

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PACIRA BIOSCIENCES, INC.,

Plaintiff,

v.

AMERICAN SOCIETY OF
ANESTHESIOLOGISTS, INC., et al.,

Defendants.

Civil Action No. 21-9264

OPINION

ARLEO, UNITED STATES DISTRICT JUDGE

THIS MATTER comes before the Court on (1) Defendants Nasir Hussain’s, Brendan Sheehy’s, Michael K. Essandoh’s, David L. Stahl’s, and Tristian E. Weaver’s (the “Ohio State Defendants”) Motion to Dismiss pursuant to Rules 12(b)(1) & 12(b)(2), ECF No. 55; (2) Defendants Richard Brull’s, Faraj W. Abdallah’s, Brian M. Ilfeld’s, James C. Eisenach’s, Rodney A. Gabriel’s, and Mary Ellen McCann’s (the “Author Defendants”) Motion to Dismiss Plaintiff’s Complaint pursuant to Rule 12(b)(2), ECF No. 57; and (3) Defendants American Society of Anesthesiologists, Inc.’s (the “ASA”), Evan D. Kharasch’s (“Kharasch”),¹ and the Author Defendants’ Motion to Dismiss pursuant to Rule 12(b)(6), ECF No. 58. Plaintiff Pacira Biosciences, Inc. (“Plaintiff”) opposes each Motion. ECF Nos. 70, 73. For the reasons explained below, the Rule 12(b)(6) Motion is **GRANTED**, the Complaint is **DISMISSED WITH PREJUDICE**, and the remaining Motions are **DENIED AS MOOT**.

¹ The Court collectively refers to the Ohio State Defendants, Author Defendants, the ASA, and Kharasch as “Defendants.”

I. BACKGROUND²

This trade libel action arises out of allegedly false and misleading statements published in a leading medical journal about liposomal bupivacaine, a pain medication that Plaintiff manufactures under the name EXPAREL.³ See generally Compl.

Plaintiff's allegations stem from the February 2021 issue of Anesthesiology, the ASA's official, peer-reviewed academic journal. Id. ¶¶ 2, 29.⁴ The cover of the February 2021 issue states that "Liposomal Bupivacaine Is Not Superior to Standard Local Anesthetics" and contains several articles that allegedly contain false and misleading statements disparaging EXPAREL. Id. ¶¶ 34-35. Plaintiff specifically challenges three articles published in Anesthesiology: (1) a meta-analysis of studies conducted on EXPAREL, id. Ex. 1 (the "Hussain Article"); (2) a narrative review of EXPAREL trials, id. Ex. 2 (the "Ilfeld Review"); and (3) an editorial based on the meta-analysis and narrative review, id. Ex. 3 (the "McCann Editorial") (collectively, the "Articles").⁵ Plaintiff generally alleges that each of the Articles employed flawed methodologies by, among other things, cherry-picking data, relying on studies that Plaintiff believes were deficient, improperly discrediting studies favorable to EXPAREL, and failing to properly limit their conclusions that EXPAREL is not effective. See id. ¶¶ 37-57.

The ASA also offered a CME program linked to the Articles, for which participants could access questions about the Articles and receive credit to satisfy medical licensure requirements (the "CME"). Id. ¶ 59. Plaintiff alleges that these questions restate as fact the flawed and

² These facts are drawn from the Complaint, ECF No. 1 ("Compl.").

³ EXPAREL is a local anesthetic administered at the time of surgery to control pain. Compl. ¶ 26. Pacira is the only FDA-approved manufacturer of liposomal bupivacaine, meaning that as compared to standard bupivacaine, EXPAREL is encased in a liposomal chamber. Id. ¶ 22, 26.

⁴ Kharasch is the editor-in-chief of the journal, while the remaining Defendants are co-authors of the articles at issue. Id. ¶¶ 8-19.

⁵ The Articles are attached as exhibits to the Complaint and so may be considered on a motion to dismiss.

misleading conclusions reached by the Articles. Id. Finally, Anesthesiology produced a podcast that allegedly repeated the conclusions of the Articles without acknowledging their flaws (the “Podcast”). Id. ¶ 65.

Plaintiff filed its Complaint on April 14, 2021, alleging a single count of trade libel against all Defendants. Id. ¶¶ 74-83. The instant Motions followed. ECF Nos. 55, 57, 58.

II. LEGAL STANDARD

In considering a Rule 12(b)(6) motion to dismiss, the Court accepts as true all of the facts in the complaint and draws all reasonable inferences in favor of the plaintiff. Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008). Dismissal is inappropriate even where “it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits.” Id. The facts alleged, however, must be “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). The allegations in the complaint “must be enough to raise a right to relief above the speculative level.” Id. Accordingly, a complaint will survive a motion to dismiss if it provides a sufficient factual basis such that it states a facially plausible claim for relief. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

III. DISCUSSION

Defendants argue that the Complaint should be dismissed because Plaintiff has failed to allege that the challenged statements in the Articles are susceptible to a defamatory meaning. The Court agrees.

Under New Jersey law,⁶ plaintiffs must allege four elements to state a valid claim for trade libel: “(1) publication (2) with malice (3) of false allegations concerning plaintiff’s property or product (4) causing special damages, i.e., pecuniary harm.” Intervet, Inc. v. Mileutis, Ltd., No. 15-1371, 2016 WL 740267, at *6 (D.N.J. Feb. 24, 2016) (quoting Sys. Operations, Inc. v. Sci. Games Dev. Corp., 555 F.2d 1131, 1140 (3d Cir. 1977)). The element of falsity requires a threshold showing that the allegedly defamatory statement is a statement of fact “capable of objective proof of truth or falsity,” as opposed to an opinion protected by the First Amendment. See, e.g., Ward v. Zelikovsky, 136 N.J. 516, 530-31 (1994). The New Jersey Supreme Court has emphasized that to avoid a chilling effect on speech, a defendant generally should not be held liable for a statement that “could be construed as either fact or opinion.” Lynch v. New Jersey Educ. Ass’n, 161 N.J. 152, 168 (1999).

The line between “fact” and “opinion” is often ill-defined and becomes particularly blurry in areas of scientific uncertainty. While “statements about contested and contestable scientific hypotheses . . . are in principle matters of verifiable ‘fact,’ . . . they are more closely akin to matters of opinion, and are so understood by the relevant scientific communities.” ONY, Inc. v. Cornerstone Therapeutics, Inc., 720 F.3d 490, 497 (2d Cir. 2013); cf. Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 596-97 (1993) (observing the existence of “important differences between the quest for truth in the courtroom and the quest for truth in the laboratory” because “[s]cientific conclusions are subject to perpetual revision”); United States v. Mitchell, 365 F.3d 215, 252 (3d Cir. 2004) (“[A] scientific conclusion—something which is subject to revision—[is] not a ‘fact.’”). By their nature, scientific conclusions published in an academic journal are

⁶ The parties agree, at least for purposes of this Motion, that New Jersey law governs Plaintiff’s claim. See Def. Mem. at 9, ECF No. 58.1; Pl. Opp. at 16, ECF No. 70.

“tentative,” and made “available to other scientists who may respond by attempting to replicate the described experiments, conducting their own experiments, or analyzing or refuting the soundness of the experimental design or the validity of the inferences drawn from the results.” ONY, Inc., 720 F.3d at 497. The peer-review process—not a courtroom—thus provides the best mechanism for resolving scientific uncertainties.

Consequently, courts have determined that scientific conclusions are protected speech to the extent they are “draw[n] . . . from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement.” ONY, Inc., 720 F.3d at 498; see also, e.g., Underwager v. Salter, 22 F.3d 730, 736 (7th Cir. 1994) (“Scientific controversies must be settled by the methods of science rather than by the methods of litigation.”); Saad v. Am. Diabetes Ass’n, 123 F. Supp. 3d 175, 179 (D. Mass. 2015) (holding that a dispute “over the reliability of the data in [a medical doctor’s] articles is not fit for resolution in the form of a defamation lawsuit”). This is especially true where, as here, a challenged statement occurred in a peer-reviewed journal “directed at the scientific community,” as opposed to an advertisement directed at consumers. See Eastman Chem. Co. v. Plastipure, Inc., 775 F.3d 230, 235-36 (5th Cir. 2014); CareDx, Inc. v. Natera, Inc., No. 19-662, 2019 WL 7037799, at *9 (D. Del. Dec. 20, 2019).

With no clear guidance from the Third Circuit, the Court finds no cause to depart from these well-reasoned precedents. Absent an allegation that the author of a scientific article falsified the data from which she drew her conclusions, a plaintiff cannot sustain a claim for trade libel by alleging that some methodological flaw led to a scientifically “incorrect” answer. Stated differently, a scientific conclusion based on nonfraudulent data in an academic publication is not a “fact” that can be proven false through litigation. To hold otherwise would chill robust and open

debate about the efficacy of drugs within the medical community—particularly here, where Plaintiff seeks retraction of the articles in question, removal of related materials from the Internet, and compensatory and punitive damages against the scientists who published their academic opinions.

Plaintiff does not—and cannot—dispute the existence of “ongoing scientific disagreement” concerning the effectiveness of EXPAREL. Indeed, the crux of this action is Plaintiff’s disagreement with scientific conclusions attributed to a professional medical association and 12 members of the scientific community. The Court must therefore determine whether Plaintiff has identified any aspect of the Articles, CME, or Podcast that bring their conclusions outside the protected realm of scientific opinion.

A. The Hussain Article

Plaintiff contends that the Hussain Article’s overall conclusion that EXPAREL is “not superior” to standard analgesics is susceptible to defamatory meaning. Pl. Opp. at 19.⁷ The Court disagrees.

Critically, Plaintiff does not allege that the Hussain Article falsified any of the data it relied upon. Instead, Plaintiff simply argues that methodological flaws in the Article led to an incorrect conclusion. Among other things, Plaintiff asserts that the authors relied on deficient studies, Compl. ¶¶ 37, 43, improperly disregarded studies favorable to EXPAREL, *id.* ¶¶ 39, 41, failed to

⁷ The Hussain Article’s abstract summarizes its overall conclusion as follows:

Perineural liposomal bupivacaine provided a statistically significant but clinically unimportant improvement in the AUC of postoperative pain scores compared with plain local anesthetic. Furthermore, this benefit was rendered nonsignificant after excluding an industry-sponsored trial, and liposomal bupivacaine was found to be not different from plain local anesthetics for postoperative pain and all other analgesic and functional outcomes. High-quality evidence does not support the use of perineural liposomal bupivacaine over nonliposomal bupivacaine for peripheral nerve blocks.

Hussain Article at 1.

consider whether the effectiveness of EXPAREL may differ across different types of surgical procedures, id. ¶ 38, and employed a flawed method known as “crude pooling,” id. ¶ 42. The Complaint itself makes clear that Plaintiff’s primary grievance is the Article’s selection of “methodologies that would bias the results.” Id. ¶ 46.

Plaintiff’s attempt to reframe these perceived flaws in methodology as “false descriptions of data on which the studies rely,” Pl. Opp. 19, is unavailing. For example, Plaintiff contends that the Hussain Article “failed to disclose” certain studies and data favorable to EXPAREL. Id. at 21. But a scientific conclusion need not account for every piece of data that was not relied on to receive protection. See ONY, Inc., 720 F.3d at 497 (holding that an allegation that “competent scientists would have included variables that were available to the defendant authors but that were not taken into account in their analysis” cannot create an actionable falsehood). Plaintiff further argues that the Hussain Article falsely states that studies into EXPAREL were “characterized by low levels of heterogeneity” but that the authors did not actually assess the heterogeneity for “pain scores” amongst the studies. Pl. Opp. at 21-22. However, the Article never claims to have assessed the heterogeneity for pain scores and, in fact, expressly discloses that it did not. See Hussain Article at 10. Notwithstanding Plaintiff’s characterization, these arguments amount to a mere dispute over methodology and in no way suggest that any underlying data was falsified. While Plaintiff has perhaps identified grounds for legitimate scholarly debate, it cannot breach the legal protection otherwise afforded to scientific conclusions.⁸

⁸ Plaintiff’s opposition also argues that the Hussain Article failed to disclose alleged shortcomings of studies it relied upon, Pl. Opp. at 21, and omitted “trial-level numerical information,” id. at 23. Once again, the fact that the authors could have conducted a more comprehensive analysis of the underlying data does not suggest that Defendants falsified the data. See Saad, 123 F. Supp. 3d at 179 (“[T]he reliability of data in [scientific] articles is not fit for resolution in the form of a defamation lawsuit.”).

For these reasons, Plaintiff has failed to allege that the Hussain Article's conclusion is capable of defamatory meaning.

B. The Ilfeld Review

Like the Hussain Article, Plaintiff challenges the Ilfeld Review's conclusion that liposomal bupivacaine is not a superior alternative to other anesthetics. Plaintiff's arguments suffer from the same shortcomings.

Plaintiff chiefly contends that the Ilfeld Review improperly excluded studies and data favorable to EXPAREL while failing to properly account for the "biases and problems" of the studies it did rely upon. Compl. ¶ 47; Pl. Opp. 24-26. Importantly, Plaintiff does not allege that Defendants distorted the findings of the underlying studies in any way; it instead argues that those studies should not have been taken at face value due to the presence of bias, methodological flaws, and contrary evidence. As discussed above, such attacks on a scientific article's selection of and analysis of data cannot support a claim for trade libel.

Moreover, Plaintiff alleges that two authors of the Ilfeld Review failed to disclose certain conflicts of interest. Compl. ¶¶ 49-52; Pl. Opp. at 26-27. The Court acknowledges that a substantial undisclosed conflict of interest may provide some further support to a plaintiff who is otherwise able to allege a defamatory statement and must prove "actual malice." Cf. ONY, Inc., 720 F.3d at 498 (observing that otherwise actionable claims are "weakest" where potential shortcomings in methodology and conflicts of interest are fully disclosed). However, the mere presence of an undisclosed conflict does not eliminate a plaintiff's threshold obligation to demonstrate that a scientific conclusion is capable of defamatory meaning.⁹ Plaintiff has failed to do so here with respect to the Ilfeld Review.

⁹ Regardless, the conflicts alleged in the Complaint appear to be tenuous, at best. Plaintiff alleges that Brian Ilfeld's employer—a large public research university—received funding from one of Plaintiff's competitors but does not

C. The McCann Editorial, CME, and Podcast

Finally, Plaintiff has failed to allege an actionable falsehood arising from the McCann Editorial, CME, or Podcast. Plaintiff initially argues that these publications “contain or repeat” the alleged falsehoods in the Hussain Article and Ilfeld Review. Pl. Opp. at 27. However, a mere summary or repetition of an otherwise protected scientific opinion is not an independently defamatory statement—at least where the secondary statement was not made in connection with a consumer-facing advertisement, CareDx, Inc., 2019 WL 7037799, at *9, and did not “misstate[] the article’s conclusions,” ONY, Inc., 720 F.3d at 499.

Plaintiff suggests that two statements in the McCann Editorial and CME materials go beyond the scope of the other challenged Articles. First, Plaintiff alleges that the McCann Editorial “suggest[s] that Pacira is lining its pockets with revenue from an ineffective drug.” Compl. ¶ 54. Plaintiff’s opposition appears to refer to the following passage from the editorial’s conclusion:

New drugs can be very financially rewarding for pharmaceutical companies. Once Exparel was approved, Pacira Biosciences began an aggressive and powerful marketing strategy. Between 2013 and 2019, they paid \$25.8 million to more than 27,000 physicians for a variety of services including compensation for being a speaker or faculty at nonaccredited educational events. Sales of liposomal bupivacaine increased during this time with the company reporting a 25% growth in 2019 over 2018 with full-year revenues of \$421 million in 2019. The cost of a single dose of 266 mg of Exparel brand liposomal bupivacaine is about \$334.16. Nonliposomal bupivacaine costs about \$3 per dose. In this era of medical austerity,

suggest that Ilfeld himself received any such funding. Compl. ¶ 52. The Complaint takes further issue with Ilfeld’s receipt of grant funding from the United States Department of Defense, which is a government agency—not a pharmaceutical company that competes with Plaintiff. Id. Upon closer examination of the public online profile for Ilfeld, which the Complaint relies upon, the offending grants appear to be for “congressionally directed medical research” into alternative treatments for postoperative pain generally and post-amputation phantom limb pain specifically. See UC San Diego, UCSD Profiles: Brian Ilfeld, <https://profiles.ucsd.edu/brian.ilfeld> (last visited Feb. 3, 2022). It also bears noting that Ilfeld received funding from Plaintiff in the past as well. Compl. ¶ 52. Finally, the Complaint alleges that co-author Rodney Gabriel received a single consulting payment from Plaintiff’s competitor in 2019, id. ¶ 51, a conflict that appears de minimis and is, at most, a factor that could be considered in assessing the presence of malice. Certainly, these conflicts are a far cry from those discussed in ONY, Inc., where the challenged articles themselves were admittedly funded by the plaintiff’s competitors. See ONY, Inc. v. Cornerstone Therapeutics, Inc., No. 11-1027, 2012 WL 1835671, at *11 (W.D.N.Y. May 18, 2012), aff’d, 720 F.3d 490 (2d Cir. 2013).

when the benefits and costs of expensive drugs are being considered, one would hope that newly approved expensive drugs would at least be an improvement over existing, inexpensive drugs.

McCann Editorial at 141. Plaintiff does not, however, identify any particular statement concerning Plaintiff's marketing practice that is demonstrably false beyond the insinuation that EXPAREL is not "an improvement over existing, inexpensive drugs." See Pl. Opp. at 28-29. And that statement fully accords with the conclusions of the Hussain Article and Ilfeld Review that EXPAREL is "not superior" to standard local anesthetics.

Second, Plaintiff notes that the CME materials state that "a high percentage of randomized control trials showed that infiltration of the surgical site with liposomal bupivacaine provides inferior analgesia to a peripheral nerve block with local anesthetics," whereas the Hussain Article states only that EXPAREL is "not superior." Compl. ¶ 60. As Defendants observe, the Ilfeld Review states that after canvassing randomized, controlled trials, it found that "[n]inety-two percent of trials (11 of 12) suggested a peripheral nerve block with unencapsulated bupivacaine provides superior analgesia to infiltrated liposomal bupivacaine." Ilfeld Review at 283 (emphasis added). The CME materials are therefore entirely consistent with the Ilfeld Review's summary of the relevant studies.¹⁰

Plaintiff has consequently failed to demonstrate that any statement in the McCann Editorial, CME, or Podcast is susceptible to defamatory meaning. The Complaint fails to state a claim for trade libel against any Defendant.¹¹

¹⁰ Plaintiff does not argue that any aspect of the Podcast misrepresents the conclusions of the Hussain Article or Ilfeld Review. See Pl. Opp. at 29.

¹¹ As the Court finds the Complaint fails to state a claim upon which relief may be granted, it declines to reach the Ohio State and Author Defendants' respective arguments that they are immune from suit or outside this Court's personal jurisdiction.

D. Amendment Would be Futile

The Court last addresses Plaintiff's alternative request for leave to file an amended pleading. While leave to amend must be freely given when justice so requires, leave may be denied where amendment would be futile. See Holst v. Oxman, 290 F. App'x 508, 510 (3d Cir. 2008). The Court finds that here, any amendment would be futile.

Plaintiff contends that it has developed additional support for its claims through expert reports that further explain "why Defendants' disparaging statements are inaccurate and represent significant and inexplicable departures from established scientific norms." Pl. Opp. at 40.¹² In light of the Court's holding that even a methodologically flawed conclusion in an academic publication on an area of scientific uncertainty is incapable of defamatory meaning, any further explanation as to why the Articles' conclusions are "inaccurate" or otherwise contrary to scientific norms would not cure the deficiencies identified herein.

The Court therefore finds amendment would be futile and dismisses the Complaint with prejudice for failure to state a claim upon which relief may be granted.

IV. CONCLUSION

For the reasons stated above, the ASA's, Kharasch's, and the Author Defendants' Motion to Dismiss pursuant to Rule 12(b)(6), ECF No. 58, is **GRANTED**. The Complaint is **DISMISSED WITH PREJUDICE**. The remaining Motions of the Ohio State Defendants, ECF No. 55, and Author Defendants, ECF No. 57, are **DENIED AS MOOT**. An appropriate order follows.

Date: February 4, 2022

/s/ Madeline Cox Arleo
Hon. Madeline Cox Arleo
UNITED STATES DISTRICT JUDGE

¹² Indeed, Plaintiff relies heavily on expert reports going well beyond the allegations in the Complaint in opposing the instant Motion. See e.g., Pl. Opp. at 19-24. Yet as discussed in detail above, Plaintiff has still failed to identify any falsification of data that might suggest the Articles fall outside the scope of protected scientific opinion.