UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

Undetermined quantities of all articles of finished and in-process foods, etc.

Defendants,

and

HI-TECH PHARMACEUTICALS, INC. and JARED WHEAT,

Claimants.

HI-TECH PHARMACEUTICALS, INC.,

Plaintiff,

v.
MARGARET A. HAMBURG, M.D., *et al*.

Defendants.

Civil Action No. 1:13-cv-3675

Hon. Willis B. Hunt, Jr.

CLAIMANTS HI-TECH PHARMACEUTICALS, INC., AND JARED WHEAT'S REPLY BRIEF IN SUPPORT OF THEIR MOTION FOR RECONSIDERATION AND TO VACATE THE SUMMARY JUDGMENT ORDER AND JUDGMENT

I. INTRODUCTION

Claimants Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech") and Jared Wheat respectfully file this brief in reply to the Government's Opposition, Doc. 144, to Claimants' Motion to Reconsider the Court's April 3, 2017 Order (the "April 3 Order"), Doc. 140, and to Vacate the Judgment (the "April 3 Judgment,") Doc. 141, which granted the Government's motion for summary judgment and denied Claimants' motion for summary judgment.

Although the Government is obliged to attempt to defend the Court's novel interpretation of DSHEA, its defenses fall far short and only further demonstrate the manner in which the Court, respectfully, committed legal error. Rather than engage in a plain-meaning analysis of the statute—as the Government contends occurred—the Court's interpretation of the term "botanical" under DSHEA read the word "constituent" completely out of the statute. A plain reading of a statute cannot omit a critical modifying term from its analysis and the Government's own citations support Claimants' position on this issue. The Court committed clear legal error when it reached its conclusion that a "botanical"—for purposes of qualifying as a dietary ingredient under DHSEA—must have been "extracted in usable quantities from a plant or plant like organism . . . ." April 3 Order at 9. Therefore, reconsideration of this holding is required.

Moreover, the Government's defense of the record upon which the Court issued the April 3 Order and Judgment is lacking. It is indisputable that the issues surrounding the Court's holding that a botanical only qualifies as a dietary ingredient under DSHEA when there is a history of its extraction in "usable quantities from a plant or plant like organism" was never briefed by the parties. Claimants were also never afforded an opportunity to present additional facts that would have further supported a finding that DMAA can be extracted from geraniums in usable quantities. Entry of summary judgment based on this record, and without proper notice to Claimants, is another basis for reconsideration of the April 3 Order and vacating the April 3 Judgment.

Finally, contrary to the Government's misinformed assertions, Claimants do not lightly or "routinely file motions for reconsideration." Gov't Opp'n Br. at 4 n.1, Doc. 144. The on-going litigation cited by the Government in which Hi-Tech filed three motions for reconsideration has been pending for more than **13 years** and involves scores of motions and resulting orders and opinions. Moreover, as a cursory review of the docket in that matter makes clear, a costly appeal to the Eleventh Circuit, which was eventually resolved in Hi-Tech's favor, could have been avoided if the district court had granted one of Hi-Tech's motions for reconsideration now ridiculed by the Government. *See FTC v. Nat'l Urological*

Grp., Civil Action No. 1:04-CV3294-CAP (N.D. Ga.), Doc. 396 (motion for reconsideration) and Doc. 815 (subsequent grant of appeal based on issues raised in motion for reconsideration).

For these reasons, as explained more fully below, Claimants' Motion for Reconsideration and to Vacate the Summary Judgment Order and Judgment should be granted.

II. ARGUMENT

A. The Court's Interpretation of DSHEA Resulted in Clear Error

In opposition to Claimants' request for reconsideration, the Government asserts that the Court merely used "standard canons of statutory construction to define the term 'botanical,' and by extension, what comprises a 'constituent' of a botanical in 21 U.S.C. § 321(ff)(1) . . . ." as the basis for its Order. Gov't Opp'n Br. at 5, Doc. 144. The Government's reading of the April 3 Order fails to accurately describe either the April 3 Order or the Court's analysis of what qualifies as a dietary ingredient under DSHEA. Indeed, the primary case cited by the Government makes clear the manner in which the Court erred in its interpretation of DSHEA. *See* Gov't Opp'n Br. at 6-8 (citing *United States v. DBB, Inc.*, 180 F.3d 1277, 1284 (11th Cir. 1999)).

The *DBB* Court set out several basic rules regarding statutory interpretation that the Court failed to adhere to in the April 3 Order. "The starting point for all statutory interpretation is the language of the statute itself." *DBB*, 180 F.3d at 1281. The statutory provision at issue here is 21 U.S.C. § 321(ff)(1), which states that the following substances qualify as dietary ingredients for purposes of DSHEA:

> (A) a vitamin;
>
> (B) a mineral;
>
> (C) an herb or other botanical;
>
> (D) an amino acid;
>
> (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
>
> (F) a concentrate, metabolite, **constituent**, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

21 U.S.C. § 321(ff)(1) (emphasis added).

The Eleventh Circuit made clear in *DBB* that courts must "read [a] statute to give full effect to **each** of its provisions" and shall **"not look at one word or term in isolation, but instead [must] look to the entire statutory context**." *DBB,* 180 F.3d at 1281 (emphasis added). Indeed, special care must be given to avoid "interpretations of statutes that render language superfluous" or result in words

being "discarded as meaningless, redundant, or mere surplusage." *Id.* at 1285 (quoting *Connecticut Nat. Bank v. Germain*, 503 U.S. 249, 253 (1992); *United States v. Canals-Jimenez*, 943 F.2d 1284, 1287 (11th Cir. 1991)).

Here, the Court's ultimate conclusion that "in using the term botanical, Congress intended that there must be at least some history of the substance in question having been extracted in usable quantities from a plant or a plant-like organism," April 3 Order at 9, violates each of the rules set forth by the Eleventh Circuit. The Court's exclusive focus on the definition of "botanical" is the result of a failure to "look at the entire statutory context," which clearly instructs that a mere "constituent" of a botanical also qualifies as a dietary ingredient under DSHEA.[1] *See DBB*, 180 F.3d at 1281; 21 U.S.C. § 321(ff)(1)(F). The Court's conclusion also, *a fortiori*, led to the term "constituent" being "discarded as meaningless, redundant, or mere surplusage." *Id*. at 1285. This result is prohibited under not only *DBB* but also under other Eleventh Circuit case law, which requires that courts **"take the provision as Congress wrote it, and neither add words to nor subtract them from it**." *Korman v. HBC Fla., Inc.*, 182 F.3d 1291, 1296 (11th

[1] Strangely, the Court seemingly acknowledged the concept of an "extract" of a "botanical" yet ignored the concept of a "constituent" of a "botanical," even though the statute clearly commands that **both** are sufficient to qualify as dietary ingredients under DSHEA.

Cir. 1999) (emphasis added). These are clear errors in statutory interpretation and are not the result of some run-of-the-mill plain meaning analysis, as the Government contends.

Moreover, the Court's analysis also ignored subsection (E) of 21 U.S.C. § 321(ff)(1), which states that the term "dietary supplements" also includes "a dietary substance for use by man to supplement the diet by increasing the total dietary intake." This catch-all provision demonstrates Congress's intent to include a wide variety of dietary ingredients under DSHEA and is further evidence that the Court's restrictive reading of 21 U.S.C. § 321(ff)(1) should be reconsidered.

"Where the intent of Congress is expressed in the text of a statute in reasonably plain terms, [courts] must give effect to that intent." *Nat'l Coal Ass'n v. Chater*, 81 F.3d 1077, 1081 (11th Cir. 1996) (citing *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 570 (1982)). Here, the intent of Congress is clear: even mere constituents of a botanical can qualify as a dietary ingredient under DSHEA. Prior to the filing of its opposition to Claimants' Motion for Reconsideration, this was a concept that the Government freely agreed to. *See* Gov't Motion for Summary Judgment, Doc. No. 107-1, at 1 (explaining that the key legal and factual issue in this case revolved around whether DMAA is present in geraniums at any detectable level). Regardless of the Government's unsurprising

current change of heart, the Court's interpretation of DSHEA constitutes clear error that requires reconsideration.

B. The Court Incorrectly Concluded that Claimants Lack Evidence that DMAA Can Be Extracted from Geraniums in a Commercially Usable Quantity and Prevented Claimants from Presenting Additional Evidence on This Issue

The Court's entry of the April 3 Order against Claimants on the basis that DMAA cannot be extracted in "usable quantities" was inappropriate because Claimants were never put on notice that such evidence would be dispositive. This was a *de facto sua sponte* grant of summary judgment against Claimants on an issue that was never raised by the parties or the Court prior to the issuance of the April 3 Order. It is hornbook law that the party against whom summary judgment is entered in such a situation must be provided with the opportunity to present evidence in support of its position. *See* 11-56 Moore's Federal Practice - Civil § 56.71 ("A court may not grant summary judgment for a nonmovant, grant summary judgment on a ground not specified in a motion, or grant summary judgment *sua sponte* until the court provides the parties 'notice' of its intention to do so and grants the parties 'a reasonable time' to respond to the proposed summary judgment before acting.").

The Government wrongly argues that Claimants' arguments regarding this issue are "revisionist" because "whether geraniums can naturally produce DMAA

was **the** focus of both parties' discovery" and "central to the dispute" in this case. Gov't Opp'n Br. at 14 (emphasis in source). Just as the Court read the term "constituent" out of DSHEA, the Government's interpretation of the April 3 Order reads the Court's "usable quantities" requirement out of the Court's opinion. Although it is true that that the ability of geraniums to produce DMAA was disputed in this case and was the subject of discovery, the parties had agreed that the production of DMAA by geraniums, even at trace levels, would render DMAA a dietary ingredient under DHSEA.

The Government can attempt to run from its previous position on this issue, or even advocate for the Court's newly minted "usable quantities" requirement, but that does not change the record in this case. The "**commercial** extraction of DMAA from geraniums in usable quantities," Gov't Opp'n Br. at 15 (emphasis added)—which adds another requirement above and beyond the Court's "usable quantities" requirement—was never litigated by the parties because it is not required under DSHEA. As a result, Claimants had zero notice that they would be required to marshal such evidence in order to defeat summary judgment. The Government did not advocate this position because such an interpretation of DSHEA was contrary to the plain meaning of the word "constituent." For the Government to now argue that Claimants should have predicted that the Court

would rule in such a novel way on an issue the Government did not advocate is bad-faith and contrary to the law. *See Artistic Entm't, Inc. v. City of Warner Robins*, 331 F.3d 1196, 1201 (11th Cir. 2003) (*sua sponte* summary judgment decision appropriate only where "(1) purely legal issues are involved or (2) the evidentiary record is complete and the parties have been given the opportunity to respond."). Reconsideration of the April 3 Order and vacating the April 3 Judgment is required, at a minimum, in order to provide Claimants with their right to provide additional evidence regarding the ability to extract DMAA from geraniums in a usable quantity.

Moreover, because the Court's April 3 Opinion necessarily created a **factual** test to determine whether a substance qualifies as a botanical under DSHEA (i.e. whether the substance has "been extracted in usable quantities from a plant or a plant-like organism"), that does not exist in either the language of the statute or in case law, entry of summary judgment on the current record was inappropriate. There is no evidence in the record that DMAA **cannot** be extracted from geraniums in a usable amount. Instead, one of Claimants' experts, Dr. Marvin Heuer, whose declaration was submitted in support of Claimants' motion for summary judgment and whose deposition transcript is also part of the record, Doc.

130, noted that patent applications were filed to commercially extract DMAA from geraniums. MSJ Wenik Decl. (Doc. 108-3), Ex. 38, Heuer Decl., ¶ 58.

The Government criticizes Claimants' citation of these patent applications at this juncture as untimely and of little evidentiary value. Gov't Opp'n Br. at 10-13. Those criticisms are misplaced. First, Claimants—as explained above and in their moving papers—had no reason to believe that the extraction of DMAA from geraniums in "usable quantities" would be a dispositive issue in this case. Claimants brought this evidence, which **was** part of the record (the Government admits that it questioned Dr. Heuer about these patent applications), *see* Heuer Dep. Tr. (Doc. No. 130), at 225:21-232:12, to the Court's attention at the earliest juncture that it became evident that it would be relevant to the Court's analysis of whether DMAA qualifies as a dietary ingredient. Second, although the Government may not agree with the import of this evidence, it is evidence nonetheless that creates an issue of fact as to whether DMAA can be extracted from geraniums in "usable quantities." As such, entry of summary judgment against Claimants was erroneous and must be reconsidered.

III. CONCLUSION

For the foregoing reasons, Claimants respectfully request that the Court enter an order granting Claimants' Motion for Reconsideration, vacating the April

3 Order and granting Claimants' Motion for Summary Judgment and dismissing the United States' seizure action, lifting the Government's detention of Claimants' goods, and granting summary judgment on the claims articulated in Claimants' Administrative Procedure Act Complaint.

Respectfully submitted,

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CERTIFICATION PURSUANT TO LOCAL RULE 7.1(D)

Pursuant to Local Rules 5.1(C) and 7.1(D), I hereby certify that the above document was prepared in Microsoft Word using 14-point Times New Roman font.

CERTIFICATE OF SERVICE

I hereby certify that the above document was electronically filed using the CM/ECF system and was served upon counsel of record via electronic mail on this 8th day of May, 2017.

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