Merck Eprova AG v. Brookstone Pharmaceuticals, LLC Doc. 184

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

No. 09 Civ. 9684 (RJS)

MERCK EPROVA AG,

Plaintiff,

VERSUS

BROOKSTONE PHARMACEUTICALS, LLC
A/K/A ACELLA PHARMACEUTICALS, LLC, *ET AL.*,

Defendants.

OPINION AFTER BENCH TRIAL
January 31, 2013

RICHARD J. SULLIVAN, District Judge:

Plaintiff Merck & Cie ("Merck"), formerly known as Merck Eprova AG, a producer of pharmaceutical and dietary ingredients, brings this action against Defendant Acella Pharmaceuticals LLC ("Acella"), formerly known as Brookstone Pharmaceuticals LLC, a corporation that develops, markets, and sells low-cost vitamins and nutritional supplements; Merck also names two of Acella's officers as defendants (collectively, "Defendants"). In this action, Merck alleges that Acella falsely labeled its folate products, leading customers to believe that Acella's mixture products were identical to Merck's chemically pure folate product. Merck further alleges that this false labeling prompted pharmaceutical databases to "link" the cheaper Acella products to the more expensive Merck product, inducing pharmacies and others to believe that Acella's folate could be substituted for Merck's despite their different chemical compositions. As a result, Merck seeks to hold Acella and its officers liable for false advertising, contributory false advertising, and deceptive trade practices under both federal and state law. Acella, by turn, seeks a declaratory judgment that it did not engage in false advertising. It also brings a counterclaim against Merck, alleging that it improperly marketed its folate products.

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Having presided over a bench trial in this action, the Court issues the following findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a). For the reasons set forth below, the Court finds that: (1) Acella engaged in false advertising in violation of the Lanham Act; (2) Acella engaged in contributory false advertising under the Lanham Act; and (3) Merck failed to meet its burden to prove that Acella engaged in a deceptive trade practice or false advertising in violation of New York state law. Accordingly, the Court hereby enters judgment for Merck and awards Merck damages in the amount of $11,606,400.00 plus interest, as well as injunctive relief and attorneys' fees. Further, the Court dismisses Acella's request for a declaratory judgment and counterclaim.

I. PROCEDURAL HISTORY

Merck filed this action on November 20, 2009. The case was assigned to my docket because it was related to a case already before me. *See Merck Eprova AG v. Gnosis S.p.A.*, No. 07 Civ. 5898. At a December 3, 2009 conference, Acella made an oral motion to transfer this action to the Northern District of Georgia. Merck moved for a preliminary injunction on December 4, 2009. By Order dated December 15, 2009, the Court denied both motions.

Merck filed an Amended Complaint on January 13, 2010. Acella answered the Amended Complaint and made counterclaims against Merck on January 29, 2010. On August 5, 2010, Merck filed a motion for partial summary judgment, and Acella filed a motion for summary judgment. The Court heard oral argument on the parties' motions on March 10, 2011, and, in a Memorandum and Order dated March 17, 2011, the Court denied both parties' motions.

On April 15, 2011, Merck filed its Second Amended Complaint, adding Harold Arthur Deas ("Deas"), Acella's Chief Operating Officer, and Thomas Jeffrey Bryant ("Bryant"), Acella's Director of Business Development, as defendants. The Second Amended Complaint also dropped Merck's prior claims for federal and common law unfair competition. Acella answered and made counterclaims against Merck on April 29, 2011, and Deas and Bryant both answered the Complaint on May 12, 2011. Merck filed its Third Amended Complaint, which consisted of minor alterations and clarifications, on August 11, 2011. Defendants answered on September 1, 2011, reasserting their counterclaims.

The case proceeded to trial on November 14, 2011. The trial was conducted without objection in accordance with the Court's Individual Rules for the conduct of non-jury proceedings. Accordingly, the parties submitted affidavits containing the direct testimony of their respective witnesses, as well as copies of all the exhibits and deposition testimony that they intended to offer as evidence at trial. The parties were then invited to call those witnesses whom they wished to cross-examine at trial. In all, thirteen witnesses submitted affidavits, and twelve witnesses testified before the Court at trial. Closing arguments took place on December 7, 2011. The parties then submitted post-trial memoranda on January 6, 2012 and reply post-trial memoranda on January 20, 2012.

II. FINDINGS OF FACT[1]

This case concerns a brand-name pharmaceutical manufacturer, a developer of generic substitutes, and the inner-workings of the pharmaceutical substitution process. Merck, the brand-name manufacturer, produces a chemically pure version of the nutritional supplement folate called Metafolin. Acella, the generic substitute developer, sells mixed folate products known as Xolafin and Xolafin-B. Though their products indisputably differ, Merck alleges that Acella labeled its substitute products to appear identical to and interchangeable with Merck's, in violation of the Lanham Act and state law. In response, Acella asserts that Merck mislabeled its own products and seeks a declaratory judgment that its labeling is truthful, because the labels properly identify their products' active – if not inactive – ingredients.

A. The Parties

Plaintiff Merck is a Swiss corporation with its principal place of business in Schaffhausen, Switzerland. (PTO Facts ¶ 1.) Merck manufactures and distributes pharmaceutical and dietary ingredients to the pharmaceutical and nutritional industry for use in final consumer products. (*Id.* ¶ 8.) Accordingly, Merck does not directly sell any finished products to consumers. (*Id.* ¶ 9.) Instead, Merck's customers use Merck ingredients to manufacture their own finished consumer products. (*Id.* ¶ 8.)

Defendant Acella is a limited liability corporation organized under the laws of Georgia, with its principal place of business in Alpharetta, Georgia. (*Id.* ¶ 2.) Deas is Acella's Chief Operating Officer, and Bryant is its Director of Business Development. (*Id.* ¶¶ 5, 7.) Acella develops, markets, and sells lower cost, finished consumer pharmaceutical products. (*Id.* ¶ 10.)

B. Chemical Concepts[2]

Stereochemistry refers to the spatial arrangement of atoms within a molecule. (*Id.* ¶ 31.) Stereoisomers are molecules that have the same composition of atoms and bond connectivity of atoms, but may differ with respect to the arrangement of those atoms in space. (*Id.* ¶ 30.) When two stereoisomers have different configurations, they are called "diastereoisomers," and when two or more diastereoisomers are combined, they create a diastereoisomeric mixture. (*Id.* ¶¶ 32-33.) Despite their identical molecular formulas, diastereoisomers can have different physical, chemical, and biological properties due to their different structural formations; thus, they may also have different effects in the human body. (Aff. of Dr. Jesse Gregory, dated Oct. 14, 2011 ("Gregory Aff.") ¶ 34; Aff. of Daniel W. Armstrong, dated Oct. 7, 2011 ("Armstrong Aff.") ¶ 35.)

The naming conventions for stereoisomers are similarly complex. However, for present purposes, it is necessary only to know that stereoisomers can be identified by several prefixes, including "R" and "S" under the Cahn-Ingold-Prelong rules, "D" and "L" under the Fischer-Rosanoff convention, and "(+)" and

[1] To the extent that any finding of fact reflects a legal conclusion, it shall to that extent be deemed a conclusion of law, and vice versa. As indicated, many of these factual findings are taken directly from the parties' experts' affidavits and the Joint Pretrial Order ("PTO").

[2] These facts are largely undisputed; however, the Court believes that it would be impossible to understand the contested issues in this case without a brief explanation of stereochemical terms and naming conventions related to the products at issue.

"(-)" under a third convention based on optical activity, which are also referred to as "d" and "l." (Gregory Aff. ¶ 34.) When a mixture of different isomers, rather than a pure isomer, is referenced, this may be indicated by using the symbols "D,L," "R,S," or "(±)" as a prefix before the chemical name. (Armstrong Aff. ¶¶ 27, 30).

C. Folates

The products at issue in this case are types of folate, a B vitamin essential to creating new cells. Though folate is essential for all living things, it is notably used to lessen the risk of certain cancers and cardiovascular disease, as well as to promote prenatal health in women. (Gregory Aff. ¶¶ 18-20.) The most recognizable form of folate, folic acid, does not occur naturally in large quantities, but because it is relatively easy to synthesize, it is the primary folate form used in food fortification and dietary supplements. (*Id.* ¶ 24.) In contrast, tetrahydrofolates are the predominant naturally occurring forms of folate and are more easily metabolized and processed by the human body. (*Id.* ¶¶ 25-26, 40.) However, tetrahydrofolates are much more difficult to synthesize. (*Id.* ¶ 35.) This is because tetrahydrofolate exists in nature in the "L" stereochemical form, but when synthetically manufactured, takes the form of a stereochemical mixture, having both "L" and "D," "S" and "R," or "(-)" and "(+)" stereoisomers. (*Id.* ¶ 25.) In general terms, L-5-methyltetrahydrofolate ("L-methylfolate" or "L-5-MTHF"), refers to the naturally occurring isomer, whereas D-5-methyltetrahydrofolate ("D-5-methylfolate" or "D-5-MTHF") refers to the synthetic isomer.[3] (*Id.* ¶¶ 38, 48-50; PTO Facts ¶ 39.) D,L-5-MTHF is the diastereoisomeric mixture of the two that is created in the synthetic manufacturing process. (Gregory Aff. ¶ 52.)

Finally, these distinct stereochemical forms have distinct effects on the human body. L-5-MTHF is the predominant naturally occurring folate and, as would be expected, is easily used and absorbed by the human body. (Gregory Aff. ¶¶ 28; 38, 48.) D-5-MTHF, in contrast, is not active in the body, is not easily absorbed, and its full impact on the body is unclear. (*Id.*)

C. The Products

Synthetic tetrahydrofolate, or D,L-5-MTHF, has been available in the United States as a dietary supplement in varying levels of purity since the turn of the century. (Gregory Aff. ¶¶ 28, 51; Tr. 17:11-15; DTX 157.) However, after expending tens of millions of dollars on research and development, Merck was the first company to offer a substantially pure L-5-MTHF product. (PTO Facts ¶¶ 8, 9, 11, 13; Affidavit of Roger Weibel, dated May 20, 2010 ("Weibel Aff."), at ¶¶ 8, 9.) In September 2000, Merck submitted to the Food and Drug Administration ("FDA") a "new dietary ingredient notification" ("NDI") – which is required to sell a dietary ingredient in the United States – specifying that its product, Metafolin, contained at least ninety-nine percent L-5-MTHF. (DTX 158; PTX 286; Tr. 28:3-9.) As such, Metafolin both set and satisfied the international standard for L-5-MTHF purity. (Tr. 1403.) That standard – which was later adopted by the FDA, the United Nations and World Health Organization's Joint Food and Agriculture Organization Expert Committee on Food Additives (JECFA), and the

[3] Merck challenges Acella's use of the terms "L-methyfolate" and "6(S)-5-MTHF" on its labels. These terms are both synonyms for the pure, natural isomer. Throughout the trial, however, the parties referred to the pure isomer as "L-methylfolate" and "L-5-MTHF." Accordingly, the Court will continue to use those terms throughout the Opinion.

European Food and Safety Authority (EFSA) – limits D-5-MTHF impurities to one percent. (*Id.*) In time, Merck's pure isomer product outpaced its competitors, which had previously offered D,L-5-MTHF mixture products with approximately fifty percent of the natural isomer and fifty percent of the synthetic D-isomer. (Tr. 17:11-15, 71:17-72:9; DTX 157.)

As the only substantially pure entrant in the synthetic tetrahydrofolate market, Merck built a following of customers who touted the inclusion of Metafolin in their products as a unique selling point. (PTO Facts ¶ 14.) Included in Merck's customers list were Pamlab, LLC ("Pamlab") and Sciele Pharma, Inc., now known as Shionogi Pharma, Inc. ("Sciele"). (*Id.* ¶ 13.) As a Merck customer, Pamlab both produces its own finished consumer products containing Metafolin, and, under a license agreement with Merck, sells Metafolin to Sciele for use in Sciele's Prenate Elite, Prenate DHA, and Prenate Essential prescription prenatal dietary supplements (the "Sciele products"). (*Id.* ¶ 16.)

Recognizing an opportunity to enter a market with limited competition, Acella initially tried to purchase L-5-MTHF from Merck through a proposed licensing agreement. (Tr. 1677:13-15.) When Merck rebuffed that offer, Acella began to develop its own folate source to compete with the Sciele and Pamlab finished consumer products. (Tr. 1679:21-1680:8.) In 2009, after seeing an internet advertisement by a Chinese manufacturer of pharmaceutical ingredients for the "racemic" form of 5-MTHF – that is, a folate compound with equal parts L-5-MTHF and D-5-MTHF – Acella officers Deas and Bryant, along with Acella's Chief Executive Officer Mark Pugh, traveled to China to buy the mixture. (Tr. 1250:7-1251:20; 1660:3-13; PTX 19.) At the time, the cost of pure L-5-MTHF was approximately $10,000 per kilogram, whereas the racemic form of 5-MTHF was $2,000 per kilogram. (Tr. 1697:11-17.) After traveling to China, Acella entered into a supply agreement with the Chinese producer, Jinkang, to purchase the 5-MTHF compound. (PTX 18.) In the supply agreement with Jinkang, Acella specified that it was developing "racemic 5-methyltetrahydrofolate, calcium salt." (*Id.*) Moreover, a certificate of analysis regarding the Jinkang folate referred to the compound as "5-methyltetrahydrofolate calcium (racemate)" (PTX 22), and e-mails between Bryant and Jinkang refer to the product as "racemic methylfolate." (PTX 119.)

Following its purchase of the racemic folate source from Jinkang, Acella developed its own folate product called Xolafin that contained a mixture of approximately fifty percent L-5-MTHF and fifty percent D-5-MTHF. (*Id.* ¶¶ 20, 21; Tr. 1240:8-11; 1264:25-1265:1.) Acella began selling finished consumer products with Xolafin in 2009, making if the first company to directly compete with Metafolin-containing products.[4] (Tr. 164:17-19.) Nevertheless, despite the mixed contents of the Acella product, the company labeled its folate source as "L-methylfolate" – the name of the pure L-isomer – without acknowledging the presence of D-5-MTHF in the product. (Tr. 1292:3-8.) This was in marked contrast to the GNC fifty-fifty mixture product, which labeled its folate source as "D,L-methylfolate" – a fact of which Acella was well aware. (DTX 157.)

[4] The supplement store GNC has marketed a folate product since 1998. However, its product was a fifty-fifty mixture of the natural isomer and the synthetic isomer, was labeled as such, and as a result, it did not directly compete with Merck's pure isomer product. (Tr. 18: 20; 20:5-6.)

In 2010, Acella replaced Xolafin with a successor folate source, Xolafin-B, in several prescription dietary supplements. (PTO Facts ¶ 20.) Unlike Xolafin, Xolafin-B contains between ninety and ninety-five percent L-5-MTHF and between five and ten percent D-5-MTHF. (*Id.* ¶ 22.)

Taken together, Acella's Xolafin and Xolafin-B products either compete or competed with the following Metafolion-containing Sciele products: (1) Acella's PNV Select competes with Sciele's Prenate Elite; (2) Acella's PNV-DHA competed with Sciele's Prenate DHA; and (3) Acella's PNV Omega competes with Sciele's Prenate Essential. (*Id.* ¶ 23.) The folate content of both Sciele's Metafolin-containing products and Acella's Xolafin- and Xolafin-B-containing products appear on the labels and package inserts associated with these products. Specifically, Sciele's Prenate Elite states that its one milligram of folate is present as "L-methylfolate calcium 676 mcg (as *Metafolin*) molar equivalent to 600 mcg of Folic Acid" with 400 micrograms of folic acid. (DTX 375.) In a near mirror image, Acella's PNV Select states that its one milligram of folate is present as "L-methylfolate calcium as *Xolafin-B* 600mcg" with 400 micrograms of folic acid. (DTX 27; *see also* PTX 11 (Acella's prior PNV Select label, which described its folate content as "L-methylfolate as *Xolafin* 600 mcg" with 400 micrograms of folic acid).)

After Acella entered the market with its purported L-methylfolate product, the sales of the Merck-licensed products plunged. (Tr. 1048:6-12; Aff. of Ivan T. Hofmann, dated Nov. 9, 2011 ("Hofmann Aff.") ¶ 25.) For example, while average sales per unit of Prenate Elite and Prenate DHA steadily increased from their respective launches in 2004 and 2006, their sales tumbled for the first time upon Acella's entrance into the folate market in November 2009. (Hofmann Aff. ¶ 25, Figures 1 & 2.)

D. Pharmaceutical Substitution

In the pharmaceutical industry, "pharmaceutical substitution" is the process by which a pharmacist chooses to dispense a different product – generally a less expensive, generic product – in place of the product specifically prescribed by a healthcare professional. (*Id.* ¶ 41.) The process of "pharmaceutical substitution" begins when a pharmaceutical database, such as Medi-Span and First DataBank, collects product information from pharmaceutical manufacturers for entry into their electronic data banks. (*Id.* ¶ 42.) Based on the information provided by the manufacturers – such as labels and package inserts – databases then decide whether to "link" products containing the same ingredients. (Tr. 38:23-39:2.) Databases generally "link" products that contain the same active ingredients, and generally do not "link" products whose ingredients differ. (Tr. 1372:16-23.) This is because a "link" is meant to inform pharmacies and health care professionals that a generic product is an appropriate substitute for a brand name prescription. (*Id.*) Once databases collect product information and make linking choices, the information is then sent to pharmacies and health care professionals who use the data – often in conjunction with state law governing pharmaceutical substitutions – to decide whether to substitute one product for another. (Tr. 39:2-5; 67:13-20.)

As a manufacturer of generic substitutes, Acella aims to have pharmaceutical databases link their products with branded products in order to open new channels for sales. (Tr. 1372:12-15.) To that end, Acella provides databases with the labels and package inserts of its products. (Tr.

1375:10-17.) In or around November 2009, Acella provided pharmaceutical databases with the labels and package inserts for its Xolafin-containing PNV Select and PNV-DHA products, and around March or April of 2010, Acella supplied the databases with labels and package inserts for its Xolafin-B-based PNV Omega product. (PTO Facts ¶¶ 43, 44.) Acella's admitted business strategy was to ensure that each of its products was linked to a higher-priced product that contained Metafolin. (1375:24-1376:2.)

However, in order for a database to link the Acella and Metafolin-containing products, the supplements typically had to have identical active ingredients. (Tr. 1372:16-23.) If the labels listed different ingredients, there was a significant risk that the databases would not link the products – a risk Acella was mindful of based on at least one database's refusal to link its product with Sciele's Prenate DHA due to a temporary difference between their labels. (*See* PTX 32; Tr. 1374:8-1375:9.) Consequently, Acella actively monitored the labels of Metafolin-containing products to make sure that Acella's own products had identical ingredients listed on its labels. (Tr. 1376:3-6.) Indeed, the trial record reflects that *every single time* a Metafolin-containing product changed its label, Acella made a corresponding change to the labels of its products to avoid "delinkage." (Tr. 1422:25-1428:21.)

III. CONCLUSIONS OF LAW

As noted above, Merck alleges the following claims in this action: (1) false advertising under Section 43(a)(1)(B) of the Lanham Act; (2) contributory false advertising under Section 43(a) of the Lanham Act; (3) deceptive trade practices in violation of New York law; and (4) false advertising in violation of New York law. To prevail on its claims, Merck bears the burden of proof to present evidence in support of the allegations set forth in its Complaint and to prove those allegations by a preponderance of the evidence, as does Acella for its counterclaims. *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1548-49 (2d Cir. 1991). "'The burden of showing something by a preponderance of evidence . . . simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence.'" *Metro. Stevedore Co. v. Rambo*, 521 U.S. 121, 137 n.9 (1997) (quoting *Concrete Pipe & Prod. Of Cal., Inc. v. Constr. Laborers Pension Trust for S. Cal.*, 508 U.S. 602, 622 (1993)). As the finder of fact, the Court is entitled to make credibility findings of the witnesses and testimony.

A. Jurisdiction

The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338. The Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367. Venue in the Southern District of New York is proper under 28 U.S.C. § 1391.

B. Standing

"[I]n order to establish standing under the Lanham Act, a plaintiff must demonstrate (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). It is not required that litigants be in competition, but competition is viewed "as a strong indication of why the plaintiff has a reasonable basis for believing that its interest will be damaged by the alleged false advertising." *Id.*

Merck clearly has standing to bring these claims. Although Merck and Acella are not direct competitors, insofar as Merck does not produce finished consumer products, Merck and Acella both produce competing sources of folate for use in dietary supplements. Accordingly, Merck's "stake in the [folate] market gives it a reasonable interest to be protected against the alleged false advertising." *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.3d 186, 190 (2d Cir. 1980). For the same reasons, Merck has standing to pursue its claims under New York state law.

C. False Advertising Under Lanham Act Section 43(a)(1)(B)

Merck challenges Acella's labeling of its Xolafin and Xolafin-B products. Specifically, Merck asserts that Acella's use of the natural isomer names "L-methylfolate" and "6(S)-5-MTHF" on its labels and package inserts for certain Acella mixture products was false and therefore violated the Lanham Act. (*See* Pl. Post-Trial Mem. at 3.)

The Lanham Act expressly forbids false or misleading descriptions or representations of fact "in commercial advertising or promotion" concerning "the nature, characteristics, qualities, or geographic origin of . . . goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B). To establish a false advertising claim under Section 43(a) of the Lanham Act, a plaintiff must prove the following elements: (1) the defendant has made a false or misleading statement; (2) the false or misleading statement has actually deceived or has the capacity to deceive a substantial portion of the intended audience; (3) the deception is material in that it is likely to influence purchasing decisions; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products. *S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.2d 232, 238 (2d Cir. 2001); *Cashmere & Camel Hair Mfrs., Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 310-11 (1st Cir. 2002). "[T]he touchstone of whether a defendant's actions may be considered 'commercial advertising or promotion' under the Lanham Act is that the contested representations are part of an organized campaign to penetrate the relevant market. Proof of widespread dissemination within the relevant industry is a normal concomitant of meeting this requirement." *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 57 (2d Cir. 2002).

To prove the first element of a Lanham Act claim, a plaintiff must show either: (1) that the "challenged advertisement is literally false, *i.e.*, false on its face," or (2) "that the advertisement, while not literally false, is nevertheless likely to mislead or confuse customers." *Tiffany (NJ) Inc. v. eBay, Inc.*, 600 F.3d 93, 112 (2d Cir. 2010). To succeed under a "literal falsity" theory, a plaintiff must show that the challenged advertisement is "false on its face" or "explicitly false." *Johnson & Johnson Vision Care, Inc.*, 348 F. Supp. 2d at 178. That is, the message must be unambiguous. *Time Warner Cable, Inc. v. Directv, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007). When a plaintiff demonstrates the literal falsity of an advertisement, consumer deception is presumed. *Id.* at 153. Thus, "[w]here the advertising claim is shown to be literally false, the court may enjoin the use of the claim 'without reference to the advertising's impact on the buying public.'" *Johnson & Johnson Vision Care, Inc.*, 348 F. Supp. 2d at 178 (citing *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991)). Further, injury may be presumed when the plaintiff is an obvious competitor with respect to the

misrepresented product. *Reckitt Bensicker v. Motomco Ltd.*, 760 F. Supp. 2d 446, 453 (S.D.N.Y. 2011).

However, "if the language . . . is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false." *Time Warner Cable, Inc.*, 497 F.3d at 158. Then, "a plaintiff can show that the advertisement, while not literally false, is nevertheless likely to mislead or confuse customers." *Time Warner*, 497 F.3d at 153. "[P]laintiffs alleging an implied falsehood are claiming that a statement, whatever its literal truth, has left an impression on the listener [or viewer] that conflicts with reality.'" *Id.* (quoting *Schering Corp. v. Pfizer Inc.*, 189 F.3d 218, 229 (2d Cir. 1999). In a case where a plaintiff seeks to prove that an advertisement is implicitly false, the plaintiff must put forth extrinsic evidence of consumer deception. *Id.* Nevertheless, there is a "narrow exception to this rule" – where a plaintiff demonstrates that a defendant has "intentionally set out to deceive the public, and the defendant's deliberate conduct in this regard is of an egregious nature, a presumption arises that consumers are, in fact, being deceived." *Tiffany (NJ), Inc. v. eBay, Inc.*, 04 Civ. 4607 (RJS), 2010 WL 3733894, at *3 (S.D.N.Y. Sept. 13, 2010) (quoting *Johnson & Johnson * Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.3d 294, 298 (2d Cir. 1992). The burden then shifts to the defendant to show that consumers were not misled or confused. *Id.*

1. Literal Falsity

Merck claims that Acella's use of the term "L-methylfolate" or "6(S)-5-MTHF" on its products' labels and package inserts is literally false because the ingredient used in Acella's products is not pure L-methylfolate. Acella admits that both Xolafin and Xolafin-B are not pure L-methylfolate – rather, both are diastereoisomeric mixtures of D,L-methylfolate. However, several witnesses at trial testified that, technically, the labels properly identified the presence of the active L-isomer – or "L-methyltetrohydrofolate" – and the net amount of that isomer, even if they did not identify the presence and amount of the inactive D-isomer. (Tr. at 324; 350; 416-17; 526-28.) Under this interpretation, Acella's labels would be deemed literally true because they properly identify the net amount of L-isomer in their products – they simply neglect to disclose the amount of D-isomer. Because Acella's labels are thus "susceptible to more than one reasonable interpretation," *Time Warner Cable, Inc.*, 497 F.3d at 158, the Court finds that Merck has not proven by a preponderance of the evidence that Acella's labels were literally false.

2. Implied Falsity

Although Merck has not demonstrated that Acella's labels are literally false, it may still succeed on its Lanham Act false advertising claim on an implied falsity theory. Typically, to demonstrate implied falsity, a plaintiff must present evidence of consumer deception or confusion. That is, "a district court *must* rely on extrinsic evidence [of consumer deception or confusion] to support a finding of an implicitly false message." *Time Warner Cable*, 497 F.3d at 153 (internal quotation marks and citation omitted). Such extrinsic evidence is generally provided by customer surveys exhibiting consumer confusion. "'[T]he success of a plaintiff's implied falsity claim usually turns on the persuasiveness of a consumer survey' that shows that a substantial percentage of consumers are taking away the message that the plaintiff contends the advertising is conveying." *Procter & Gamble Co. v. Ultreo, Inc.*, 574 F. Supp. 2d 339, 345 (S.D.N.Y. 2008) (quoting *Johnson &*

*Johnson*Merck*, 960 F.2d at 297). "After a plaintiff has established that a substantial number of consumers [has] taken away the purported message, the district court must then evaluate whether the message is false or likely to mislead or confuse, and may consider factors such as the commercial context, the defendant's prior advertising history, and the sophistication of the advertising audience." *Id.* at 346.

However, where a plaintiff "'adequately demonstrates that a defendant has intentionally set out to deceive the public,' and the defendant's 'deliberate conduct' in this regard is of an 'egregious nature,'" a court may presume that consumers are being deceived. *Johnson & Johnson*Merck*, 960 F.2d at 298 (quoting *Resource Developers, Inc. v. Statue of Liberty-Ellis Island Found., Inc.*, 926 F.2d 134, 140 (2d Cir. 1991). In such cases, a plaintiff need not rely on consumer surveys to prove an implied falsity claim; instead, the *defendant* must disprove consumer confusion. *Id.*

For the reasons set forth below, the Court finds that although Merck cannot prove literal falsity, it has proven implied falsity.

a. Consumer Surveys

In determining whether a challenged advertisement is likely to confuse or mislead customers, courts must look to the person to whom the advertisement is addressed. *Am. Home Products Corp. v. Johnson & Johnson*, 577 F.2d 160, 166 (2d Cir. 1978). Because Acella's labels and package inserts were intended to encourage product substitution, and thus directed in part to pharmacists and physicians (Tr. 1372:12-1376:2), Merck surveyed those groups. Specifically, Merck conducted two surveys to assess confusion among pharmacists and physicians. The first, designed and conducted by Hal Poret ("Poret") in June 2011, attempted to determine whether the designation "L-methylfolate" conveyed to pharmacists and physicians that Xolafin is made up of the "substantially pure isomer." (Poret Aff. at 7.) The second, designed by Dr. Brian Reisetter ("Reisetter"), a pharmacist and pharmacy expert, attempted to assess product substitutions by pharmacists.

In his survey, Poret showed participants Acella labels and package inserts and asked questions to determine what the term "L-methylfolate" on those labels and inserts communicated to them. (Poret Aff. at 4.) Both the pharmacist group and the physician group had a Test Group and a Control Group. (*Id.* at 4-9.) The Test Group was shown an actual Acella label, which read: "Folate (L-methylfolate as Xolafin 600 mcg)," while the Control Group was shown a modified label that read "Folate (D,L-methylfolate as Xolafin 600 mcg)." (*Id.* at 6.) Survey participants were then asked, "What, if anything, does this communicate to you about the folate ingredient termed Xolafin contained in this vitamin?" (*id.* at 6), and, "Do you think that the folate ingredient termed Xolafin contained in this vitamin <u>is</u> or <u>is not</u> a substantially pure isomer?" (*Id.* at 7 (emphasis in original).)

Among the pharmacists surveyed, 45% of the Test Group indicated that the Xolafin designated L-methylfolate is a substantially pure isomer, and 9% answered that it is not. (*Id.* at 9-10.) In the Control Group, 24% of the pharmacists answered that the Xolafin designated D,L-methylfolate is a substantially pure isomer. (Tr. 601:20-602:12.) Thus, Poret's study concluded that a net of 21% of pharmacists believed that Xolafin was a substantially pure isomer based on the "L" designation. (Tr. 601:20-602:12.)

In the physician sample, 37% of the Test Group responded that the Xolafin designated as L-methylfolate is a substantially pure isomer and 4% answered that it was not. (Poret Aff. at 11.) By contrast, 26% of the physicians in the Control Group responded that Xolafin designated as D,L-methylfolate is a substantially pure isomer. Thus, 11% of the surveyed physicians believed that Xolafin was a substantially pure isomer based on the "L" designation. (*Id.*) Because the labels for the Acella products that contain Xolafin-B provide the same information as the products containing Xolafin, Poret concluded that it "is highly likely [that] pharmacists and physicians observing Xolafin-B labels and inserts would have similar responses as they did to Xolafin labels and inserts." (Pl. Post-Tr. Mem. at 13.)

Dr. Reisetter's study surveyed retail pharmacists to determine whether Acella's labeling materially affected pharmacists' decisions regarding product substitution. (Aff. of Dr. Brian Reisetter, dated Oct. 14, 2011, PTX 292 ("Reisetter Aff."), at ¶ 7.) Essentially, the goal of Dr. Reisetter's survey was to determine whether pharmacists and databases treated Acella products as "pharmaceutical equivalents" of Merck products, which would result in the generic Acella products being substituted for the more expensive Merck products. (*Id.* ¶ 49, 58, 74.)

To do this, Dr. Reisetter conducted studies comparing the Acella products with the Metafolin-containing Pamlab and Sciele products, in turn. In the Pamlab study, Dr. Reisetter surveyed 150 pharmacists, and posed questions about how similar the Pamlab and Acella products were based on the labels, and whether mixture products would be an appropriate substitute for Pamlab products. (*Id.* ¶ 86.) From these surveys, Dr. Reisetter concluded that 45.3% of the respondents believed that Acella products were appropriate for substitution for Pamlab products. (*Id.* ¶ 94.) Respondents most often based this conclusion on their belief that the products contained the same ingredients, as stated on Acella's labels. (*Id.* ¶ 94.) Conversely, when asked whether a mixture product would be an appropriate substitute for the pure Pamlab product, only 10% of respondents said that it would be without contacting the prescribing physician. (*Id.* ¶ 98.)

Similarly, in his study of Sciele products, Dr. Reisetter found that 75.3% of respondents concluded that, based on the respective products' package inserts, Acella products were an appropriate substitute for Sciele products. (*Id.* ¶ 101.) Again, when asked whether they would reach the same conclusion for a racemic mixture product, only 33.3% of the pharmacists said that they would substitute the Acella product without first contacting the prescribing physician. (*Id.*) Consequently, Dr. Reisetter concluded that a "majority of pharmacists would not substitute Acella's products for any of the branded Metafolin-containing products if they had the full information that the products did not meet the compendia purity standards for L-methylfolate by the use of D,L-methylfolate in their formulation." (*Id.* ¶ 104.) Thus, the labels on Acella products "resulted in the market believing these products to be pharmaceutically equivalent and, therefore, appropriate generic substitutes." (*Id.* ¶ 1.)

Although Acella attempts to poke holes in these surveys (*see* Def. Post-Tr. Mem. at 6-7, 11), the Court nonetheless finds them to be sufficiently reliable. Both surveys used adequate control groups, which "enable[d] the surveyor[s] to separate the wheat (the effect of the advertisement, alone, on the participant) from the chaff (the effect of the

participant's prior knowledge and/or prior (mis)conceptions)." *Procter & Gamble*, 574 F. Supp. 2d at 351 (quoting *Pharmacia Corp. v. GlaxoSmithKline Consumer Healthcare, L.P.*, 292 F. Supp. 2d 594, 601 (D.N.J. 2003)). Furthermore, by showing survey participants labels for products containing Metafolin and Xolafin, both surveys "replicate[d] real-world conditions with respect to packaging." *See Gucci Am., Inc. v. Guess?, Inc.*, 831 F. Supp. 2d 723, 744 (S.D.N.Y. 2011). Considering that 21% of the pharmacists and 11% of the physicians surveyed in Poret's studies, and even larger numbers of pharmacists in Dr. Reisetter's studies, believed that Xolafin was the pure L-isomer, the Court has little difficulty concluding that the surveys demonstrate that "a substantial percentage of consumers are taking away the message that the plaintiff contends the advertising is conveying." *Procter & Gamble*, 574 F. Supp. 2d at 345. *Compare Paco Sport, Ltd. v. Paco Rabanne Parfums*, 86 F. Supp. 2d 305, 322-24 (S.D.N.Y. 2000) ("[T]he levels of confusion are negligibly low (below 5%) and virtually indistinguishable from levels of confusion in the control group.").

Having determined that Acella's labels delivered the alleged message, the Court must next "evaluate whether [that] message is false or likely to mislead or confuse." *Procter & Gamble Co.*, 574 F. Supp. 2d at 346. The Court finds that the Xolafin and Xolafin-B labels were plainly false and designed to confuse. First, as evidenced by GNC's labeling practices, in the context of folate sales, mixture products customarily identify the presence of the D-isomer. Acella's labels pointedly failed to do so. The fact that Acella purposefully sought out a "racemic" mixture product also underscores the deceptive nature of its "L-methylfolate" labels. Finally, while Acella's target audience was a sophisticated one, Merck has demonstrated that the pharmacists and physicians reading Acella labels were often led to believe that Xolafin products contained the pure L-isomer, an unsurprising result given labeling customs and database linkage. Accordingly, Merck has provided sufficient extrinsic evidence of consumer confusion to prove implicit falsity.

b. Deliberate Misconduct

Even without the consumer surveys, the Court finds that Merck is entitled to a presumption of consumer deception because it has demonstrated that Acella intentionally set out to deceive its consumer base. "[W]here a plaintiff adequately demonstrates that a defendant has intentionally set out to deceive the public," and the defendant's "deliberate conduct" in this regard is of an "egregious nature," a presumption arises "that consumers are, in fact, being deceived." *Resource Developers, Inc.*, 926 F.2d at 140. Although a "high level [of evidence is] required to show the kind of 'egregious' misconduct required to meet this standard," *Stokely-Can Camp, Inc. v. Coca-Cola Co.*, 646 F. Supp. 2d 510, 527 (S.D.N.Y. 2009), Merck has met this bar by demonstrating that Acella intentionally marketed Xolafin and Xolafin-B to create the impression in customers that the Acella products were identical to Merck's Metafolin.

Simply put, D,L-methylfolate and L-methylfolate are chemically distinct substances. Acella purposefully sought out the former mixture product with complete knowledge that it was distinct from the latter pure product. Despite that knowledge, Acella then labeled its mixture product identically to the pure product. Acella's actions thus dictate a finding of intentional consumer deception.

First, prior to Acella's production of Xolafin, Bryant drafted a proposal

suggesting that Acella not use pure L-methylfolate in order to avoid infringing Merck's patents – clear evidence that Acella understood the difference between its own products and Metafolin. (Tr. 1253-54.) Furthermore, Bryant testified that, when seeking out a folate source, he purposefully inquired as to whether Jinkang could produce an impure or "racemic" mixture – again belying knowledge of the distinction between its products and Merck's pure L-methylfolate product. (Tr. 1253-54.) Though Bryant disputes the apparent import of that inquiry, he admits that Acella intended to develop a "custom blend" of D,L-methylfolate to avoid purchasing the purest form of the L-isomer. (Tr. 1254.) Finally, throughout the course of their extended electronic communications, Bryant never once referred to purchasing L-methylfolate from Jinkang, but instead consistently referred to a "racemic mixture." (PTX 327, PTX 330, PTX 19.) In short, Acella *knew* that its products were a D,L-methylfolate blend that was distinct from Merck's pure, and more expensive, product.

Nevertheless, Acella made the conscious decision to label its products with the pure chemical name so that pharmaceutical databases would link Xolafin and Xolafin-B to Metafolin-containing products. (Tr. 1375:24-1376:6; 1427:22-1428:22; 1455:16-1456:15; 1481:4-10; 1723:24-1729:25; 1772:22-1773:5.) The intentional nature of this decision is obvious from the continual labeling changes Acella made to track the ingredients of Metafolin-containing products and thereby avoid de-linking. (Tr. 1376:3-6; 1418:24-1419:9; 1639:24-1641:23; 1723:24-1729:25.) Significantly, when questioned by a pharmaceutical database employee on the *specific* chemical makeup of Acella's folate products, Deas deliberately avoided answering the question, knowing that a truthful response would likely result in delinking. (PTX 34, 35.)

Acella struggles to avoid this conclusion, claiming that its labels merely reflect that the "active ingredient" in Xolafin and Xolafin-B is the L-isomer, and that the D-isomer is an "impurity" not requiring acknowledgement. However, this explanation does not obscure the fact that Acella purposefully blended that L- and D-isomers in its products, and that Acella's failure to acknowledge that blend was part of a deliberate effort to compete with the pure Metafolin products. (Tr. 1238-39.) Thus, the Court does not find Bryant's explanation of wanting to avoid infringing Merck's patents credible, nor does it credit Bryant's testimony that identifying only the L-methylfolate component of Acella's diasteroisomeric mixture comported with his understanding of FDA requirements. (PTX 327; Tr. 1561:19-1564:23.) Indeed, these explanations are contradicted by Acella's own internal references to its folate ingredient as a mixture product, as well as Acella's identification of "subcomponents" of ingredients in its other product labels. (*See* Tr. 1342-46; 1355-56.) Furthermore, Acella's contract manufacturer for producing Xolafin, Arizona Nutritional Supplements, referred to Acella's products as "D,L-methylfolate." (Trial Tr. 1244-47.) Moreover, Bryant admitted that Acella was aware of the FDA, JECFA, and EFSA labeling standard for pure folate products, which limits the presence of D-isomers to one percent, and even cited these standards in communication with Arizona Nutritional while making its labeling decisions. (Tr. 1403-06.) Finally, it would have been illogical for Acella to initiate development of Xolafin-B – with its purer chemical makeup – if the amount of D-isomer is irrelevant, as several Acella witnesses suggested at trial.

Given these glaring incongruities, the Court must conclude that Acella's explanations are nothing more than post-hoc

rationalizations for a policy that was designed to track Sciele's and Pamlabs's labels at all costs. Acella sold a D,L-methylfolate product that was distinct from the pure L-methylfolate product. Acella's folate supplier knew this, Acella's contract manufacturer knew this, and it is clear that Acella knew this. Acella admittedly endeavored to make a product distinct from and cheaper than Merck's Metafolin. It did so by using a significantly less expensive mixture ingredient while nevertheless insisting through its labels that Xolafin and Xolafin-B were identical to Metafolin. These labels, in intent and effect, obscured the true chemical composition of Acella's mixture products from consumers. As a result, Acella was able to capture a portion of the lucrative folate market that otherwise would have been closed to it.

These acts, in addition to the consumer confusion established by the surveys, entitle Merck to the presumption that consumers were deceived. *See The Am. Auto Ass'n v. AAA Auto. Club of Queens, Inc.*, 1999 WL 97918, at *7 (E.D.N.Y. Feb. 8, 1999) (holding that plaintiff satisfied the "egregious" misconduct standard by demonstrating that defendant acted with the intent to capitalize on plaintiff's market goodwill and provided some evidence of actual confusion). This finding is only compounded by the substantial resources Acella expended in executing its scheme. From contracting with Jinkang and Arizona Nutritional, to promoting its Xolafin-based products as chemically pure, Defendants went to great lengths to capture Merck's market, bolstering Merck's claim to a presumption of consumer deception. *See Resource Developers, Inc.*, 926 F.2d 134, 140 (2d Cir. 1991) ("It seems fair . . . that [t]he expenditure by a competitor of substantial funds in an effort to deceive consumers and influence their purchasing decisions justifies the existence of a presumption that consumers are, in fact, being deceived." (internal quotation marks omitted)).

Once a plaintiff has made a proper showing of deliberate deceptive conduct, the burden shifts to the defendant to demonstrate the absence of consumer confusion. *Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp.*, 348 F. Supp. 2d 165, 179 (S.D.N.Y. 2004) (quoting *Resource Developers, Inc.*, 926 F.2d at 140)). Acella has not met that burden. Indeed, although Acella raises issues with regard to Merck's surveys, they have offered no surveys of their own or any other evidence to demonstrate the absence of consumer confusion. *See also Pfizer, Inc. v. Y2K Shipping & Trading, Inc.*, 2004 WL 896952, at *5-6 (E.D.N.Y. Mar. 26, 2004) (finding actual bad faith where the defendant "set out to intentionally deceive purchasers" by advertising the similarity of its product to plaintiff's, and failed to rebut the presumption of consumer confusion by producing surveys or evidence of its own).

Accordingly, the Court finds that the labels and package inserts associated with Acella's folate products to be impliedly false in violation of the Lanham Act.

3. Materiality

Having demonstrated falsity, Merck must also demonstrate that Acella's misrepresentations involved an "inherent or material quality of the product." *Time Warner Cable, Inc.*, 497 F.3d at 153 n.3. Drawing on precedent from other circuits, the Second Circuit has explained that "satisfying this materiality requirement depends on whether the alleged inaccuracy in the statements at issue would affect the purchasing decisions of consumers." *Mylan Pharm., Inc. v. Proctor & Gamble Co.*, 443 F. Supp. 2d 453, 462 (S.D.N.Y. 2006)

(citing *Nat'l Basketball Assoc. v. Motorola, Inc.*, 105 F.3d 841, 855 (2d Cir. 1997)). The materiality requirement "is based on the premise that not all deceptions affect consumer decisions." *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242, 1250 (11th Cir. 2002). To satisfy the materiality requirement, "[t]he plaintiff does not need to demonstrate that the defendant's representations actually affected consumer behavior, but rather only that they were likely to have done so." *Mylan Pharm.*, 443 F. Supp. 2d at 462.

Acella strenuously disputes the materiality of its labeling. (Tr. 1972:1-4.) However, the evidence at trial leads inescapably to the conclusion that the "inaccuracy in the statements at issue [affected] the purchasing decisions of customers." *Mylan Pharm.*, 443 F. Supp. 2d at 462. The products at issue are nutritional supplements designed to deliver folates to those who consume them. As discussed above, the L- and D-isomers have distinct effects in the human body. Indeed, health care professionals prescribe and pharmacists dispense folate supplements based on their L-methylfolate content, and databases make substitutions based on the "pharmaceutical equivalence" of products' L-methylfolate content. Acella's practice of changing its labels to reflect those of Metafolin-containing products reveals that Acella believed the L-methylfolate content, or at least consumer perception of L-methylfolate content, was a fundamental characteristic of its products as well. Thus, the Court concludes that the purity of a product's folate source "defines the product at issue, as well as the market in which it is sold," and that such purity is an "inherent and important" characteristic of a folate supplement. *See Cashmere & Camel Hair Mfrs. Inst.*, 284 F.3d at 312 ("[D]efendants' aggressive marketing strategy highlighting the 'cashmere' nature of the blazers [indicated] that defendants themselves believed cashmere to be an inherent and important characteristic of the blazers."). (*See also* Tr. 1375:24-1376:6; 1427:22-1428:22; 1455:16-1456:15; 1481:4-10; 1723:24-1729:25; 1772:22-1773:5.)

Additional evidence and testimony confirms that the L-methylfolate content of Acella's products mattered to the relevant audience. First, the pharmaceutical database First DataBank e-mailed Deas upon receipt of information that Acella's folate "is actually DL-methylfolate" and inquired as to whether Acella's label was accurate. (PTX 34.) Though Acella avoided responding directly to the inquiry, the inquiry itself clearly suggests that the chemical makeup of Acella's products was material to databases. Moreover, had First DataBank been given a direct and honest response, it likely would have considered delinking. (Tr. 1717:5-14.) Indeed, Acella's deliberate efforts to skirt the issue and avoid a direct response to First DataBank's inquiry suggest Acella's awareness of the D-isomers's materiality. A similar e-mail exchange between Acella and the pharmaceutical database Gold Standard only confirms these findings. (PTX 32.)

Moreover, defense witness Dr. Karl Williams, a pharmacy professor and licensed pharmacist, admitted that he would not substitute a product of lesser chemical purity for a substantially pure brand product, and acknowledged that labeling would play a critical role in that distinction. (Tr. 648-50.) Further, defense witness Dr. Jacob Spanier conceded that for certain patients, consuming pure L-methylfolate is essential, that the presence of D-methylfolate in a product should be acknowledged on the label, and, as a result, that accurate labeling plays an important role in his decisions to prescribe medications and supplements. (Dep. of De. Jacob Spanier, dated May 14, 2010 ("Spanier. Dep."), at 48:8-49:12;

49:13-50:5; 60:3-5.) Finally, a Merck witness, Dr. Brian Buell, asserted that he "d[id] not want" his patients consuming any amount of D-methylfolate due to its potential biological effects, and that Acella's marketing misled him into believing that he could safely substitute its products for Merck's.[5] (Aff. of Dr. Brian Buell, dated Oct. 14, 2011 ("Buell Aff."), at ¶¶ 9, 19.) To each of these witnesses, Acella's folate source and labeling decisions were plainly material.

Further, to the extent that the Acella labels led pharmaceutical databases to "link" Acella's generic products to Metafolin-containing brand products, the law, in many cases, *required* pharmacists to substitute Acella products for prescribed Metafolin-containing products. (Tr. 1876:12-21.) Thus, Acella's decision to mislabel its folate source was material in every imaginable way: to the doctors prescribing it, the databases linking it, the pharmacists dispensing it, the patients consuming it, and, most importantly to Acella, to its own bottom line. The Court therefore finds Acella's misrepresentations to be materially misleading.

4. Organized Campaign

The last element of a false advertising claim made under the Lanham Act is that the misleading representations must have been "part of an organized campaign to penetrate the relevant market." *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 57 (2d Cir. 2002). "Proof of widespread dissemination within the relevant industry is a normal concomitant of meeting this requirement." *Id.* Although Acella indicated that one of its affirmative defenses was that "Defendants' labeling is not advertising under the Lanham Act or New York State law," Acella neither argued this point in its post-trial briefing, nor did it present evidence at trial to indicate otherwise.

Even if Acella had pressed this argument, however, its labels clearly constitute advertising under the Lanham Act. By specifically distributing its labels and package inserts to pharmaceutical databases, Acella engaged in an "organized campaign" to penetrate the pharmaceutical database market, which resulted in linkage between Acella's products and the Metafolin-containing goods. Indeed, Acella's entire business strategy was an "organized campaign" to co-opt Merck's Metafolin market with its distinct and cheaper products. Thus, the Court finds that Acella engaged in an organized campaign to disseminate its misleading labels throughout the nutritional supplement industry.

Accordingly, the Court finds that Acella engaged in false advertising in violation of Section 43(a)(1)(B) of the Lanham Act.

B. Contributory False Advertising

A contributory false advertising claim is "based on the theory that one who intentionally induces another to infringe a trademark is contributorily liable for this infringement." *Societe des Hotels Meridien v. LaSalle Hotel Operating P'ship, L.P.*, 380 F.3d 126, 132-33 (2d Cir. 2004). Thus, in order to prove that Acella engaged in contributory false advertising in violation of the Lanham Act, Merck must establish false advertising by the databases.

[5] Although there was no evidence introduced to conclusively demonstrate the negative health consequences of consuming D-methylfolate, the fact that certain consumers attached significance to the presence of D-methylfolate renders it material as a factor "affect[ing] the purchasing decision of consumers." *Mylan Pharm., Inc.*, 443 F. Supp. 2d at 462.

The second count of Merck's Third Amended Complaint alleges that "Defendants induced the national pharmaceutical databases to engage in false advertising by describing the [Acella products] as pharmaceutically equivalent to and substitutable for [Metafolin-containing products]," and that "Defendants also induced the national pharmaceutical databases to engage in false advertising by describing the [Acella products] as therapeutically equivalent and substitutable for [Metafolin-containing products]." (Third Am. Compl. ¶ 101.) The evidence at trial clearly demonstrated that Acella led the databases to make misleading claims regarding Xolafin and Xolafin-B's chemical composition.

As an initial matter, it has been well-established that Acella's intentionally misleading labels caused the databases to link as chemically equivalent Acella and Metafolin-containing products, a falsehood, and that this linkage caused the marketplace to treat the products as similar or, in some states, commanded their substitution. Further, Acella's success in persuading at least two of the major pharmaceutical databases to link its products with Merck products shows a significant penetration of the market. (Tr. 68:18-19.) Consequently, the Court finds that Acella intentionally induced the databases to falsely advertise and that Merck has prevailed on its contributory false advertising claim.

D. State Law Claims[6]

Merck also asserts a claim for deceptive trade practices under New York General Business Law Section 349, as well as a claim for false advertising under Section 350. A plaintiff bringing a claim of deceptive trade practices under Section 349 "must prove three elements: first, that the challenged act or practice was consumer-oriented; second, that it was misleading in a material way; and third, that the plaintiff suffered injury as a result of the deceptive act." *Stutman v. Chem. Bank*, 95 N.Y.2d 24, 29 (2000). A claim of false advertising under Section 350 must meet all of the same elements as a claim under Section 349, and the plaintiff must further demonstrate proof of actual reliance. *Rodriguez v. It's Just Lunch, Int'l*, No. 07 Civ. 9227(SHS) (KNF), 2010 WL 685009, at *10 (S.D.N.Y. Feb. 23, 2010).

Corporate competitors have standing to bring a Section 349 claim if "the gravamen of the complaint [is] consumer injury or harm to the public interest." *Azby Brokerage, Inc. v. Allstate Ins. Co.*, 681 F. Supp. 1084, 1089 n.6 (S.D.N.Y. 1988). Injury or harm that satisfies this standard includes "potential danger to the public health or safety." *Gucci Am. v. Duty Free Apparel, Ltd.*, 277 F. Supp. 2d 269, 273 (S.D.N.Y. 2003). With regard to "disputes between competitors where the core of the claim is harm to another business as opposed to consumers," courts have found that the "public harm . . . is too insubstantial to satisfy the pleading requirements of § 349." *Id.* at 273.

Merck has not alleged a public harm sufficient to state a claim under Section 349. While Merck has provided some evidence of consumer confusion and suggested the risk of negative health consequences from the D-isomer, neither provides an adequate injury. First, Merck's evidence of consumer confusion was introduced to prove the materiality of Acella's misleading labels, not to redress any public harm, and was therefore peripheral to the "core" of Merck's claims. *See id.*, 277 F. Supp. 2d at 774 (rejecting

[6] Merck did not address its state law claims in its post-trial brief and may also be deemed to have waived them. *Cf. Ortho Pharm. Corp. v. Cosprophar, Inc.*, 32 F.3d 690, 697 (2d Cir. 1994).

Section 349 claim in trademark infringement action where "core harm" was to corporate competitor and not to the public, despite consumers' purchase of counterfeit goods). Second, while Merck's experts posited that there may be negative health consequences associated with the D-isomer, they offered little evidence to conclusively support such assertions. Nor did Merck establish that those consequences are associated with the D,L-methylfolate mixture – in fact, before it developed Metafolin, Merck itself sold and marketed a racemic mixture product.

Instead, Merck's allegations focus almost entirely on losses suffered by Merck itself, not to the eventual – and theoretical – harm suffered by the public at large. *See Vitolo v. Mentor H/S, Inc.* 426 F. Supp. 2d 28, 34 (E.D.N.Y. 2006) (finding that plaintiff had not demonstrated "consumer-oriented conduct" when the alleged harm was suffered by plaintiff himself and his business instead of consumers or the public). Accordingly, Merck's claims under New York General Business Law Sections 349 and 350 must fail.

E. Individual Liability of Deas and Bryant

Employees who direct, control, ratify, participate in, or are the moving force behind a Lanham Act violation can be held personally liable for those violations. *Mattel, Inc. v. Internet Dimensions Inc.*, No. 99 Civ. 10066 (HB), 2000 WL 973745, at *9 (S.D.N.Y. July 13, 2000); *see also Ramada Franchise Sys., Inc. v. Boychuk*, 283 F. Supp. 2d 777, 788 n.14 (N.D.N.Y. 2003) ("It is well established that a corporate officer directly participating in a Lanham Act violation will be held liable for damages."); *Monsanto Co. v. Haskel Trading, Inc.*, 13 F. Supp. 2d 349, 354 (E.D.N.Y. 1998) ("[W]hile a corporate officer is not necessarily individually liable for torts committed on behalf of the corporation, personal liability for trademark infringement and unfair competition is established if the officer is a moving, active[,] conscious force behind [the defendant corporation's] infringement." (internal quotation marks and citations omitted)).

Defendants argue that most claims of individual liability under the Lanham Act arise out of counterfeiting cases, "where the concerns of classic fraud are most pressing" (Def. Reply at 20), and one-person companies, where the individual defendant is the *sole* officer, shareholder, or employee of the corporation (*id.*).[7] Be that as it may, courts in this Circuit have consistently found individual defendants personally liable for corporate Lanham Act violations when the record indicated that the individual was "a moving, active[,] conscious force" behind the corporation's infringement. *Ramada*, 283 F. Supp. 2d at 788; *Mattel*, 2000 WL 973745, at *9; *Monsanto*, 13 F. Supp. 2d at 354.

The evidence in this case demonstrates that Deas, Accella's Chief Operating Officer, and Bryant, Acella's Director of Business Development, were the "moving forces" behind the development, marketing, and labeling of Xolafin and Xolafin-B. Testimony at trial indicated that Deas and Bryant were the two individuals primarily responsible for developing Acella's products. (Tr. 1377:10-1381:6; 1650:12-1651:9; 1655:3-13.) Deas and Bryant were also the driving force behind the development and labeling of Xolafin and Xolafin-B. The evidence at trial clearly established that Bryant initiated contact with Acella's Chinese supplier, seeking the

[7] Interestingly, the Court agrees that "[t]he circumstances that allow recovery directly against individual corporate officers and agents [in Lanham Act cases] is . . . litigated with far less frequency than one might expect." *Century 21 Real Estate, LLC v. Destiny Real Estate Prop.*, No. 4:11-CV-38 JD, 2011 WL 6736060, at *6 (N.D. Ill. Dec. 19, 2011).

"racemic" mixture (PTX 19 at BK-GA-00812), and that Deas and Bryant travelled to China to meet with Jinkang (Tr. 1658:8-19). Bryant then coordinated with Acella's contract manufacturers after procuring the raw folate material. (Trial Tr. 1301:18-1302:3.) In developing Acella's labels, both Bryant and Deas testified that one of their considerations in using the term "L-methylfolate" as opposed to "D,L-methylfolate" was their desire to ensure that Xolafin and Xolafin-B would be substituted for Metafolin-containing products. (Trial Tr. 1375:24-1376:6; 1455:16-1456:15; 1772:22-1773:5.) Ultimately, both Deas and Bryant approved the resulting labels and package inserts. (Trial Tr. 1387:6-22; 1655:3-5.)[8]

Although Defendants argue that Deas and Bryant instead "participated in a team effort to introduce competitive products on the market" (Def. Reply at 21), the record belies that claim. The "team members" that Deas and Bryant identified as having assisted them in the development of the Xolafin products – Chief Executive Officer Mark Pugh and President Phillip Vogt – each credibly testifed that they did not play significant roles in developing the Acella products, with Pugh testifying that he had little involvement in the development of the Xolafin products (Pugh Dep. Tr. 8:10-18), and Vogt testifying that he did not even know what Xolafin or Xolafin-B were (Vogt Dep. Tr. 46:2-47:4). Because the Court finds that the testimony of Deas and Bryant regarding other "team members" lacks credibility, it will instead credit the testimony of those supposed "team members" who deny involvement in the development of the Acella products.

Accordingly, the Court finds Deas and Bryant individually liable for Acella's violations of the Lanham Act.

IV. DAMAGES

Merck seeks lost royalties, Acella's profits, Merck's litigation costs, and injunctive relief.[9] (Pl. Post-Tr. Mem. at 26.) Furthermore, Merck argues that it is entitled to have its damages award trebled because Acella's false advertising was intentional. (*Id.*)

When a plaintiff establishes a violation of the Lanham Act, the plaintiff is entitled,

> subject to the principles of equity, to recover (1) defendant's profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action. The court shall assess such profits and damages or cause the same to be assessed under its direction. In assessing profits the plaintiff shall be required to prove defendant's sales only; defendant must prove all elements of cost or deduction claimed. In assessing damages the court may enter judgment, according to the circumstances of the case, for any

[8] Contrary to Defendants' assertion that "Merck must prove that [Deas and Bryant] intended to engage in false advertising by creating confusion" (Def. Reply at 21), courts in this district have held that to impose liability on individual defendants under the Lanham Act, plaintiffs need not show that an individual defendant "consciously sought to commit a trademark violation." *Calvin Klein Jeanswear Co. v. Tunnel Trading*, 2001 WL 1456577, at *6 (S.D.N.Y. Nov. 16, 2001). Even if this were a requirement, however, the evidence adduced at trial suggests that both Deas and Bryant intended their products – which were purposely different from the Metafolin-containing products – to be seen as identical to the Merck-licensed products.

[9] Merck's monetary damages request is limited to the Acella products that were substituted for Sciele products, as the parties entered into a separate settlement with regard to Acella products that were substituted for Pamlab products.

> sum above the amount found as actual damages, not exceeding three times such amount. If the court shall find that the amount of the recovery based on profits is either inadequate or excessive the court may in its discretion enter judgment for such sum as the court shall find to be just, according to the circumstances of the case.

15 U.S.C. § 1117(a).

Ultimately, "the Second Circuit has noted that 'the [Lanham Act's] invocation of equitable principles as guideposts in the assessment of monetary relief vests the district court with some degree of discretion in shaping that relief.'" *Spotless Enter., Inc. v. Carlisle Plastics, Inc.*, 56 F. Supp. 2d 274, 287-88 (E.D.N.Y. 1999) (quoting *George Basch Co. v. Blue Coral, Inc.*, 968 F.2d 1532, 1537, 1539 (2d Cir. 1992)). Thus, while "causation [of damages] must first be established," "a court may engage in some degree of speculation in computing the *amount* of such damages." *Burndy Corp. v. Teledyne Indus., Inc.*, 748 F.2d 767, 771 (2d Cir. 1984) (emphasis in original).

Accordingly, for the reasons set forth below, the Court finds that Merck is entitled to damages for its lost licensing fees and injunctive relief with regard to the labels and package inserts of Acella's products. Because the proven damages do not fully compensate Merck for its injury, and because Acella's violations were willful, Merck is entitled to trebled damages. However, the Court finds that granting Merck's request for Acella's profits and the full injunctive relief it seeks would be excessive. Finally, because of Acella's willfully deceptive conduct both in its labeling and its conduct at trial, the Court finds that Merck is entitled to attorney's fees.

A. Merck's Damages

Recoverable damages include harm to market reputation and lost profits, which can be calculated by estimating the plaintiff's revenues lost as a result of the unlawful conduct and subtracting any expenses associated with the lost revenues. *FTFM, Inc. v. Solid Clothing, Inc.*, 215 F. Supp. 2d 273, 305 (S.D.N.Y. 2002). A plaintiff need only show that its damages calculation is a "fair and reasonable approximation" of its lost profits. *Id.* Here, the Court finds that (1) Merck is entitled to damages based on its royalty payments lost as a result of Acella products being sold in place of Metafolin-containing products, and (2) Merck's damages estimates are a "fair and reasonable approximation" of the appropriate size of the award.

To avert this finding, Acella asserts that Merck's injury is purely speculative as "Merck has not proved that any lost sales of Metafolin-containing products are attributable to Acella." (Def. Post-Tr. Mem. at 19.) This argument is contradicted by Acella's entire business strategy, which sought to link its products to the more expensive Metafolin-containing products, in hopes that pharmacists would dispense the Acella product instead of the Merck-licensed good. (Tr. 1375:24-1376:2.) Furthermore, the evidence shows that identical labels were necessary for that linkage. (Tr. 1375:24-1376:6; 1427:22-1428:22; 1455:16-1456:15; 1481:4-10; 1723:24-1729:25; 1772:22-1773:5; PTX 32; 34.) Moreover, the undisputed record reflects that sales of Metafolin-containing products declined for the first time, and markedly, when Xolafin entered the market. (Tr. 1048:6-12; Hofmann Aff. ¶ 25, Figures 1 & 2.) Given Acella's admitted business strategy, the fact that Metafolin-containing products are "obviously in competition with" Acella products, and the timing of the decrease in Merck's sales, the Court finds that

Merck has adequately demonstrated causation and is entitled to damages. *See Ortho Pharm. Corp. v. Cosprophar, Inc.*, 32 F.3d 690, 694 (2d Cir. 1994) (noting that while a Lanham Act plaintiff must demonstrate causation, "[t]he type and quantity of proof required to show injury and causation" may be lesser where the plaintiff's and defendant's products are "obviously in competition").

Merck calculated its damages by multiplying the units of Acella's PNV products sold through the end of 2011 by the net sales price of the corresponding Sciele products, which Merck based on historic trends in pricing for the Merck-licensed products. (Hofmann Aff. ¶¶ 24-27; Tr. 1051:1-10.) The result of that calculation is approximately $80.6 million. (Aff. of Ivan Hoffman, dated Nov. 9, 2011 ("Hoffman Aff."), at Tables 1-3.) That figure was then multiplied by .048, the net royalty rate from Merck's licensing agreements, with Merck's variable expenses then subtracted to arrive at $3,869,460.00, the net profits that Merck would have received from Sciele sales were it not for Acella's false advertising. (Tr. 259:22-262:18; Hofmann Aff. ¶¶ 29-36.)

According to Acella's damages expert, Merck's calculation must be reduced because of "cross-price elasticity," which is to say that the presence of less expensive Acella products in the marketplace increased total sales overall, such that not every sale of an Acella PNV product could be assumed to have supplanted a potential Sciele sale. (Tr. 1085-86.) However, given that Acella did not demonstrate that it marketed its products in any other way than database linkage, and because Acella's product would thus presumably only be sold when a pharmacist dispensed it instead of a prescribed Metafolin-containing product, the Court finds that this "elasticity" theory is irrelevant to the calculation of damages. Rather, the Court credits the explanation of Merck's damages expert, Ivan Hofmann, concerning market expansion. According to Hofmann, the cause of any market expansion was the launch of Sciele's Prenate Essential product and the associated marketing and promotional activity that accompanied that launch. (Tr. 1062:5-1063:13.)

Acella also argues that Merck did not account for the entry into the market of Sciele's competitor Trigen, whose products were also linked to Sciele's in pharmaceutical databases. (Tr. 1031:21-1032:3.) In essence, Acella argues that all – or a substantial portion – of its sales would have gone to Trigen rather than Sciele because Trigen's products were also cheaper than the Metafolin-containing products. But, while it is true that Trigen may have shifted market share away from Metafolin-containing products, its entry into the market does not alter the damages calculation. First, Merck based its assessment of lost profits on actual sales *made by Acella*, and not those *lost by Sciele*. Merck has established that, unlike a typical market with multiple suppliers, Acella's very presence in the folate market depended upon the direct substitution of Xolafin and Xolafin-B for Metafolin-containing products. Thus, while a portion of these sales may have diverted to Trigen in Acella's absence, the close nexus between Acella's sales and Merck's losses, as well as the admonition that "[a]ny doubts regarding the amount of damages must be resolved against the infringer," suggest that sales of Xolafin and Xolafin-B are an appropriate marker for Merck's actual damages. *See Victoria Cruises, Inc. v. Changjiang Cruise Overseas Travel Co.*, 630 F. Supp. 2d 255, 262 (E.D.N.Y. 2008) (quoting *Lam, Inc. v. Johns–Manville Corp.*, 718 F.2d 1056, 1065 (Fed.Cir.1983)).

Second, and more importantly, Merck's royalty-based calculation reflects the profit Merck would have earned had it chosen to

license its folate to Acella, regardless of Trigen's presence in the market. As noted above, Acella initially approached Merck to license Metafolin for use in its products, a right for which Acella would have paid Merck a royalty on each sale. It was not until Merck rebuffed this offer – as it was entitled to do – that Acella commenced its scheme to infringe on Merck's product. In light of these facts, it would be inappropriate for Acella to be rewarded with a windfall for its infringing activity. Thus, at a minimum, Merck is entitled to the amount it would have received had Acella legitimately licensed its product and not falsely claimed its likeness.

Accordingly, the Court concludes that Merck's methodology for calculating its damages is a "reasonable approximation" of its losses stemming from Acella's false advertising. *GTFM, Inc.*, 215 F. Supp. 2d at 305. The Court therefore finds that Merck lost $3,869,460.00 in profits due to Acella's Lanham Act violations.

B. Trebling

By its plain language, the Lanham Act permits a district court to enter judgment for "any sum above the amount found as actual damages, not exceeding three times such amount." 15 U.S.C. § 1117(a). However, enhanced damages "shall constitute compensation and not a penalty." *Id.* Thus, "enhanced damages awarded *solely* for purposes of deterrence are an impermissible penalty." *Braun, Inc. v. Optiva Corp.*, 2000 WL 1234590, at *3 (S.D.N.Y. Aug. 31, 2000) (emphasis added). But enhanced damages may serve both "a compensatory purpose when the damages related to the defendant's falsehoods are difficult to quantify," *id.* (quoting *Mobius Mgmt. Sys., Inc. v. Fourth Dimension Software, Inc.*, 880 F. Supp. 1005, 1025 (S.D.N.Y. 1994), as well as a deterrent purpose where the violation was willful. *Mobius Mgmt. Sys., Inc.*, 880 F. Supp. at 1025 (S.D.N.Y. 1994) (citing *Getty Petroleum Corp. v. Bartco Petroleum Corp.*, 858 F.2d 103, 113 (2d Cir. 1988)).

Considering the equities in this case, the Court concludes that Merck is entitled to have its award of damages trebled. If Merck were awarded only its lost royalties, it would be no different from effectively forcing Merck to license its Metafolin product to Acella, which Merck affirmatively declined to do. (Tr. 1674:10-20; 1676:11-1677:15.) Moreover, Acella's staggering volume of infringing sales – resulting in $50.2 million of profit – suggests that a similar volume of sales of Sciele's higher-priced priced products would have resulted in even greater royalties for Merck than are captured in the damages calculation. Furthermore, Acella's very presence as a competitor in the pure folate market, as well as Merck's concomitant loss of likely market growth and customers, are not accounted for in Merck's lost profits calculation. (Tr. 983:6-984:7.) That is, Acella's infringement enabled the company to gain a foothold in the lucrative nutritional supplement market, an opportunity whose profits funded Acella's development of a cost-effective folate supplement that, if properly labeled, may compete with Metafolin-containing goods. Thus, Acella's rise as a legitimate competitor today was premised on the production and false advertising of a willfully infringing product prior to this action.

Because the "intangible benefits" that accrued to Acella as a result of its Lanham Act violations are thus not fully reflected in a calculation of Merck's damages, the Court will treble the lost profits damages award. *See N.Y. Racing Ass'n, Inc. v. Stroup News Agency Corp.*, 920 F. Supp. 295, 301 (N.D.N.Y. 1996) (trebling the profits award in Lanham Act case because "[t]he Court cannot compute the value of the intangible benefits [defendant] received as a result of its

deliberate, flagrant, and mulish violation of [plaintiff's] mark"); *cf. Mobius Mgmt. Sys., Inc.*, 880 F. Supp. at 1025 (enhancing monetary award to compensate plaintiff for the "difficult to quantify" loss of customer goodwill). This finding is only confirmed by the need to deter Acella from engaging in such willful violations in the future. *Id.* at 1025-26 ("In the instant case, I find it appropriate to enhance the monetary award, both to compensate the plaintiff . . ., and to provide some deterrence for future violations by [the defendant]."). Accordingly, Merck's total damages amount to $11,608,380.00.

C. Acella's Profits

In addition to seeking lost royalties, Merck also requests Acella's profits, a total of $50.2 million. The Lanham Act permits plaintiffs to recover defendant's profits. 15 U.S.C. § 1117(a). Generally, a court may award recovery of a defendant's profits "on a discretionary basis upon a finding that the defendant acted in bad faith." *Viacom Int'l Inc. v. Fanzine Int'l, Inc.*, No. 98 Civ. 7448 (RCC), 2001 WL 930248, at *5 (S.D.N.Y. Aug. 16, 2001). Such an award is justified by three rationales: (1) to deter a willful wrongdoer from doing so again; (2) to prevent the defendant's unjust enrichment; and (3) to compensate the plaintiff for harms caused by the infringement. *Pedinol Pharmacal, Inc. v. Rising Pharm. Inc.*, 570 F. Supp. 2d 498, 504 (E.D.N.Y. 2008) (citing *George Basch Co. v. Blue Coral, Inc.*, 968 F.2d 1532, 1537 (2d Cir. 1992)). In determining the appropriateness of an award of profits, a court must also consider other factors, such as "(1) the degree of certainty that the defendant benefit[t]ed from the unlawful conduct; (2) availability and adequacy of other remedies; (3) the role of a particular defendant in effectuating the [wrongdoing]; (4) plaintiff's laches; and (5) plaintiff's unclean hands." *George Basch Co., Inc. v. Blue Coral, Inc.*, 968 F.2d 1532, 1540 (2d Cir. 1992). The district court has discretion to "assess[] the relative importance of these factors and determin[e] whether, on the whole, the equities weigh in favor of an accounting." *Id.*

A full accounting would unquestionably serve as a compelling deterrent and eliminate Acella's ill-gotten gains. However, in this case, the Court concludes that disgorging Acella's profits and awarding that sum to Merck would be an impermissible windfall to Merck. As the supplier of raw folate, Merck never stood to gain profit from the sale of a finished consumer product. Merck made its profit from the sale of the raw material to companies such as Sciele, which then developed and sold consumer products. Thus, to the extent that any entity deserves an accounting against Acella, it would be Sciele rather than Merck. The Court, exercising its discretion in balancing the equities, thereby concludes that Merck is not entitled to Acella's profits. *George Basch*, 968 F.2d at 1540 (noting cases in which district courts exercised discretion in choosing not to award a defendant's profits so as to avoid creating an "undue windfall" to the plaintiff).

V. INJUNCTIVE RELIEF

Merck also requests that the Court permanently enjoin Acella from (1) labeling its Xolafin and Xolafin-B products with the name "L-methylfolate" or any synonyms thereof, and (2) selling any methylfolate product for a period of five years. (Pl. Post-Tr. Mem. at 39.) In addition, Merck requests that the Court order Acella to engage in a campaign of corrective advertising, at Merck's discretion, explaining the distinctions between Metafolin and Xolafin products. (*Id.*)

To obtain a permanent injunction, a plaintiff must satisfy a four factor test, demonstrating "(1) that it has suffered an

irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). "The historic purpose of an injunction is to ensure that past wrongdoing is not repeated, not to further punish the wrongdoer. Accordingly, an injunction is unnecessary if there is no reasonable likelihood that the conduct at issue will be repeated." *Pedinol Pharmacal, Inc*, 570 F. Supp. 2d at 507.

To show irreparable harm, a plaintiff "most show two things: (i) that the parties are competitors in the relevant market, and (ii) that there is a 'logical causal connection between the alleged false advertising and its own sales position.'" *Zeneca Inc. v. Eli Lilly & Co.*, No. 99 Civ. 1452 (JGK), 1999 WL 509471, at *36 (S.D.N.Y. July 19, 1999). The Court has already found that, as producers of methylfolate ingredients, Merck and Acella are competitors in the same market. Furthermore, there is a logical causal connection between Acella's false advertising and Merck's sales position – Acella sells a cheaper, competing product that it attempts to pass off as identical to Merck's purer product. Therefore, Merck has met its burden of demonstrating irreparable harm.

While damages have partially compensated Merck for its injuries, damages cannot compensate Merck for the enviable market position – and the corresponding decline in its own market position – that Acella has acquired thanks to its false advertising. Accordingly, the Court finds that equitable relief is appropriate.

Nevertheless, balancing the equities and examining the public interest, the Court concludes that Merck is entitled to some of the relief it seeks, but not the full extent. Specifically, the Court will order Acella to engage in a campaign of corrective advertising to explain the differences between Xolafin and Metafolin. In particular, Acella must explain to the relevant consumer populations that Xolafin products contain a mixture of the D- and L-isomers. Such corrective advertising shall be approved by the Court, with input from Merck. Alternatively, the parties may elect to have Merck develop its own corrective advertising campaign, for which Merck shall be compensated by Acella.

However, the Court will not permanently enjoin Acella from labeling its Xolafin and Xolafin-B products with the name L-methylfolate or any synonyms thereof. Instead, the Court orders Acella to label its methylfolate products in the future in a way that alerts consumers to the presence and relative amounts of both the D- and L-isomers in the products. *See Reckitt Benckiser, Inc. v. Motomco Ltd.*, 760 F. Supp. 2d 446, 456-57 (S.D.N.Y. 2011) (holding that, despite prior Lanham Act violations, defendant would not be prohibited from disseminating truthful, accurate information). The Court sees no reason why Acella should be prevented from using the term L-methylfolate and its synonyms, so long as they accurately reflect the product they advertise.

Nor will the Court ban Acella from selling any methylfolate product for five years, as Merck requests. First, Merck cites no case where a court banned a non-infringing product for five years, nor is the Court aware of one. Second, the Court has already enjoined Acella from repeating the misleading advertising at issue, and fully compensated Merck with trebled damages. Accordingly, a market ban for a period of five

years is not narrowly tailored to fit the specific legal violations and imposes a burden on lawful activity. *See Waldman Pub. Corp. v. Landoll, Inc.*, 43 F.3d 775, 785 (2d Cir. 1994) (denying injunctive relief that would have prohibited defendant from publishing "adapted classics" instead of "books with a false representation as to their source" for those reasons). Finally, banning non-infringing Acella products from the market would likely "disserve[]" the public interest by artificially inflating prices and decreasing consumer choice. Therefore, the Court will not ban Acella from selling methylfolate products in the United States, provided that it complies with the Court's prior directives.

VI. ATTORNEYS' FEES

The Lanham Act permits "[t]he court in exceptional cases [to] award reasonable attorney fees to the prevailing party." 15 U.S.C. § 1117(a). The Second Circuit permits recovery of fees only "on evidence of fraud or bad faith." *Conopco, Inc. v. Campbell Soup Co.*, 95 F.3d 187, 194 (2d Cir. 1996) (quoting *Twin Peaks Prods., Inc. v. Publ'ns Int'l, Ltd.*, 996 F.2d 1366, 1383 (2d Cir. 1993)). Though "even the intent to communicate a false message does not support a finding of 'bad faith' necessary to make a case 'exceptional,'" *Braun*, 2000 WL 1234590, at *4, "[e]xceptional circumstances" do include cases of "willful infringement." *Bambu Sales, Inc. v. Ozak Trading Inc.*, 58 F.3d 849, 854 (2d Cir. 1995).

As noted above, the Court finds that Acella's false advertising was willful and done in bad faith, as demonstrated by Acella's deliberate deception of the public as well as the pharmaceutical databases. Moreover, Acella's defense – premised as it was on a post hoc rationalization of its willfully infringing conduct – smacked of disdain for this Court. Deas's and Bryant's testimony concerning their decision to label Acella's folate product as "L-methylfolate" directly conflicted with FDA guidance, Acella's own practice with respect to all ingredients other than D,L-methylfolate, and Acella's internal communications. For instance, Bryant admitted that FDA guidance directs that *all compounds* used to manufacture dietary supplements be identified as ingredients. (Tr. 1349:9-11, 1351:21-24; PTX 326.) Although the FDA guidance did not carry the force of law, it must be noted that Acella *did* identify all compounds in its supplements, except for D,L-methylfolate, in conformity with that guidance. (*See* PTX 11, 31 (PNV Select label identifying Vitamin E content as the racemic mixture dl-alpha tocopheryl acetate, but identifying folate content as the pure L-methylfolate).) Further, Acella used the very nomenclature urged by Merck (D,L-methylfolate) in its internal communications and in correspondence with its supplier and manufacturer. (*See, e.g.*, PTX 18, 19, 22, 92, 119, 136, 327, 330.) It was only on the company's labels – which would be the key determinant in the pharmaceutical database linkage decision – that Defendants insisted on identifying their folate ingredient as L-methylfolate. The glaring conflicts between Deas's and Bryant's private exchanges and their public testimony convinces the Court that Acella's labeling practices and litigation strategy were nothing short of deliberately misleading. In light of this conduct, the Court finds that this case is an "exceptional" one justifying the award of attorneys' fees.

VII. CONCLUSION

For the reasons stated above, the Court finds in favor of Merck on its false advertising claim under the Lanham Act, and awards damages in the amount of $11,608,380.00. For the same reasons, the Court dismisses Acella's request for declaratory judgment and counterclaim.

Further, the Court also grants injunctive relief as follows:

(1) Acella is ordered to label its methylfolate products in a way that accurately reflects the presence and relative amounts of both the D- and L-isomers.

(2) Acella is ordered to engage in a campaign of corrective advertising that is either approved by the Court or developed by Merck.

IT IS HEREBY ORDERED THAT, no later than March 15, 2013, Merck shall submit a fee application to the Court, including a sworn declaration providing each attorney's background, experience, and billing rate at the time the work was expended, as well as copies of the attorneys' time sheets. Acella may submit papers opposing the amount of fees requested, though not the imposition of fees themselves, no later than March 31, 2013.

The Clerk of the Court is respectfully directed to enter judgment in favor of Merck and to terminate the motion located at docket entry 127.

SO ORDERED.

RICHARD J. SULLIVAN
United States District Judge

Dated: January 31, 2013
New York, New York

* * *

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