UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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ENZYMOTEC LTD.,

Plaintiff,

-against-

MEMORANDUM OF DECISION AND ORDER
08-CV-2627 (ADS)(ETB)

NBTY, INC.,

Defendant.

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APPEARANCES:

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SPATT, District Judge.

The plaintiff Enzymotec Ltd. ("Enzymotec") commenced this action against defendant NBTY, Inc. ("NBTY") alleging, among other things, that NBTY violated 15 U.S.C. 1125(a) (the

"Lanham Act") by misrepresenting the character, nature, and quality of certain NBTY products. In an order dated December 7, 2010, the Court granted NBTY's motion for partial summary judgment dismissing the Lanham Act claim, finding that Enzymotec lacked standing to assert the claim. Presently before the Court is a motion for reconsideration by Enzymotec pursuant to Local Rule 6.3. For the reasons set forth below, Enzymotec's motion for reconsideration is denied.

I. BACKGROUND

The relevant facts in this case are set forth in detail in the Court's previous decision in this matter. See Enzymotec Ltd. v. NBTY, Inc., 754 F. Supp. 2d 527 (E.D.N.Y. 2010) ("Enzymotec I"). Familiarity with that decision is assumed, and the Court here only briefly outlines the pertinent background in this case and the Court's holding in Enzymotec I.

The plaintiff, Enyzmotec Ltd., is a privately-owned Israeli company that produces, among other things, phosphatidylserine ("PS"), as well as soft-gel capsules containing PS, which it sells to wholesalers, distributors, and retailers. The defendant, NBTY, Inc., is a manufacturer, marketer, and distributor of nutritional supplements, including a product called Neuro-PS and its in-store brand formulations (collectively "Neuro-PS"), which contains as a principal ingredient PS-20 (material containing twenty percent PS by weight). On July 1, 2008, Enzymotec brought an action against NBTY alleging, among other things, that NBTY violated the Lanham Act by misrepresenting the character, nature, and quality of its product because the label on Neuro-PS stated that it contained 100 milligrams of PS-20 when NBTY knew it contained a lower quantity of PS-20 .

In Enzymotec I, the Court granted NBTY partial summary judgment and dismissed the Lanham Act claim on the ground that Enzymotec lacked standing. In its motion for summary

judgment, NBTY argued that Enzymotec lacked standing to assert a claim against them for mislabeling under the Lanham Act because Enzymotec could not meet the two-pronged standing requirement, namely: "(1) a reasonable interest to be protected against the alleged false advertising and (2) a reasonable basis for believing that the interest is likely to be damaged by the alleged false advertising." Famous Horse Inc. v. 5th Ave. Photo Inc., 624 F.3d 106, 113 (2d Cir. 2010). With regard to the first prong of the test, the Court found that Enzymotec had a "reasonable interest to be protected" because of its status as "a commercial actor with a pecuniary interest potentially affected by the false advertising." Enzymotec I, 754 F. Supp. 2d at 542. However, the Court ultimately held that Enzymotec had failed to raise an issue of fact with respect to the reasonable basis requirement.

"The 'reasonable basis' prong embodies a requirement that the plaintiff show both likely injury and a causal nexus to the false advertising." Ortho Pharm. Corp. v. Cosprophar, Inc., 32 F.3d 690, 694 (2d Cir.1994). In addition, "[a] reasonable basis to believe the likelihood of injury for purposes of Lanham Act standing also requires that the injury not be speculative" and "[i]n order to show an injury is not speculative, a plaintiff must provide evidence of a causal connection between the alleged mislabeling and the potential injury." Enzymotec I, 754 F. Supp. 2d at 547. Enzymotec asserted that it was injured by NBTY's alleged mislabeling because, had NBTY recalled the mislabeled products and discontinued selling additional mislabeled products, it would have resulted in a void in the market. Based on its market share and the alleged supply agreement with NBTY, Enzymotec argued that it would have experienced an increase in sales to meet the demand created by the void in the market. The Court referred to this theory of damages based on injury resulting from loss of increased sales revenue as the "recall theory" of damages.

Ultimately, the Court held that Enzymotec lacked standing because the purported causal link between the mislabeling and its alleged injury—a void in the marketplace caused by the mislabeling—was too "hypothetical." Specifically, the Court stated:

> However, the Court ultimately finds that the recall theory is unsustainable because Enzymotec has offered no evidence to support the causal connection between its "reasonable interest" and the potential injury, namely that a recall should have occurred. To establish the causal connection Enzymotec needed to show the recall was more than "hypothetical," meaning that NBTY had either represented that it would recall the mislabeled products, or that a recall was required by a rule or regulation. Enzymotec only states that it "thought" a recall would have been NBTY's proper course of action once it learned that its product has less than 20% PS, and that once that recall occurred, the result would have been a substantial void in the market that would likely have been filled, at least in part, by Enzymotec. (Opp. Br. at 14.) In addition, the factual allegations in the complaint that mention a potential recall also indicate Enzymotec's expectation of a recall as opposed to alleging an agreement by NBTY to recall the product. (PAC ¶¶ 61, 110.)
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> In fact, the evidence provided by Enzymotec indicates that NBTY never agreed to a recall, and never stated that it would recall non-conforming products. Enzymotec discussed the recall, not NBTY. For example, in a May 2, 2006 letter from Enzymotec's counsel Michael C. Foley to NBTY's CEO and President Harvey Kamil, Foley stated that "[i]f NBTY really acquired Enzymotec's knowledge and know how in order to ascertain a problem with its current supplies of PS20, it would have taken steps to recall its product once it determined they did not conform." (Horowitz Decl., Ex. H at 2.) Furthermore, Enzymotec does not allege that NBTY agreed to recall non-conforming PS-20, but rather that NBTY had agreed that "it would stop purchasing from Lipogen and switch to Enzymotec as its exclusive supplier of PS-20." (Katz Decl. ¶ 6.) Moreover, Enzymotec does not cite any rule or regulation that would have required NBTY to recall the products rather than take some other action to cure the alleged problem.

Id. at 548–49. Enzymotec now moves pursuant to Local Rule 6.3 for reconsideration.

II. DISCUSSION

Enzymotec contends that reconsideration is proper because the Court "overlooked" its argument in opposition to summary judgment that NBTY "continued to sell its mislabeled product in clear violation of the law". (Pl.'s Br. at 1.) Enzymotec identifies the "law" that NBTY was allegedly violating as the Dietary Supplement Health and Education Act ("DSHEA"), which is part of the Federal Food Drug and Cosmetic Act ("FDCA"). The FDCA governs the regulation of food—including certain dietary supplements—drugs, cosmetics, and tobacco products. 21 U.S.C. §301 et seq.; see also 21 U.S.C. § 321(ff) (defining the dietary supplements subject to the regulations). In particular, the FDCA prohibits the "manufacture . . . of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(g). A nutritional supplement is considered "misbranded" under the DSHEA when it "fails to have the identity and strength that the supplement is represented to have" or "fails to meet the quality (including tablet and capsule disintegration), purity, or compositional specifications, based on a validated assay or other appropriate methods, that the supplement is represented to meet." Id. at §343(s)(E)(ii).

Assuming Enzymotec's allegations about the instability and nonconformity of the PS-20 in Neuro-PS in late 2005 and early 2006 are true, then Neuro-PS could qualify as "misbranded" under the DSHEA. Thus, under Enzymotec's interpretation of the statute, the DSHEA would have required NBTY to stop selling Neuro-PS. Therefore, Enzymotec contends that the Court should grant its motion for reconsideration and deny NBTY's motion for partial summary judgment on the Lanham Act claim because the DSHEA requirement that NBTY discontinue selling the mislabeled Neuro-PS is sufficient evidence that the causal link between the mislabeling and its injury is not hypothetical.

A motion for reconsideration in the Eastern District of New York is governed by Local Rule 6.3. "The standard for granting such a motion is strict, and reconsideration will generally be denied unless the moving party can point to controlling decisions or data that the court overlooked—matters, in other words, that might reasonably be expected to alter the conclusion reached by the court." Shrader v. CSX Transp., Inc., 70 F.3d 255, 257 (2d Cir. 1995). "The major grounds justifying reconsideration are an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice." Virgin Atl. Airways, Ltd. v. Nat'l Mediation Bd., 956 F.2d 1245, 1255 (2d Cir. 1992) (internal quotation marks omitted).

Of importance, a motion for reconsideration is not an opportunity for litigants to reargue their previous positions or present new or alternative theories that they failed to set forth in connection with the underlying motion. See Trans-Pro Logistic Inc. v. Coby Elecs. Corp., No. 05-CV-1759, 2010 WL 4065603, at *1 (E.D.N.Y. Oct. 15, 2010) (citing Ferrand v. Credit Lyonnais, 292 F. Supp. 2d 518, 520 (S.D.N.Y. 2003)); see also Zdanok v. Glidden Co., Durkee Famous Foods Div., 327 F.2d 944, 953 (2d Cir. 1964) ("[W]here litigants have once battled for the court's decision, they should neither be required, nor without good reason permitted, to battle for it again."). Indeed, Rule 6.3 should be "narrowly construed and strictly applied so as to avoid repetitive arguments on issues that have already been considered fully by the court" and is considered an "extraordinary remedy to be employed sparingly in the interests of finality and conservation of scarce judicial resources." Trans-Pro Logistic Inc., 2010 WL 4065603 at *1 (internal quotation marks omitted).

Ultimately, the decision as to whether to grant a motion for reconsideration rests within the sound discretion of the district court. Kapsis v. Bloom, No. 08-CV-3092, 2009 WL 414001,

at *1 (E.D.N.Y. Feb. 17, 2009). As set forth below, the Court finds that Enzymotec has failed to show that it is entitled to this "extraordinary remedy". In addition, the Court finds that even if it reconsidered the "overlooked" argument, it would not alter the Court's holding in Enzymotec I granting NBTY partial summary judgment dismissing the Lanham Act claim.

First, although in support of the instant motion Enzymotec highlights numerous statements in its summary judgment motion papers where it raised the argument that NBTY improperly "continued to sell" Neuro-PS, Enyzmotec does not cite a single instance—nor can the Court find any reference—to an assertion that NBTY's continued sale of Neuro-PS was "in clear violation of the law." Rather, Enzymotec consistently stated that NBTY should have "*act[ed] responsibly* by recalling the mislabeled product and not introducing additional mislabeled product onto the market". (See Pl.'s SJ Opp. 1, 14 (emphasis added).) Because the arguments that NBTY's continued sale of Neuro-PS was "in clear violation of the law" and specifically the DSHEA are "entirely new to the annals of this protracted litigation", they are improperly raised on a motion for reconsideration. See Koehler v. Bank of Berm. Ltd., No. M18-302, 2005 WL 1119371, at *1 (S.D.N.Y., May 1, 2005) (denying a motion for reconsideration because the movant's argument on reconsideration centered principally on a statute which the movant failed to raise in connection with the underlying motion).

Furthermore, the fact that the Court referred to Enzymotec's theory of damages as the "recall theory" does not mean that the Court did not address Enzymotec's argument that NBTY should have stopped selling Neuro-PS. Indeed, in Enzymotec I, the Court characterized Enzymotec's theory of damages by stating: "Enzymotec alleges that it made NBTY aware of the deficiency in late 2005, and that NBTY *nevertheless continued to sell* the products without disclosing the problem to its customers and recalling the product." Enzymotec I, 754 F. Supp. 2d

at 540 (emphasis added) (internal quotation marks omitted). While phrased differently, both Enzymotec's contention that NBTY failed to recall the mislabeled product—*i.e.*, remove Neuro-PS already on the shelves at retailers—as well as Enzymotec's assertion that NBTY should have ceased selling the product—*i.e.*, stop selling and shipping *new* orders of Neuro-PS, were offered for the same purpose: to show that the resulting void in the market was the requisite causal connection between the alleged mislabeling and the potential injury to Enzymotec.

Although the Court predominantly discussed Enzymotec's theory of damages in terms of recalling existing products, the Court's analysis is equally applicable to the argument that NBTY would have had to stop selling Neuro-PS. Whether the void in the market was created by removing existing products from the shelves, or by not placing new products on the shelves, the likelihood that a void would have occurred and subsequently would have resulted in an increase in Enzymotec's sales is simply too speculative to raise a genuine issue of fact as to whether Enzymotec can meet the "reasonable basis" requirement for Lanham Act standing. The Court's decision in Enzymotec I sufficiently addressed, and rejected, the argument that NBTY should have "stopped selling" Neuro-PS, and therefore it cannot serve as a basis for reconsideration. See Williams v. County of Nassau, No. 03-CV-6337, 2011 WL 1240699, at *3 (E.D.N.Y. Mar. 30, 2011) ("Defendants' argument in support of reconsideration … reflects either a misreading of the [original order], which clearly and adequately addressed the issue of causation, or is an attempt to take 'a second bite at the apple.'" (quoting Sequa Corp. v. GBJ Corp., 156 F.3d 136, 144 (2d Cir. 1998))).

Moreover, it is apparent to the Court that Enzymotec's motion for reconsideration is premised on a misinterpretation of the Court's holding in Enzymotec I. In discussing the deficiency in Enzymotec's recall theory of damages, the Court stated that "[t]o establish the

causal connection Enzymotec needed to show the recall was more than 'hypothetical,' meaning that NBTY had either represented that it would recall the mislabeled products, or that a recall was *required by a rule or regulation*." Enzymotec I, 754 F. Supp. 2d at 548 (emphasis added). Based on the emphasized language, Enzymotec found what it believed to be an applicable regulation that, while not requiring a recall, allegedly required NBTY to stop selling mislabeled Neuro-PS. Because Enzymotec admittedly did not raise the existence of the DSHEA in opposition to the motion for summary judgment, it attempts to weave it into a motion for reconsideration by claiming it is simply "directing the Court to the statute" that supports the "overlooked" argument that NBTY should have stopped selling its mislabeled product. (Pl.'s Reply Mem. at 3.)

Contrary to Enzymotec's characterization, the Court did not reject Enzymotec's theory of damages *because* it did not put forth a rule or regulation. Rather, the Court found that Enzymotec failed to show that the purported causal link between the mislabeling and its alleged injury—a void in the marketplace caused by the mislabeling—was more than "hypothetical." Although the Court noted that the existence of an agreement to recall between NBTY and Enzymotec, or a rule or regulation requiring a recall *could potentially* raise the argument beyond speculation, this was not equivalent to a holding that the mere existence of an agreement, rule, or regulation would create a genuine issue of fact sufficient to defeat a motion for summary judgment. In fact, as the Court noted in Enzymotec I, a rule or regulation might be sufficient to show that the injury was not speculative if it *required* NBTY to remove the allegedly mislabeled product from the shelves "*rather than take some other action to cure the alleged problem.*" Enzymotec I, 754 F. Supp. 2d at 549 (emphasis added).

As NBTY notes in opposition to the instant motion the DSHEA does not create a mandatory, self-imposed requirement that supplement manufacturers cease selling mislabeled products. Moreover, although one penalty for a DSHEA violation is injunctive relief, see 21 U.S.C. § 332, it is not the exclusive remedy. In fact, there are a number of potential penalties for DSHEA violations that do not involve recalling or discontinuing sales. See, e.g., 21 U.S.C. § 333(a) (criminal penalties); United States v. Rx Depot, Inc., 438 F.3d 1052, 1058 (10th Cir. 2006) (disgorgement of profits); United States v. Lane Labs-USA Inc., 427 F.3d 219, 223 (3d Cir. 2005) (payment of restitution to customers). Accordingly, even if Enzymotec could prove a violation of the DSHEA that statute does not necessarily cure the deficiency in Enzymotec's standing to assert the Lanham Act claim.

However, it is unnecessary for the Court to consider the impact of the alleged DSHEA violation on Enzymotec's Lanham Act standing because there is no private right of action under the DSHEA. See NVE, Inc. v. Dep't of Health & Human Servs., 436 F.3d 182, 189 (3d Cir. 2006). As previously stated, the DSHEA is a part of the FDCA. Congress delegated the responsibility for administering the FDCA to the Food and Drug Administration ("FDA"). 21 U.S.C. §371; see generally 21 C.F.R. §111 et seq. The Court is cognizant of the fact that Enzymotec is not attempting to gain standing to prosecute NBTY for violating the DSHEA. Rather, Enzymotec seeks to satisfy the standing requirement for a Lanham Act claim based on NBTY's alleged violation of the DSHEA. However, "[b]ecause the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation." PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 924 (9th Cir. 2010).

Accordingly, given that the FDA has not concluded that NBTY violated the FDCA by mislabeling Neuro-PS, Enzymotec's cannot gain Lanham Act standing by attempting to privately enforce the FDCA. See PDK Labs, Inc. v. Friedlander, 103 F.3d 1105, 1113 (2d Cir. 1997) (holding "that Friedlander lacks standing to sue PDK under § 43(a) of the Lanham Act" because "Friedlander's dogged insistence that PDK's products are sold without proper FDA approval suggests … that Friedlander's true goal is to privately enforce alleged violations of the FDCA."); Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993) (holding that because the appellant may not independently enforce the FDCA, it also may not use the Lanham Act "as a vehicle by which to enforce the [FDCA]"); Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 230 (3d Cir. 1990) (holding that a Lanham Act false labeling claim does not exist against a manufacturer who failed comply with the FDCA's labeling requirements).

III. CONCLUSION

For the above stated reasons, it is hereby:

ORDERED, that Enzymotec's motion for reconsideration is denied.

Dated: Central Islip, New York
June 29, 2011

/s/ Arthur D. Spatt
ARTHUR D. SPATT
United States District Judge