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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PACIRA BIOSCIENCES, INC.,

Plaintiff,

v.

AMERICAN SOCIETY OF ANESTHESIOLOGISTS, INC., EVAN D. KHARASCH, NASIR HUSSAIN, RICHARD BRULL, BRENDAN SHEEHY, MICHAEL K. ESSANDOH, DAVID L. STAHL, TRISTAN E. WEAVER, FARAJ W. ABDALLAH, BRIAN M. ILFELD, JAMES C. EISENACH, RODNEY A. GABRIEL, AND MARY ELLEN McCANN,

Defendants.

Civil Action No. 21-cv-9264-MCA-JSA

ECF Case

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS WITH PREJUDICE PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6)

Motion Date: July 6, 2021

Oral Argument Requested

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PRELIMINARY STATEMENT

Pacira did not file this "trade libel" action because Defendants wrote anything false or malicious. It did so to squelch legitimate scientific criticism of its marquee product, EXPAREL (liposomal bupivacaine). The three articles published in the February 2021 issue of *Anesthesiology* reported scientific conclusions about EXPAREL: Compared to standard bupivacaine, it does not provide a clinically-significant benefit in reducing pain. Pacira knows this. For years, multiple clinical trials and peer-reviewed papers have reached the same conclusion, using the same or similar methodologies Defendants used here. And since February, other studies and research papers have concurred: EXPAREL's equivalent efficacy does not justify its $335 per-vial price as compared to the $3 per-vial price of standard bupivacaine.

Nor did Pacira file this lawsuit because it suffered any actual damage from the three articles. The Complaint asserts that Pacira has lost or will lose significant sales because of Defendants' statements. But on May 4 Pacira told its investors the opposite. In an earnings call, an analyst asked if there were any reason to be concerned about the articles Pacira is suing over. Pacira's CFO brushed it off: "I think we see a clear separation between the Journal and the Society and the folks who are actually practicing regional blocks in the marketplace. So if you judge by April and the first few days in May, we don't have anything to worry about in terms of any kind of a retributive action, actually things are going very, very well …."[1]

Although Pacira has no valid basis to allege trade libel, this lawsuit gave it a public relations platform to say what it wanted about its controversial drug, and especially those who have studied it, to deter other scientists from reporting findings and opinions that undermine the EXPAREL sales pitch. To that end, on the same day Pacira sued, it issued a press release and

[1] *See* Marino Decl. Ex. 1 at 15 (Pacira Q1 Earnings Call Transcript).

posted its Complaint, Motion for Preliminary Injunction (asking that the articles be "electronically retracted"), and four declarations critical of the articles.[2] During the May 4 earnings call, Pacira boasted that it has been widely distributing one declaration to sell its EXPAREL counter-narrative.[3] To make it easier for the media to understand, Pacira posted PowerPoint decks to make its points.

Running a PR campaign to make up for the lack of scientific evidence to support a drug and chill research about the drug are not valid reasons to assert a claim for trade libel against anyone. That Pacira targeted a 54,000-member medical organization, the leading journal in its field, and widely-respected doctors at Harvard, Duke, the University of California, the University of Toronto, the Ohio State University, and the University of Ottawa—including two elected Members of the National Academy of Medicine, the country's most esteemed medical policy organization—underscores the speciousness and implausibility of Pacira's claim.

All of this became clear when Defendants met Pacira's filing head on, asking for expedited discovery and a short extension on the default briefing schedule to oppose its preliminary injunction motion. Rather than let the Court assess Pacira's likelihood of success on the merits, Pacira withdrew its motion. Its claim of irreparable harm is now a dead letter.

Fortunately, the Court can dispose of Pacira's lawsuit before it goes any further. Pacira does not allege that the underlying data in the *Anesthesiology* articles are falsified. They weren't. Pacira does not assert that Defendants failed to disclose their methodology or the basis for their opinions. They did. Pacira does not even allege that the underlying data do not support the conclusions drawn—they do—or that the authors lacked the necessary qualifications to

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[2] *See* Marino Decl. Exs. 2–3 (Pacira's ASA Complaint Webpage; Pacira Press Release.

[3] *See* Marino Decl. Ex. 1 (Pacira Q1 Earnings Call Transcript).

conduct the analyses—they are highly qualified. Instead, Pacira claims the authors would have reached different conclusions if they had analyzed different studies and used different methodologies. But even if correct, that does not come close to the standard for removing speech from the protections of the First Amendment, particularly when the speech Pacira seeks to punish is scientific debate.

As a matter of law, scientific conclusions and accurate summaries of those conclusions published in peer-reviewed journals cannot give rise to a claim for libel. Such statements are subject to revision based on additional data, different methodologies, a growing understanding of the subject, and further debate, and thus for libel purposes constitute inactionable statements of opinion, so long as those conclusions do not rest on falsified data. Scientific conclusions are to be scrutinized and rebutted by peer review rather than judicial review. Were that not the case, the methodological criticisms Pacira raises here would be defamatory.

Pacira also failed to adequately allege falsity. Although Pacira criticizes the authors' data-sampling and other methodological choices, such allegations are insufficient as a matter of law where, as here, the authors fully disclosed such choices and the limitations they impose.

Nor can Pacira allege actual malice, i.e., that Defendants had knowledge of the falsity of such statements. To the contrary, the articles state that their conclusions must be read in light of the methodology used and its stated limitations. Those conclusions are also consistent with prior EXPAREL research—including Pacira's own. Pacira's conspiracy theory—that the authors plotted to make false statements that could evade peer review while disclosing the underlying data—is so far-fetched that it fails *Iqbal*'s requirement of a "plausible" claim.

In contrast to the vague and speculative harm Pacira claims, the harm from allowing this lawsuit to proceed is clear. Pacira has stained Defendants' reputations, particularly with its

accusation of malice. Just as bad, the mere pendency of this action stifles the important First Amendment right to scientific debate, chills the analysis of claimed drug benefits, and deprives doctors and patients of the results. To stop such cases at the outset, courts routinely do so under Rule 12(b)(6). This Court should do so here, and dismiss the Complaint with prejudice.

BACKGROUND

A. ASA publishes *Anesthesiology*, the leading peer-reviewed journal in its field.

The ASA is a non-profit medical association focused on the practice of anesthesiology. Compl. ¶ 5. It publishes a monthly peer-reviewed medical journal, *Anesthesiology* ("the Journal"), the leading source of medical and scientific developments for anesthesiologists. The Journal is the most cited and most trusted authority in its field. Compl. ¶ 29.

When the Journal receives a manuscript, it goes through a rigorous process. Submissions are assessed for merit in a four-week preliminary review. *See* Marino Decl. Ex. 4 (Eisenach, *To Our Authors*).[4] If preliminarily accepted, the authors may receive edits from a handling editor, peer reviewers, and a statistical reviewer. *Id.* *Anesthesiology* is "blind" peer-reviewed, meaning that outside experts anonymously vet the proposed paper. *See* Marino Decl. Ex. 5 (Kharasch, *Peer Review Matt*ers). This gives the reviewers freedom to do their work. *Id.*

B. Pacira's EXPAREL is a controversial drug.

Last year, Pacira generated estimated revenues of $429 million, 96% of which came from sales of EXPAREL. Compl. ¶ 28 n.15. Pacira makes EXPAREL by encasing small amounts of

[4] The Complaint incorporates material available on the ASA and *Anesthesiology* websites, including the three articles and their supporting documentation, the CME materials, the Podcast transcript, the ICMJE disclosure rules, the "About the Journal" page, the "Instructions for Authors" page, and the "Editorial Board" page. A court "may consider documents that are attached to or submitted with the complaint, and any 'matters incorporated by reference or integral to the claim.'" *Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006). Because Pacira has relied on the publicly available portions of the ASA's website in the Complaint, the Court may rely on other publicly available information on the ASA's website.

standard bupivacaine, a recognized analgesic, in a fatty acid (lipid). Pacira charges $335 per vial of EXPAREL, Compl. Ex. 3 at 141, which it claims provides longer-lasting pain relief than non-liposomal bupivacaine, which sells for $3 per vial. *Id.*; *see also* Compl. ¶¶ 1, 25–26, 28.

Neither form of bupivacaine is an opioid replacement. Compl. ¶ 27 n.14. Rather, both are administered post-surgery as a temporary pain medication, blocking regional pain before the use of post-surgical opioids, if needed. Compl. ¶¶ 25, 26. Pacira claims EXPAREL is capable of prolonging the post-operative analgesia of peripheral nerve blocks for up to three days. Compl. ¶ 26 n.9. There is little evidence that EXPAREL better eliminates patients' need for post-treatment opioids as compared to non-liposomal bupivacaine. *See* Compl. ¶ 26 n.9.

Pacira filed for FDA approval in 2006. *See* Compl. Ex. 3 at 140. It submitted the results of clinical trials, but none found that the drug had a clinically-significant benefit over standard bupivacaine or other non-opioids. *Id.* Pacira withdrew its application and reapplied for approval in 2009, relying on studies that compared its drug to a placebo (saline) rather than to standard bupivacaine. *Id.* at n.7 (citing Marino Decl. Ex. 6 (Cross Discipline Team Leader Review: Exparel)). In 2011, the FDA approved EXPAREL for limited post-surgical use.

Pacira later sought FDA approval for additional uses, relying on studies that sometimes showed a pain management benefit, but only as compared to a placebo. During the approval process, the FDA examined nine trials that Pacira had conducted that showed "no clinical or statistical difference" between EXPAREL and regular bupivacaine. *Id.* at 140; Marino Decl. Ex. 7 (FDA EXPAREL Presentation 2017). Yet Pacira has promoted EXPAREL aggressively, and not always appropriately. In July 2020, Pacira paid $3.5 million to settle a False Claims Act lawsuit bought by the Department of Justice and 15 states in this District alleging that Pacira paid

kickbacks to doctors to prescribe the drug. *See U.S.A. ex rel. Schneider v. Pacira Pharms., Inc*., No. 2:14-cv-07021 (D.N.J.); Marino Decl. Ex. 8 (USAO Press Release).

C. The February 2021 *Anesthesiology* Articles, Podcast, and CME Materials

In its February 2021 issue, *Anesthesiology* featured three articles about liposomal bupivacaine anesthetics: a meta-analysis of prior studies, a narrative review of prior studies, and an editorial. Compl. ¶ 35. The meta-analysis examined nine randomized trials of EXPAREL that evaluated how the studies measured the effectiveness of peripheral nerve blocks . Compl. Ex. 1 ("Hussain Meta-Analysis") at 1. The Hussain Meta-Analysis found that the difference between liposomal and standard bupivacaine in reported pain between 24 and 72 hours post-surgery did not reach the level of clinical significance, i.e., the patient was unlikely to perceive a benefit. Compl. ¶ 39. The paper was subject to peer-review. *See* Marino Decl. Ex. 9.

The narrative review ("Ilfeld Review") examined 76 randomized controlled trials involving liposomal bupivacaine. Compl. Ex. 2 at 284–285. It too was subject to peer review. These trials compared infiltrated EXPAREL with (a) placebos, (b) other infiltrated local anesthetics, and (c) peripheral nerve blocks. The trials also compared EXPAREL nerve blocks with local anesthetic nerve blocks. In evaluating the drug trials, the authors applied the Cochrane Risk of Bias Version 2 tool, "the most commonly used tool for randomized studies" evaluation, to assess the risk of bias in the studies. *Id.* The authors concluded that 30–40% of the studies on EXPAREL had a high risk of bias, and that one-half were marred by a conflict of interest. Compl. Ex. 2 at 283. When these studies were removed, EXPAREL provided no apparent benefit over standard bupivacaine. *Id.* As is the norm in a narrative review, *see* Marino Decl. Ex. 9 (Instructions for Authors), the Ilfeld Review identified future areas of study, including the concurrent use of liposomal and standard bupivacaine. Compl. Ex. 2 at 238.

Finally, Dr. Mary Ellen McCann, a Harvard Medical School Assistant Professor of Anesthesia and anesthesiologist at the Boston Children's Hospital, wrote an editorial (the "McCann Editorial"). Compl. ¶¶ 19, 35, 54. It received peer review. *See* Marino Decl. Ex. 4 (Eisenach, *To Our Authors*). Citing her experience as a member of the FDA Anesthetic and Analgesic Drug Products Advisory Committee, Compl. ¶ 56, Dr. McCann opined that the FDA should give more consideration during the approval process to a drug's efficacy relative to other approved drugs, rather than as to placebos. Compl. Ex. 3 at n.11. She suggested that hospitals also conduct that analysis, especially when there is a large cost disparity, as is the case with EXPAREL, which costs 100 times more than standard bupivacaine. *Id.* at 141.

Coinciding with the articles' publication, the ASA produced a podcast interview of Drs. Abdallah and McCann. Compl. ¶ 65–67. Dr. Abdallah summarized the results of the meta-analysis. Compl. Ex. 5. Consistent with her editorial, Dr. McCann positively reviewed the Hussain Meta-Analysis and the Ilfeld Review and framed the issues around EXPAREL's efficacy relative to other analgesics as a commentary on the FDA's approval process. *Id.*

Anesthesiology also publishes monthly continuing medical education ("CME") materials. Those who have subscribed can access online quiz questions and receive credits to satisfy their licensure requirements. Compl. ¶ 59. The CME questions restate research findings and are understood in the context of the underlying articles they reference. Compl. Ex. 6. Participants must first read the articles in whole, including methodologies and any limitations. *See id.* at 1.

The February 2021 papers were not the first to express doubt that EXPAREL provides a clinically-significant pain benefit as compared to standard bupivacaine or other non-opioids. Numerous other studies and analyses have similarly concluded that EXPAREL does not produce

a clinically-significant pain benefit as compared to standard bupivacaine.[5] Even Pacira's own funded studies have struggled to demonstrate such a benefit.[6]

The marketplace has rendered its own judgment about EXPAREL. Whether because of the published research or the $335 per vial price Pacira charges—likely both—the company sustained significant net losses in 2017, 2018, and 2019.[7]

D. Pacira Sues

After publication of the February 2021 issue, an anesthesiologist wrote to *Anesthesiology*'s Editor-In-Chief, Dr. Evan Kharasch, describing his favorable personal experience prescribing EXPAREL and quarreling with the articles' analyses. Compl. ¶ 68. Dr. Kharasch responded that instances of favorable experience and similar anecdotal evidence are no substitute for the scientific research that merits publication in *Anesthesiology*. Dr. Kharasch said that if the doctor or Pacira wanted to submit any research on EXPAREL, it could do so through the submission channel at *Anesthesiology* or any other journal. Instead, Pacira sued all Defendants for trade libel. Pacira also filed a motion for preliminary injunction, seeking to force the ASA to retract the article. Dkt. 3. When Defendants asked for expedited discovery and additional time to respond, Pacira withdrew it. Dkt. 39. This motion follows.

LEGAL STANDARD

To survive a motion to dismiss, a complaint must "contain sufficient factual matter" that "state[s] a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Whether a claim is plausible depends on the factual allegations because "the tenet that a

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[5] Compl. Ex. 2 at n. 6 & Marino Decl. Ex . 10 (Clinical Efficacy of Liposomal Bupivacaine). *Id.* at n. 7 & Marino Decl. Ex. 11 (Liposome Bupivacaine Compared to Plain Local Anesthetics).

[6] *See e.g.,* Compl. Exh. 3 at n.6 & Marino Decl. Ex. 7 (FDA EXPAREL Presentation 2017)

[7] *See* Marino Decl. Ex. 12 (Pacira 2020 Form 10-K).

court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Id.* A "pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Id.* (quoting *Twombly*, 550 U.S. at 555 (2007)). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citation omitted).

ARGUMENT

I. PACIRA'S TRADE LIBEL CLAIM FAILS BECAUSE THE STATEMENTS ARE NOT REASONABLY SUSCEPTIBLE OF A DEFAMATORY MEANING

Pacira's Complaint attacks scientific conclusions based on disclosed data and methodologies. Pacira does not allege that the underlying data were falsified. Pacira does not allege that any of the publications misrepresented their methods. Instead, Pacira asks this Court to rule that the conclusions that well-qualified scientists drew, based on those data and methodologies, are not entitled to the protection of the First Amendment. But the law forecloses Pacira's trade libel claim. Scientific conclusions are not capable of a defamatory meaning because they reflect scientific opinion. The Complaint should be dismissed for this reason alone.

A. Scientific Conclusions Based On Disclosed Data And Methodology Are Not Capable of Defamatory Meaning

To state a trade libel claim under New Jersey law, "a threshold issue is whether the allegedly defamatory statements are reasonably susceptible of a defamatory meaning." *Petersen v. Meggitt*, 407 N.J. Super. 63, 74 (App. Div. 2009). "Whether a statement is defamatory depends on its content, verifiability, and context." *Lynch v. N.J. Educ. Ass'n*, 161 N.J. 152, 167 (1999). "A statement's verifiability refers to whether it can be proved true or false …. Statements of opinion, like unverifiable statements of fact, generally cannot be proved true or false." *Id.* And "[i]f a statement could be construed as either fact or opinion, a defendant should not be held liable" for making it. *Id.* at 168. *See also Knierim v. Siemens Corp.*, 2008 WL

906244, at *15 (D.N.J. Mar. 31, 2008) (verifiability analysis requires determination of whether a statement is one of fact or opinion because opinions "cannot be proved true or false" and "are not actionable") (citations omitted).[8] "Whether the meaning of a statement is susceptible of a defamatory meaning" poses a question of law, *Ward v. Zelikovsky,* 136 N.J. 516, 529 (1994), and is therefore appropriate for resolution at the pleading stage. *Turner v. Wells*, 879 F.3d 1254, 1262-63 (11th Cir. 2018) ("Whether the statement is one of fact or opinion and whether a statement of fact is susceptible to defamatory interpretation are questions of law.").

"As a matter of law, statements of scientific conclusions about unsettled matters of scientific debate cannot give rise to liability for damages sounding in defamation." *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 492 (2d Cir. 2013); *Yourman v. People's Sec. Life Ins. Co.,* 992 F.Supp. 696, 706 (D.N.J. 1998) ("[S]tatements ... of opinion premised on disclosed facts [are], as a matter of law, not defamatory."). Nor are accurate summaries of those scientific conclusions actionable statements for libel purposes. *See ONY*, 720 F.3d at 499.

Courts have long recognized that scientific conclusions are to be rebutted by "peer review rather than judicial review." *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 2012 WL 1835671, at *10 (W.D.N.Y. May 18, 2012), *aff'd,* 720 F.3d 490 (2d Cir. 2013). The Supreme Court in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), noted that "there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory"

[8] *Peterson*, *Lynch*, and *Knierim* concern claims for defamation. Under New Jersey law, trade libel is a "form of defamation." *Read v. Profeta*, 397 F. Supp. 3d 597, 651 n.37 (D.N.J. 2019). Claims that fail to allege defamation fail to allege trade libel, because "[t]he elements of proof for product disparagement [trade libel] are much more stringent than those for defamation." *Gillon v. Bernstein*, 218 F. Supp. 3d 285, 295 (D.N.J. 2016) (quoting *Dairy Stores, Inc. v. Sentinel Publ'g Co., Inc.*, 104 N.J. 125, 159 (1986) (Garibaldi, J., concurring)). Moreover, a claim for trade libel must establish that the statements are verifiable (i.e., statements of fact, not opinion). *See Wolfe v. Gooding & Co., Inc.*, 2017 WL 3977920, at *3 (D.N.J. Sept. 11, 2017) (court must first determine "whether statements were of fact or opinion.").

because "[s]cientific conclusions are subject to perpetual revision." 509 U.S. at 596–97; *see also 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…. More papers, more discussion, better data, and more satisfactory models—not larger awards of damages—mark the path toward superior understanding of the world around us."). As the Second Circuit explained:

> It is the essence of the scientific method that the conclusions of empirical research are tentative and subject to revision, because they represent inferences about the nature of reality based on the results of experimentation and observation.… These conclusions are then 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. In a sufficiently novel area of research, propositions of empirical "fact" advanced in the literature may be highly controversial and subject to rigorous debate by qualified experts. Needless to say, courts are ill-equipped to undertake to referee such controversies. Instead, the trial of ideas plays out in the pages of peer-reviewed journals, and the scientific public sits as the jury.

ONY, 720 F.3d at 496–97.

ONY affirmed dismissal of claims alleging that "statements about scientific findings … were intentionally deceptive and misleading," rejecting the plaintiff's arguments that "scientific claims made in print purport to be statements of fact that are falsifiable, and such statements can be defamatory … if known to be false when made." *Id.* at 496. Such statements cannot be libelous because, "while statements about contested and contestable scientific hypotheses constitute assertions about the world that are in principle matters of verifiable 'fact,' for purposes of the First Amendment and the laws relating to … defamation, they are more closely akin to matters of opinion, and are so understood by the relevant scientific communities." *Id.* at 497.

Based on these principles, courts routinely dismiss claims that attack "the validity of experiments and conclusions published in peer-reviewed scientific journal articles" because such disputes are better addressed "in the scientific, not legal, realm." *See Biolase, Inc. v. Fotona D.*

D., 2014 WL 12579802, at *4 (C.D. Cal. June 4, 2014) ("even assuming [plaintiff's] allegations are true, this Court is not the place to resolve them."); *Joseph v. Springer Nature*, 2021 WL 1372952, at *7 (S.D.N.Y. Apr. 12, 2021) (Scientific disagreement that "remains one of the great mysteries of our time" is "one that the Court has no business solving," and "[f]or that reason alone, [such] statements … cannot be libelous."); *Saad v. Am. Diabetes Ass'n*, 123 F. Supp. 3d 175, 179 (D. Mass. 2015) ("the reliability of the data in [defendant's] articles is not fit for resolution in the form of a defamation lawsuit. Instead, this is a case where 'the trial of ideas plays out in the pages of peer-reviewed journals, and the scientific public sits as the jury.'" (citation omitted)). Disputed scientific conclusions simply do not give rise to libel claims. *See Arthur*, 2010 WL 883745, at *6 ("Plaintiff's claim … threatens to ensnare the Court in the thorny and extremely contentious debate over the perceived risks of certain vaccines, their theoretical association with particular diseases or syndromes, and, at bottom, which side of this debate has 'truth' on their side. That is hardly the sort of issue that would be subject to verification based upon a 'core of objective evidence.'" (citation omitted)); *Underwager,* 22 F.3d at 736.[9]

B. Pacira's Claim Is Barred As A Matter Of Law

Each of the publications on which Pacira bases its trade libel claim represents scientific conclusions based on disclosed methodologies presented in a peer-reviewed journal, or summaries of those conclusions. Such statements are not capable of a defamatory meaning.

[9] The Fifth Circuit distinguished *ONY* in *Eastman Chem. Co. v. Plastipure, Inc.*, 775 F.3d 230 (5th Cir. 2014), but recognized its applicability to statements, like those here, made "within the academic literature and directed at the scientific community." *Id.* at 236. Such conclusions are opinion. *See Hi-Tech Pharms., Inc. v. Cohen*, 277 F. Supp. 3d 236, 244 (D. Mass. 2016).

1. The Challenged Statements In The February 2021 Issue Of *Anesthesiology* Are Not Susceptible Of A Defamatory Meaning

Pacira's allegations primarily concern the Hussain Article—specifically, the article's selection of studies used in the meta-analysis (Compl. ¶¶ 37, 39, 41), the methodology used to analyze those studies (*id.* ¶¶ 42–43), and the ultimate inferences or conclusions contained in the article. *Id.* ¶ 38. Pacira alleges similar deficiencies in the Ilfeld Review, asserting that it failed to account for a particular anesthesia procedure that Pacira contends is "the most relevant." *Id.* ¶ 47. As to the McCann Editorial, Pacira alleges only that it "rehashes the conclusions of the Hussain and Ilfeld articles." *Id.* ¶ 54. Pacira's allegations represent only scientific disagreements, which are inadequate as a matter of law to sustain a claim for trade libel.

First, as to the selection of studies for the meta-analysis, Pacira alleges that the authors included "only nine highly curated studies," that the Hussain Article "fail[s] to account for statistical heterogeneity," and that the Ilfeld Review failed to account for the purportedly "most relevant anesthesia procedure." *Id.* ¶¶ 41–42, 47. But Pacira does not assert that the articles falsely represented the included studies or that the Hussain Article and Ilfeld Review claimed to have accounted for variables they in fact omitted. Indeed, Pacira acknowledges that "Defendant Abdallah *did* briefly *acknowledge* that the lack of clinical homogeneity analysis among the analyzed studies may limit the conclusions that can be drawn from the meta-analysis." *Id.* ¶ 66 (emphasis added). Absent misrepresentations of the underlying data, allegations "that competent scientists would have included variables that were available to the defendant authors but that were not taken into account in their analysis" do not adequately plead claims sounding in defamation. *ONY*, 720 F.3d at 497. Thus, if Pacira believed a more accurate meta-analysis would rely on a different or broader range of studies and account for a different or broader range

of variables, its recourse is "in the scientific, not legal, realm." *Biolase*, 2014 WL 12579802, at *4. Such "dispute[s] … over the reliability of the data in [scientific] articles [are] not fit for resolution in the form of a defamation lawsuit." *Saad*, 123 F. Supp. 3d at 179.

Second, as to the articles' methodology, Pacira alleges the articles should not have discredited industry-sponsored (e.g., Pacira-sponsored) trials, should not have relied on studies that do not account for other medications, and that the Hussain Article should not have employed "crude pooling" but rather "stratified pooling." Compl. ¶¶ 37, 39, 42. But again Pacira does not (and cannot) allege that the "studies described in the articles weren't actually performed or that they didn't produce the findings described." *Biolase*, 2014 WL 12579802, at *4–5 (applying *ONY* to dismiss false advertising claims). Such methodological challenges are insufficient. *Biolase*, 2014 WL 12579802, at *4 (dismissing claim premised in allegations "that the methodologies used in the studies described in the scientific articles are unreliable"). Indeed, "any perceived fault in the method by which the authors reached their conclusions should be subjected to peer review rather than judicial review." *ONY,* 2012 WL 1835671, at *10.

Third, as to the conclusions, Pacira complains the articles should not have reached "blanket, unqualified conclusions that EXPAREL is not effective," Compl. ¶ 38, such that the cover statement, "Liposomal Bupivacaine Is Not Superior to Standard Local Anesthetics," is defamatory, Compl. ¶ 32. But the articles reported that EXPAREL was no more effective than standard bupivacaine. Absent falsification or misstatement of underlying data, such disputes over the conclusions to be drawn are not actionable: "[W]hen the conclusions reached by experiments are presented alongside an accurate description of the data taken into account and the methods used, the validity of the authors' conclusions may be assessed on their face by other members of the relevant discipline or specialty." *ONY*, 720 F.3d at 497–98; *see also Biolase*,

2014 WL 12579802, at *5 ("if [plaintiff] thinks the accurately portrayed results of the studies are misleading, [it] has sufficient recourse in scientific discourse…."); *Joseph*, 2021 WL 1372952, at *7 (dismissing libel claim where conclusion "is ultimately a critique of a scientific work").[10]

As to the McCann Editorial, on its face it is a textbook example of non-actionable opinion. Its statements about the need for improvements in pain studies and FDA approvals are beyond the scope of trade libel. *See Lynch*, 161 N.J. at 167–8.

Finally, even if there were any uncertainty over whether the statements made in *Anesthesiology* are actionable, a general presumption against subjecting academic works published in a peer-reviewed journal to judicial scrutiny under libel laws justifies dismissal. Pacira acknowledges that *Anesthesiology* is a "peer reviewed medical journal," and "the most cited medical journal on anesthesiology." Compl. ¶¶ 7, 29 82. The Court must therefore be "especially careful when applying defamation and related causes of action to academic works, because academic freedom is 'a special concern of the First Amendment.'" *Catalanello v. Kramer*, 18 F. Supp. 3d 504, 517 (S.D.N.Y. 2014) (citation omitted); *see also Immuno AG. V. Moor-Jankowski*, 77 N.Y.2d 235, 256 (1991) ("The chilling effect of protracted litigation can be especially severe for scholarly journals, such as defendant's, whose editors will likely have more than a passing familiarity with the subject matter of the specialized materials they publish.").

2. The CME Activity And Podcast Lack Defamatory Statements

Pacira's allegations as to the CME materials and a podcast fail because Pacira does not allege that these materials "misstated the article's conclusions" or "distorted the article's

[10] Pacira alleges that the Ilfeld Review is libelous because of undisclosed conflicts of interest. Defendants dispute that. Regardless, such matters cannot be libelous because they do not address EXPAREL, and therefore have no bearing on whether the statements that do address EXPAREL are actionable. *See Biolase*, 2014 WL 12579802, at *1 (dismissing claims despite allegation that "the authors of the articles don't disclose their affiliation with [defendant]").

findings; rather, its theory is that by presenting accurately the allegedly inaccurate conclusions, [defendants] committed a separate tort." *ONY*, 720 F.3d at 499. Because the underlying articles are "not actionable" and the articles did not misrepresent the conclusions in those underlying articles, any secondary claim must also be dismissed. *Id.*

As to the CME activity, Pacira alleges that "[t]he questions in the CME activity *restate* as fact the various flawed and misleading *conclusions* reached by these articles about the effectiveness of EXPAREL." Compl. ¶ 59 (emphasis added); *see also id.* ¶ 64 ("[T]his CME activity compounds the issues identified in the three articles discussed above…"). But, as in *ONY*, a claim that defendants "present[ed] accurately the allegedly inaccurate conclusions" cannot survive. 720 F.3d at 499; *see also Biolase*, 2014 WL 12579802, at *4 ("where statements in the underlying article are not actionable for false advertising, accurate restatements of the article's conclusions in advertising are not actionable either.").

Pacira's claims fail because the CME program is linked to the *Anesthesiology* articles, Compl. ¶ 61, requiring the participant to first read the articles in their entirety. Pacira contends that the CME materials are independently defamatory because they say EXPAREL provides "inferior analgesia to a peripheral nerve block with local anesthetics," whereas the Hussain Article indicates "only that EXPAREL was 'not superior.'" Compl. ¶ 60. But the Ilfeld Review states, "Ninety-two percent of trials (11 of 12) suggested a peripheral nerve block with unencapsulated bupivacaine provides superior analgesia to infiltrated liposomal bupivacaine." Compl. Ex. 2. The CME materials thus accurately reflect the materials. *ONY*, 720 F.3d at 499; *Biolase*, 2014 WL 12579802, at *4. And courts will not engage in "hypertechnical parsing of written … words for the purpose of identifying possible facts that might form the basis of a

sustainable libel action." *Doe v. White Plains Hosp. Med. Ctr.*, 2011 WL 2899174, at *3 (S.D.N.Y. July 8, 2011), *aff'd sub nom. Doe v. French,* 458 F. App'x 21 (2d Cir. 2012).

Pacira's allegations are equally deficient as to the Podcast. Pacira claims it "discusses the conclusions of both the Hussain Article and the Ilfeld Review," and "repeated the conclusions of both articles without acknowledging their many flaws." Compl. ¶ 65; *see also id*. ¶ 67. Such statements are non-actionable absent some allegation that the secondary statements distort the conclusions contained in the underlying articles. *ONY*, 720 F.3d at 499; *Biolase*, 2014 WL 12579802, at *4. But Pacira does not allege that. To the contrary, Pacira affirmatively pleads that one defendant expressly qualified the article's conclusions on the Podcast. *Id*. ¶ 66.

II. PACIRA FAILS TO PLEAD THE ELEMENTS OF A TRADE LIBEL CLAIM

A. Pacira Fails To Allege The Existence Of Any False Statement

A claim for trade libel requires: "(1) publication; (2) with malice; (3) of false allegations concerning [plaintiff's] property, product or business, and (4) special damages, *i.e.* pecuniary harm." *Buying For The Home, LLC v. Humble Abode, LLC*, 459 F. Supp. 2d 310, 326 (D.N.J. 2006). Failure to plead falsity requires dismissal. *Arista Records, Inc. v. Flea World, Inc.*, 356 F. Supp. 2d 411, 428 (D.N.J. 2005) ("Defendants have not shown falsity…. Thus, Defendants' counterclaim for trade libel shall be dismissed as legally insufficient under well-settled New Jersey law."); *Read v. Profeta*, 397 F. Supp. 3d 597, 652 (D.N.J. 2019) (dismissing trade libel claim "for failure to establish an actionable false statement"). Because trade libel "imposes an additional cost in the form of potentially deterred speech" it is subject to "close scrutiny" at the pleading stage. *Arthur*, 2010 WL 883745, at *3. That is particularly important here because this is not a case arising from statements in the commercial arena by one competitor about another. Pacira is attacking fully-protected scientific speech.

Pacira's unsupported and vague assertion that the challenged journal articles "contain false and misleading conclusions, based on faulty scientific research," Compl. ¶ 2; *see also id.* ¶¶ 22, 34–35, 53, 65, does not satisfy the pleading standard for falsity. *Iqbal*, 556 U.S. at 678 (A "pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'") (quoting *Twombly*, 550 U.S. at 555). And Pacira's specific allegations do not go to the falsity of the underlying publications but only allege disagreements about scientific methodology and conclusions. As a matter of law, that is insufficient.

1. Pacira's allegations of falsity fail as to the three Articles.

Pacira's allegations of falsity as to the three *Anesthesiology* articles concern primarily three purported "significant problems" or "flaws" with data sampling, methodology, and conclusions: (a) the articles rely on pain studies that do not account for other medications the study subjects receive; (b) the articles reach blanket and unqualified conclusions that Pacira argues are incorrect; and (c) the articles discredit industry-funded trials. *See* Compl. ¶¶ 37–40. Assuming Pacira's allegations are true (they are not), such a "flaw" or methodological flaws do not equate to falsity, particularly because they are fully disclosed within the articles.

The first and third "flaws" both concern the sampling of studies and trials used in the meta-analysis and other variables the authors consider. Significantly, Pacira does not allege that the articles misrepresent the studies analyzed or falsify the resulting analysis. Nor could Pacira. The articles affirmatively acknowledge the "notable limitations" of their review in light of their inability to "investigate the impact of potentially relevant covariates on the estimate of effect." *See, e.g.,* Hussain Meta-Analysis at 12.

Pacira argues instead that "it is important to look to studies that gather the data needed to make calculations to account for the additional pain medicine," and that the "authors of all three studies rely heavily on trials that did not do that." Compl. ¶ 37. But a dispute over sampling

practices when conducting meta-analyses of pain studies cannot establish falsity: Where "Plaintiff's allegations of 'falsity' essentially are disagreements with the statistical methodology adopted by the doctors and scientists who designed and conducted the study, wrote the journal article, and selected the article for publication," they … concern two different judgments about the appropriate statistical methodology to be used by Defendants…." Such allegations "are not about false statements." *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 878 (9th Cir. 2012); *see also In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 568 n.15 (E.D. Pa. 2009) (That "there may be a disagreement about how to conduct and analyze a study … does not suggest that Adolor's approach was wrong or improper, and therefore misleading.").

"Because Plaintiff does not allege that Defendants misrepresented their own statistical methodology, analysis, and conclusions, but instead criticizes only the statistical methodology employed by Defendants, Plaintiff did not adequately plead falsity with respect to statistic results." *Rigel*, 697 F.3d at 879[11]; *see also Hoey v. Insmed Inc.*, 2018 WL 902266, at *10 (D.N.J. Feb. 15, 2018) ("Plaintiff's allegations attempt to establish the falsity of Insmed's statements with regard to the results of the Phase 2 Trial, by attacking its underlying methodology …. [C]ourts throughout the country have consistently rejected this approach."); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1225 (S.D. Cal. 2001) (allegations that

[11] That *Rigel* and the other cases cited *supra* address securities fraud claims does not render them distinguishable. Falsity is also an element of the claims in those cases. *See, e.g., id.* at 876. Because the element of falsity is the same across causes of action sounding in defamation and fraud, the Supreme Court has cited defamation cases to construe allegations of falsity under the securities laws. *See, e.g., Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1097 (1991). Other federal courts have relied on securities fraud cases to dismiss defamation claims. *See, e.g., ONY*, 720 F.3d at 497 (quoting *Padnes v. Scios Nova Inc.*, 1996 WL 539711 (N.D.Cal. Sept. 18, 1996), for the proposition that "[t]he securities laws do not impose a requirement that companies report only information from optimal studies, even if scientists could agree on what is optimal"). In any event, libel cases have also held that methodological disagreements are insufficient to plead falsity. *See, e.g., Ony*, 2012 WL 1835671, at *10.

"analysis does not properly … take into account the increased incidents of chemical anachnoiditis suffered by DepoCyt patients and the possibility that some patients prematurely ended treatment" amounts to a "a legitimate difference in opinion as to the proper statistical analysis" and does not render statements false); *Mulquin v. Nektar Therapeutics*, 2020 WL 7773580, at *10 (N.D. Cal. Dec. 30, 2020) ("It is insufficient to allege that the challenged statements … were false or misleading because the Defendants did not use Plaintiffs' preferred statistical methodology.").

Pacira's allegations regarding sampling and methodological deficiencies also fail to allege falsity. Pacira does not allege the Hussain Meta-Analysis falsified or misrepresented the underlying data. It asserts instead that the authors "employ a flawed method known as 'crude pooling' rather than the methodologically correct approach known as 'stratified pooling,'" and that the authors "fail to account for statistical heterogeneity…" Compl. ¶¶ 42-43. Similarly, as to the Ilfeld Review, Pacira alleges only that the authors "never discuss the most relevant anesthesia procedure" and "made other design choices in the study" that Pacira disputes. *Id*. at ¶¶ 47-48. Such allegations do not identify a false statement. *See Abely v. Aeterna Zentaris Inc.*, 2013 WL 2399869, at *8 (S.D.N.Y. May 29, 2013) (finding absence of falsity where "plaintiff's critiques all go toward the design of the study").[12]

Nor do Pacira's allegations as to the articles' conclusions adequately allege falsity. Pacira does not allege that the underlying data do not support the conclusions. Instead, Pacira asserts that the article should have considered other "infiltration methods for specific surgical

[12] To establish intent, Pacira also alleges that Drs. Ilfeld and Gabriel failed to disclose financial conflicts of interest. Compl. ¶ 49. But allegations of misleadingly disclosed bias cannot give rise to a claim for trade libel because the disclosure of such statements does not "concern[] [plaintiff's] property, product or business." *Buying For The Home*, 459 F. Supp. 2d at 326.

procedures" and, *if it had done so*, the articles' conclusions would be false. Compl. ¶ 38. But this counter-factual assertion that the authors should have considered other factors that would have altered the conclusions does not constitute a sufficient allegation of falsity because the articles fully disclose the data and factors on which they rely. *See Rigel*, 697 F.3d at 878 (dismissing claim for lack of falsity because "Plaintiff is alleging that Defendants should have used different statistical methodologies, not that Defendants misrepresented the results they obtained from the methodologies they employed"); *ONY*, 2012 WL 1835671, at *10 (dismissing claim where challenged article "reflects the facts on which the authors' conclusions are based, and does not imply that undisclosed facts also exist supporting the authors' conclusions.").

In fact, the articles affirmatively acknowledged that the review comes "with notable limitations." Hussain Meta-Analysis at 12. Because the review "investigated perineural liposomal bupivacaine across a variety of surgical procedures and block techniques," the Hussain Meta-Analysis states that the methodology employed could "potentially limit the external validity of our results and limit their broad applicability." *Id.* But even if those conclusions were unqualified and even if Pacira were disputing the conclusions drawn from the disclosed data, such allegations do not amount to falsity. *Adolor*, 616 F. Supp. 2d at 568 n. 15 ("The fact that Variant's statistician reached a different conclusion than Adolor does not establish that Adolor's interpretation of the results were false or misleading").

Similarly, while Pacira disagrees with the statement on the cover of *Anesthesiology* ("Liposomal Bupivacaine Is Not Superior to Standard Local Anesthetics"), Compl. ¶ 35, that statement conveys a conclusion that is supported by the underlying meta-analysis, even with Pacira's disagreement over the parameters of that meta-analysis. An accurate summary of a study cannot constitute a false statement, even where a plaintiff challenges the underlying

study's conclusions. *Padnes v. Scios Nova Inc.*, 1996 WL 539711, at *5 (N.D. Cal. Sept. 18, 1996) ("The fact that plaintiffs disagree with the Colorado researchers and with defendants about the import of the Colorado data does not make defendants' summaries of the study false or misleading."). The title of the Hussain Meta-Analysis must be read in context. The article explains why liposomal bupivacaine is not superior. *See Read*, 397 F. Supp. 3d at 651 ("A court must consider a statement as a whole to determine the impression it will make on a reader."). *See also Immuno AG.*, 77 N.Y.2d at 255 ("Isolating challenged speech and first extracting its express and implied factual statements, without knowing the full context in which they were uttered, indeed may result in identifying many more implied factual assertions than would a reasonable person encountering that expression in context.").

As to the McCann Editorial, Pacira alleges that it contains "false" "insinuations" by criticizing Pacira for EXPAREL's cost. Compl. ¶ 54. But Pacira does not (and cannot) allege that the McCann Editorial misrepresents EXPAREL's $335 cost per vial. Accordingly, Pacira's allegations must be dismissed. *ONY*, 2012 WL 1835671, at *10 (dismissing where "the Article is not misleading with respect to the facts on which it is and is not based…").

2. Pacira falsity allegations fail as to the CME Activity and the Podcast.

Pacira alleges that the answers to two of the questions posed at the end of the CME Activity are libelous: The answer to Question 1, because it states a majority of studies reporting positive results for liposomal bupivacaine were deemed to be high risk for bias, and the answer to Question 2, because it states a high percentage of randomized control trials showed liposomal bupivacaine provides inferior analgesia compared to local anesthetics. Compl. ¶¶ 60-61. Both answers must be read in the context of the referenced articles. That context makes clear that the answers do not contain false statements. Pacira speculates that Question 1 "misleads the reader to assume that funding source is considered a primary component when determining the risk of

bias in clinical trials." Compl. ¶ 61. But a reader would reach the answer to Question 1 only after reading the two articles, which state the authors' definition of bias. *See, e.g.,* Hussain Meta-Analysis at 2 ("Industry-sponsored trials were *a priori* considered a potential source of bias to be identified in the literature search and subsequent analysis.").

Nor is the answer to Question 2 even a "misstatement" of the articles. The Ilfeld Review concludes: "Ninety-two percent of trials (11 of 12) suggested a peripheral nerve block with unencapsulated bupivacaine," a form of localized anesthesia, "provides superior analgesia to infiltrated liposomal bupivacaine." Ilfeld Review at 1. Because that percentage of trials show that localized anesthesia provides superior analgesia to EXPAREL, a high percentage of the randomized control trials necessarily also shows that infiltrated liposomal bupivacaine provides *inferior* analgesia to local anesthetics. The answer therefore accurately summarizes the underlying data. *Padnes*, 1996 WL 539711, at *5. Only by ignoring the context of the CME Activity and the underlying articles can Pacira characterize the answer to Question 2 as false and misleading; but as explained *supra,* at 16 , courts should not extract single sentences to engage in "'hypertechnical parsing' of written … words for the purpose of identifying 'possible facts' that might form the basis of a sustainable libel action." *Doe*, 2011 WL 2899174, at *3.

As to the statements contained in the podcast, Pacira alleges only that the podcast "discusses the conclusions of both the Hussain Article and the Ilfeld Review," and "repeated the conclusions of both articles without acknowledging their many flaws." Compl. ¶ 65; *see also id*. ¶ 67 (alleging the podcast "only perpetuates the articles' inaccuracies and further spreads the falsehoods contained therein."). But Pacira does not allege that the statements misrepresented the articles' conclusions. *Padnes*, 1996 WL 539711, at *5 (dismissing for lack of falsity where "Plaintiffs have not pled facts sufficient to explain why defendants' summaries of the Colorado

study were false"). In fact, Pacira pled that Dr. Abdallah expressly qualified his conclusions on the podcast, Compl. ¶ 66, showing that he took care not to overstate the article's content.

B. Pacira Fails To Plead Actual Malice.

Pacira fails to state a claim because its allegations of malice, an element of the cause of action, *see Buying For The Home*, 459 F. Supp. 2d at 326, are inadequate as a matter of law.

To plead malice, a plaintiff must allege each defendant's knowledge that the purportedly libelous statements were false. *Lynch*, 161 N.J. 166-67 ("The existence of malice depends on publishing with knowledge that a statement is false, rather than [made] with ill will."). Allegations of ulterior motives, including "spite, hostility, hatred, or the deliberate intent to harm demonstrate possible motives for making a statement, but not publication with a reckless disregard for its truth," are insufficient to state a claim. *Id.* Nor is the conclusory assertion that defendants must have knowledge of falsity: "In the wake of *Iqbal* and *Twombly*, adequately pleading actual malice is an onerous task … that regularly results in early dismissal of an action." *Pace v. Baker-White, 432 F. Supp. 3d 495, 513-514 (E.D. Pa. 2020)* (citations and quotations omitted). The failure to adequately plead malice requires dismissal. *Arista*, 356 F. Supp. 2d at 428 ("Defendants … have failed to sufficiently plead malice … Thus, Defendants' counterclaim for trade libel shall be dismissed as legally insufficient under well-settled New Jersey law."). Here, Pacira fails to clear the "high hurdle" of actual malice. *Earley v. Gatehouse Media, Inc.*, 2015 WL 1163787, at *3 (M.D. Pa. Mar. 13, 2015).

First, to the extent the Complaint grounds its assertion of actual malice in purported conflicts of interest, such allegations go to defendants' alleged motive and not subjective knowledge of falsity and are thus irrelevant. *Lynch*, 161 N.J. at 166-67; *Harte–Hanks Comm., Inc. v. Connaughton,* 491 U.S. 657, 666 (1989) (The "actual malice standard is not satisfied merely through a showing of ill will or 'malice' in the ordinary sense of the term.").

Second, the remaining allegations assert only that the alleged "errors" were "likely not inadvertent." Compl. ¶ 48. But blanket assertions that the statements "were known … to be false at the time they were made" are "precisely the sort of allegations that *Twombly* and *Iqbal* rejected." *Mayfield v. Nat'l Ass'n for Stock Car Auto Racing, Inc.*, 674 F.3d 369, 378 (4th Cir. 2012). Nor do allegations of failure to investigate purportedly suspect conclusions, made as to Dr. McCann and other defendants (*see* Compl. ¶ 56), sufficiently plead malice. *Marcone v. Penthouse Int'l Mag. For Men*, 754 F.2d 1072, 1089 (3d Cir. 1985) ("Failure to investigate, without more, does not demonstrate actual malice."). At most, Pacira's assertions that defendants "turned a blind eye to these problems" (Compl. ¶ 56) or "disregarded the large body of research favorable to EXPAREL" (Compl. ¶ 48) alleges carelessness. But carelessness "is an indication of negligence, not actual malice." *Levesque v. Doocy,* 560 F.3d 82, 91 (1st Cir. 2009).

Third, none of the allegations as to each individual Defendant adds anything because, even if true, such allegations would not establish that each Defendant acted with actual malice:

Dr. Kharasch. Pacira's conclusory allegations of Dr. Kharasch's knowledge of falsity fail as a matter of law because they merely restate the legal standard, Compl. ¶ 8, which was inadequate to plead actual malice even before *Twombly*/*Iqbal*. *See Darakjian v. Hanna*, 840 A.2d 959, 965-66 (N.J. Super. Ct. App. Div. 2004) (dismissing complaint that contained only a "conclusory allegation" of malice with "no other factual reference to lend support"); *see also Durando v. Nutley Sun*, 2010 WL 1424376, at *5 (N.J. Super. Ct. App. Div. Apr. 8, 2010), *aff'd,* 209 N.J. 235 (2012) ("Sufficient evidence [of actual malice] does not exist, however, when the only evidence offered is that defendants 'should have known the [defamatory statements] were false, or they at least should have doubted their accuracy.'"). Pacira alleges that Dr. Kharasch "appears to have a significant bias against EXPAREL, in favor of opioids for treatment of pain"

by having conducted studies supporting opioid use to alleviate pain in post-surgery patients. Compl. ¶ 31. But allegations of bias or other forms of ill will are irrelevant to actual malice. *Lynch*, 161 N.J. at 166-67; *Harte–Hanks,* 491 U.S. at 666; *Lipsky v. Connecticut Gen. Life Ins. Co.*, 2013 WL 5354511, at *3 (D.N.J. Sept. 24, 2013) ("Simply stating that the statement was made with malice without additional facts that support the notion that Defendants knew the statement was false or had a reckless disregard for the truth is insufficient to survive a motion to dismiss."). In short, "[e]ven if plaintiff's allegations are true, none prove[s] with convincing clarity that [defendant] published his statements about plaintiff with knowledge of their falsity or reckless disregard of whether they were true or false." *Berkery v. Est. of Stuart*, 412 N.J. Super. 76, 93 (App. Div. 2010) (citations and quotations omitted).

The Authors Of The Hussain Meta-Analysis. Pacira's allegations regarding actual malice as to the authors of the Hussain Meta-Analysis fare no better. Beyond conclusory statements of knowledge that fail as a matter of law, *supra*, at 24–25, Pacira claims that two of the authors, Dr. Brull and Dr. Abdallah, practice in Canada where EXPAREL is not available. Pacira offers no explanation for why a statement about a drug constitutes actual malice merely because the speaker has not prescribed it for patients. Nor could it: The article assesses studies and is not based on experience from prescribing EXPAREL.

Pacira alleges that malice can also be established from the article's use of "crude pooling," improper "selection of trials for review," and failure to account for clinical diversity because they show an intent to disparage EXPAREL. Compl. ¶ 46. Pacira fails to allege why these methodological judgments are improper. *See id.* But even if Pacira had done so, such allegations do not show knowing falsity. Rather, they show only the making of a statement that truthfully reflects the underlying data. And even "'extreme departure from professional

standards' fails to meet the actual malice standard." *McCafferty v. Newsweek Media Grp. Ltd.*, 2019 WL 1078355, at *6 (E.D. Pa. Mar. 7, 2019), *aff'd,* 955 F.3d 352 (3d Cir. 2020) (quoting *Harte-Hanks*, 491 U.S. at 665); *Tucker v. Fischbein*, 237 F.3d 275, 286 (3d Cir. 2001) (same).

The Authors Of The Ilfeld Review. Pacira similarly fails to sufficiently plead actual malice as to these Defendants. It points to the authors' choice of a narrative review, disregard of research favorable to EXPAREL, inadequate execution of a Cochrane Bias Risk Assessment, and failure to disclose financial conflicts of interest. Compl. ¶¶ 48-49. Even if true, none of these allegations is sufficient to establish that the authors knowingly published false statements. Allegations of the failure to disclose a purported conflict concern motivation for making the statement rather than knowledge of falsity. *Lynch*, 161 N.J. at 166-67; *Harte–Hanks,* 491 U.S. at 666; *Lipsky*, 2013 WL 5354511, at *3. The authors expressly disclosed that they discounted some studies on the basis of bias, explained the definition of bias they applied, and did not claim that their conclusions reflected more than an assessment of the included studies. *Supra* at 6. The failure to consider certain contrary information cannot constitute actual malice. *New York Times Co. v. Sullivan,* 376 U.S. 254, 287-288 (1964) (failure of newspaper to verify the facts contained in an ad against new stories in its own files amounted at most to negligence, and was "constitutionally insufficient to show the recklessness required for a finding of actual malice"); *Marcone*, 754 F.2d at 1089 (similar). The allegedly incorrect selection of a narrative review or execution of a Cochrane Bias Risk Assessment (allegations Defendants dispute) are irrelevant to whether the statements were known to be true. *McCafferty*, 2019 WL 1078355, at *6.

Dr. McCann. Pacira's allegations of malice as to Dr. McCann are only that the "editorial relied heavily on, and adopted, the conclusions of the Hussain and Ilfeld Review" despite making "no effort to check the accuracy or methodology of their analyses." Compl. ¶ 56. But

allegations of inadequate investigation fail as a matter of law to establish actual malice. *Marcone*, 754 F.2d at 1089; *St. Amant v. Thompson*, 390 U.S. 727, 730-731 (1968) (holding that a defendant's "fail[ure] to verify the information with those ... who might have known the facts" fell short of establishing actual malice); *Pippen v. NBCUniversal Media, LLC*, 734 F.3d 610, 614 (7th Cir. 2013) ("[F]ailure to investigate is precisely what the Supreme Court has said is insufficient to establish reckless disregard for the truth.").

Finally, that the statements were subject to anonymous peer review renders any allegation of actual malice "implausible" on its face under *Iqbal*. Pacira nowhere pleads how one dozen authors conspired to publish false statements that could evade the peer review process while disclosing the very bases for their statements. Indeed, any such inference defies logic.

C. Pacira's Allegations As To Special Damages Are Insufficient.

"The special damages requirement goes to the cause of action itself, such that a plaintiff will be denied even nominal or punitive damages if he cannot show special damages." *Patel v. Soriano*, 369 N.J. Super. 192, 248 (App. Div. 2004). Such a showing must be "specific: plaintiff must establish pecuniary loss that has been realized or liquidated, such as lost sales, or the loss of prospective contracts with customers. Traditionally, plaintiff was required to identify particular business interests who have refrained from dealing with him, or explain the impossibility of doing so." *Id.* at 248-49. Allegations of general loss fail as a matter of law. *Bocobo v. Radiology Consultants of S. Jersey, P.A.*, 477 F. App'x 890, 901 (3d Cir. 2012). In addition, a plaintiff "must show that their general loss of business was a direct result of Defendant's purportedly disparaging statements." *Gillon v. Bernstein*, 218 F. Supp. 3d 285, 299 (D.N.J. 2016) (alterations, citations, and quotations omitted). The entirety of Pacira's allegations as to loss are contained in paragraph 83 and lack the required detail:

> Defendants' false and misleading statements regarding EXPAREL have caused Pacira pecuniary loss. Based on the statements made in the February 2021 issue of *Anesthesiology*, several of Pacira's existing customers have discontinued, or are threatening to discontinue, their use of EXPAREL. Pacira has also lost potential customers who expressed interest in purchasing a supply of EXPAREL, but then backed out after seeing Defendants' disparaging statements about EXPAREL.

"Stating that [parties] were 'damaged' and that the statements 'curtail legitimate business' is simply not sufficient." *Arista*, 356 F. Supp. 2d at 428. Pacira's vague references to unnamed "existing" or "potential" customers is not enough. A party must do more than "alleg[e] generally that [plaintiff] has lost sales from existing and prospective customers." *NY Mach. Inc. v. Korean Cleaners Monthly*, 2018 WL 2455926, at *6 (D.N.J. May 31, 2018). Pacira had to identify the specific lost customers or facts "showing an established business, the amount of sales for a substantial period preceding the publication, the amount of sales for a [period] subsequent to the publication, facts showing that such loss in sales were the natural and probable result of such publication, and facts showing the plaintiff could not allege the names of particular customers who withdrew or withheld their custom." *Intervet, Inc. v. Mileutis, Ltd.*, 2016 WL 740267, at *6 (D.N.J. Feb. 24, 2016). Pacira failed. *Burr v. Newark Morning Ledger Co.*, 2018 WL 1955050, at *3 (N.J. Super. Ct. App. Div. Apr. 26, 2018) (affirming dismissal of trade libel count with prejudice where "complaint was devoid of any reference to particularized damages and failed to identify the prospective clients allegedly lost as a direct result of the article's publication").[13]

Pacira gave none of the necessary detail because it knows it cannot do so—at least not without facing serious liability exposure to its shareholders and the SEC. Two weeks after filing this lawsuit, its CEO gave a fireside chat to discuss Q1 results. In response to a question about

[13] Pacira's allegations as to customers who "are threatening to discontinue[] their use of EXPAREL" (Compl. ¶ 83) fail also because, to state a claim for trade libel, all alleged pecuniary losses must have "been realized or liquidated…" *Patel*, 369 N.J. Super. at 248-49.

whether investors should be worried by the February 2021 articles in *Anesthesiology*, the CFO said they should not, that sales were strong, and that "the lawsuit was having its desired effect." *See* Marino Decl. Ex. 13.

But even if Pacira had identified lost sales, it failed to plead that the articles were the cause. *See Bocobo*, 477 F. App'x at 901 (plaintiff must allege "extrinsic facts showing that such special damages were the natural and direct result of the false publication") (quotations omitted). Beyond its conclusory references to "statements made in the February 2021 issue of *Anesthesiology*," Compl. ¶ 83, Pacira fails to connect any loss to any statement. *Intervet*, 2016 WL 740267, at *7; *Arista*, 356 F. Supp. 2d at 428 (dismissing trade libel claim for, *inter alia*, failure to adequately plead special damages).

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court dismiss the Complaint with prejudice.

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Respectfully submitted,

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