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

SCIELE PHARMA, INC.,

Plaintiff,

v.

BROOKSTONE PHARMACEUTICALS, LLC a/k/a ACELLA PHARMACEUTICALS, LLC

Defendant.

CIVIL ACTION NO.
1:09-CV-3283-JEC

ORDER AND OPINION

This case is presently before the Court on plaintiff's Motion for a Preliminary Injunction [9], defendant's Motion for a Continuance [46], defendant's Motion to Dismiss [49], plaintiff's Motions for Changes in Confidentiality Designations [68] and [115], plaintiff's Motion to Dismiss Defendant's Counterclaim [75], plaintiff's Motion for a Special Setting [86], plaintiff's Motions to Seal [89], [101], [114], and [123], plaintiff's Motion to Amend [90], defendant's Second Motion to Dismiss [92], plaintiff's Motion for Leave to File a Sur-reply [93], defendant's Motion to Quash [120], defendant's Motion to File Supplemental Authority [127], and plaintiff's Supplemental Motion to Seal its Response to Defendant's Notice of Status of the Case [133].

The Court has reviewed the record and the arguments of the parties and, for the reasons set out below, concludes that plaintiff's Motion for a Preliminary Injunction [9] should be **DENIED**, defendant's Motion for a Continuance [46] should be **GRANTED**, defendant's Motion to Dismiss [49] should be **DENIED**, plaintiff's Motions for Changes in Confidentiality Designations [68] and [115] should be **GRANTED**, plaintiff's Motion to Dismiss Defendant's Counterclaim [75] should be **DENIED**, plaintiff's Motion for a Special Setting [86] should be **DENIED as moot**, plaintiff's Motions to Seal [89], [101], [114], and [123] should be **GRANTED as unopposed**, plaintiff's Motion to Amend [90] should be **GRANTED**, defendant's Second Motion to Dismiss [92] should be **DENIED**, plaintiff's Motion for Leave to File a Sur-reply [93] should be **GRANTED**, defendant's Motion to Quash [120] should be **GRANTED**, defendant's Motion to File Supplemental Authority [127] should be **GRANTED**, and plaintiff's Supplemental Motion to Seal [133] should be **GRANTED**.

BACKGROUND

This is a Lanham Act case. Plaintiff Sciele Pharm, Inc. ("Sciele") is a pharmaceutical company that develops and sells branded prescription products, including the prenatal vitamins PRENATE ELITE and PRENATE DHA. (Compl. [1] at ¶¶ 9-10.) Defendant Brookstone Pharmaceuticals, LLC ("Brookstone") is a pharmaceutical company that develops and sells generic pharmaceuticals. (*Id.* at ¶

24.) Sometime in 2009, defendant developed a line of prescription prenatal vitamins known as PNV and PNV-DHA. (*Id.* at ¶¶ 26-27.) PNV and PNV-DHA compete with PRENATE ELITE and PRENATE DHA in the prescription prenatal vitamin market. (*Id.* at ¶ 37.)

Folate is one of the most important nutrients found in prenatal vitamins. (*Id.* at ¶ 11.) Most prenatal vitamins contain only folic acid, a synthetic form of folate that must be metabolized by the body. (Compl. [1] at ¶ 11.) Some women are unable to metabolize folic acid into its active form because of a common genetic mutation. (*Id.*) A distinctive feature of PRENATE vitamins is that they contain a 1 mg combination of 400 mcg of folic acid and 600 mcg of L-Methylfolate ("L-MTHF"), a natural, bioactive form of folate that is directly usable by the body without additional metabolism. (*Id.* at ¶ 12.) The inclusion of L-MTHF in PRENATE vitamins ensures that all women are provided with the full benefits of folate. (*Id.*)

Defendant's labels and package inserts represent that PNV vitamins contain the same 1 mg folate combination of 400 mcg of folic acid and 600 mcg of L-MTHF. (*Id.* at ¶ 28.) However, plaintiff claims that PNV vitamins do not contain L-MTHF, but a different dietary ingredient known as D,L-MTHF. (Compl. [1] at ¶ 32.) While L-MTHF is comprised almost entirely of the L-isomer of MTHF, D,L-MTHF contains an equal (or "racemic") mixture of the L-isomer and the D-isomer of MTHF. (*Id.* at ¶ 34.) D,L-MTHF is recognized by the FDA and the dietary supplement industry as a distinct dietary ingredient.

(*Id.* at ¶¶ 33-35.) In addition, the presence of the D-isomer of MTHF is potentially harmful to women who take prescription prenatal vitamins, as it may compete with the uptake and the activity of L-MTHF. (*Id.* at ¶ 20.) Thus, plaintiff contends that the labels and package inserts for PNV vitamins are literally false and likely to deceive consumers as to the contents of the product. (*Id.* at ¶¶ 41-42.)

Plaintiff argues, further, that defendant's labels and commercial advertising are likely to mislead pharmacists and others in the pharmaceutical distribution chain. (Compl. [1] at ¶ 40.) When two prescription products contain the same doses of identical ingredients, they become "linked" in various pharmaceutical databases. (*Id.* at ¶ 37.) Linkage between two products leads pharmacists to believe that the products are interchangeable. (*Id.*) Pharmacists are permitted, and even incentivized, to fill prescriptions with a less expensive linked product. (*Id.* at ¶¶ 37, 44.) PNV vitamins are less expensive than PRENATE vitamins and, as a result of defendant's allegedly inaccurate labels and advertising, PNV vitamins have been linked with PRENATE vitamins in the major pharmaceutical databases. (*Id.* at ¶¶ 38, 40.) Thus, plaintiff contends that pharmacists are likely to fill prescriptions for PRENATE vitamins with PNV, even though the two products actually contain different ingredients. (Compl. [1] at ¶ 40.)

Plaintiff filed this lawsuit in an effort to prevent what it regards as the improper substitution of PNV vitamins for PRENATE vitamins. (*Id.* at ¶ 96.) In its complaint, plaintiff asserts claims under the Lanham Act for false advertising and unfair competition. (*Id.* at ¶¶ 53-73.) Plaintiff also asserts a state law claim under the Georgia Uniform Deceptive Practices Act. (*Id.* at ¶¶ 82-88.) In its request for relief, plaintiff seeks money damages, and an injunction permanently prohibiting defendant from representing that PNV vitamins contain L-MTHF, or that PNV vitamins are equivalent to or interchangeable with PRENATE vitamins. (*Id.* at 26-29.)

In conjunction with its complaint, plaintiff filed a motion for a preliminary injunction. (Pl.'s Mot. for Preliminary Injunction [9] at 2.) The Court held a hearing on the motion on December 15, 2009. (Minute Entry [23].) During the hearing, defendant raised the issue of FDCA preclusion as a grounds for dismissal of plaintiff's complaint. (*Id.*) The Court instructed defendant to file a motion to dismiss on preclusion grounds, which it has done. (Def.'s Mot. to Dismiss [49].) That motion, as well as a second motion to dismiss on alternative grounds and plaintiff's original motion for a preliminary injunction, are all presently before the Court. (*See* Def.'s Second Mot. to Dismiss [92].)

Since the preliminary injunction hearing, both parties have filed numerous motions on other matters. Those motions include plaintiff's motion for changes in confidentiality designations [68]

and [115], plaintiff's motion to dismiss defendant's counterclaim [75], defendant's motion to quash certain discovery requests [120], and plaintiff's motion to amend its complaint [90]. All of those motions are also presently before the Court.

DISCUSSION

I. Plaintiff's Motion for a Preliminary Injunction

Plaintiff is only entitled to a preliminary injunction if it can show: (1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable injury if the injunction is not granted, (3) that the threatened injury to plaintiff outweighs the harm an injunction might cause defendant, and (4) that granting the injunction is not contrary to the public interest. *N. Am. Med. Corp. v. Axiom Worldwide, Inc.*, 522 F.3d 1211, 1217 (11th Cir. 2008). "'[A] preliminary injunction is an extraordinary and drastic remedy not to be granted unless the movant clearly establish[es]'. . . all four elements." *CBS Broad., Inc. v. Echostar Commc'n Corp.*, 265 F.3d 1193, 1200 (11th Cir. 2001).

As mentioned, the Court held a hearing on plaintiff's motion for a preliminary injunction on December 15, 2009. (Minute Entry [23] and Hearing Tr. [24].) At the hearing, the Court heard testimony from several witnesses, in addition to argument from the parties. (*Id.*) At the end of the hearing, the Court found that plaintiff had not presented any evidence that it would suffer irreparable harm in the absence of an injunction. (*Id.*) Indeed, the evidence adduced at

the hearing showed that any harm resulting from defendant's Lanham Act violations is easily quantified, and compensable by monetary damages. Accordingly, the Court **DENIES** plaintiff's motion for a preliminary injunction.

II. Defendant's Motions to Dismiss

A. Standard

In deciding a motion to dismiss, the Court assumes that all the allegations in the complaint are true and construes all the facts in favor of the plaintiff. *Scott v. Taylor*, 405 F.3d 1251, 1253 (11th Cir. 2005). That said, a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Bell Atl. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim has "facial plausibility" when it contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

B. FDCA Preclusion

Prescription vitamins are subject to regulation by the FDA pursuant to the Food, Drug, and Cosmetic Act ("FDCA"). *See* 21 U.S.C. §§ 321(ff)(1)(A), 343(a). Specifically, the FDA has broad authority under the FDCA to determine whether dietary supplements such as prenatal vitamins are misbranded, or accompanied by labeling that is "false or misleading." *Id.* The FDCA does not provide for a private cause of action to enforce its provisions. *Adventure Outdoors, Inc.*

v. Bloomberg, 552 F.3d 1290, 1295 (11th Cir. 2008). Rather, enforcement actions must be initiated by the Government. 21 U.S.C. § 337(a).

Plaintiff's claims do not arise under the FDCA, but under the Lanham Act. The Lanham Act creates a private cause of action to redress injury resulting from false or misleading statements about a product. *N. Am. Med. Corp.*, 522 F.3d at 1224. Plaintiff need not invoke any provision of the FDCA to prevail on its Lanham Act claim. Instead, plaintiff merely needs to show that: (1) defendant made false or misleading statements about its product, (2) the statements deceived, or were likely to deceive, the targeted audience, (3) the deception was material, and (4) plaintiff has been or is likely to be injured as a result of the statements.[1] *Id.*

Nevertheless, courts have recognized that there is some tension between the FDCA and the Lanham Act in cases involving products that are subject to regulation under the FDCA. To that end, courts have not permitted plaintiffs to use the Lanham Act as a vehicle to enforce the FDCA. *See Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3rd Cir. 1990)(precluding a Lanham Act claim based on the labeling of an ingredient as "inactive" when FDA standards suggested that the ingredient was "active"). Courts have also precluded Lanham Act labeling claims that "stray 'too close to the

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[1] There is also an interstate commerce element of a Lanham Act claim, but that element is not presently at issue. *N. Am. Med. Corp.*, 522 F.3d at 1224.

exclusive enforcement domain of the FDA.'" *Graceway Pharm. LLC v. River's Edge Pharm., LLC,* 2009 WL 3753586 at *6-7(N.D. Ga. 2009)(Story, J.)(quoting *Summit Tech., Inc. v. High-Line Med. Instruments Co., Inc.*, 922 F. Supp. 299, 306 (D. Cal. 1996)). *See also POM Wonderful LLC v. Ocean Spray Cranberries, Inc.* 642 F. Supp. 2d 1112, 1118 (D. Cal. 2009)(noting that Lanham Act claims are barred when they require the district court to determine preemptively how the FDA will interpret its regulations).

According to defendant, courts distinguish between implied and express misrepresentations to determine whether a Lanham Act claim "strays too close" to the FDCA. (Def.'s Mem. in Supp. of Mot. to Dismiss ("Def.'s Mem.") [49] at 9-12.) Specifically, defendant contends that courts generally allow FDCA-related Lanham Act claims to proceed if they are based on an express misrepresentation, but preclude such claims if they are based on an implied misrepresentation. (*Id.*) Defendant suggests that plaintiff's Lanham Act claims are dependent upon the implied misrepresentation that defendant's vitamins are approved generics for, or are pharmaceutically and/or therapeutically equivalent to, plaintiff's vitamins. (*Id.* at 17.) Thus, applying the implied/express distinction, defendant argues that plaintiff's claims are precluded. (*Id.*)

As an initial matter, the Court does not agree that plaintiff's claims are based on an implied misrepresentation. In support of its

Lanham Act claim, plaintiff alleges that defendant has represented on the label and package inserts that PNV vitamins contain 600 mcg of L-MTHF, when in fact PNV vitamins contain 1200 mcg of D,L-MTHF. (Compl. [1] at ¶¶ 28-32.) Contrary to defendant's argument, no implication is necessary to adjudicate a claim based on that allegation. Assuming the allegation is true, as the Court must at this juncture, defendant's labels and package inserts include an express, and literally false, statement about the contents of PNV vitamins.

In any case, the Court rejects the implied/express distinction for purposes of FDCA preclusion. In determining whether a claim is precluded by the FDCA, most courts have focused not on the nature of the expression at issue, but on the extent to which the plaintiff relies on the FDCA as a basis for its claim or, alternatively, the extent to which the claim would require the Court to interpret or apply the FDCA or FDA regulations. *See Graceway,* 2009 WL 3753586 at *6 ("courts have been wary of allowing Lanham Act claims where determining the falsity of the representation at issue would require the court to interpret and apply the regulatory and statutory provisions of the FDCA") and *Alpharma, Inc. v. Pennfield Oil Co.,* 411 F.3d 934, 939 (8th Cir. 2005)("this is not the rare case requiring 'expert consideration and uniformity of resolution'")(quoting *United States v. McDonnell Douglas Corp.,* 751 F.2d 220, 224 (8th Cir.

1984)).[2]

Plaintiff does not rely extensively on the FDCA or FDA regulations in support of its Lanham Act claims. Again, plaintiff's central claim is that defendant is representing to consumers and pharmacists that its vitamins contain L-MTHF, when they actually contain D,L-MTHF. (Compl. [1] at ¶¶ 28-32.) Plaintiff notes in its complaint that the FDA has recognized D,L-MTHF as a different dietary ingredient than L-MTHF. (*Id.* at ¶ 33.) However, at the preliminary injunction hearing, plaintiff cited other industry and market evidence tending to show that D,L-MTHF is not the same ingredient as L-MTHF. (Hearing Tr. [24].) *See Axcan Scandipharm, Inc. v. Ethex Corp.*, 585 F.Supp. 2d 1067, 1074-76 (D. Minn. 2007)(allowing a Lanham Act claim to proceed where the plaintiff offered evidence of the generally understood meaning of the terms "substitute" and "generic") and *Sirius Lab., Inc. v. Rising Pharm., Inc.*, 2004 WL 2902227 at * 3 (N.D. Ill. 2004)(finding no preclusion where the plaintiff's claim could be resolved by relying on a USP standard for the product).

Neither does plaintiff's claim require the Court to interpret or apply any provision of the FDCA or any FDA regulation. According to plaintiff, the definition of L-MTHF, and its distinction from D,L-MTHF, is well-established in science and well-accepted in the market.

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[2] *See also Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.*, 388 F.Supp. 2d 967, 975 (E.D. Wis. 2005)(allowing the plaintiff to proceed on its Lanham Act claims "to the extent that it is not seeking the interpretation or direct application of any FDA regulation").

(Pl.'s Resp. to Def.'s Mot. to Dismiss [80] at 30.) Thus, plaintiff credibly argues that the standard for L-MTHF can, and will, be proven without reference to the FDCA. (*Id.* at 25.) *See POM Wonderful*, 642 F. Supp. 2d at 1118 (defining the key issue in a preclusion case as whether the false advertising involves a fact that can be verified without any action by the FDA) and *Pediamed Pharm., Inc. v. Breckenridge Pharm., Inc.*, 419 F. Supp. 2d 715, 725-26 (D. Md. 2006)(distinguishing between claims that involve application and interpretation of the FDCA and claims that do not).

In resolving the tension between the FDCA and the Lanham Act, courts strive to give as much effect as possible to both statutes. *Schering-Plough Healthcare Prod., Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 507 (7th Cir. 2009). Courts have been careful to prevent plaintiffs from using the Lanham Act as a back door to enforce the FDCA, and hesitant to issue rulings that would determine preemptively how the FDA will interpret the FDCA and its implementing regulations. *See POM Wonderful*, 642 F.Supp. 2d at 1118. On the other hand, courts have been loathe to apply the FDA's administrative scheme so as to eviscerate the Lanham Act in cases that happen to involve products regulated by the FDCA. *Id.*

In short, the simple fact that a Lanham Act claim touches upon an area that is within the purview of the FDCA is not a bar to proceeding. *Id.* Yet, that is the only factor in favor of preclusion here. Moreover, the Lanham Act prohibits exactly the type of

misconduct that plaintiff alleges in its complaint: the misrepresentation and false description of the nature of a product. *N. Am. Med. Corp.*, 522 F.3d at 1224. Defendant has not presented a persuasive argument, or any controlling authority, for precluding plaintiff's claims.[3] Accordingly, defendant's motion to dismiss on the grounds of FDCA preclusion is **DENIED**.

C. Defendant's Disclaimers and Compliance with the Georgia Pharmacy Act

In its second motion to dismiss, defendant addresses the merits of plaintiff's Lanham Act claims. (Def.'s Mem. in Supp. of its Second Mot. to Dismiss [92].) Defendant contends that plaintiff cannot succeed on its Lanham Act claims because defendant has complied with Georgia law regarding pharmaceutical substitution. (*Id.* at 2-3.) Defendant also suggests that certain disclaimers used in conjunction with its products insulate it from liability under the Lanham Act. (*Id.* at 3.)

As to the first argument, Georgia is a "pharmaceutical equivalence" state. *See* O.C.G.A. §§ 26-4-81(a) and 26-4-5(27). This

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[3] In reaching this decision, the Court has considered the supplemental authority provided by defendant in support of its motion to dismiss, including *Graceway Pharm., LLC v. River's Edge Pharm., LLC*, 2010 WL 2036492 (11th Cir. May 25, 2010) and *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 922-23 (9th Cir. 2010). Both cases simply confirm what the Court already has recognized: Lanham Act claims are precluded when they are based on an FDCA violation or rely too heavily on the FDCA or its implementing regulations. *Graceway*, 2009 WL 3753586 at *6 (affirmed in an unpublished per curiam opinion in *Graceway*, 2010 WL 2036492) and *PhotoMedex*, 601 F.3d at 924.

means that substitution is permitted when two products have the same active ingredients, although they may not have the same inactive ingredients. *Id.* Defendant contends that PNV vitamins contain the same active ingredient as PRENATE: L-MTHF. (Def.'s Mem. in Supp. of its Second Mot. to Dismiss [92] at 2-3.) According to defendant, it is irrelevant, in a pharmaceutical equivalence state, that PNV contains more of the inactive ingredient D-MTHF. (*Id.*) Thus, defendant concludes, its labeling of PNV cannot be regarded as false or misleading, because PNV is legally substitutable for PRENATE in Georgia and in other states with similar pharmacy laws. (*Id.*)

To grant defendant's motion to dismiss on the above theory, the Court would have to accept as true defendant's claim that PNV and PRENATE contain the same active ingredient. Depending on the evidence that is adduced during discovery, that claim may ultimately be proven to be accurate. However, at the motion to dismiss stage, the Court must accept plaintiff's allegations as true. The crux of plaintiff's complaint is that PNV vitamins contain D,L-MTHF, a different and entirely distinct ingredient than the L-MTHF that is contained in PRENATE vitamins. (Compl. [1] at ¶¶ 28-32.) Assuming that is true, PNV is not legally substitutable for PRENATE in Georgia and other pharmaceutical equivalence states. More to the point, and regardless of Georgia pharmacy law, if plaintiff's allegations are true then defendant is misrepresenting that its product contains L-MTHF when it actually contains D,L-MTHF. That misrepresentation is

unquestionably actionable under the Lanham Act. *See N. Am. Med. Corp.*, 522 F.3d at 1224.

With regard to the disclaimer argument, defendant points out that its labels and package inserts do not refer to PNV as a generic for PRENATE. (Def.'s Mem. in Supp. of its Second Mot. to Dismiss [92] at 7.) Further, defendant cites specific language on its inserts stating that PNV has not been subjected to FDA therapeutic equivalency or other equivalency testing, and indicating that all substitutions of PNV for PRENATE are "subject to state and federal statutes as applicable." (*Id.*) Given the disclaimers, defendant argues that consumers and pharmacists cannot possibly be deceived by the PNV label and package inserts: an essential element of plaintiff's Lanham Act claim. (*Id.* at 8.)

The Court agrees with plaintiff that the disclaimer issue is more appropriately resolved on a motion for summary judgment or at trial. Plaintiff contends that defendant's disclaimers are inadequate, and that they were not intended to, and in fact did not, ensure that pharmacists and consumers received accurate information about defendant's product. (Pl.'s Resp. to Def.'s Second Mot. to Dismiss [98] at 17-20.) Even at this early stage in the litigation, there is some indication that plaintiff may be correct. (*Id.*) In any case, this issue cannot be resolved without a more fully developed record. Plaintiff has adequately alleged all of the

essential elements of a Lanham Act claim.[4] (Compl. [1] at ¶¶ 53-57, 66-73.) Accordingly, defendant's second motion to dismiss is **DENIED.**

III. Plaintiff's Motion to Dismiss Defendant's Counterclaim

In its amended answer to plaintiff's complaint, defendant asserts a counterclaim against plaintiff. (Amended Answer [37] at 20-27.) The counterclaim, in which defendant alleges that PNV vitamins are accurately and properly labeled, is essentially a mirror image of the complaint. (*Id.* at 24.) In the counterclaim, defendant seeks a declaratory judgment that its "accurate and truthful" labels for PNV do not violate federal or state law. (*Id.* at 26-27.) Plaintiff has filed a motion to dismiss or strike the counterclaim as "redundant." (Pl.'s Mot. to Dismiss or Strike Def.'s Counterclaim [75] at 6-13.)

The Court is at a loss to understand why plaintiff filed this motion. Even if the Court were to grant the motion, dismissing or striking defendant's counterclaim would provide no practical benefit to plaintiff whatsoever. In the counterclaim, defendant simply seeks a declaration that its label for PNV is "accurate and truthful" and that the label complies with federal and state law. Assuming that plaintiff prevails on its claims, defendant's request for such a declaration will be moot. On the other hand, if defendant prevails,

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[4] The same is true for plaintiff's contributory false advertising claim. (Compl. [1] at ¶¶ 58-65.) Defendant's motion to dismiss that claim is thus **DENIED.**

the requested declaratory relief will not impose any additional burden on plaintiff.

Whatever plaintiff's reason for expending resources on this purely academic motion, the motion is meritless. Rule 12(f) of the Federal Rules of Civil Procedure authorizes the Court to strike from a pleading "any redundant, immaterial, impertinent, or scandalous matter." FED. R. CIV. P. 12(f). However, motions to strike on any of the grounds enumerated in Rule 12(f) are disfavored. *See Manhattan Constr. Co. v. McArthur Elec., Inc.*, 2007 WL 295535 at *6 (N.D. Ga. 2007)(Duffey, J.)(noting that such motions are often considered to be "purely cosmetic or time wasters"). Courts generally deny such motions "unless the challenged allegations have no possible relation or logical connection to the subject matter of the controversy." *Id.*

Plaintiff concedes that the counterclaim is logically related to the subject matter of the controversy. (Pl.'s Reply in Supp. of Mot. to Dismiss or Strike [95] at 2.) Moreover, the counterclaim is not entirely redundant of the complaint, because defendant requests in the counterclaim a type of relief that would not necessarily be granted in the absence of the counterclaim. Specifically, defendant seeks in the counterclaim a declaratory judgment clarifying that the PNV label is accurate and truthful, and that it complies with federal and state law without the addition of any information concerning the D-MTHF that admittedly is contained in the product. (Def.'s Resp. to Pl.'s Mot. to Dismiss or Strike [88] at 7-8.) Accordingly,

plaintiff's motion to dismiss or strike defendant's counterclaim is **DENIED.**

IV. Plaintiff's Motion to Amend

Plaintiff has filed a motion to amend its complaint to assert claims against the manufacturers of PNV, Best Formulations ("Best") and Arizona Nutritional Supplements, Inc. ("Arizona"). (Pl.'s Mot. to Amend [90].) Defendant disclosed Best and Arizona as the manufacturers of PNV on December 29, 2009. (*Id.*) On January 15, 2010, defendant produced additional documents describing Best and Arizona's involvement in the PNV manufacturing process. (*Id.*) According to plaintiff, these documents show that Best and Arizona were aware of defendant's plan to falsely advertise and promote PNV vitamins, but that they continued to manufacture and supply PNV to defendant. (*Id.* at 3.) Consequently, plaintiff contends that Best and Arizona have "contributory liability" for the harm to plaintiff resulting from the false advertisement. (*Id.*)

Federal Rule 15(a) provides that leave to amend shall be "freely give[n] . . . when justice so requires." FED. R. CIV. P. 15(a)(2). Courts therefore generally grant leave unless there is a substantial reason to deny it. *Garfield v. NDC Health Corp.*, 466 F.3d 1255, 1270 (11th Cir. 2006)("'In the absence of any apparent or declared reason . . . the leave sought should, as the rules require, be freely given.'")(quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)). Denial of a motion to amend is an abuse of discretion in the absence of some

factor to justify the decision, such as "undue delay, undue prejudice to the defendants, [or] futility." *Carruthers v. BSA Adver., Inc.*, 357 F.3d 1213, 1218 (11th Cir. 2004).

There is no reason to deny leave in this case. Contrary to defendant's argument, plaintiff's motion to amend is timely. Plaintiff filed its motion within three months of filing its original complaint, and only a month after discovering documents that revealed the manufacturers' potential liability. (Pl.'s Mot. to Amend [90] at 2.) Further, there is no indication that the motion will unnecessarily delay the case or prejudice defendant. Although the case originally was on an expedited discovery and trial schedule, the Court expanded the time for discovery and continued the trial at defendant's request. (Order [67].) The parties now have, or can request, sufficient time to complete any additional discovery necessitated by the addition of Best and Arizona. Accordingly, plaintiff's motion to amend is **GRANTED**.

V. Plaintiff's Motion to Modify Confidentiality Designations

Prior to discovery, the parties entered into a consent protective order that was designed to protect trade secrets and other confidential information. (Pl.'s Mot. to Change Confidentiality Designations [68] at 2.) The protective order permits either party to designate information as confidential or highly confidential, and thus subject to limited disclosure. (*Id.*) Pursuant to the protective order, defendant designated the following information as

confidential: (1) the names of its manufacturers and suppliers, and (2) certain manufacturing records and communications with its suppliers demonstrating that PNV vitamins contain a racemic mixture of D-MTHF and L-MTHF. (*Id.* and Def.'s Second Mot. to Change Confidentiality Designations [115] at 4.) Plaintiff claims that neither category of information is confidential, and has filed motions to change defendant's confidentiality designation as to the identity of defendant's manufacturers and suppliers, as well as the referenced documents. (*Id.*)

As to the identity of the manufacturers and suppliers, defendant's confidentiality designation is moot, as a practical matter, as a result of plaintiff's amendment to its complaint to assert claims against Best and Arizona. In any case, the identity of product manufacturers and suppliers is not generally considered to be a trade secret. *See Panther Sys. II, Ltd. v. Panther Computer Sys., Inc.*, 783 F. Supp. 53, 70 (E.D.N.Y. 1991)("[i]n general, the identity of suppliers is not a trade secret entitled to protection since they can be readily learned in any productive industry") and *SI Handling Sys., Inc. v. Heisley*, 753 F.2d 1244, 1257 (3rd Cir. 1985)(reversing the district court's finding that the identity of suppliers was protectable as a trade secret).

Defendant asserts in a conclusory manner that it maintains a competitive advantage in the dietary supplement industry by keeping the identity of its suppliers confidential. (Def.'s Resp. to Pl.'s

Mot. to Change Confidentiality Designations [69] at 2.) However, plaintiff has produced evidence that the entities in question already have publicly accessible websites describing their activities as manufacturers of dietary supplements, including the ingredients used in the products they manufacture. (Pl.'s Mot. to Change Confidentiality Designations [68] at 3.) Moreover, the Court is inclined to agree with plaintiff that the general public has a right to know the source of the products that it ingests. Accordingly, the Court **GRANTS** plaintiff's motion to remove the confidentiality designation as to the identity of defendant's manufacturers and suppliers.

With regard to the documents, defendant argues that they are confidential because they identify defendant's suppliers and "proprietary ingredients." (Def.'s Resp. to Pl.'s Mot. to Change Confidentiality Designations [119] at 2.) The identity of defendant's suppliers is no longer confidential. Moreover, defendant can have no reasonable expectation of confidentiality as to the current formulation of PNV. Indeed, state and federal regulations require that defendant accurately list the ingredients of PNV on the label. *See* O.C.G.A. § 26-2-28 and 21 C.F.R. §§ 101.4, 101.5. On this point, the Court again rejects defendant's argument that the public has no right to know the current formulation and actual ingredients used in its products. The Court thus **GRANTS** plaintiff's motion to remove the confidentiality designation as to the referenced

documents to the extent that those documents (1) identify defendant's manufacturers and suppliers and (2) state the current formulation and/or ingredients of PNV vitamins.

Of course, before the documents are revealed to any third party, they should be redacted to remove confidential information. Confidential information would include any proposed but unused formulations or ingredients for PNV while the product was in the development stage, or other research and development material. In addition, the documents should be redacted to remove confidential communications between defendant and its suppliers, such as discussions concerning pricing or other contract terms. The Court urges the parties to reach an agreement on redacting the documents that does not require further involvement of the Court.

VI. Defendant's Motion to Quash

Plaintiff has served a subpoena on Encompass Pharmaceutical Services, Inc. ("Encompass"), a consultant retained by plaintiff in connection with this litigation. (Def.'s Mot. to Quash [120] at 4.) Apparently, defendant accidentally produced a document relating to Encompass at some point prior to the deposition of Jeff Bryant, defendant's director of business development. (*Id.* at 2.) Plaintiff attempted to question Bryant about the Encompass document during the deposition. (*Id.*) Defendant informed plaintiff that the document should not have been produced, and objected on the record that Encompass's work in connection with the litigation was protected from

discovery by the work product doctrine. (*Id.*) Plaintiff subsequently served a subpoena on Encompass, demanding broad categories of documents relating to its work for defendant. (*Id.* at 3.)

The Court agrees with defendant that the Encompass documents are protected work product. After plaintiff filed its complaint, defendant retained Encompass as a consulting laboratory to perform testing and other work related to the products and testing methods at issue in this case. (Parker Aff. at ¶ 4, attached to Pl.'s Reply [128] at Ex. 3.) Defendant engaged Encompass for the specific purpose of helping prepare defendant for trial. (*Id.* at ¶ 5.) All work done by Encompass as it relates to the products at issue in this case was done at the direction of defendant's attorneys. (*Id.* at ¶ 6.)

Rule 26(b)(3) provides that:

> Ordinarily, a party may not discover documents and tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative (including the other party's attorney, consultant, surety, indemnitor, insurer, or agent). But . . . those materials may be discovered if: . . . the party shows that it has substantial need for the materials to prepare its case and cannot, without undue hardship, obtain their substantial equivalent by other means.

FED. R. CIV. P. 26(b)(3) (emphasis added). There is no question that the Encompass documents were prepared "in anticipation of litigation or for trial." Although plaintiff obviously would like to examine

the documents, it has not shown that it has a "substantial need" for them. Accordingly, defendant's motion to quash is **GRANTED**.

VII. Defendant's Motion for a Continuance

This case originally was put on an expedited discovery and trial schedule, with trial set for February 22, 2010. (Def.'s Mot. for Continuance [46] at 2.) Defendant filed a motion for a continuance of at least 90 days to allow more time for defendant to obtain testimony crucial to its defense and adequately prepare for trial. (*Id.* at 1.) The Court granted the motion, and the parties subsequently engaged in extensive discovery over the course of several months. However, the docket reflects that defendant's motion for a continuance remains pending. Accordingly, the Court confirms that defendant's motion for a continuance has been **GRANTED**, and directs the clerk to note this change on the docket.

In a related motion, plaintiff requests an order specially setting the case for trial in late July or early August, 2010. (Pl.'s Mot. for an Order Specially Setting the Case for Trial [86].) In addition, plaintiff recently filed a "notice" indicating that the parties had attempted settlement, but were unsuccessful as a result of "differing beliefs and expectations" as to how the Court would rule on the motions that have been addressed in this order. (Pl.'s Notice of Case Status and Request for a Scheduling Conference [131].) In response to the notice, defendant claims that plaintiff has stalled defendant's efforts to complete discovery and contends that

plaintiff's repeated requests for a quick trial are contradicted by defendant's dilatory discovery practices. (Def.'s Notice of Case Status and Request for a Scheduling Conference [132].) Defendant proposes a revised discovery schedule, to conclude on September 17, 2010. (*Id.*)

The Court directs the parties to attempt settlement again, in light of the rulings in this order. The parties should submit a joint report on the status of settlement negotiations by **Tuesday, July 6, 2010.**

If settlement negotiations are unsuccessful, the parties should agree on a revised schedule for completing discovery and submitting dispositive motions. The parties should submit the proposed revised schedule, along with their report on settlement negotiations, by **Monday, July 12, 2010.** A refusal to agree on a scheduling order will further delay this case, so the parties should act reasonably and cooperatively.

The parties should <u>not</u> file any additional motions until after they have submitted their joint report of settlement negotiations and proposed schedule for completing discovery and dispositive motions.

CONCLUSION

For the foregoing reasons, the Court **DENIES** plaintiff's Motion for a Preliminary Injunction [9], **GRANTS** defendant's Motion for a Continuance [46], **DENIES** defendant's Motion to Dismiss [49], **GRANTS** plaintiff's Motions for Changes in Confidentiality Designations [68] and [115], **DENIES** plaintiff's Motion to Dismiss Defendant's Counterclaim [75], **DENIES** plaintiff's Motion for a Special Setting [86], **GRANTS** as unopposed plaintiff's Motions to Seal [89], [101], [114], and [123], **GRANTS** plaintiff's Motion to Amend [90], **DENIES** defendant's Second Motion to Dismiss [92], **GRANTS** plaintiff's Motion for Leave to File a Sur-reply [93], **GRANTS** defendant's Motion to Quash [120], **GRANTS** defendant's Motion to File Supplemental Authority [127], and **GRANTS** plaintiff's Supplemental Motion to Seal [133].

SO ORDERED, this 23 day of June, 2010.

JULIE E. CARNES
CHIEF U. S. DISTRICT JUDGE