

## Promote Scientific Discourse, Not Lawsuits

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### Editor's note

The outcome of this legal case regarding a pharmaceutical has implications for authors publishing original research in the field of telehealth.

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The United States District Court for the District of New Jersey recently granted a motion to dismiss the case *Pacira Biosciences, Inc. v. American Society of Anesthesiologists, Inc.*<sup>1</sup> The dismissal has important and welcome implications for journals and other publications commenting on the quality and impact of studies. The asserted claims of trade libel raised concerns about the potential chilling effect of publishing analyses critical of outcomes or benefits.

### The Case

Pacira Biosciences, Inc. (“Pacira”) brought trade libel claims against a host of parties in a case labeled *Pacira Biosciences, Inc. v. American Society of Anesthesiologists, Inc., et al.* (Complaint). These claims arose out of articles, editorial comments, continuing medical education (CME) materials, and a podcast published in or in connection with the February 2021 edition of *Anesthesiology*—the peer-reviewed journal published by the American Society of Anesthesiologists, Inc. The trade libel claims were dismissed with prejudice by the United States District Court for the District of New Jersey in an opinion dated February 4, 2022 (Opinion). Dismissal with prejudice means Pacira cannot attempt to amend its complaint to assert claims that could be allowed to proceed. The dismissal means Pacira cannot try to refile the claims in a new suit.

### The Claims

The Complaint asserted three instances of alleged trade libel. The first claim alleged that a meta-analysis of studies examining the efficacy of liposomal bupivacaine

marketed by Pacira as EXPAREL (bupivacaine) contained false and misleading statements (labeled the “Hussain Article” in the Opinion). The second claim alleged that a narrative review of EXPAREL trials was inaccurate (labeled as the “Ilfeld Review” in the Opinion). The third claim focused on an editorial based on the Hussain Article (labeled as the “McCann Editorial” in the Opinion). Finally, questions that could provide CME credit and a podcast that repeated the same conclusions were also identified as being allegedly libelous.

Each claim asserted different forms of trade libel. Trade libel is a claim based on the state law. The Complaint was filed in New Jersey, which resulted in New Jersey law being applied. As summarized by the court, in New Jersey, trade libel requires proving publication with malice of the false statements concerning the plaintiff’s property or product that caused special damages to the plaintiff.

### Scientific Background

EXPAREL is a commercial formulation of bupivacaine delivered via a liposomal carrier and indicated to be used for extending the duration of anesthetic agents. On a cellular level, bupivacaine binds to sodium channels on a neuron and prevents the entry of sodium ions into the cell. In turn, this blocks the generation and conduction of nerve impulses, including impulses that would carry the pain signal from a nerve. As a result, the propagation of pain signals is halted, making it an effective anesthetic. Broadly speaking, bupivacaine is used as a local anesthetic. However, the focus of this piece is on the efficacy of delivering bupivacaine via a carrier in order to extend

the analgesic properties of other anesthetics given in a nerve sheath in a process called a peripheral nerve block.

Clinical evidence for the effectiveness of perineural (inside a nerve sheath) administration of liposomal bupivacaine is mixed at best. A meta-analysis study that pooled nine clinical trials involving 619 patients from centers across the United States was carried out to evaluate effectiveness compared with nonliposomal local anesthetics and published in *Anesthesiology*.<sup>2</sup>

This meta-analysis had a primary outcome of looking at how pain severity scores changed at the 24- and 72-hour mark and evaluated the receiver operating characteristics (ROC) curve (referred hereafter as AUC [area under the curve]: area under the ROC curve). Secondary outcomes included the amount of postoperative analgesia that was taken, the incidence of opioid side effects, length of stay, side effects from liposomal bupivacaine, and clinical recovery.

From the pooled study, perineural liposomal bupivacaine did not significantly influence the pain scores—shown only as a 1-cm improvement on the AUC compared with nonliposomal formulations—at least in the clinical setting. Secondary outcomes did not point to directly benefit from liposomal bupivacaine in pain severity either. The amount of analgesic consumed or hospital length of stay or opioid-related side effects did not differ significantly.

Even though liposomal bupivacaine provided statistically significant benefits, it was not clinically relevant in looking at the postoperative pain scores of liposomal versus nonliposomal local anesthetic. Therefore, the meta-analysis soundly pointed out that evidence does not point to benefit of using liposomal bupivacaine over other nonliposomal alternatives for peripheral nerve blocks.

### Moving to Dismiss

The various defendants moved to dismiss the Complaint—stopping the litigation without having to go through the entire process. Courts follow a very specific standard of judgment when evaluating a motion to dismiss. The standard requires taking all of the allegations in the complaint as true and making all reasonable inferences in favor of the plaintiff (in this case, Pacira). Dismissal is then appropriate if it appears unlikely that the plaintiff would be able to succeed on its claims with the assumptions in favor of the plaintiff.

### The Decision

As already stated, the court granted the motion to dismiss because it did not find that falsity could reasonably be found in any of the actions forming the basis of the Complaint. For falsity to be established, the plaintiff must be able to prove that the statement is capable of being objectively determined true or false. An opinion is protected under the First Amendment and unlikely to

constitute trade libel. Looking at the claims in the Complaint broadly, the court explained that matters of scientific uncertainty and conclusions are best resolved among the scientists, not in court. The court referenced legal precedent that scientific conclusions will not be libelous if derived from nonfraudulent data, based on accurate references to the data and underlying methodology, and related to issues where ongoing scientific debate exists. Essentially, unless a claim exists that a scientific article falsified data, a claim for libel cannot be sustained.

The court broke down its decision by each aspect of the claim as follows:

- *The Hussain Article*: Even though the plaintiff claimed the article authors were selective in the choice of data and methodology, quibbling over methodology does not rise to libel. Fighting over methodology is a scientific issue.
- *The Ilfeld Review*: Similar to the Hussain Article, complaining about the selection of and analysis of data do not form the basis for a trade libel claim; therefore, the same conclusion was reached. The court did give slightly more credence to Pacira's allegation that conflicts of interest were not disclosed, noting that substantial undisclosed interests could be a problem. Fatal to Pacira's claim though was the nonmaterial nature of the conflicts, which conflicts the court found attenuated at best.
- *The McCam Editorial, CME, and Podcast*: The court found that each of these materials summarized or repeated otherwise protected opinion and could not then independently qualify as a libelous statement. Further, the court did not find a statement summarizing profits and marketing practices to constitute libel as the opinion was in accord with the findings of the other materials.

Based on all of that reasoning, the court granted the motion to dismiss with prejudice. The court detailed that even if additional evidence, as asserted by Pacira, was developed, the new evidence would not change the determination that all of the materials complained about were not false. The court concluded that the deficiencies in the Complaint could not be resolved. Therefore, no further attempts should be allowed.

### The Impact

The Opinion is a necessary affirmation of the important role the scientific discourse plays in healthcare and medicine. As the court noted, the legal system is not the appropriate venue for addressing competing hypotheses or resolving unsettled scientific determinations. Research and peer review are among the better means of refining understanding and advancing the broader knowledge

base. By dismissing Pacira's claims, the court held up the principles of reasoned scientific debate as opposed to permitting one point of view to hinder the dissemination of different perspectives. Ultimately, the scientific process (and healthcare) benefits from a thorough vetting of claims and continually developing data to enable the development of evidence-based decisions.

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Neither author has a conflict of interest.

#### **Authors' contributions**

Both authors approved the final draft of this opinion.

#### **References**

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