JS-6

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:19-cv-05526-SVW	Date	August 17, 2021
Title	*Darlene Hollins et al. v. Walmart Inc. and International Vitamin Corporation*		

Present: The Honorable	STEPHEN V. WILSON, U.S. DISTRICT JUDGE
Paul M. Cruz	N/A
Deputy Clerk	Court Reporter / Recorder
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
N/A	N/A

Proceedings: ORDER GRANTING SUMMARY JUDGMENT IN FAVOR OF DEFENDANTS AND DENYING [141] MOTION FOR SANCTIONS.

Walmart Inc. and International Vitamin Corporation (collectively "Defendants") previously filed a motion for summary judgment on the preemption issue in this case. *See* Dkt. 69. The Court scheduled a hearing so the parties could present additional evidence on that issue. *See* Dkt. 79. Prior to the hearing, the Court narrowed the scope of the preemption inquiry and explained that—because Plaintiffs tested 12 samples from the same lot but did not use the AOAC method in their testing—the only issue remaining was whether (1) the AOAC Official Method 2005.01 is "appropriate," and (2) Plaintiffs' expert's method is "reliable and appropriate." Dkt. 131; *see also* 21 C.F.R. § 101.9(g)(2) (explaining that samples "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").

The Court held an evidentiary hearing on July 12, 2021. *See* Dkt. 133. In light of the evidence and testimony presented by the parties, the Court concludes that Plaintiffs' expert's method is not reliable and appropriate for determining whether Defendants' products are mislabeled. Accordingly, Defendants have met their burden on the preemption issue and are entitled to summary judgment.

I. The Court Concludes Spingarn Is Not Credible.

At the outset, the Court concludes that Plaintiffs' expert Neil Spingarn is not credible because he made false—or, at the least, highly misleading—statements in his declarations.

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First, in his declaration submitted to this Court, Spingarn stated that it is impossible to compare the FTIR spectra to a reference standard for glucosamine sulfate potassium chloride. *See* Spingarn Decl. ¶ 29. Later, at his deposition, Spingarn doubled down on this statement:

> Q: Are you saying it's impossible to buy a certified reference standard for glucosamine sulfate potassium chloride?
>
> A: That's correct.

See Spingarn Depo. at 131:8-16.

This was untrue or, at the least, highly misleading. During the evidentiary hearing, Spingarn admitted that he purchased a certified reference standard of glucosamine sulfate potassium chloride from European Pharmacopeia (hereinafter "the EP standard") and tested it. *See* Dkt. 136 at 5:16-24. On its face, this admission contradicts Spingarn's deposition testimony that it is impossible to buy a certified reference standard for glucosamine sulfate potassium chloride. *See* Spingarn Depo. at 131:8-16.

To the extent Plaintiffs argue that Spingarn's inconsistent testimony simply reflects his belief that the certified reference standard itself is mislabeled, the Court rejects that argument as too clever by half. If Spingarn intended to say the reference standard is mislabeled, then that is what he should have said: "the certified reference standard is mislabeled," "the only reference standard you can purchase is incorrectly labeled as glucosamine sulfate potassium chloride," or, most clearly, "it depends how you define glucosamine sulfate potassium chloride." Instead, Spingarn misleadingly testified that it was "impossible" to buy a certified reference standard for glucosamine sulfate potassium chloride.

The second false statement is contained in Spingarn's declaration in support of Plaintiffs' opposition to Defendants' ex parte application prior to the evidentiary hearing. *See* Dkt. 123 (Defendants' ex parte application); Dkt. 129-1 (Spingarn Decl. ISO Opp. to Ex Parte). In that declaration, Spingarn stated that any tests he had conducted on the EP standard were "not conducted in the scope of [his] engagement in this or related litigation." *Id.* ¶ 4. He further stated that he "performed the testing on [his] own time [and] did not perform it related to any specific case." *Id.* ¶ 5.

That testimony is contradicted by documents Plaintiffs produced regarding Spingarn's testing. The documents contain several test results. Some of those results list the "client" as "S&N Labs." *See* PLTFS-WLMRT000055–62. Those results are also labeled with the word "internal" rather than with a specific file number. *See id.*

However, on the results for testing conducted on the EP standard, the "client" is listed as Wolf Popper LLP—*i.e.*, Plaintiffs' counsel. *See* PLTFS-WLMRT000096–104. Moreover, the results for testing conducted on the EP standard are not labeled "internal." Instead, they have a specific file number assigned to them (24486). *Id.* That file number matches the file number on the test results submitted in support of Spingarn's original declaration (which also list the client as Wolf Popper LLP). *Compare* PLTFS-WLMRT000096–104 *with* Dkt. 113-5. This is strong circumstantial evidence that, contrary to his declaration, Spingarn's testing on the EP reference standard was, in fact, conducted in the scope of this litigation or, at the least, related glucosamine litigation.

Further confirming that conclusion is internal correspondence between Spingarn and his colleague, Chris French. French began corresponding with the European Directorate for the Quality of Medicines & HealthCare ("EDQM"), the publisher of the European Pharmacopeia. PLTFS-WLMRT000092. French forwarded his correspondence to Spingarn and suggested that it was "pointless to debate" with EDQM. *Id.* In response, Spingarn stated as follows: "Since it carries over into the legal realm I think it is worth another round of clarification." *Id.*

In other words, Spingarn was actively considering the legal ramifications of his testing on the EP reference standard. Yet, in his declaration, he stated that his testing was "not conducted in the scope of [his] engagement in this or related litigation" and was not "related to any specific case." Dkt. 129-1 (Spingarn Decl. ISO Opp. to Ex Parte) ¶¶ 4–5.

These statements substantially undermine Spingarn's testimony, and the Court concludes he is not credible.

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II. Spingarn's Testing Method is Not Reliable and Appropriate.

The Court concludes that, regardless of his lack of credibility, Spingarn's testing methods are not reliable and appropriate. This is so for several reasons.

First, Spingarn's method is not validated. "Method validation is the process of demonstrating or confirming that a method is suitable for its intended purpose." Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products (Oct. 2019) at 4. "Validation includes demonstrating performance characteristics such as accuracy, precision, sensitivity, selectivity, limit of detection, limit of quantitation, linearity, range, and ruggedness, to ensure that results are meaningful." *Id.*

Spingarn admitted at the evidentiary hearing that none of his test methods are validated.

Q: All right. You have not prepared a validation report for the use of EDX to distinguish between glucosamine sulfate potassium chloride and glucosamine hydrochloride with potassium sulfate; correct?

A: Correct.

Q: You haven't done that for your XRD testing either; correct?

A: Correct.

Q: And you haven't done it for your FTIR testing; correct?

A: Correct.

Dkt. 136 at 27:8-18.

Defendants argue that alternative methods need not be validated. This is incorrect. Regulatory guidance promulgated by the FDA expressly states that an alternative method "must be suitable to

achieve the purpose for which it is used." 58 Fed. Reg. 2079-01, 1993 WL 1537, at *2110 (Jan. 6, 1993).[1] That is the very definition of a "validated" method. *See* Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products (Oct. 2019) at 4. ("Method validation is the process of demonstrating or confirming that a method is suitable for its intended purpose.").

Moreover, even if Defendants were correct, that would not mean the lack of validation is irrelevant. To the contrary, it would still be relevant to the overall analysis of whether Spingarn's method is reliable and appropriate. Indeed, even Plaintiffs acknowledge that the FDA prefers validated methods. Dkt. 139 at 13 ("The FDA thus expresses a preference for validated methods over non-validated methods . . . .").[2]

Second, Spingarn's method is not peer reviewed, published, or documented in a standard operating procedure. Regulatory guidance promulgated by the FDA states as follows: "Alternative methodology is recommended only in the absence of AOAC Official Methods. If alternative methods are developed and/or used, they should be accompanied by documentation that describes in detail the analytical procedures and performance characteristics of the method." Guidance For Industry FDA Nutrition Labeling Manual -- A Guide For Developing and Using Data Bases, 1998 WL 34327548, at *15.

Here, Spingarn has not subjected his methodology to peer review. *See* Dkt. 136 at 22:7-9. He has not published his methodology. *See id.* His method is not a compendial method. *See id.* at 19-21.

[1] The Court previously noted that the regulation at issue here "expressly allows for someone ensuring compliance—here, Plaintiff[s]—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." Dkt. 79 at 6. While this remains true, that does not mean that FDA guidance is irrelevant. To the contrary, given the dearth of authority on this issue, the Court will rely on FDA guidance.

[2] Plaintiffs' sentence continues: "but this is assuming that the validated methods are valid in the first instance to do what they are being asked to do. Here, the AOAC method may be a validated method for determining the amount of glucosamine—but it is not a valid test to determine whether the substance contains glucosamine sulfate specifically." Dkt. 139 at 13. The AOAC method is irrelevant to the instant issue. Specifically, the instant inquiry is not whether the AOAC method is valid but, rather, whether Spingarn's method is reliable and appropriate.

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Spingarn has not even documented his methodology in a standard operating procedure. *See id.* at 22:10-12. Not only does this raise serious *Daubert* concerns, but it also further persuades this Court that Spingarn's method is not reliable and appropriate.[3]

Finally, Spingarn admits that when he tested Spring Valley Glucosamine Sulfate against the certified EP reference standard, the results showed that the Spring Valley products matched the reference standard. Spingarn argued that this was because both the Spring Valley products *and* the EP reference standard are mislabeled. *See* Dkt. 136 at 23:18-24:20. Spingarn essentially argues that this Court should reject a certified reference standard that says a substance containing a blend of glucosamine hydrochloride and potassium sulfate is sufficient to be labeled glucosamine sulfate potassium chloride.

The Court declines to do so. Regulatory guidance promulgated by the FDA consistently emphasizes that the accuracy of a particular testing method depends, at least in part, on whether that method incorporates certified reference standards. *See, e.g.*, Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products (Oct. 2019) at 6 ("The use of known reference materials (when available and applicable) should be incorporated to assess the accuracy or bias of the method, as well as for obtaining information on interferences."); Guidance For Industry FDA Nutrition Labeling Manual -- A Guide For Developing and Using Data Bases, 1998 WL 34327548, at *16 ("When new methods are under development or when older methods are modified, the precision and accuracy of the new applications should be established. While precision can usually be demonstrated with replicate assays, *determination of accuracy requires a material or a standard with a certified concentration of the analyte being measured*.") (emphasis added).

The implication of the FDA's emphasis on certified reference standards is clear: those standards are valuable because they are authoritative and trustworthy. Here, substances containing a blend of glucosamine hydrochloride and potassium sulfate satisfy the certified EP standard for glucosamine sulfate potassium chloride. *See* Dkt. 136 at 29:10-20.

[3] Plaintiffs may argue that none of these elements—*i.e.*, validation, peer review, publication, or documentation in a standard operating procedure—are *required* for a method to be reliable and appropriate. Yet, even if each one individually is not required, a method is not "reliable and appropriate" when *all* of them are missing.

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Spingarn disagrees with the EP's definition of glucosamine sulfate potassium chloride. Indeed, this entire dispute appears to be definitional: whether "glucosamine sulfate potassium chloride" is properly defined as including both the blend and the single crystal forms. Spingarn's colleague French admitted as much in internal correspondence with Spingarn: "[p]robably pointless to debate [with EP] as it appears to be a regulatory definition and not a chemical definition." PLTFS-WLMRT000091.

For now, regulatory agencies have decided that the blended form is accurately labeled "glucosamine sulfate potassium chloride." *See* 21 C.F.R. § 101.36(b)(3)(i) (explaining that ingredients such as glucosamine sulfate potassium chloride should be declared by their "common or usual name"); 60 Fed. Reg. 67194-01, 1995 WL 760960, at *67201 (Dec. 28, 1995) (explaining that the "common or usual name" should be drawn from "an official compendium" like EP or United States Pharmacopeia ("USP")); *see also* Dkt. 136 at 45:11-15 (Spingarn admitting that both the single crystal form and blended form satisfy the EP and USP monographs for glucosamine sulfate potassium chloride).

Spingarn's retort that the EP and USP monographs do not distinguish between the blended form and the single crystal form is, essentially, a criticism of the official compendiums that the FDA relies on. But that criticism is better addressed by the EP, USP, or FDA. Once the FDA chooses to rely on official compendiums, Plaintiffs cannot disregard those compendiums, and it is not this Court's role to second guess the scientific and technical judgment of the FDA.[4] *See Charles D. Bonanno Linen Serv., Inc. v. N.L.R.B.*, 454 U.S. 404, 418 (1982) ("[T]he dissenting Justices would have us substitute our judgment for those of the [agency] with respect to the issues that Congress intended the [agency] should resolve. This we are unwilling to do."); *see also Durnford v. MusclePharm Corp.*, 907 F.3d 595, 602 (9th Cir. 2018) (challenges to labels complying with federal regulations are preempted); *Gubala v. Allmax Nutrition, Inc.*, 2015 WL 6460086, at *3 (N.D. Ill. Oct. 26, 2015) (claim preempted where it was "really an attack on the manner in which the FDA permits protein content to be calculated").

For the foregoing reasons, the Court concludes that Spingarn's method is not reliable and appropriate.

[4] This is particularly true where the Court would be substituting the judgment of the regulating agency based on the testimony of an expert whose methodology is not validated, peer reviewed, or published.

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III. Conclusion.

This case cannot proceed on the basis of a testing method that has not been validated, subjected to peer review, published, or documented in a standard operating procedure. Moreover, this is not the proper forum to resolve Spingarn's definitional dispute with the FDA and the scientific community, particularly where Spingarn lacks credibility and where authoritative scientific bodies (*e.g.*, the EP and USP) currently allow the blended form to be labeled "glucosamine sulfate potassium chloride."

For the foregoing reasons, Defendants have met their burden of establishing that all of Plaintiffs' claims are preempted.[5] Accordingly, summary judgment is hereby GRANTED in favor of Defendants.[6]

IT IS SO ORDERED.

[5] Because the Court finds that Defendants have met their burden of establishing that Plaintiffs' expert's method is not reliable and appropriate, the Court need not address whether the AOAC method is appropriate.

[6] The Court concludes that sanctions are not warranted under the Court's inherent authority or Rules 37 and 56 of the Federal Rules of Civil Procedure. Accordingly, the motion for sanctions is DENIED.

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