:4-45:21); A-961-1013 (141-17). Plaintiff submitted evidence, including from the EP itself, showing that the EP reference material for glucosamine sulfate potassium chloride is not a valid standard of identity (*i.e.*, that it is not meant to be an exemplar of what the substance is). A-840-41 (141-12) (EP Origin of Goods); A-842-44 (141-13) (EP Leaflet); A-521 (141-2_ ¶ 1.8); A-331 (141-1_¶ 6.3).

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[14] However, Drs. Spingarn, Jackson, Beauchamp, and Klibanov all agreed that USP ***defines*** glucosamine sulfate potassium chloride as a ***single crystal*** and not a blend of multiple substances. *Supra* n.3. The record therefore shows that the Product contained the glucosamine blend, which is different from single-crystal glucosamine as claimed on the Product's label and as defined by USP.

E. The District Court's Orders

After the close of discovery, Plaintiff moved for partial summary judgment on the basis that Defendants had no admissible testing evidence showing that their Product was accurately labeled, and that Plaintiff was therefore entitled to, at least, statutory damages on her N.Y. G.B.L. claim. *See* ECF 139. Defendants also moved for summary judgment on the basis that Plaintiff's claims were federally preempted by provisions of the FDCA. *See* ECF 135. The District Court denied Plaintiff's motion for partial summary judgment on liability and statutory damages, granted Defendants' motion for summary judgment, and thereafter denied Plaintiff's motion for reconsideration. SA-13-34, SA-36-40 (154, 161).

First, the District Court held that Defendants had prevailed, as a matter of law, on their affirmative defense of FDCA preemption. Specifically, the District Court—ignoring Plaintiff's testing evidence—found that Plaintiff's claim was preempted because the contents of the Defendants' products "passed the USP's chemical identity test" and "matched the EP certified reference standard." SA-23-24 (Op._11-12). The District Court reached this conclusion by ignoring the record and wrongly concluding that FDA grants legal deference to USP and EP (which it does not). The District Court noted that "these preemption issues are novel in the Second Circuit." SA-31 (*Id.* at 19).

Second, the District Court also held, alternatively, that Plaintiff's N.Y. G.B.L. § 349 claim failed for lack of injury because Plaintiff purportedly lacked evidence that there was no demand for glucosamine hydrochloride. SA-31-34 (Op._19-22). The District Court reached this conclusion even though it was undisputed that there is no product on the market that is labeled as containing glucosamine hydrochloride mixed with potassium sulfate.

Plaintiff moved for reconsideration of the District Court's summary judgment order; the District Court denied that motion. SA-36-40 (161). This appeal followed.

F. Courts Have Struggled with this Preemption Issue in Related Litigation

Federal courts in New York and California have grappled with the issue of preemption on this specific substance with varying results. For example, the District Court here initially found that Plaintiff's claims were not preempted on a motion to dismiss standard. *See* ECF 27 at 2-4. Two other courts in the Central District of California also found that preemption did not apply on a motion to dismiss when considering similar glucosamine sulfate-labeled products manufactured by IVC or its subsidiaries. *See Diamos v. Walmart Inc.*, 2:19-cv-05526-SVW-GJS, 2020 U.S. Dist. LEXIS 73972, at *4-8 (C.D. Cal. Jan. 9, 2020); *Amavizca v. Nutra Mfg., LLC*, 8:20-cv-01324-RGK-MAA, 2020 U.S. Dist. LEXIS 251947, at *12-15 (C.D. Cal. Oct. 20, 2020).

The two California courts also found that preemption did not apply at later stages. *See Diamos v. Walmart Inc.*, 2:19-cv-05526-SVW, 2021 U.S. Dist. LEXIS 34613, at *13 (C.D. Cal. Jan. 19, 2021) (no preemption on summary judgment); *Amavizca v. Nutra Mfg.*, LLC, 8:20-cv-01324-RGK-MAA, 2021 U.S. Dist. LEXIS 36009, at *7-14 (C.D. Cal. Jan. 27, 2021) (no preemption at class certification). However, on a second summary judgment motion, the Court in the *Walmart* case found that the claims were preempted by the FDCA. *Hollins v. Walmart Inc.*, 2:19-cv-05526-SVW, 2021 U.S. Dist. LEXIS 162030 (C.D. Cal., Aug. 17, 2021). On appeal, the Ninth Circuit found—in a divided panel with a well-reasoned dissent—that preemption did apply. *Hollins v. Walmart Inc.*, 67 F.4th 1011 (9th Cir. 2023).

Notwithstanding these competing decisions, it should be clear that the FDCA seeks to protect consumers from fraudulent misrepresentations on food labels. The Second Circuit now has the opportunity to establish clear guidelines on this "novel" preemption issue to deter consumer fraud.

SUMMARY OF THE ARGUMENT

Defendants' Product was called "Glucosamine Sulfate" and later renamed "Glucosamine Sulfate Potassium Chloride,"[15] but it actually contains a blend of

[15] Defendants changed the name of the Product from "Glucosamine Sulfate" to "Glucosamine Sulfate Potassium Chloride" after this litigation was filed; the substances inside remained the same (*i.e.* glucosamine hydrochloride mixed with potassium sulfate). A-241-47 (139-12) (images of bottle purchased by Plaintiff); A-264 (139-18_¶ 8) (Defendants admitting that this was the bottle purchased by

glucosamine hydrochloride and potassium sulfate. Indeed, Defendants' product is, in fact, chemically mislabeled—a point that Defendants could not dispute. Such mislabeling is not permissible under state or federal law. Therefore, Plaintiffs' claims are not preempted.

Plaintiff's argument on appeal can be summarized as follows: ***First***, Plaintiff's claims are not preempted because her claims are consistent with the FDCA's prohibition against calling a dietary supplement by the wrong name. ***Second***, to the extent FDA testing regulations do apply, Plaintiff's testing of the Product did in fact comply with those regulations. ***Third***, Plaintiff's tests show that the Product was materially mislabeled because instead of glucosamine sulfate, it contains glucosamine hydrochloride blended with fertilizer—a combination of chemicals that is not sold as a dietary supplement.

First, the FDCA prohibits calling a dietary supplement by the wrong name, and there are no regulations that limit or qualify this fundamental rule. FDA testing regulations apply only to "nutrition labeling," *i.e.* the Supplement Facts panel on the back of a dietary supplement label. *See Hollins v. Walmart Inc.*, 67 F.4th 1011, 1022 (9th Cir. 2023) (Wardlaw, J., dissenting); *Durnford v. MusclePharm Corp.*, 907 F.3d

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Plaintiff); A-1014-23 (141-18) (IVC interrogatory responses referring initially to the product as "Finest Nutrition-brand Glucosamine Sulfate 1000mg" (Interrogatory No. 8) and in a supplemental response calling it "Finest Nutrition Glucosamine Sulfate Potassium Chloride" (Interrogatory No. 2), reflecting the intra-litigation label change).

595, 597 (9th Cir. 2018). Therefore, because the Product was ***named*** "Glucosamine Sulfate" or "Glucosamine Sulfate Potassium Chloride," instead of merely stating those ingredients in the Supplement Facts panel on the back, FDA testing regulations do not apply to the front of the label. Accordingly, the issue of what the Product contains and whether its name is misleading should have simply been treated as questions of fact. *See Hollins*, 67 F.4th at 1022; *Amavizca v. Nutra Mfg., LLC*, No. 8:20-cv-01324-RGK-MAA, 2021 U.S. Dist. LEXIS 36009, at *12-13 (C.D. Cal. Jan. 27, 2021).

Second, even if FDA regulations do apply, which they do not, those regulations say that a "common or usual name" is established by "common usage," and that identity testing can be performed by any method that is "reliable and appropriate." 21 C.F.R. §§ 102.5, 101.9(g). Unlike other substances, there are no FDA regulations requiring any specific test to identify glucosamine products; nor does the FDA defer to USP or EP testing methods or reference standards. Instead of contesting Plaintiff's science or testing results, Defendants cherry-picked FDA guidance and convinced the District Court that single-crystal glucosamine sulfate and the glucosamine hydrochloride/potassium sulfate blend are legally interchangeable due to the blind spot in the USP test method. But for purposes of both chemistry and consumer perception, the record is clear that they are not interchangeable. The difference matters, and the Product is mislabeled.

Third, the District Court erred in holding as a matter of law that "there is consumer demand for glucosamine hydrochloride based on the fact that it is offered for sale." SA-33-34 (Op._21-22). This holding conflates the blend at issue with ***un-blended*** (*i.e.* pure) glucosamine hydrochloride. Here, the blend in Defendants' Product contains glucosamine hydrochloride ***mixed with potassium sulfate***. Defendants did not dispute that potassium sulfate is not found in dietary supplements, either blended with glucosamine hydrochloride or otherwise. *See* A-270-71 (139-18_¶ 16). Thus, there is no demonstrable consumer demand for such a supplement. The record therefore contained evidence that Plaintiff was injured because she paid for one thing, but received something that is so undesirable that it is not even offered for sale.

ARGUMENT

I. PLAINTIFF'S CLAIMS ARE NOT PREEMPTED

A. Standard of Review

The Second Circuit reviews a district court's application of preemption principles *de novo*. *New York SMSA Ltd. P'ship v. Town of Clarkstown*, 612 F.3d 97, 103 (2d Cir. 2010) (per curiam).

B. Statutory and Regulatory Framework

Dietary supplements are considered "food" for purposes of the FDCA. 21 U.S.C. § 321(ff). The FDCA provides a list of circumstances in which food is considered "misbranded." 21 U.S.C. § 343. The list is disjunctive, meaning a

violation of any of the items renders the food misbranded. *See id.* For example, as applicable here, food is misbranded if it "is offered for sale under the name of another food" (*id.* § 343(b)); if the label does not "bear[] the common or usual name of the food, if any there be" (*id.* § 343(i)); ***or*** if the food "is a dietary supplement and the label or labeling of the supplement fails to list the name of each ingredient of the supplement" (*id.* § 343(s) (formatting omitted)). Separately, 21 U.S.C. § 343(q) contains requirements for "nutrition labeling," which are implemented in the case of dietary supplements by 21 C.F.R. §§ 101.36 & 101.9(g). The District Court acknowledged that, "[i]mportantly, § 343(q) applies exclusively to the 'supplement facts' panel located on the side of supplement labels." SA-22 (Op._10).

The FDCA contains an express preemption provision, added by the Nutrition Labeling and Education Act ("NLEA") in 1990, that bars "any requirement for nutrition labeling of food that is not identical to the requirement of" certain sections thereof. 21 U.S.C. §§ 343-1(a)(3)-(4); *Parks v. Ainsworth Pet Nutrition, LLC*, 377 F. Supp. 3d 241, 245 (S.D.N.Y. 2019)). FDCA preemption is construed narrowly due to "the FDCA's stated purpose of promoting public policy by retaining parallel avenues for private and public enforcement actions against false or misleading statements." *Kroessler v. CVS Health Corp.*, 977 F.3d 803, 814 (9th Cir. 2020) "[P]laintiffs may avoid the statute's preemptive force . . . if the plaintiffs' claims seek to impose requirements that are identical to those imposed by the FDCA." *Niles*

v. Arizona Beverages USA LLC, CV 19-1902 (GRB) (ARL), 2021 U.S. Dist. LEXIS 135064, at *21 (E.D.N.Y. July 19, 2021) (quotation omitted)). Such is the case here.

C. The FDCA Prohibits Calling a Dietary Supplement by the Wrong Name

Plaintiff's claims do not merely challenge a misstated ingredient in the Product's Supplement Facts panel; they challenge the very name of the Product on its front label. As explained above, under the FDCA "a food shall be deemed to be misbranded if it is offered for sale under the name of another food." 21 U.S.C. § 343(b). There are no FDA regulations applicable to this provision that would constrain Plaintiff's claims here or modify Plaintiff's burden of proof. Accordingly, the issue of what Defendants' Product contains and whether its label is misleading should have been treated as questions of fact.

"Challenges to the label under 21 U.S.C. § 343(b) are distinct from those to the nutrition facts panel (the 'nutrition panel') under 21 U.S.C. § 343(q), such that the 21 C.F.R. § 101.9(g) federal testing requirements do not apply to the label outside of the nutrition panel, and, therefore, these claims are not preempted by federal law." *Hollins v. Walmart Inc.*, 67 F.4th 1011, 1022 (9th Cir. 2023) (Wardlaw, J., dissenting).[16] More specifically,

[16] The Ninth Circuit's decision in *Hollins v. Walmart* affirmed dismissal based on the same preemption argument. The panel majority in *Hollins* got it wrong, and this Court should follow the dissent. The majority's legal analysis of the FDCA statute was wrong as explained herein.

> [the] allegation that the "Supplement Facts" panels on Defendants' products contain misrepresentations implicates 21 U.S.C. § 343(q) and 21 C.F.R. § 101.36, which govern the nutrition labeling of dietary supplements. Plaintiff's allegation that Defendants' Products have the words "Glucosamine Sulfate" displayed prominently on the label, however, implicates 21 U.S.C. § 343(b), under which a food is deemed misbranded "[i]f it is offered for sale under the name of another food." 21 U.S.C. § 343(b) . . . . [T]he requirements of 21 C.F.R. §§ 101.36 and 101.9(g) govern "the nutrition labeling of dietary supplements," and "FDA regulations define 'nutrition labeling' as synonymous with 'Supplement Facts' panels." *Id.* Accordingly, . . . claims that are not premised on the "'nutrition labeling' or 'Supplement Facts' panels do not implicate the testing method set forth in 21 C.F.R. § 101.9(g)(2).

Id. at 1025 (quoting *Amavizca v. Nutra Mfg., LLC*, No. 20-01324, 2021 U.S. Dist. LEXIS 36009, at *10-12 (C.D. Cal. Jan. 27, 2021)).

Consequently:

> To prevail on h[er] claims, Plaintiff would be required to prove that Defendants' Products were "offered for sale under the name of another food." *See* 21 U.S.C. § 343(b). To do so will necessarily require Plaintiff to establish that, despite bearing the name "Glucosamine Sulfate," Defendants' Products do not contain the chemical compound glucosamine sulfate. However, because Plaintiff's claims are not based on the representations about the dietary ingredients listed on the nutrition labeling of the Products, Plaintiff need not prove h[er] case in accordance with the 12-subsample testing method set forth in 21 C.F.R. § 101.9(g)(2). That section and 21 C.F.R. § 101.36 govern the "nutrition labeling of dietary supplements," not the name or trademark under which a defendant chooses to sell its product.

Amavizca, 2021 U.S. Dist. LEXIS 36009, at *13. Accordingly, because Plaintiff's claims challenge the very identity of the Product, the FDCA does not preempt those claims, because the FDCA identically prohibits calling a dietary supplement by the wrong name. 21 U.S.C. § 343(b). Consequently, there is no preemption.

The District Court found that 21 U.S.C. § 343(s)(2)(B) required a different conclusion due to principles of conflict preemption because that section, applicable specifically to dietary supplements, purportedly allows the use of the name of an "ingredient" from the Supplement Facts, which can be determined by the FDA testing regulations, on the front label. SA-26-28 (Op._14-16). But this conclusion was wrong because unlike 21 U.S.C. § 343(***q***), the provision at § 343(***s***) does not deal with what is allowed to be said in the Supplement Facts panel and, even if it did, it does not override 21 U.S.C. § 343(b) (*i.e.*, products cannot be offered for sale under the name of another food). To the contrary, the FDA has said that "section 403(s)(2)(B) of the act [*i.e.*, 21 U.S.C. § 343(s)(2)(B)] . . . must be read in conjunction with the other provisions of the act that address how food products are to be identified," and that dietary supplements must be identified on their "principal display panel" using their "common or usual name," as determined by "common usage." 60 Fed. Reg. at 67195; 21 C.F.R. 102.5(d).[17]

[17] Moreover, compliance with both laws is not "impossible" even if conflict preemption applies; as the Ninth Circuit has noted, even a "***requirement*** to state certain facts in the nutrition label is not a license to make that statement elsewhere on the product." *Reid v. Johnson & Johnson*, 780 F.3d 952, 960 (9th Cir. 2015). The District Court attempted to distinguish *Reid* as involving a different regulatory provision, but the principle is the same: it is not "impossible" for Defendants to comply with state and federal law unless they "stop selling" their Product (SA-27-28 (Op. at 15-16)). Defendants may permissibly continue to sell the product, if it is called glucosamine hydrochloride and potassium sulfate, consistent with the FDCA's directives that products be named accurately.

Plaintiff's claims are not preempted because her claims are consistent with the FDCA's prohibition against calling a product by the wrong chemical name. The District Court's decision should be reversed for this reason alone.

D. USP and EP Test Methods Do Not Provide a Safe Harbor for Defendants' Mislabeling

Assuming Plaintiff was required to comply with FDA testing regulations, she did so, both with respect to how to determine the common or usual name of a supplement, as well as what identity testing method should be used. The core of the District Court's opinion granting summary judgment is that "glucosamine's inclusion in compendial sources blessed by the FDCA and its regulations," *i.e.* USP and EP, "controls how it can be identified on the Product's 'supplement facts' label," and therefore also on its front label. SA-26 (Op._14). The District Court misread the FDA regulations in coming to this conclusion. In fact, FDA does not "bless" or otherwise defer to USP or EP. Instead, the FDA requires the use of "reliable and appropriate" test methods and "common usage" to determine the common or usual name of a substance.[18] *See* 21 C.F.R. §§ 101.9(g) & 102.5.

[18] As mentioned above, the District Court should have considered Plaintiff's request for judicial notice, which introduced various authoritative sources showing common usage differentiating between glucosamine sulfate and glucosamine hydrochloride. A-28-35 (104).

1. The FDA Does not Defer to USP or EP for the Common or Usual Name of a Substance

The District Court's sole basis for deferring to the USP and EP comes from one passage in agency commentary. *See* SA-23 (Op._11) (citing 60 Fed. Reg. 67194-01 at 67201, 1995 WL 760960 (Dec. 28, 1995) ("To the extent that another dietary ingredient is covered by an official compendium, FDA would expect that the dietary ingredient's common or usual name to be drawn from that source.")). The District Court failed to read all of this commentary, which explains that "common usage" takes precedence.

The section quoted by the District Court comes later in the commentary and refers to labeling of "other dietary ingredients" within the Supplement Facts panel. 60 Fed. Reg. 67194, 67201. However, earlier in this guidance, there is a much more extensive discussion of the "statement of identity" of dietary supplements pursuant to 21 U.S.C. § 343(s)(2)(B) (the operative statutory provision according to the District Court). *Id.* at 67195. This statutory provision, according to the commentary, "states that a food shall be deemed to be misbranded if it is a dietary supplement, and the label or labeling of the dietary supplement fails to identify the product by using the term 'dietary supplement,' which term may be modified with the name of such an ingredient." *Id.* The FDA observed:

> It is a general rule of statutory construction that the act must be read as a whole. Thus, section 403(s)(2)(B) of the act, which states that the term must "identify the product," must be read in conjunction with the other

> provisions of the act that address how food products are to be identified. These provisions, which have been in effect for many years, are section 403(g)(2) and (i)(1) of the act. Section 403(g)(2) of the act, which pertains to a food for which a definition and standard of identity have been prescribed by regulation, provides that the food label must bear the name of the food specified in the definition and standard. ***Section 403(i)(1) of the act, which pertains to all other foods, provides that the food label must bear the common or usual name of the food***, if any exists. Dietary supplements are labeled subject to the provisions of section 403(i)(1) of the act.

Id.

The commentary goes on to say:

> FDA has implemented section 403(g)(2) and (i)(1) of the act by adopting § 101.3 (21 CFR 101.3) on the identity of food in packaged form. This regulation states that the principal display panel of a food shall bear as one of its principal features a statement of the identity of the commodity (§ 101.3(a)). The regulation goes on in § 101.3(b) to state that the statement of identity shall be in terms of: (1) The name specified in or required by any applicable Federal law or regulation; or, in the absence thereof, (2) ***the common or usual name of the food***; or, in the absence thereof, (3) an appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

60 Fed. Reg. at 67195 .

The commentary further observes:

> This proposed requirement [that dietary supplements use the term 'dietary supplement' modified by the name of the ingredient] is further supported by § 102.5 of FDA's regulations. This regulation sets out general principles for arriving at the common or usual name of a nonstandardized product, that is, a product that is not subject to a definition adopted under section 401 of the act (21 U.S.C. 341). Section 102.5(a) states in part:
>
> 'The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as

> possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.'

Id. (citing 21 C.F.R. § 102.5). That regulation further elaborates that "[a] common or usual name of a food may be established by common usage or by establishment of a regulation in Subpart B of this part, in Part 104 of this chapter, in a standard of identity, or in other regulations in this chapter." 21 C.F.R. § 102.5(d).

Thus, because "the act must be read as a whole," the FDA's equivocal statement that it "***would expect*** that the dietary ingredient's common or usual name . . . be drawn from [a compendial] source" does not create an outright safe harbor where the ingredient passes the compendial test. Again, the FDA regulations contain no definitions or standards of identity with respect to glucosamine products. *See* 60 Fed. Reg. at 67195. Therefore, the common or usual name of such products must conform to "common usage" per 21 C.F.R. §§ 101.3 and 102.5. *See id.* USP cannot be read or applied in a way that contradicts common usage.

Accordingly, the commentary's instruction that the FDA would expect "the dietary ingredient's common or usual name to be drawn from [a compendial] source" does not override the chemical definition or declare the compendial test method to be infallible. As discussed *infra* at Section I(D)(4)(b), the ***test*** provided by the USP

is not specific enough to distinguish between real single-crystal glucosamine sulfate and the blend of glucosamine hydrochloride and potassium sulfate. However, the ***chemical formula*** provided in the USP for glucosamine sulfate potassium chloride clearly shows that it is exclusively intended to be the single-crystal formulation. Defendants' own expert, Dr. Beauchamp, confirmed this as well. *See infra* Section I(D)(4)(b). As a result, Defendants' blend of two distinct substances is not even "drawn from th[e] source" of the USP because it does not meet the USP's chemical definition provided for glucosamine sulfate potassium chloride.

This analysis, requiring a product's name to conform to commonly understood definitions, comports with how district courts in the Second Circuit have treated similar claims. *See Rodriguez v. Target Corp.*, 22 Civ. 2982 (LGS), 2022 U.S. Dist. LEXIS 233767, at *14 (S.D.N.Y. Dec. 30, 2022) (no preemption where plaintiffs "allege that using the name 'fish oil' for [a fatty acid ethyl esters] product is misleading in part because it is ***inconsistent with 'common usage,'*** . . . and 'fails to distinguish it from different foods'—*i.e.*, 'natural' fish oil" (formatting omitted)); *Warren v. Stop & Shop Supermarket, LLC*, 592 F. Supp. 3d 268, 280-83 (S.D.N.Y. 2022) (sustaining claim that "Graham Crackers" product was mislabeled because it was comprised primarily of enriched flour rather than whole grain flour; noting that "reasonable consumers understand that a 'graham cracker,' ***as its dictionary definitions confirm***, is 'a slightly sweet cracker made of whole wheat flour' or 'a

semisweet cracker, usually rectangular in shape, made chiefly of whole-wheat flour'").

2. The FDA Does not Defer to USP or EP Test Methods

Relatedly, the FDA also does not defer to USP or EP when it comes to the proper method of identity testing, and instead requires test methods that are "reliable and appropriate" regardless of whether they are compendial. 21 C.F.R. § 101.36(f); *id.* § 101.9(g). The testing regulation states that supplements "shall be analyzed by appropriate methods as given in the 'Official Methods of Analysis of the AOAC International,'[19] or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures."[20] The FDA has explained that "§ 101.9(g)(2) of these final rules allows for the use of other reliable and appropriate analytical procedures if no AOAC method is available or appropriate," and that

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[19] The Association of Official Analytical Chemists ("AOAC") "is a major international organization with the purpose of collecting analytical methods for use primarily in food and agricultural products." A-330 (141-1_¶ 6.1).

[20] The District Court did not reach the issue of whether the AOAC International methods contained an "appropriate" method to identify the form of glucosamine present in a sample. As discussed below, the record was unequivocal that the AOAC does not put forth such a test, because its test merely measures the amount of glucosamine in a sample and cannot determine whether it is glucosamine sulfate, glucosamine hydrochloride (or, by extension, a complex versus a blend). *Infra* Section I(D)(4)(a). Notably, the same logic applies to the USP identity tests: they are not appropriate because they are unable to tell the difference between effective glucosamine sulfate and ineffective glucosamine hydrochloride mixed with fertilizer.

"[t]he method of analysis used must be suitable to achieve the purpose for which it is used." 58 Fed. Reg. 2079, 2110 (Jan. 6, 1993). This regulation "expressly allows for someone ensuring compliance—here, Plaintiff—to use an alternative method if no AOAC method is 'appropriate.' No language limits the use of alternative methods, or the determination of whether a method is 'appropriate,' to the FDA." *Diamos v. Walmart Inc.*, No. 2:19-cv-05526-SVW, 2021 U.S. Dist. LEXIS 34613, at *12 (C.D. Cal. Jan. 19, 2021)

It bears repeating that USP itself acknowledges that "[t]he existence of a monograph for a dietary supplement does not provide independent evidence that a particular product may be lawfully marketed in the United States under the FD&C Act and its implementing regulations."[21] This is because the FDA has explicitly rejected deference to compendial test methods. *See generally* 72 Fed. Reg. 34752 (Jun. 25, 2007). The FDA observed that "[s]ome comments state we should acknowledge methods from the . . . European Pharmacopoeia . . . as scientifically valid analytical methods. One comment notes the USP establishes scientifically valid procedures in its compendia and encouraged us to designate compendial procedures as 'scientifically valid' by defining 'scientifically valid' to include compendial procedures." *Id.* at 34805. The FDA declined, noting that "we did not

[21] https://www.usp.org/about/legal-recognition/standard-categories (last accessed August 25, 2023) [https://perma.cc/E5ML-Q7HW].

list specific compendia that would be suitable sources or scientifically valid analytical tests," and that "[t]he compendia identified in the comments, *i.e.*, [among others] USP, may include some methods that are based on scientific data or results . . . but also contain some methods that are not based on such data or results." *Id.*

Therefore, the FDA concluded that "whether or not a method is scientifically valid is not determined solely by its inclusion in a compendium. Rather, it is the responsibility of quality control personnel to approve the use of those scientifically valid tests that will ensure a product's identity, purity, strength, and composition whether or not such tests are contained in a particular compendium." *Id.* The FDA "decline[d] th[e] request" to "incorporate by reference authoritative sources of compendial methods" or to "designate USP to develop appropriate standards." *Id.* at 34893-94. Thus, the fact that the ineffective blend passes the USP test does not magically turn it into the effective single-crystal glucosamine sulfate.

The District Court cited other language from this guidance saying that "section 403(s)(2)(D) of the act . . . acknowledges the role of compendia, by considering a dietary supplement misbranded if the supplement is covered by the specifications of an official compendium, is represented as conforming to the specifications of an official compendium, and fails to so conform." 72 Fed. Reg. at 34,805. This statement was a ***comment made to the FDA*** arguing that USP tests

should be considered valid, not the FDA's stated position. *See id.* The FDA responded to the comment by disagreeing with it and saying (as cited above) that "USP[] may include some methods that are based on scientific data or results . . . but also contain some methods that are not based on such data or results." *Id.* Furthermore, as the FDA also notes, "section 403(s)(2)(D) of the act" "applies to ***representations*** about a particular ingredient and not the entire supplement." 60 Fed. Reg. at 67205. USP itself says that "[t]he dietary supplement must be ***represented*** as conforming to a USP–NF dietary supplement monograph in order for the compendial standards to apply. This contrasts with pharmaceutical products, wherein conformance to the monograph is mandatory whether or not the product claims to conform."[22] Here, the Product was not ***represented*** as conforming to USP on its label; rather, its conformity to USP was raised in litigation only. Thus, FDCA section 403(s)(2)(D) is inapposite.

Furthermore, the Product does not, in fact, conform to the "specifications" of USP because it is not single-crystal glucosamine, which is how USP defines the substance (as explained further *infra* at Section I(D)(4)(b)). Ultimately, as a consumer protection statute, the FDCA is concerned foremost with scientific validity and common usage of terms, not technicalities in proprietary compendial tests or

[22] https://www.usp.org/about/legal-recognition/standard-categories (last accessed August 25, 2023).

definitions—and the FDA has instructed that the FDCA must be read "as a whole." *See* 60 Fed. Reg. at 67195; 72 Fed. Reg. at 34805.

3. The FDA Does not Defer to USP or EP Reference Materials

Finally, the FDA also does not defer to compendial reference materials. FDA regulations "allow for the use of both compendia reference standards and noncompendia reference standards," and the FDA "s[aw] no reason to require the use of compendia standards in all circumstances." 72 Fed. Reg. 34752, 34893 (June 25, 2007). Thus, matching the EP reference material also does not preempt Plaintiff's claims.

4. Compendial Methods and Reference Materials Are Inappropriate Here

Although there is no legal deference given to USP and EP (as shown above), nor to AOAC testing if it is not appropriate, the question remains whether their test methods would, as a matter of fact, be scientifically useful to determine the identity of the Product here. Plaintiff showed that they would not be.

a. The AOAC Method Does not Determine the Form of Glucosamine

The AOAC method for glucosamine products is "[a]pplicable to the analysis of ***glucosamine*** in raw materials and dietary supplements containing glucosamine sulfate and/or glucosamine hydrochloride." A-59-62 (137-4). As Plaintiff's experts explained—and as Defendants' experts agreed—the AOAC method cannot

determine ***whether*** a supplement is glucosamine sulfate or glucosamine hydrochloride.

Professor Jackson explained that "[t]he stated purpose of the AOAC method is to quantify the amount of glucosamine free base in a finished product." A-521 (141-2_¶ 1.7). Therefore, it "does not attempt to identify the solid-state form of glucosamine" and is not "fit for the purpose of discriminating between glucosamine hydrochloride and glucosamine sulfate." *Id.* Similarly, Dr. Spingarn explained that the AOAC "does not establish any criteria for identification of glucosamine sulfate potassium chloride," but "provides calculations that allow conversion from glucosamine content to other forms of glucosamine," but only on "the assumption and requirement that all of the glucosamine in the product already be known to be in that exact form." A-330 (141-1_¶ 6.1). This is because "[t]he testing method utilizes HPLC [High Performance Liquid Chromatography], which measures only the amount of glucosamine and cannot measure or account for sulfate, potassium or chloride. As such, it is incapable of distinguishing between" different forms of glucosamine. *Id.*

Defendants' experts did not disagree. In prior litigation, Mr. Sullivan, an administrator at Eurofins Scientific, testified that "using that [AOAC] test standing alone, no, it would not distinguish between the two forms." A-637-640 (141-5_23:25-26:3). In a different prior litigation, Sullivan said in a declaration that the

AOAC method "does not include a test to distinguish which form of glucosamine is present." A-654 (141-6_9). At a hearing in that same litigation, he agreed that "the [AOAC] testing itself does not distinguish between the two forms" and that "in order to distinguish between those forms, you would have to perform additional tests." A-819 (141-11_81:2-7). And in this case, Sullivan testified that the "distinction" between the forms "is not part of the definition of the AOAC method." A-679 (141-7_47:14-25). Likewise, Dr. Klibanov in prior litigation stated in a declaration that "salt dissociation does not allow one to distinguish between glucosamine sulfate sodium chloride and glucosamine hydrochloride + sodium sulfate . . . by standard chromatographic methods, such as HPLC . . . or titration, standing alone." A-1355 (141-27_¶ 28). And in another prior litigation, Dr. Klibanov stated that the AOAC method "does not allow one to distinguish between glucosamine sulfate potassium chloride (*i.e.*, a mixed salt) and glucosamine hydrochloride + potassium sulfate (*i.e.*, a physical mixture)." A-763-64 (141-9_13-14).[23]

[23] Defendants also admitted that the AOAC method was not appropriate by arguing before the District Court that "[w]hether to convert the amount of glucosamine free base to glucosamine hydrochloride or glucosamine sulfate is determined by which raw material has been shown by compendial testing to be included in the finished product." ECF 138 at 8 (Def. SJ brief). This is an admission that the AOAC method cannot answer the question.

The AOAC method is therefore not "appropriate" because it is not "suitable to achieve the purpose for which it is used," *i.e.*, determining whether a supplement is glucosamine sulfate or glucosamine hydrochloride. 58 Fed. Reg. 2079 at 2110.

b. The USP Test Method Contains a Blind Spot that Would Allow a Manufacturer to "Defraud the Consumer"

Defendants' Product was manufactured using a 2:1 blend of glucosamine hydrochloride and potassium sulfate. ECF 141-22 (Ex. V, flowcharts, sealed); A-519 (141-2_¶ 1.3) ("the manufacturing process requires the dissolution of the reagents in a ratio of two moles of Glucosamine.HCl to one mole of K_2SO_4"). The USP test method for single-crystal glucosamine will register a false positive when faced with this specific blend. This critical limitation of the test was acknowledged by all of the expert testimony before the District Court and by USP itself.

Importantly, USP ***defines*** glucosamine sulfate potassium chloride consistent with how Plaintiff's experts define it. The USP monograph defines "glucosamine sulfate potassium chloride" using the chemical formula $(C_6H_{14}NO_5)_2SO_4 \cdot 2KCl$ and describes it as a "complex." *See* A-176-78 (137-28). The use of a dot (" · ") instead of a plus (" + "), along with the term "complex," means it is a single-crystal substance and ***cannot*** be a blend of multiple substances.[24] Defendants' own

[24] *E.g.* A-177 (137-28_1); A-325 (141-1_¶ 2.1.6); A-518 (141-2_¶ 1.2); A-853 (141-14_48:9-25); A-569-72 (141-3_21:9-24:25); A-579 (141-4_34:7-21); A-633-34 (141-5_14:5-15:20); A-734-35, A-738-39 (141-8_23:5-24:7, 54:6-55:8); A-756,

expert—Dr. Beauchamp—testified that USP defines glucosamine sulfate potassium chloride as a complex (*i.e.* a single crystal), and not a blend. A-598-603 (141-4_60:6-65:8).[25] Thus, the glucosamine blend simply does not meet the USP definition for single-crystal glucosamine.

USP admits, however, that its test cannot distinguish between a complex and a blend. In correspondence with Dr. Spingarn, a representative from USP stated that USP is "working with a sponsor to develop . . . a method to distinguish between complex and blend." A-955 (141-16_1) (USP correspondence)). Later, the USP representative confirmed: "***Sorry***, the current USP monograph is not ***capable*** of distinguishing between the complex and blends." A-960 (*Id.* at 6).[26]

A-763-64 (141-9_6, 13-14); A-254 (139-17_99:2-4); A-31 (104_4 n.6 (citing https://pubchem.ncbi.nlm.nih.gov /compound/Glucosamine-sulfate-potassium-chloride (last accessed January 28, 2022)).

[25] Dr. Beauchamp was shown the USP monograph and asked, "What does this description mean to you?" A-600-01 (141-4_62:25-63:3). He responded, "It tells me that the glucosamine sulfate potassium chloride is a complex between glucosamine sulfate and potassium chloride, there's a complex formed between the two." *Id.* at 63:3-7. He was then asked, "The fact that this monograph is titled Glucosamine Sulfate Potassium Chloride, does that indicate to you in any way that this could be a blend of two different materials, a physical blend of two different materials?" *Id.* at 64:17-22. Dr. Beauchamp responded, "No, I [sic] would lead to that being a complex, seeing that title." *Id.* at 64:24-65:2. Finally, he was asked, "Is that further clarified by these three lines below it with the chemical formula and the two written descriptions?," to which he responded, "Yes." *Id.* at 65:3-8.

[26] Notably, the USP representative did not claim that the distinction was irrelevant or that the test did not ***seek*** to make that distinction; he said that the test was not ***capable*** of making that distinction, and he apologized for it. *Id.*

Although it is icing on the cake, the experts all agreed that the USP test cannot distinguish chemically between the complex and the blend. Professor Jackson noted that the USP method "does not attempt to identify the solid-state form of glucosamine" and is not "fit for the purpose of discriminating between glucosamine hydrochloride and glucosamine sulfate." A-521 (141-2_¶ 1.7). Similarly, Dr. Spingarn explained each component test of the USP test method, and concludes that none of them "can distinguish between the labeled substance of glucosamine sulfate potassium chloride and the blended materials." A-331 (141-1_¶ 6.2.4).

Defendants' expert Dr. Klibanov has also repeatedly testified that this limitation of the USP test could be exploited by companies seeking to defraud consumers. In a prior case, Dr. Klibanov testified that it would be fraud to sell glucosamine hydrochloride labeled as glucosamine sulfate potassium chloride, saying: "if you have an intent to defraud the consumer in fact and try to counterfeit the product, you potentially can achieve that [2:1] ratio" inherent to single-crystal glucosamine sulfate by simply mixing glucosamine hydrochloride and potassium sulfate in a 2:1 ratio. A-744-45 (141-8_60:7-61:18). Dr. Klibanov confirmed this deficiency in another litigation, where he testified that "[t]here is only one potential blend that will match [single-crystal glucosamine sulfate]; but in order to create that blend, one has to have the intent to defraud," and so "if one intended to defraud the consumer, one would take the ratio two glucosamines for one sulfate." A-252-55

(139-17_97:1-100:7). In that case Dr. Klibanov further testified that the USP "doesn't deal specifically with the issue of distinguishing" between the salt forms (*i.e.* glucosamine sulfate or glucosamine hydrochloride). *Id.* at 99:15-18.7. Similarly, in prior litigation, Mr. Sullivan was asked whether he "agree[d] that the USP testing cannot distinguish between these two forms," he responded "I agree that they cannot." A-820 (141-11_82:6-9).

The District Court accepted Defendants' argument that the definition of "glucosamine sulfate potassium chloride" could encompass a 2:1 blend of glucosamine hydrochloride and potassium sulfate, because that blend will pass the USP test. SA-24 (Op._12). But the experts uniformly agreed that glucosamine sulfate potassium chloride is a complex, and cannot be a blend.[27] Again, Dr. Klibanov was very explicit in agreeing that there is a difference "between glucosamine sulfate potassium chloride (*i.e.*, a mixed salt) and glucosamine hydrochloride + potassium sulfate (*i.e.*, a physical mixture)." A-763-64 (141-9_13-14). The fact that the 2:1 blend will pass the USP test for the complex reveals a blind spot in the test, not a flexible definition for the substances. Importantly, as Dr. Klibanov pointed out in his testimony quoted above, any random blend of glucosamine hydrochloride and potassium sulfate would ***not*** pass the USP test; only

[27] A-325 (141-1_¶ 2.1.6); A-518 (141-2_¶ 1.2); A-633-34 (141-5_14:5-15:20); A-734-35 (141-8_23:5-24:7); A-763-64 (141-9_13-14); A-254 (139-17_99:2-4); A-569-72 (141-3_21:9-24:25); A-579, A-592 (141-4_34:7-21, 54:9-55:9).

that blend in a precise 2:1 ratio will fool the test into thinking it is the complex. This shows the limitation of the USP test in detecting the compound as the USP defines it, and it explains why Dr. Klibanov testified that using the 2:1 blend to exploit the USP test would show "intent to defraud" the consumer. A-252-55 (139-17_97:1-100:7).

There is thus no factual dispute that the USP test cannot answer the question posed by Plaintiff's claims: namely, whether the Product contains glucosamine sulfate or a mixture of glucosamine hydrochloride and potassium sulfate.

c. The EP Reference Material Is a Red Herring Because It Is not a Standard of Identity

The District Court found that the Product "matched the EP certified reference standard" for glucosamine sulfate potassium chloride. SA-23-24 (Op._11-12). This is a red herring because the EP reference material is not a standard of identity. The District Court failed to consider Plaintiff's evidence about the nature of the EP reference material, much less construe it in Plaintiff's favor as the non-moving party on summary judgment.

The EP reference material is inappropriate to use as a standard of identity because it is not one. Again, the EP reference material for glucosamine sulfate potassium chloride is a bottle of powder, provided by the private company MilliporeSigma, that is meant to pass the EP's test for that material. *See* A-856-57 (141-14_51:20-52:12); A-582-83 (141-4_44:4-45:21); A-961-1013 (141-17). The

EP provides an "Origin of Goods" document, which states that "[a]ll substances supplied by the European Directorate for the Quality of Medicines are supplied exclusively as European Pharmacopoeia Reference for use as standards or reference materials in tests and assays carried out in accordance with the official methods of the European Pharmacopoeia and ***for no other purpose***." A-840-41 (141-12) (emphasis in original). The EP also provides an information leaflet, which similarly states that it is a "Reference Standard for laboratory tests as prescribed in the European Pharmacopoeia only," and that "[t]he Council of Europe does not offer any warranty concerning the quality or safety of any item supplied, the absence of any defects, or its fitness for any particular purpose except that of use . . . as reference standards in tests and assays carried out in accordance with the official methods of the European Pharmacopoeia." A-842-44 (141-13).

Furthermore, the record contained correspondence from a representative of the supplier of the EP reference material confirming these representations from the leaflets and stating: "Please note that we distribute EP Reference standards, such as no. Y0001685 [for glucosamine sulfate potassium chloride], but that we carry out no quality testing on these products. They are to be used only as standards for carrying out EP compendial testing (Monograph 2708) as set forth in their Leaflet. . . . We offer no quality guarantee beyond what is outlined by the EP." A-973 (141-17_12) (EP supplier correspondence).

Citing the EP leaflet, Professor Jackson explained (and Defendants did not dispute) that the EP test method, just like the USP method, cannot distinguish between the complex and the blend. A-521 (141-2_ ¶ 1.8). Therefore, the EP reference material is not valid as a reference standard because it "is not adequate for validating a method that could resolve the salt form of glucosamine." *Id.* Thus, "the [EP] method and [reference material] are self-consistent, but they are equally deficient." *Id.* Dr. Spingarn agreed. A-856-57 (141-14_51:20-52:12). And other scientists have tested the EP reference material independently of this litigation and found that it was ***not glucosamine sulfate***. A-36-43 (127-2) (article by Sahoo et al.); A-521 (141-2_¶ 1.8 n.17) (citing study by Sahoo et al.); A-334-37 (141-1_attachment SOP 3203 at 2) (also citing Sahoo et al.). Put differently, the EP reference material will pass the EP test, but that is not a ground-truth guarantee that it is the chemical that it claims to be. As Professor Jackson explained, "the Sahoo article in particular does a pretty compelling job of describing the ways in which . . . the [EP reference material] product labeled glucosamine sulfate potassium chloride doesn't actually contain that substance. So to say when you buy that reference material, ground truth is not established." A-925 (141-15_83:10-16). Indeed, the scientists involved in the Sahoo et al. study concluded based on their testing that there is an "absence of a reference sample of glucosamine sulfate." A-40 (127-2_¶ 3.2).

Defendants did not rebut, and the District Court did not consider, the record evidence that the EP reference material (1) is not a standard of identity and is therefore irrelevant, and (2) is chemically mislabeled in any event.

E. Reliable and Appropriate Testing Shows that Defendants' Product is Mislabeled

As explained above, the AOAC test, the USP test, and the EP reference material are neither federally required nor scientifically appropriate. Accordingly, Plaintiff used other valid laboratory testing methods to show that Defendants' Product is mislabeled. The following demonstrates that Plaintiff's testing methods were "reliable and appropriate" to the extent required by the FDA regulations, and that Plaintiff provided conclusive evidence that the Product was chemically mislabeled.

The District Court found, in dicta,[28] that Plaintiff "fail[ed] to comply with [the] sampling and testing requirements" of 21 C.F.R. § 101.9(g)(2) and 21 C.F.R. § 101.36. SA-29-30 (Op._17-18). This was wrong. To the extent these regulations apply (which they do not, as explained *supra* Section I(C)), Plaintiff amply demonstrated that "[t]he method[s] of analysis used [were] suitable to achieve the

[28] In its decision denying reconsideration, the District Court again offered no explanation for why Plaintiff's testing was inadequate, but said that "this finding had no effect on the Court's grant of summary judgment, as the Order had already held that claims regarding the supplement facts panel were expressly preempted by other labeling requirements." SA-39 (161_4).

purpose for which [they were] used" as required by these regulations. 58 Fed. Reg. 2079, 2110 (Jan. 6, 1993).

Plaintiff sent pills from the bottle of the Product that she purchased, as well as twelve other unopened bottles of the Product supplied by Defendants in discovery, to an analytic laboratory (S&N Labs) for testing. A-321-515 (141-1). The testing was performed under the direction of Dr. Spingarn, a pharmacologist with a Ph.D from Yale University and more than 30 years of laboratory experience. *Id.* (*Id*. at Attachment 1). S&N analyzed samples of the Product using three independently valid testing methods (FTIR, XRD, and SEM-EDX). A-321-515 (141-1). Professor Jackson reviewed and endorsed these methods, saying that they are each "fit-for-purpose," "common, published, and validated methods of analysis . . . for the characterization of pharmaceuticals in their native, solid state," such as the Product. *See* A-518 (141-2_1); *see also* A-519 (*id.* ¶ 1.4) (noting that these methods are "common, commercially available, and exquisitely suited to the task").[29]

[29] These methods are routinely accepted as valid for a variety of substances in litigation. *E.g. JetEx, Ltd. Liab. Co. v. Ross Scottsdale, Ltd. Liab. Co.*, No. CV-09-01561-PHX-NVW, 2011 U.S. Dist. LEXIS 66219, at *13 (D. Ariz. June 21, 2011) (rejecting *Daubert* challenge; noting that "[i]n simple terms, a micro-FTIR spectrum test discerns a compound's elemental composition by measuring its light absorption properties, and an SEM-EDS test discerns a compound's elemental composition by measuring its emissions when bombarded with charged particles"); *see also, e.g., In re Mentor Corp. Obtape Transobturator Sling Products Liability Litigation*, No. 4:08-MD-2004 (CDL), 2016 U.S. Dist. LEXIS 145290, at *28 (M.D. Ga. Oct. 20, 2016), *aff'd sub nom. Taylor v. Mentor Worldwide LLC*, 940 F.3d 582 (11th Cir. 2019) (electron microscope examination and FTIR are "widely accepted methods");

1. Fourier-Transform Infrared Spectroscopy ("FTIR")

FTIR uses infrared light to examine a substance and generate a "spectrum" image that provides information about its molecular structure. A-325 (141-1_¶ 2.2.1). "FTIR is one of the most common instrumental methods of analysis in analytical chemistry." A-519 (141-2_ ¶ 1.4).

S&N Labs followed a micro-FTIR procedure to obtain spectra of individual crystals, and then, using software, compared them against reference spectra contained in a database associated with the instrument. A-334-37 (141-1_attachment SOP 3203, ¶ 8). According to Professor Jackson, this micro-FTIR procedure "is even more suitable than any form of 'bulk' FTIR measurement because micro-FTIR can elucidate mixtures of . . . finely-ground, but chemically distinct, crystals," as the Product is constituted. A-519 (141-2_ ¶ 1.4).

S&N Labs tested one tablet of the Product from the bottle that Plaintiff purchased using FTIR prior to the commencement of this lawsuit, and "the results showed the tablet to contain both glucosamine hydrochloride and potassium sulfate." A-327 (141-1_¶ 4). S&N Labs later tested samples from twelve unopened bottles

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Warner Chilcott Labs. Ir., Ltd. v. Impax Labs., Inc., No. 2:08-cv-06304 (WJM), 2012 U.S. Dist. LEXIS 60386, at *95 (D.N.J. Apr. 30, 2012) (FTIR and SEM-EDS are "widely-accepted scientific testing methods"); *Jaske v. Zimmer, Inc.*, No. 03 C 2939, 2009 U.S. Dist. LEXIS 3912, at *7-8 (N.D. Ill. Jan. 20, 2009) ("FTIR test has acceptance in the professional community"); *Astra Aktiebolag v. Andrx Pharm., Inc.*, 222 F. Supp. 2d 423, 490 (S.D.N.Y. 2002) (FTIR is a "well known and widely accepted technique").

of the Product produced by Defendants in discovery, and the results likewise "showed two individual components present: glucosamine hydrochloride and potassium sulfate." A-328 (141-1_¶ 5.1). "No evidence for the presence of glucosamine sulfate or glucosamine sulfate potassium chloride was observed." *Id.*; A-352-446 (test results available at *id.* Attachment 4). According to Dr. Spingarn, "[t]his testing, by itself, is sufficient to conclude that the product is mislabeled and does not contain, as its principal component, glucosamine sulfate potassium chloride." A-328 (*Id.* at ¶ 5.1). Professor Jackson reviewed the results and concurred, finding that "the FTIR spectra of each glucosamine-containing crystal are ***indisputable matches to standards of glucosamine hydrochloride***, and the spectra of the questioned samples do not contain any extra peaks that would be indicative of an impurity or a mixed salt." A-520 (141-2_ ¶ 1.5).

2. Scanning Electron Microscopy with Energy-Dispersive X-Ray Analysis ("SEM-EDX")

SEM-EDX uses an electron beam to reveal the elements present in a substance. A-324 (141-1_¶ 2.2.2). "[E]lemental analyses using SEM/EDX . . . are useful for qualitative and semiquantitative determination of elemental content." A-519 (141-2_ ¶ 1.4) (citation omitted).

S&N Labs tested samples from the twelve bottles of the Product produced by Defendants in discovery using SEM-EDX. A-328 (141-1_¶ 5.2); A-44772 (results available at *id.* Attachment 5). The results "showed two individual components

present: an organic hydrochloride [*i.e.*, glucosamine hydrochloride] and potassium sulfate." *Id.* This method was capable of excluding any form of glucosamine sulfate because it can "determine that the organic material is attached to chlorine but no other elements," and "that particles present in the tablets contained a combination of potassium and sulfur with no other elements." *Id.* "Thus, ***the material tested cannot be glucosamine sulfate*** since that would contain carbon and sulfur, but not potassium or chlorine. And the material tested also ***cannot be glucosamine sulfate potassium chloride*** since that would contain carbon, sulfur, potassium and chlorine all in the same crystal." *Id.* According to Dr. Spingarn, "[t]his testing, by itself, is sufficient to conclude that the product is mislabeled and does not contain detectable glucosamine sulfate potassium chloride." *Id.* Again, Professor Jackson concurred. A-520 (141-2_ ¶ 1.5).

3. X-Ray Diffraction ("XRD")

XRD uses x-rays to generate a "diffractogram" that provides information about the molecular arrangement of atoms in crystals. A-326 (141-1_¶ 2.2.3). "XRD provides information about the 3-dimensional arrangement of atoms in a crystal lattice," relying on the principle that "[e]very crystal form of a compound produces its own characteristic X-ray diffraction pattern." A-519 (141-2_ ¶ 1.4) (citation omitted).

S&N Labs tested samples from the twelve bottles of the Product produced by Defendants in discovery using XRD. A-329 (141-1_¶ 5.3); A-473-97 (test results available at *id.* Attachment 6). The results "showed two individual components present: glucosamine hydrochloride and potassium sulfate." A-329 (141-1_¶ 5.3). Notably, glucosamine sulfate and glucosamine sulfate potassium chloride could be excluded because "[n]o additional peaks were present to indicate any detectable additional components . . . ." *Id.* Therefore, "[t]his testing, by itself, is sufficient to conclude that the product is mislabeled and does not contain, as its principal component, glucosamine sulfate potassium chloride." *Id.*

Once again, Professor Jackson concurred, finding that "[t]he XRD results also confirm that there are two distinct chemical structures contributing to the bulk formulation. The XRD results show diffraction patterns that are ***consistent with a mixture of glucosamine hydrochloride and potassium sulfate***." A-520 (141-2_ ¶ 1.5). Furthermore, "the XRD diffractograms showed no evidence of extra peaks or unidentified peaks, so there is no evidence for an additional substance like glucosamine sulfate." *Id.*

Defendants' own expert, Dr. Derek Beauchamp, also tested a sample of the Product using the XRD method and obtained the same results as S&N Labs: *i.e.*, results that are consistent with glucosamine hydrochloride mixed with potassium

sulfate. A-582-83, A-606-10, A-625-26 (141-4_44:18-45:6, 68:16-72:13; 87:21-88:3).

4. Summary of Plaintiff's Testing Results

Based on the data obtained, Dr. Spingarn concluded as follows: "The products tested did not contain glucosamine sulfate potassium chloride. The products tested did contain a blend of glucosamine hydrochloride and potassium sulfate. Since these are distinctly different materials, the products (and, by extension, any other products containing the same raw materials) are mislabeled." A-332 (141-1_¶ 7). Likewise, Professor Jackson concluded that "S&N labs used common, standard, recommended, and valid methods of instrumental analysis to determine the chemical composition of solid-state particles present in the product: 'Finest Nutrition Glucosamine Sulfate Potassium Chloride.' The product contains two physically distinct salts: glucosamine hydrochloride and potassium sulfate. There is no evidence for the presence of glucosamine sulfate nor glucosamine sulfate potassium chloride." A-523-24 (141-2_7-8).

Plaintiff therefore established, to a degree at least sufficient to survive summary judgment, that Defendants' product is chemically (and materially[30]) mislabeled.

[30] The District Court did not reach the issue of whether the mislabeling was material. *See* SA-13-34 (154). Plaintiff showed that it was, as explained above at

5. Plaintiff Tested an Adequate Sample

Professor Jackson noted that the samples tested were statistically adequate for the conclusions reached, and elaborated that "[c]onfidence in the analysis is supported through the analysis of numerous particles from each pill, with each pill taken from one of 12 different bottles of the same lot." A-523-24; A-518 (141-2_7-8; *id.* ¶ 1.1).

The testing regulations (if they apply) require that "the sample for analysis shall consist of a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot, whichever is smaller, randomly selected to be representative of the lot." 21 C.F.R. § 101.36(f). FDA regulations and guidance confirm that the testing sample need not come from any particular lot.[31]

Background Section II(A), *supra.* Defendants submitted no admissible evidence to the contrary. *See* Argument Section I(E)(6) below.

[31] For dietary supplements, 21 C.F.R. § 101.36(f)(1) requires that the sample be drawn from an "***inspection lot (that is, the product available for inspection at a specific location)*** and be randomly selected to be representative of that [inspection] lot." 62 Fed. Reg. 49826, 49839 (Sept. 23, 1997); *accord* 62 Fed. Reg. 9826, 9828 (Mar. 4, 1997) ("inspection lot" "means the collection of packages from which the sample is collected that consists of the same food, with the same label (but not necessarily the same production lot code or, in the case of random packages, the same actual quantity), and from the same packer."); *Hollins v. Walmart Inc.*, No. 2:19-cv-5526-SVW, 2021 U.S. Dist. LEXIS 220473, at *3-4 (C.D. Cal. July 8, 2021) ("the regulatory solution . . . is to require Plaintiffs to test 12 bottles from the same lot rather than different lots. . . . Nothing about the regulatory scheme goes further or suggests that a plaintiff's 12 samples must come from the same lot that the bottle identified in her complaint came from").

Here, Plaintiff tested a compliant sample of twelve bottles from the same lot, per 21 C.F.R. § 101.36(f).

Notably, the sample at issue was provided by Defendants themselves (specifically IVC) in discovery. Plaintiff requested a "sample" of the Product, and specified in her request that "'Sample' has the same meaning ascribed thereto by 21 C.F.R. § 101.36(f)(1); that is, 'a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot, whichever is smaller, randomly selected to be representative of the lot.'" A-1025-26 (141-19_2-4). IVC responded that "IVC has already produced 12 consumer packages (bottles) of Finest Nutrition Glucosamine Sulfate Potassium Chloride 1000 mg from a single lot." A-1034 (141-20_5). The sample provided by IVC was, by IVC's admission, compliant with the FDA testing regulations.

6. Defendants' Purported Testing Results Were Not Admissible

In response to Plaintiff's testing evidence, Defendants relied on purported raw material and bulk product testing results from manufacturers in China through Mr. Sullivan's purported expert report. *See* ECF 138 at 10-11. These documents are inadmissible for multiple reasons.

Sullivan testified that he did not know the provenance of these documents and did not speak to anyone at the companies that purportedly performed the testing. A-688-719 (141-7_78:12-109:20). Furthermore, the documents lack the required

certificate of authenticity. *See* Fed. R. Evid. 803(6)(D) and 902(12). There is simply nothing in the record establishing when, how, why, or by whom these tests were conducted, nor is it clear which tests were done or what the results showed other than a conclusory "pass." They are therefore inadmissible. *See* Fed. R. Civ. P. 56(c)(2).

Moreover, the testing purportedly reflected in these documents was not done on a 12-bottle sample, was not designed to satisfy the USP method, and did not, in fact, follow all of the required steps of the USP method. A-688-719 (141-7_78:12-109:20); *see also* A-603-04 (141-4_65:9-66:3). Sullivan testified that these test results did not comply with the USP monograph; some of them were "not designed to satisfy the requirements of USP," and others did not use all of the required component tests. A-688-719 (141-7_78:12-109:20). For example, the raw material supplier's testing does not show what "reference standard" it was testing against,[32] and the test did not include a test for potassium (one of the four required tests in the USP monograph). A-689-05 (141-7_79:19-95:6). Mr. Sullivan also did not know how the supplier performed its tests or whether they were USP methods, but his

[32] Mr. Sullivan assumed that the reference standard was "glucosamine sulfate potassium chloride," but importantly the USP does not provide a reference standard for this substance, nor does it require the use of one from the EP or anywhere else. *See* A-699-700 (141-7_89:14-90:13); A-521 (141-2_¶ 1.8) (there is no USP reference material for glucosamine sulfate potassium chloride); A-331 (141-1_¶ 6.3) ("While USP sells reference standards for almost every one of their listed drugs, they conspicuously do not sell one of glucosamine sulfate potassium chloride.").

"***assumption*** was that they used a scientifically valid method that was comparable to the USP method." A-710-12 (*Id.* at 100:5-102:24). As Mr. Sullivan also agreed, instead of performing all four USP tests as written, the testing documents did not mention the infrared absorption test (USP Identification A), did not test for potassium (USP Identification B), and did not perform the prescribed method for testing for sulfate (USP Identification D). A-715-19 (*Id.* at 105:11-109:9).

Thus, even if they were admissible, the test results do not show that a sufficient sample of the Product ever actually passed the USP test method.[33] Lacking admissible and probative rebuttal evidence from Defendants, the record therefore showed conclusively that Defendants' Product was chemically mislabeled. Since Defendants did not challenge the merits of Plaintiff's breach of contract claim in opposition to her motion for partial summary judgment, Plaintiff was therefore entitled to judgment on liability on that claim. *See* Fed. R. Civ. P. 56(a).[34]

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[33] And, as stated, the USP test could not distinguish between the complex and the blend in any event. *See supra* Section I(D)(4)(b).

[34] The District Court dismissed Plaintiff's breach of contract claim solely on preemption grounds and did not address its merits because Defendants did not challenge them on summary judgment. SA-31 (Op. at 19 n.4). Since Defendants conceded the merits of Plaintiff's breach of contract claim, and this action is not subject to FDA preemption, her motion for summary judgment on liability should have been granted. *See* Fed. R. Civ. P. 56(a).

II. THE DISTRICT COURT ERRED IN DISMISSING PLAINTIFF'S N.Y. G.B.L. § 349 CLAIM

A. Standard of Review

The Second Circuit reviews a district court's grant of summary judgment *de novo*, construing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in its favor. *Dish Network Corp. v. Ace Am. Ins. Co.*, 21 F.4th 207, 212 (2d Cir. 2021).

B. There Are No Products for Sale Claiming to Contain Glucosamine Hydrochloride Blended with Potassium Sulfate

For Plaintiff's G.B.L. claim, the Court ignored Plaintiff's evidence that there is "no consumer demand for supplements containing the glucosamine blend," and found instead that "there is consumer demand for glucosamine hydrochloride based on the fact that it is offered for sale." SA-33-34 (Op._21-22). This was clearly an error.

It is irrelevant that pure glucosamine hydrochloride is offered for sale; the question is whether glucosamine hydrochloride ***blended with potassium sulfate*** is offered for sale. It is not. Defendants conceded that there are no products on the market that are labeled as containing such a blend. A-272 (139-18_¶ 16). As a matter of logic, there cannot be any measurable consumer demand for a product that does not actually exist. Again, 1/3 of this blend is potassium sulfate (by virtue of

the 2:1 manufacturing ratio), which is "used especially as a fertilizer"[35] and is not found by itself in any dietary supplements. *Id.* ¶ 15.[36] That consumers are in fact buying glucosamine hydrochloride, not knowing it has been blended with fertilizer making it worthless in treating joint pain, ***is*** the consumer fraud.

The fact that there is no discernable market for the blend of chemicals that Plaintiff actually received[37] should have been enough to show injury under G.B.L. § 349 on summary judgment, especially considering that "a price premium is but one recognized method of establishing injury under §§ 349 and 350 . . . and a plaintiff need not allege a price premium in every case under these statutes" because "there is no such rigid 'price premium' doctrine under New York law." *Shaya Eidelman v. Sun Prods. Corp.*, 21-1046-cv, 2022 U.S. App. LEXIS 15480, at *3 (2d Cir. June 6, 2022) (reversing summary judgment on basis of lack of injury). Instead, "a plaintiff must [show] that, on account of a materially misleading practice, she purchased a product and did not receive the full value of her purchase." *Orlander v. Staples, Inc.*, 802 F.3d 289, 302 (2d. Cir. 2015). Plaintiff made such a showing here: she purchased what she thought was glucosamine sulfate but instead received a blend

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35 https://www.merriam-webster.com/dictionary/potassium%20sulfate

36 Just because Walgreens sells both bottles of water and bottles of laundry detergent, does not mean that there is a market for bottles of water mixed with laundry detergent for people to drink.

37 The lack of market was not disputed by Defendants or their damages expert. A-272 (139-18_¶ 16); A-1327-28 (141-25_84:20-85:15).

of different, ineffective chemicals that is so apparently undesirable that it cannot even be found for sale. *See Lambert v. Nutraceutical Corp.*, 870 F.3d 1170, 1183 (9th Cir. 2017) ("Customers who purchased rhinestones sold as diamonds should have the opportunity to get all of their money back." (quotation, citation, and internal formatting omitted)), *rev'd on other grounds*, *Nutraceutical Corp. v. Lambert*, 139 S. Ct. 710 (2019).

Plaintiff therefore showed her entitlement to statutory damages under N.Y. G.B.L. § 349. *See Chery v. Conduent Educ. Servs.*, LLC, 581 F. Supp. 3d 436, 449-52 (N.D.N.Y. 2022) (denying summary judgment to defendant, granting summary judgment to plaintiff, and finding plaintiff and class members entitled to $50 per violation of N.Y. G.B.L. § 349); *see also Montera v. Premier Nutrition Corp.*, No. 16-cv-06980-RS, 2022 U.S. Dist. LEXIS 75843, at *21 (N.D. Cal. Apr. 26, 2022) ("A violation of sections 349 and 350 occurs when a consumer views the label and purchases the product. . . . A reading of sections 349 and 350 that recognizes a plaintiff experiences a violation each time the product is purchased is consistent with the text and intent of the statute. Thus, G.B.L. §§ 349(h) and 350-e allow statutory damages on a per unit basis.").

CONCLUSION

This Court should reverse the District Court and direct entry of judgment and an award of statutory damages in Plaintiff's favor, or alternatively, remand to the District Court for further proceedings.

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Local Rule 32.1(a)(4)(A) because it contains 13,098 words, excluding those parts exempted by Federal Rule of Appellate Procedure 32(f). This brief complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5)–(6) because it has been prepared in proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

January 5, 2024 */s/ Philip M. Black*