

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

ONY, INC.,

Plaintiff,

v.

DECISION AND ORDER
11-CV-1027S

CORNERSTONE THERAPEUTICS, INC., CHIESI FARMACEUTICI S.p.A., NATURE AMERICA, INC. d/b/a NATURE PUBLISHING GROUP, EDWARD E. LAWSON, M.D., AMERICAN ACADEMY OF PEDIATRICS, PREMIER, INC. d/b/a PREMIER RESEARCH SERVICES, RANGASAMY RAMANATHAN, M.D., JATINDER J. BHATIA, M.D., KRISHNAMURTHY C. SEKAR, M.D. and FRANK R. ERNST, Pharm.D.,

Defendants.

I. INTRODUCTION

Plaintiff commenced this action in December 2011 seeking damages and injunctive relief for Defendants' publication and distribution of an academic article containing allegedly false and misleading statements about Plaintiff's product. Presently before this Court are the following motions: Motion of Defendant Frank R. Ernst to Dismiss for Lack of Personal Jurisdiction (Docket No. 34); Motion of Defendants Jatinder J. Bhatia, M.D., Rangasamy Ramanathan, M.D., and Krishnamurthy C. Sekar, M.D., to Dismiss for Lack of Personal Jurisdiction and for Failure to State a Claim (Docket No. 45);¹ the Motions to

¹In December 2011, Defendants Cornerstone, Chiesi, Nature America, Lawson, American Academy of Pediatrics, Premier, and Ernst (Docket No. 21) as well as Defendants Ramanathan, Sekar, and Bhatia (Docket No. 22) moved for an extension of time to answer/reply to the Complaint. The subsequent text order granting an extension references only the motion in Docket No. 21 (see Docket No. 23). To the extent Docket No. 22 is still outstanding, that motion is granted and the submissions of Defendants Ramanathan, Sekar, and Bhatia are considered timely filed.

Dismiss for Failure to State a Claim of Defendants Nature America, Inc., and Edward E. Lawson, M.D. (Docket No. 28), Defendant Premier, Inc. (Docket No. 37), Defendant American Academy of Pediatrics (Docket No. 39), and Defendants Chiesi Farmaceutici S.p.A. and Cornerstone Therapeutics, Inc. (Docket No. 43); Plaintiff's Cross-Motion for Leave to File and Amended Complaint (Docket No. 53); Plaintiff's Motion to Expedite Discovery (Docket No. 4);² and the Motion of Defendants Cornerstone, Chiesi, Ramanathan, Bhatia, Sekar, American Academy of Pediatrics, Premier, and Ernst to Strike the Supplemental Declaration of Edmund Egan, M.D., submitted in support of Plaintiff's Motion to Expedite (Docket No. 84).

These motions are fully briefed and the Court finds oral argument unnecessary. For the reasons that follow, Defendants' motions to dismiss are granted, Plaintiff's motion to amend is denied, and the remaining motions are denied as moot.

II. BACKGROUND

Plaintiff is the manufacturer of an animal derived surfactant, a calfactant known as Infasurf®, which is used in the treatment of Respiratory Distress Syndrome ("RDS") in prematurely born infants. (Complaint, Docket No. 1, ¶¶ 14-20). Infants exhibiting RDS often suffer from inadequate lung development, specifically the lack of naturally produced surfactants which line the surface of the lungs. (Compl. ¶¶ 14-18). Infasurf® is developed from bovine lung surfactant. (Compl. ¶ 20). Defendant Chiesi Farmaceutici S.p.A. ("Chiesi"), an Italian corporation, manufactures poractant alfa, a surfactant known as Curosurf® derived from porcine lung mince. (Compl. ¶¶ 3, 22). Curosurf® is distributed

²Plaintiff also moved for expedited treatment of this discovery motion, which this Court denied (Docket No. 20).

and marketed in the United States by Defendant Cornerstone Therapeutics, Inc. (“Cornerstone”)(Compl. ¶ 22). A third surfactant, beractant (Survanta®), is manufactured from bovine lung mince by non-party Abbott Pharmaceuticals. (Compl. ¶ 21).

As alleged in the Complaint, Defendant Chiesi “directly or through an agent . . . commissioned a ‘study’ to support the claim that Curosurf® was a superior surfactant.” (Compl. ¶ 28). Chiesi hired Defendant Premier Inc., d/b/a Premier Research Services (“Premier”) to “provide a database to support the desired conclusion.” (Compl. ¶ 28). Defendant Frank D. Ernst is the Premier employee who assembled the database. (Compl. ¶ 28). Chiesi then hired Defendants Rangasamy Ramanathan, M.D., Jatinder J. Bhatia, M.D., and Krishnamurthy C. Sekar, M.D., (the “Defendant Authors”) to submit the findings to pediatric medical societies in the United States and Europe in 2007. (Compl. ¶¶ 29-33).

In March 2011, the Defendant Authors and Defendant Ernst³ submitted a revised study for publication in the Journal of Perinatology (the “Journal”) which included allegedly false claims that preterm infants treated with Chiesi’s Curosurf® have a lower mortality rate than those treated with Plaintiff’s Infasurf®. (Compl. ¶ 35). As specified in Plaintiff’s proposed Amended Complaint (Docket No. 81-1), these statements include:

“Result: Calfactant was associated with a 49.6% greater likelihood of death than poractant alfa;”

“Conclusion: Poractant alfa treatment for RDS was associated with a significantly reduced likelihood of death when compared with calfactant;”

“Calfactant was found to be associated with a 49.6% greater likelihood of death than poractant alfa;”

³Defendant Ernst, who prepared the database on behalf of Premier, is also credited as an author of the Article.

“This model found calfactant to be associated with a significantly greater likelihood of death than poractant alfa;”

This study “show[ed] a significant greater likelihood of death with calfactant than poractant alfa;” and

“[T]his large retrospective study of preterm infants with RDS found lower mortality among infants who received poractant alfa, compared with infants who received either calfactant or beractant, even after adjusting for patient characteristics such as gestational age and BW, and after accounting for hospital characteristics and center effects.”

(Prop. Amend. Compl. ¶ 35; see Docket Nos. 6-2, 30-1 (the study is entitled “Mortality in preterm infants with respiratory distress syndrome treated with poractant alfa, calfactant or beractant: a retrospective study,” hereinafter referred to as “the Article”)). The Journal is the official journal of Defendant American Academy of Pediatrics (“AAP”), the “preeminent organization for physicians who practice in general pediatrics and its subspecialties, including neonatology,” and is published by Defendant Nature America (Compl. ¶¶ 38, 59). According to the Complaint, “[a]rticles in AAP-sanctioned journals are perceived to present reliable information for patient care by neonatologists.” (Compl. ¶ 60).

Plaintiff alleges that:

“the data which served as the basis for the Article was not based upon an actual clinical study. Rather, the data was culled from a database of information which Defendant Premier collected from various reporting hospitals and physicians. As a result, the data was retrospective and was subject to selective distortion. Specifically, the reliability of any reported mortality data is a function of the similarity of the characteristics of the group of infants examined, including [length of stay, or] LOS data. Deliberate omission of the LOS data allows the Defendants to postulate, promote and disseminate false conclusions regarding any differences in the mortality of infants treated with one product versus another.”

(Compl. ¶ 37). ‘LOS data’ refers to the length of the hospital stay, and is therefore inversely proportionate to premature infant mortality. (Compl. ¶ 26). “Without the LOS

data, the conclusions of the Article are **unreliable, and therefore misleading**. Had the Article presented the Curosurf® patients as having both a lower mortality and a shorter length of stay, it would be obvious that the differences in the results were a result of differences in the groups of patients treated, not of any differences in the effect of the particular lung surfactant administered.” (Compl. ¶¶ 67 (emphasis altered)). “The Defendant Authors had access to and were aware of the pertinent LOS data, yet chose to omit it from the Article.” (Compl. 41). Plaintiff further alleges that the Defendant Authors neglected to cite at least one journal article contradicting the findings in the Article, despite knowing of its existence, and that these Defendants also submitted the Article for publication knowing that it was deficient. (Compl. ¶¶ 44-45). “Indeed, upon information and belief, the Defendant Authors did not actually write the Article, or conduct the research or reach the conclusions set forth therein. Rather, it was other, undisclosed agents of Defendants Chiesi and Cornerstone who did.” (Compl. ¶ 46).

It is further asserted that Defendant Premier benefitted economically from its employee Ernst “submit[ting] the Article for publication.” (Compl. 48). “[T]he publication of the Article reporting ‘findings’ to the benefit of its customers Defendants Chiesi and Cornerstone served as advertising for Premier’s database and related services, and announced to pharmaceutical companies and other providers of medical products and services . . . that the engagement of Premier in connection with similar self-serving ‘studies’ would be to their economic benefit as well.” (Compl. ¶ 48).

Defendant Edward E. Lawson, M.D. is the Editor-in-Chief of the Journal. (Compl. ¶ 51). Prior to being accepted for publication, the Article was sent to two peer reviewers. (Compl. ¶ 49). Lawson accepted the Article for publication despite the fact that one of the

two reviewers found the Article's conclusions therein unreliable. (Compl. ¶¶ 49-51, 54). Plaintiff alleges that this acceptance was based in part on the fact that Defendant Bhatia is an Associate Editor for the Journal and Defendant Sekar is on the Journal's Editorial Board. (Compl. ¶¶ 52-53). Defendants "Chiesi and/or Cornerstone" then paid Defendant Nature America to publish the Article in an 'open access' format, which allows non-subscribers to access the Article (Compl. ¶¶ 56-57). After the Article was published, "Defendant Cornerstone, on behalf of itself and Defendant Chiesi, issued a press release touting the Article and, upon information and belief, began distributing the Article, either in part or in whole, to current and potential customers, including hospitals and physicians nationwide which currently use [Plaintiff's] Infasurf®." (Compl. 61).

Plaintiff's president, Edmund Egan, M.D., wrote to the Journal and Defendant AAP requesting that the Article be retracted due to its deficiencies, a request that was denied. (Compl. ¶¶ 64-65, 68, 70). Plaintiff alleges that, as such, the Journal and AAP are sanctioning and condoning scientifically unreliable information which influences purchasing decisions by hospitals and prescribing decisions by neonatologists. (Compl. ¶¶ 69-71).

In light of these alleged facts, Plaintiff asserts that publication and distribution of the Article constitutes false advertising in violation of 15 U.S.C. § 1125 (a) (first cause of action against Defendants Chiesi and Cornerstone); an injurious falsehood (second cause of action against Chiesi and Cornerstone, third cause of action against Nature America and Lawson; fourth cause of action against AAP, fifth cause of action against the Defendant Authors and Ernst); tortious interference with contract (sixth cause of action against Chiesi and Cornerstone); and a violation of New York General Business Law § 349 "and Similar

Statutes of Other States”⁴ (seventh cause of action against Chiesi and Cornerstone). Plaintiff seeks injunctive relief⁵ from Chiesi, Cornerstone, and Nature America prohibiting the further distribution of the Article or statements therefrom.

III. DISCUSSION

A. Personal Jurisdiction

This Court will first address the jurisdictional issues raised by the motions. See generally Rationis Enters., Inc. of Panama v. AEP/Borden Indus., 261 F.3d 264, 267 (2d Cir. 2001). The Defendant Authors⁶ and Frank R. Ernst⁷ move to dismiss the complaint as against them on the ground that personal jurisdiction is lacking. Subject to certain constitutional limitations of due process, the breadth of a federal court’s personal jurisdiction is determined by the law of the state in which the district court is located.

⁴The arguments of the parties, including Plaintiff, on the state law claims reference only New York law.

⁵In the original Complaint, Plaintiff asserted two separate causes of action for injunctive relief against Defendants Chiesi, Cornerstone, and Nature America. (Compl. ¶¶ 122-131). In the Proposed Amended Complaint, Plaintiff has included the requests for injunctive relief in the appropriate causes of action against these Defendants. (Prop. Amend. Compl. ¶¶ 79-81, 86-88, 97-101).

⁶The Defendant Authors’ Motion to Dismiss is premised upon both the lack of personal jurisdiction and the failure of the complaint to state a claim (Docket No. 45). In support of their motion, the Defendant Authors submitted a supporting Memorandum of Law (Docket No. 46), the Declaration of J. Kevin Fee, Esq., with Exhibit A (Docket No. 46-1), Declaration of Defendant Jatinder Bhatia, M.D. (Docket No. 46-3), the Declaration of Rangasamy Ramanathan, M.D. (Docket No. 46-4); and the Declaration of Defendant Krishnamurthy Sekar, M.D. (Docket No. 46-5). Plaintiff opposed this motion with an opposing Memorandum of Law (Docket No. 60), and the Declaration of Mitchell J. Banas, Jr., Esq., with Exhibits A-D (Docket No. 61). The Defendant Authors file a reply Memorandum of Law (Docket No. 77) with supplemental Declarations from Drs. Bhatia, Ramanathan, and Sekar (Docket No. 77-1).

⁷Defendant Ernst separately moves for dismissal on personal jurisdiction grounds (Docket No. 34) and also joins in Defendant Premier’s Motion to Dismiss for failure to state a claim (Docket No. 37 at 1 n 1). In support of his motion, he submitted a supporting Memorandum of Law (Docket No. 36) and the Declaration of Frank R. Ernst (Docket No. 35). In opposition, Plaintiff submitted the Declaration of Mitchell J. Banas, Jr., with Exhibits A-D (Docket No. 58) and an opposing Memorandum of Law (Docket No. 67). Ernst filed a reply Memorandum of Law (Docket No. 74) and a supplemental Declaration of Frank R. Ernst (Docket No. 75).

Thomas v. Ashcroft, 470 F.3d 491, 495 (2d Cir. 2006), citing Henderson v. INS, 157 F.3d 106, 123 (2d Cir. 1998). Where the district court relies solely on the pleadings and supporting affidavits, as is the case here, the burden on a plaintiff facing a motion to dismiss pursuant to Fed. R. Civ. P. 12 (b)(2) is to establish only a prima facie showing of personal jurisdiction. Robinson v. Overseas Military Sales Corp., 21 F.3d 502, 507 (2d Cir. 1994); see Mattel, Inc. v. Barbie-Club.com, 310 F.3d 293, 298 (2d Cir. 2002)(prior to discovery, a plaintiff's burden is a lenient one requiring only legally sufficient allegations of jurisdiction). Although the court need not draw argumentative inferences in the plaintiff's favor, the pleadings and affidavits are considered in a light most favorable to the plaintiff. Robinson, 21 F.3d at 507; CutCo Indus., Inc. v. Naughton, 806 F.2d 361, 365 (2d Cir. 1986).

There is no dispute that Defendants Ramanathan, Bhatia, Sekar, and Ernst, the four credited authors of the Article, are not domiciliaries of New York. Compl. ¶¶ 8-11. Nor does Plaintiff dispute that the Article was written and researched outside of New York State. Decls. of Ramanathan ¶ 8, Bhatia ¶ 9, Sekar ¶ 8, Docket No. 77-1; Decl. of Ernst, Docket No. 35, ¶ 4. Plaintiff argues that personal jurisdiction is nonetheless found under subsection (a)(1) of New York's long-arm jurisdiction statute, CPLR 302. See Pl's Mem. of Law in Opposition, Docket Nos. 60 at 1-6, 67 at 1-7.⁸ Because the reach of New York's long-arm statute is not as extensive as the scope permissible pursuant to federal constitutional authority, the statutory inquiry will be conducted first. Best Van Lines, Inc. v. Walker, 490 F.3d 239, 244 (2d Cir. 2007)(only where jurisdiction is statutorily permissible

⁸Plaintiff raises no other ground for personal jurisdiction.

is the issue of constitutionality addressed). CPLR 302 (a)(1) states that a court may exercise personal jurisdiction over a non-domiciliary who in person or through an agent “[t]ransacts any business within the state or contracts anywhere to supply goods or services in the state.” See also Best Van Lines, 490 F.3d at 247 (noting that it appeared that ‘transacting business’ analysis overlapped significantly with constitution minimal contacts analysis). Personal jurisdiction pursuant to this provision also requires that there be an articulable nexus or substantial relationship between the transaction of business and the cause of action being sued upon. Sunward Electronics, Inc. v. McDonald, 362 F.3d 17, 23 (2d Cir. 2004). A single purposeful act in New York may be sufficient to meet the ‘transacting business element’ if it establishes that the defendant purposefully availed him- or herself of the privilege of conducting business in New York, thereby invoking the benefits and protections of this state’s laws. Kahn Lucas Lancaster, Inc. v. Lark Int’l. Ltd., 956 F.Supp. 1131, 1135 (S.D.N.Y. 1997); see CutCo Indus., Inc., 806 F.2d at 365, citing McKee Electric Co. v. Rauland-Borg Corp., 20 N.Y.2d 377, 382 (N.Y. 1967).

Here, it is not alleged that publication of the Article was negotiated within New York state. Indeed, publication was not negotiated but rather conditioned on separate peer reviews and left to the editorial discretion of Defendant Lawson. Compl. ¶¶ 49-53. As noted, the research and writing of the Article itself was conducted outside the state. Plaintiff does not dispute that the Defendant Authors received no payment from the Journal or its New York based publisher for publication of the Article, Decls. of Ramanathan ¶ 7, Bhatia ¶ 8, Sekar ¶ 7, Docket No. 77-1, or that Defendant Ernst was an employee of a North Carolina corporation. Compl. ¶¶ 6, 28. In support of its argument, Plaintiff notes that Nature Publishing Group requires all authors to sign a License to Publish agreement prior

to the submission of any papers for publication. Banas Decl., Docket No. 58, 61, Ex. D. The License to Publish contains a choice of law provision stating that the “Agreement shall be governed by and construed in accordance with the laws of the state of New York without regard to the principles of conflicts of law. The parties hereto submit to the non-exclusive jurisdiction of the courts of New York.” Banas Decl., Docket No. 58, 61, Ex. D. Choice of law provisions, although significant in determining whether a nondomiciliary transacted business for the purposes of CPLR 302 (a)(1), are alone insufficient to confer jurisdiction. CutCo Indus., Inc., 806 F.2d at 366-367. Further, parties may consent to personal jurisdiction through forum selection clauses in agreements. D.H. Blair & Co. v. Gottdiener, 462 F.3d 95, 103 (2d Cir. 2006). Because a matter may not be commenced or transferred to a chosen forum in the absence of personal jurisdiction over the defendant, a forum selection clause is meaningless without an express consent to personal jurisdiction,. Hearst Enter’t, Inc. v. Multichannel Dist. Servs. A.V.V., No. 96 Civ. 0310, 1997 WL 72150, *2 n 3 (S.D.N.Y. Feb. 19, 1997), citing Richard Grenshields Secs., Inc. v. Metz, 566 F.Supp. 131, 132-133 (S.D.N.Y. 1983). Here, the language of the License to Publish agreement refers only to the “non-exclusive jurisdiction” of New York courts and contains no express consent to personal jurisdiction. Cf. Maersk, Inc. v. Neewra, Inc., 554 F.Supp.2d 424, 440-441 (S.D.N.Y. 2008)(choice of forum clause stated S.D.N.Y. had “exclusive jurisdiction”); Counsel Fin. Servs., LLC v. The Dobson Firm, LLC, No. 09-CV-150S, 2010 WL 3504789, *3-4 (W.D.N.Y. Sept. 2, 2010)(language in Note and Guaranty stated that borrower expressly submitted and consented to jurisdiction in New York State Supreme Court, and that the same would be the sole and exclusive venue). Accordingly, the License to Publish agreement alone is insufficient to establish that these Defendants

consented to personal jurisdiction in New York. See also Kimco Exchange Place Corp. v. Thomas Benz, Inc., 34 A.D.3d 433, 434 (N.Y. App Div 2d Dep't 2006), lv denied 9 N.Y.3d 803 (2007)(sending of executed contracts into New York along with few telephone calls did not amount to purposeful acts constituting the transaction of business within the state).

Further, an injurious falsehood cause of action, the only cause of action asserted against these Defendants, is a claim involving a false statement made denigrating the quality of a business' goods or services. Ruder & Finn, Inc. v. Seaboard Sur. Co., 52 N.Y.2d 663, 670-671 (N.Y. 1981); see Henneberry v. Sumitomo Corp. of America, 415 F.Supp.2d 423, 470 (S.D.N.Y. 2006)(sometimes referred to as trade libel). This claim, and indeed the entire complaint, sounds in defamation. See Cantor Fitzgerald, L.P. v. Peaslee, 88 F.3d 152, 157 (2d Cir. 1996)(complaint containing injurious falsehood and tortious interference with prospective economic advantage sounded in defamation). Notably, CPLR 302 (a)(2) and (3), which provide for jurisdiction due to the defendant's commission of a tortious act,⁹ both explicitly exclude actions for defamation. Accordingly, courts considering this long-arm statute as a whole have concluded that "when the defamatory publication itself constitutes the alleged 'transact[ion of] business' for the purposes of section 302(a)(1), more than the distribution of a libelous statement must be made within the state to establish long-arm jurisdiction over the person distributing it." Best Van Lines, Inc., 490 F.3d at 248 n 11; see Kim v. Dvorak, 230 A.D.2d 286, 289-290 (N.Y. App Div 3d Dep't 1997)(no personal jurisdiction where only contact was the submission of allegedly

⁹CPLR 302 (a)(2) provides for jurisdiction over a non-domiciliary who "commits a tortious act within the state . . ." and CPLR 302 (a)(3) provides for jurisdiction over a non-domiciliary who "commits a tortious act without the state causing injury to person or property within the state . . ."

defamatory letters sent into the state). Here, with respect to Defendants Ernst and Ramanathan, the only New York contact alleged is the submission of the Article itself, which is an insufficient basis on which to establish personal jurisdiction.

Plaintiff does allege a further contact with respect to Defendants Bhatia and Sekar, specifically that Defendant Bhatia was an Associate Editor for the Journal and Defendant Sekar was on the Journal's Editorial Board. Compl. ¶ 52. Initially, an employee's contacts with a forum state "are not to be judged according to their employer's activities there," but assessed individually. Calder v. Jones, 465 U.S. 783, 790, 104 S.Ct. 1482, 79 L.Ed.2d 804 (1984). Here, Defendants Bhatia and Sekar describe the duties of their respective positions as limited to reviewing articles which are emailed to them and returning comments. Bhatia Decl., Docket No. 77-1, ¶ 14; Sekar Decl., Docket No. 77-1, ¶¶ 12-13. Plaintiff offers no allegations disputing these assertions, or allegations of further New York contacts, therefore Plaintiff has failed to provide legally sufficient allegations of personal jurisdiction over these defendants as well.

Moreover, this Court finds that, under the facts of this case, Defendants' submission of the Article to a New York publisher is akin to a mere solicitation or the placement of an advertisement. See Parsons v. Kal Kan Food, Inc., 68 A.D.3d 1501, 1502 (N.Y. App Div 3d Dep't. 2009)("mere solicitation of business in New York is insufficient to constitute doing business here"). Indeed, the essence of Plaintiff's Complaint is that the Article is itself a false advertisement. "A defendant is not subject to § 302 (a)(1) jurisdiction simply by virtue of having placed advertising in a New-York-based publication." Maranga v. Vira, 386 F.Supp.2d 299, 308 (S.D.N.Y. 2005); Davidson Extrusions, Inc. v. Touche Ross & Co., 131 A.D.2d 421, 424 (N.Y. App Div 2d Dep't 1987); see also Global Gospel Music Group LLC

v. Habukkuk Music, Inc., No. 10 Civ. 01818, 2010 WL 4968172, *4 (S.D.N.Y. 2010)(“[a]dvertising or mere solicitation is not considered transacting business”). See Maranga v. Vira, 386 F.Supp.2d 299, 308 (S.D.N.Y. 2005). Such placement “adds little justification for the assertion of personal jurisdiction under § 302 (a)(1),” especially where there is no allegation that the Journal “circulates only in New York, or even primarily in New York.” Maranga, 386 F.Supp.2d at 308. This Court therefore concludes that personal jurisdiction over these four Defendants is lacking.

B. Failure to State a Claim

In considering a motion to dismiss for failure to state a claim pursuant to Rule 12 (b)(6), a court must accept all factual allegations in the complaint as true and make all reasonable inferences in a plaintiffs’ favor. ATSI Commc’ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 98 (2d Cir. 2007). In order to survive such a motion, 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, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009), quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007); ATSI Commc’ns, Inc., 493 F.3d at 98. This assumption of truth applies only to factual allegations and is inapplicable to legal conclusions. Ashcroft, 556 S.Ct. at 1949. “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Ashcroft, 129 S.Ct. At 1949. In making its determination, a court is entitled to consider, as relevant here:

- (1) facts alleged in the complaint and documents attached to it or incorporated in it by reference, (2) documents ‘integral’ to the complaint and relied upon in it, even if not attached or incorporated by reference, (3)

documents or information contained in defendant's motion papers if plaintiff has knowledge or possession of the material and relied on it in framing the complaint, (4) . . . , and (5) facts of which judicial notice may properly be taken under Rule 201 of the Federal Rules of Evidence.

In re Merrill Lynch & Co., Inc., 273 F.Supp.2d 351, 356-357 (S.D.N.Y. 2003)(citations omitted), aff'd 396 F.3d 161 (2d Cir. 2005), cert denied 546 U.S. 935 (2005); see Weiss v. Inc. Vill. of Sag Harbor, 762 F. Supp. 2d 560, 567 (E.D.N.Y. 2011).

In opposition to Defendants' motions to dismiss, Plaintiff has cross-moved for leave to amend its complaint.¹⁰ Generally, leave to amend a pleading shall be freely given when justice so requires. Fed. R. Civ. P. 15 (a) (2). Nonetheless, it is in the sound discretion of this Court "to deny leave for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party." McCarthy v. Dun & Bradstreet Corp., 482 F.3d 184, 200 (2d Cir. 2007); see Foman v. Davis, 371 U.S. 178, 182, 83 S.Ct. 227, 9 L.Ed.2d 222 (1962). An amendment is considered futile if the amended pleading would not survive a motion to dismiss, either pursuant to Rule 12 (b)(6) or on some other basis. Dougherty v. Town of North Hempstead Bd. of Zoning Appeals, 282 F.3d 83, 88 (2d Cir. 2002); McKinney v. Eastman Kodak Co., 975 F. Supp. 462, 465 (W.D.N.Y. 1997).

1. False or Misleading Trade Practice Causes of Action

Plaintiff asserts causes of action for false or misleading advertising in violation of

¹⁰Plaintiff submitted in support of its Cross-Motion to Amend (Docket No. 53) a supporting Memorandum of Law (Docket No. 54), the Declaration of Edmund A. Egan, M.D., with Ex A (Docket Nos. 68-69, 71), the Declaration of Mitchell J. Banas, Jr., with Ex A (Proposed Amended Complaint)(Docket No. 81). Defendants' arguments in opposition are largely contained in their reply papers in support of their respective motions to dismiss, however, also filed were the opposition statements of Defendant AAP (Docket No. 85) and Defendants Premier and Ernst (Docket No. 88), and opposing Memoranda of Law from Defendants Nature America and Lawson (Docket No. 86) and Defendants Chiesi, Cornerstone, Ramanathan, Bhatia and Sekar (Docket No. 89). Plaintiff filed a reply Memorandum of Law in further support of its motion to amend (Docket No. 92).

15 U.S.C. § 1125 (a)(1) and N.Y. General Business Law § 349 against Defendants Cornerstone and Chiesi,¹¹ and for injurious falsehood against each Defendant.^{12 13 14} The Lanham Act, as codified in 15 U.S.C. § 1125 (a)(1), “makes actionable false or misleading descriptions or false or misleading representations of fact made about one’s own or another’s goods or services.” Boule v. Hutton, 328 F.3d 84, 90 (2d Cir. 2003)(internal quotation marks omitted). Similarly, N.Y. General Business Law § 349 provides a cause of action for any person who has been injured due to the use of deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in New York state. § 349 (h). Finally, under New York law, an injurious falsehood cause of action, sometimes referred to as trade libel, lies where a false statement is made denigrating the quality of a business’ goods or services. See Ruder & Finn, Inc. v. Seaboard Sur. Co., 52 N.Y.2d 663, 670-671 (N.Y. 1981) (distinguishing injurious falsehood from defamation, in that defamation pertains to statements regarding basic integrity or creditworthiness); see Henneberry v. Sumitomo Corp. of America, 415 F.Supp.2d 423, 470 -471 (S.D.N.Y. 2006). To establish such a cause of action, a plaintiff must sufficiently

¹¹In support of their motion (Docket No. 43), Defendant Chiesi and Cornerstone submitted a supporting Memorandum of Law and the Declaration of J. Kevin Fee with Ex A (Docket No. 44). Plaintiff opposed the motion with an opposing Memorandum of Law (Docket No. 66), and Defendant filed a reply Memorandum of Law (Docket No. 78).

¹²Defendants Nature America and Edward E. Lawson, M.D., submitted in support of their Motion to Dismiss (Docket No. 28) a supporting Memorandum of Law (Docket No. 29), and the Declaration of Lawson with Ex A-C (Docket No. 30). Plaintiff submitted an opposing Memorandum of Law (Docket No. 65), to which Defendants responded with a Reply Memorandum of Law (Docket No. 76).

¹³In support of its Motion to Dismiss (Docket No. 37), Defendant Premier submitted a supporting Memorandum of Law (Docket No. 38), to which Plaintiff responded with an opposing Memorandum of Law (Docket No. 64). Defendant also submitted a reply Memorandum of Law (Docket No. 73).

¹⁴In support of its Motion to Dismiss (Docket No. 39), Defendant AAP submitted a supporting Memorandum of Law (Docket No. 39-1), to which Plaintiff responded with an opposing Memorandum of Law (Docket No. 63). Defendant also submitted a reply Memorandum of Law (Docket No. 72).

allege (1) the falsity of the statements disparaging the goods or services, (2) publication to a third person; (3) malice; and (4) special damages. See Ruder & Finn, Inc., 52 N.Y.2d at 670-671; Drug Research Corp. v. Curtis Publ. Co., 7 N.Y.2d 435, 440 (N.Y. 1960).

Initially, as Defendants argue,¹⁵ statements of opinion cannot support any of the above causes of action. See Groden v. Random House, Inc., 61 F.3d 1045, 1051 (2d Cir. 1995)(a statement challenged under the Lanham Act “must be literally false or, though literally true, likely to mislead or confuse consumers,” statements of opinion are not actionable); Sandler v. Simoes, 609 F.Supp.2d 293, 297, 303 (E.D.N.Y. 2009)(an “expression of pure opinion is not actionable” by way of an injurious falsehood claim); Arts4All, Ltd. v. Hancock, 5 A.D.3d 106, 110 (N.Y. App Div 1st Dep’t 2004)(same); Verizon Directories Corp. v. Yellow Book USA, Inc., 309 F.Supp.2d 401, 405-406 (E.D.N.Y. 2004)(like actions under the Lanham Act, claims based on puffery or opinion are not actionable under General Business Law § 349); see generally Gross v. New York Times Co., 82 N.Y.2d 146, 152 (N.Y. 1993)(the dispositive inquiry in a defamation claim, under either Federal or New York law, is whether a reasonable person would have concluded that the article was conveying *facts*). “Such statements are not actionable because ‘a proffered hypothesis that is offered after a full recitation of the facts on which it is based is readily understood by the audience as conjecture.’ ” Doe v. White Plains Hosp. Med. Ctr., No. 10 Civ. 5405, 2011 WL 2899174, *3 (S.D.N.Y. July 8, 2011), quoting Gross, 80 N.Y.2d at 154, affd Doe v. French, ___ Fed.Appx. ___, 2012 WL 129836 (2d Cir. Jan. 18, 2012).

¹⁵Defendants Cornerstone & Chiesi Mem of Law, Docket No. 44, at 6-9; Mem of Law of Defendants Nature America & Ernst, Docket No. 29, at 14-20, Mem of Law of Defendants Premier & Ernst, Docket No. 38, at 4-6, AAP’s Mem of Law, Docket No. 39-1, at 5-6.

Determination of whether a statement is an expression of fact or opinion is a threshold question of law for the court. Miller v. Richman, 184 A.D.2d 191, 193 (N.Y. App Div 4th Dep't 1992), citing Silsdorf v. Levine, 59 N.Y.2d 8, 13 (N.Y. 1983), cert denied 464 U.S. 831 (1983); see Levin v. McPhee, 119 F.3d 189, 195 (2d Cir. 1997).

Here, Plaintiff's claims are based upon the conclusions of the authors published in an academic article in a scientific journal. This Court recognizes that "[a]cademic freedom is 'a special concern of the First Amendment,'" Gordon & Breach Science Publishers, S.A. v. American Inst. of Physics, 859 F.Supp. 1521, 1541 (S.D.N.Y. 1992), quoting Keyishian v. Bd. of Regents, 385 U.S. 589, 603, 87 S.Ct. 675, 17 L.Ed.2d 629 (1967), and that "[t]he chilling effect of protracted litigation can be especially severe for scholarly journals." Immuno AF. v. Moor-Jankowski, 77 N.Y.2d 235, 256 (N.Y. 1991), cert denied 500 U.S. 954 (1991). Nonetheless, there is no "wholesale exemption for anything that might be labeled as 'opinion.'" Immuno AF. v. Moor-Jankowski, 77 N.Y.2d 235, 245 (N.Y. 1991), cert denied 500 U.S. 954 (1991). Nor is there "license to misportray facts; false statements are actionable when they would be perceived as factual by the reasonable person." Id. at 254.

"[S]tatements must first be viewed in their context in order for courts to determine whether a reasonable person would view them as expressing or implying *any* facts." Id. at 254 (emphasis in original).

Distinguishing between assertions of fact and nonactionable expressions of opinion has often proved a difficult task. The factors to be considered are: "(1) whether the specific language in issue has a precise meaning which is readily understood; (2) whether the statements are capable of being proven true or false; and (3) whether either the full context of the communication in which the statement appears or the broader social context and surrounding circumstances are such as to 'signal ... readers or listeners that what is being read or heard is likely to be opinion, not fact'" (Gross v New York Times Co., [82 N.Y.2d] at 153, quoting Steinhilber v Alphonse, [68 N.Y.2d]

at 292; accord, *Immuno AG. v Moor-Jankowski*, [77 N.Y.2d 235]). It is the last of these factors that lends both depth and difficulty to the analysis.

Brian v. Richardson, 87 N.Y.2d 46, 50 -51 (N.Y. 1995). Thus, the thrust of the inquiry under both New York and federal law is whether a reasonable reader could have concluded that the Article was conveying facts about the efficacy of Plaintiff's product. See Levin, 119 F.3d at 196; Gross, 82 N.Y.2d at 152; see Johnson & Johnson * Merck Consumer Pharm. Co. v. Smithkline Beecham Corp., 960 F.2d 294, 297-298 (2d Cir. 1992)(the relevant question where a plaintiff claims an implied falsehood under the Lanham Act is what the public perceives the message to be). "The entire publication, as well as the circumstances of its issuance, must be considered in terms of its effect upon the ordinary reader." Silsdorf, 59 N.Y.2d at 13.

Plaintiff alleges that the Article, which Chiesi and Cornerstone continued to distribute after the original publication, contains "false and/or misleading representations of fact as to the relative mortality difference between Curosurf® and Infasurf®" and the "nature, characteristics, qualities and efficacy of each" surfactant. Compl. ¶¶ 35, 75-76, 80; Prop. Amended Compl. ¶¶ 35, 75-76, 83. Plaintiff specifically points to the conclusions in the Article that calfactant, which is manufactured by Plaintiff as Infasurf®, was associated "with a 49.6% greater likelihood of death" or a "significantly greater likelihood of death" than poractant alfa, manufactured by Chiesi as Curosurf®. Prop. Amend. Compl. ¶ 35. Notably, Plaintiff does not allege that these conclusions are patently false because there is evidence that calfactant is in fact more effective at treating RDS. Instead, Plaintiff asserts that these conclusions "are unreliable, and therefore misleading" because the omission of LOS data allowed the authors of the Article to "postulate, promote and disseminate false

conclusions.” Compl. ¶¶ 37, 67; Prop. Amend. Compl. ¶¶ 37, 67 (emphasis added).

The issue here is therefore whether the Article sufficiently states the facts on which these conclusions are based or whether it impermissibly implies that the conclusions reached are supported by additional information not afforded the reader:

Though some statements may be characterized as hypothesis or conjecture, they may yet be actionable if they imply that the speaker’s opinion is based on the speaker’s knowledge of facts that are not disclosed to the reader. On the other hand, if a statement of opinion either discloses the facts on which it is based or does not imply the existence of undisclosed facts, the opinion is not actionable.

Levin, 119 F.3d at 197 (internal citations omitted). Initially, the peer-reviewed journal in which the Article was published “is directed to a highly specialized group of readers – medical doctors, researchers and the medical and science libraries of academic institutions. The average reader is thus likely not a novice in the field of [pediatric medicine], but brings a well-developed understanding of the issues facing biomedical research[].” Immuno AG, 77 N.Y.2d at 253 (internal quotation marks omitted). Further, the Article itself contains an initial section detailing the patient data and research methods utilized in the retrospective observational cohort analysis conducted. The Article at 2. LOS data is not mentioned, however, the authors specifically listed what patient criteria was considered, specifically the type of surfactant administered, gestational age, birth weight, gender, race, “3m All Patient Refined Diagnosis Related Group severity of illness category and risk of mortality category.” Id. at 2-3 (chart). Accordingly, the Article reflects the facts on which the authors’ conclusions are based, and does not imply that undisclosed facts also exist supporting the authors’ conclusions. See Brian, 87 N.Y.2d at 54.

Further, consideration of the Article as a whole supports the determination that the

average reader would perceive these statements as debatable hypotheses rather than assertions of unassailable fact. See Mann v. Abel, 10 N.Y.3d 271, 277 (N.Y. 2008), cert denied 55 U.S. 1170 (2009); Immuno AF., 77 N.Y.2d at 253-254. Rather than presenting the results of their study as conclusive, the authors of the Article acknowledged that the “study has certain limitations due to the retrospective nature of the database used,” and that additional factors could likely affect the stated conclusions. The Article at 5-6; compare with Compl. ¶ 37 (alleging the retrospective nature of the data was subject to distortion). With respect to the comparative effectiveness of poractant alfa to calfactant or beractant, the authors specifically stated that the study’s findings “prompts one to look for a possible explanation for such different outcomes for poractant alfa over the other two surfactants. The most likely explanation may be due to different surfactant doses administered to the infants included in the database,” as doses of poractant alfa tended to be twice as large as doses of the other two surfactants. The Article at 6. Thus, this Court cannot conclude that a reasonable reader of the Article, even one lacking medical acumen, would have concluded that the Article was conveying proven facts about the efficacy of Plaintiff’s product. See Levin, 119 F.3d at 196; Gross, 82 N.Y.2d at 152; see Johnson & Johnson * Merck Consumer Pharm. Co., 960 F.2d at 297-298. Instead, the statements that calfactant was associated with a “significantly greater likelihood of death” than poractant alfa is a non-actionable hypothesis based upon limited and articulated facts. Compl. ¶ 35; see Levin, 119 F.3d at 197 (where the uncertainty of certain facts is emphasized, the reader is alerted that allegations are conjecture). Because the Article is not misleading with respect to the facts on which it is and is not based, any perceived fault in the method by which the authors reached their conclusions should be subjected to peer review rather

than judicial review. Underwager v. Salter, 22 F.3d 730, 736 (7th Cir. 1994)(“[s]cientific controversies must be settled by the methods of science rather than by the methods of litigation”), cert denied 513 U.S. 943 (1994).

Plaintiff further alleges that Defendants Chiesi and Cornerstone paid Premier and the Defendant Authors to compile data in support of a favorable conclusion. ¶¶ 28, 31. This source of possible prejudice was clearly indicated in the article under the heading “**Conflict of Interest**,” wherein the authors acknowledged that the “study was sponsored by Chiesi Farmaceutici SpA, the manufacturer of poractant alfa. Frank R. Ernst is an employee of Premier, which contracted with Chiesi Farmaceutici SpA to conduct the study. Rangasamy Ramanathan, Kris Sekar and Jatinder Bhatia have served as consultants to Ciesi Farmaceutici SpA.” The Article at 6 (emphasis in original). The authors therefore clearly signaled to the reader that they were not disinterested observers, thereby leaving the credibility assessment of the authors’ opinions in light of that disclosure to the reader. Brian, 87 N.Y.2d at 53-54.

Accordingly, “both the immediate context of the article itself and the broader context in which the article was published made it sufficiently apparent to the reasonable reader that its contents represented the opinion of the author[s].” Brian, 87 N.Y.2d at 54. Plaintiff has therefore failed to state a cognizable claim for violation of the Lanham Act, violation of General Business Law § 349, or injurious falsehood. In light of this conclusion, the Court does not need to address Defendants’ further arguments that Plaintiff failed to adequately plead special damages or malice in association with the injurious falsehood claims. The first through fifth and seventh causes of action in the Complaint are dismissed,

and Plaintiff's cross-motion to amend the Complaint is denied with respect to those causes of action.

2. Tortious Interference Cause of Action

Plaintiff's sixth cause of action alleges that Defendants Chiesi and Cornerstone tortiously interfered with "existing and prospective contracts which Plaintiff had or would have had with various hospitals and physicians." Compl. ¶ 112. Plaintiff concedes that the original Complaint is lacking allegations regarding the specific contracts with which Defendants purportedly interfered. Pl's Mem of Law in Opp'n, Docket No. 66 at 24. Plaintiff further concedes that it has no cause of action for tortious interference with any existent contract, but argues that the proposed Amended Complaint states a claim for interference with prospective economic advantage. Pl's Reply Mem of Law in Support of Cross-Motion to Amend, Docket No. 92, at 5-6. Plaintiff alleges therein that Chiesi and Cornerstone interfered with "contracts or prospective contracts with Norman Regional Hospital in Norman, Oklahoma, Long Beach Memorial/Miller Children's Hospital in Long Beach, California, Salinas Memorial Hospital in Salinas, California, and Lake Charles Memorial Hospital for Women in Lake Charles, Louisiana." Prop. Amended Compl. ¶123 (emphasis removed).

"[T]he tort of interfering with prospective contractual relationships has more demanding requirements for establishing liability than those required for existing contractual relationships." Perry v. Int'l Transport Workers' Fed., 750 F.Supp 1189, 1207 (S.D.N.Y. 1990). Tortious interference with prospective business relations arises in "those situations where the third party would have entered into or extended a contractual relationship with plaintiff but for the intentional and wrongful acts of the defendant.' "

Morrow v. MVP Health Plan, Inc., 307 A.D.2d 627, 628 (N.Y. App Div 3d Dep't 2003), quoting M.J. & K. Co., Inc., v. Matthew Bender and Co., Inc., 220 A.D.2d 488, 490 (N.Y. App Div 2d Dep't 1995). “ ‘To prevail on a claim for ‘tortious interference with business relations’ under New York law, a party must prove that (1) it had a business relationship with a third party; (2) the defendant knew of that relationship and intentionally interfered with it; (3) the defendant acted solely out of malice, or used dishonest, unfair, or improper means; and (4) the defendant's interference caused injury to the relationship.’ ” Darby Trading Inc. v. Shell Intern. Trading and Shipping Co. Ltd., 568 F.Supp.2d 329, 342 (S.D.N.Y. 2008), quoting State Street Bank and Trust Co. v. Inversiones Errazuriz Limitada, 374 F.3d 158, 171 (2d Cir. 2004) (internal quotation marks omitted), cert denied 543 U.S. 1177 (2005).

Where a defendant's actions were undertaken to advance its own economic interests, as alleged here,¹⁶ a claim for tortious interference will fail unless that defendant “employed ‘wrongful means,’ defined under New York law as ‘representing physical violence, fraud or misrepresentation, civil suits and criminal prosecutions, and some degrees of economic pressure; they do not, however, include persuasion alone although it is knowingly directed at interference with the [prospective] contract.’ ” Scutti Enters., LLC v. Park Place Entm't Corp., 322 F.3d 211, 216 (2d Cir. 2003), quoting NBT Bancorp v. Fleet/Norstar Fin. Group, 87 N.Y. 2d 614, 624 (N.Y. 1996); see Carvel Corp. v. Noonan, 3 N.Y.3d 182, 190 (N.Y. 2004). As concluded above, however, Chiesi and Cornerstone's promotion and redistribution of the Article is not fraudulent or misleading because the

¹⁶See e.g. Prop. Amend. Compl. ¶ 126 (alleging Defendants published and promoted the Article “in support of sales of their product, Curosurf”).

objected-to conclusions therein are statements of opinion, and no other wrongful conduct is alleged to have been directed at Plaintiff's customers. Prop. Amend. Compl. ¶¶ 121-122; see Carvel, 3 N.Y.3d at 192 (conduct must be direct "at the party with which the plaintiff has or seeks to have a relationship"). This cause of action, even considered as amended, must therefore also be dismissed.

IV. CONCLUSIONS

The motions of Defendants Ernst, Ramanathan, Bhatia, and Sekar to dismiss for lack of personal jurisdiction are granted. The remaining motions to dismiss pursuant to Rule 12 (b)(6) are also granted, and the Complaint is dismissed. Because both the Complaint and Proposed Amended Complaint are based upon non-actionable statements of opinion in the Article, Plaintiff's Motion to Amend the Complaint is denied as futile. Dougherty, 282 F.3d at 88. The remaining two motions, Plaintiff's Motion for Expedited Discovery and Defendants' Motion to Strike the Supplemental Declaration submitted in support of that motion, are denied as moot.

V. ORDERS

IT HEREBY IS ORDERED that Defendants' Motions to Dismiss are GRANTED (Docket Nos. 28, 34, 37, 39, 43, 45) and the Complaint is dismissed;

FURTHER, that Plaintiff's Motion for Leave to Amend the Complaint is DENIED (Docket No. 53);

FURTHER, that Plaintiff's Motion for Expedited Discovery (Docket No. 4) and Defendants' Motion to Strike (Docket No. 84) are DENIED as moot;

FURTHER, that the Clerk of the Court is directed to take the necessary steps to

close this case.

SO ORDERED.

Dated: May 17, 2012
Buffalo, New York

/s/William M. Skretny
WILLIAM M. SKRETNY
Chief Judge
United States District Judge