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United States Court of Appeals, First Circuit.

IN RE: APELLIS PHARMACEUTICALS, INC. SECURITIES LITIGATION
Ray Peleckas; Michigan Laborers' Pension Fund, Plaintiffs, Appellants,
Judith M. Soderberg, individually and on behalf of all others similarly situated; Raul Prado Ruiz, Plaintiffs,
v.
Apellis Pharmaceuticals, Inc.; Cedric Francois, Defendants, Appellees,
Federico Grossi; Timothy Sullivan, Defendants.

No. 25-1383
|
August 19, 2026

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS [Hon. Julia E. Kobick, U.S. District Judge]

Attorneys and Law Firms

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Peter J. Kolovos, with whom Daniel W. Halston, Dan Willey, Edward W. Hasen, and Wilmer Cutler Pickering Hale and Dorr LLP were on brief, for appellees.

Before Aframe, Lynch, and Kayatta, Circuit Judges.

Opinion

AFRAME, Circuit Judge.

***1** This appeal challenges the dismissal of a putative class action claiming securities fraud under sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Securities and Exchange Commission Rule 10b-5. In their amended complaint, plaintiffs-appellants alleged that defendants-appellees Apellis Pharmaceuticals, Inc., and Dr. Cedric Francois, Apellis's Chief Executive Officer, made several materially misleading statements about the findings of two clinical trials for its drug SYFOVRE, which was approved by the Food and Drug Administration ("FDA") and is in use today. According to the plaintiffs, the statements were half-truths rendered misleading by omissions from the defendants' public statements about the results of the trials.

The defendants moved to dismiss under Federal Rule of Civil Procedure 12(b)(6), and the district court granted the motion on two independent grounds. First, the court concluded that the plaintiffs' allegations did not support a plausible inference that the omissions in question caused the challenged statements to be materially misleading. Second, it determined that the plaintiffs' allegations fell short of establishing that the challenged statements were made with the scienter required by applicable law.

We agree that the challenged statements cannot plausibly be viewed as materially misleading and affirm on that basis without ruling on the issue of scienter. After summarizing the case on the basis of the well-pleaded allegations, as supplemented by "documents the authenticity of which are not disputed," "official public records," and "documents sufficiently referred to" in the amended complaint, Premca Extra Income Fund LP v. Angle, 178 F.4th 712, 718 (1st Cir. 2026) (citation modified), we explain our reasoning.

On August 2, 2023, plaintiffs Ray Peleckas and the Michigan Laborers' Pension Fund brought this action in the U.S. District Court for the District of Delaware on behalf of all purchasers of Apellis common stock during the class period, which ran from January 28, 2021, until July 28, 2023. On June 3, 2024, the presiding judge transferred the case to the U.S. District Court for the District of Massachusetts to satisfy venue requirements.

Apellis is a biopharmaceutical company that developed a drug known as pegcetacoplan to treat geographic atrophy ("GA"), an advanced form of age-related macular degeneration ("AMD") that can ultimately cause blindness. Pegcetacoplan is administered through a series of intravitreal injections, i.e., injections directly into the eye. The drug does not improve eyesight but rather seeks to slow GA's progression. On February 17, 2023, the FDA approved pegcetacoplan under the commercial name of SYFOVRE as a treatment for GA.

On July 15, 2023, following Apellis's commercialization and distribution of SYFOVRE as an FDA-approved treatment for GA, the American Society of Retinal Specialists ("ASRS") published a letter stating that physicians had reported six incidents of retinal vasculitis in patients treated with SYFOVRE. Retinal vasculitis is an inflammation of the vessels of the retina that can cause significant vision loss.

Two weeks later, Apellis confirmed a seventh case and stated that it was investigating a potential eighth case. During this period, Apellis's stock price declined significantly. In November 2023, SYFOVRE's label was updated to include a warning listing retinal vasculitis as a potential side effect. On December 21, 2023, an ASRS committee published a second letter stating that, while "[t]here were no reported cases of retinal vasculitis ... in the clinical trials," there also was "no defined protocol in these studies to obtain angiography in cases of intraocular inflammation," which is a possible symptom for retinal vasculitis.

***2** At the beginning of the class period, in 2021, Apellis was conducting two Phase III clinical studies, known as the OAKS and DERBY studies, to test the use of pegcetacoplan as a treatment for GA. OAKS and DERBY were two-year studies that between them enrolled more than a thousand participants aged sixty and older who had been diagnosed with GA. Study participants randomly received either pegcetacoplan injections or sham treatments.

This case involves more than a dozen statements by the defendants during the class period touting the absence of occurrences of retinal vasculitis among trial participants. Most of the challenged statements asserted that no cases of retinal vasculitis had been observed among participants during the OAKS and DERBY clinical trials, although two of the statements could be understood to have asserted more categorically that there were no cases of retinal vasculitis among participants. The plaintiffs alleged that these statements, although not themselves false, could plausibly be found to have been materially misleading. Why? Because they were unaccompanied by an express acknowledgment that the trials were not designed to detect retinal vasculitis, and reasonable investors would have failed to understand that they were not so designed. [1]

[1] The defendants say that the plaintiffs did not make this precise argument about study design to the district court and thus did not preserve it for our review. The plaintiffs disagree, arguing that this argument was the clear upshot of their pleaded case theory, as elaborated in their opposition to the defendants' motion to dismiss. We bypass any issue of forfeiture because, as we will explain, the plaintiffs' design-of-the-study argument fails on its merits. See Lafortune v. Garland, 110 F.4th 426, 432 n.2 (1st Cir. 2024) (engaging in a similar bypass of a potential forfeiture issue).

The plaintiffs further alleged that, for interrelated reasons, the defendants were concerned about the possibility of pegcetacoplan injections causing retinal vasculitis as a side effect. First, the defendants regarded pegcetacoplan as a "lead product candidate" that was crucial to Apellis's future. Second, the defendants were aware that side effects such as retinal vasculitis were likely to make doctors and patients hesitant to try pegcetacoplan because the drug has only moderate benefits and is administered through an unpleasant eye injection. Third, the defendants knew that not long before the class period began, emerging evidence that retinal vasculitis was a side effect of a competitor's FDA-approved intravitreal AMD treatment had caused an adverse impact on both the market for that treatment and the competitor's stock price.

Several important facts were either conceded by the plaintiffs or are undisputed. First, the fluorescein angiogram is the most common and accepted test used to detect retinal vasculitis. Second, the protocols for the OAKS and DERBY trials -- which were approved by the FDA and made publicly available on ClinicalTrials.gov -- required that fluorescein angiograms be administered to trial participants on three separate occasions during the two-year trial course: at the outset, at the midpoint, and at the trials' conclusion. The protocols also required that fluorescein angiograms be given to participants who dropped out of the trials, but not for at least thirty days after they stopped participating. In addition, participating clinicians were free to order fluorescein angiograms for trial participants whenever they thought that doing so was warranted by a participant's symptoms. Third, there is no evidence that any trial participants developed retinal vasculitis during or after the trials. Indeed, there is no evidence of retinal vasculitis occurring in test subjects during the more than ten years that Apellis developed and tested pegcetacoplan prior to the drug's FDA approval. Fourth, and finally, Apellis conducted the OAKS and DERBY trials by following the FDA-approved protocols.

***3** The problem, the plaintiffs argued, is that the trial protocols did not require prompt follow-up fluorescein angiograms for retinal vasculitis when study participants developed intraocular inflammation or ischemic neuropathy, which can be symptoms of retinal vasculitis and which occurred with greater frequency in study participants who received pegcetacoplan than in those who received the sham treatment. [2] Nor did they require immediate follow-up

fluorescein angiograms when participants dropped out of the studies. The plaintiffs alleged that, because the defendants would have required these actions had they designed the trials to test for retinal vasculitis, the defendants' statements about the absence of retinal vasculitis in trial participants constitute misleading half-truths. [3] The plaintiffs argued that to have made these statements in a non-misleading manner, the defendants would have needed to advise investors that the protocols were not designed to test for retinal vasculitis. The absence of such a statement was thus, according to the plaintiffs, an actionable material omission.

2 This argument was supported by the plaintiffs' expert, Dr. Demetrios Vavvas, who is the Solman and Libe Friedman Professor of Ophthalmology and Co-Director of the Ocular Regenerative Medicine Institute at Harvard Medical School. Dr. Vavvas also is the Director of the Retina Service at Massachusetts Eye and Ear.

3 The plaintiffs appear to presume, but plead no facts to support the assumption that, trial participants -- including those dropping out of the trials -- could have developed vasculitis but that it resolved on its own before their next scheduled fluorescein angiogram.

The defendants moved to dismiss the amended complaint for, inter alia, a failure to plausibly allege a material misrepresentation or omission and a failure to plausibly allege that they had acted with the requisite scienter. See Premca, 178 F.4th at 723 ("A plausible § 10(b) claim requires well-pleaded allegations of: (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." (citation omitted)). The district court agreed with both arguments and accordingly granted the defendants' motion. As noted above, we confine our focus to whether the court committed error in concluding as a matter of law that the plaintiffs failed to identify a material misrepresentation or omission. See id. (applying de novo review to the grant of a motion to dismiss a securities fraud action under § 10(b)). [4]

4 A claim for securities fraud under section 10(b) is also subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. §§ 78u-4, 78u-5. See Premca, 178 F.4th at 723. But these additional requirements do not factor into our analysis.

In ruling on the defendants' motion to dismiss, the district court identified two alleged omissions as grounding the plaintiffs' liability theory. First, the defendants failed to state how frequently Apellis used fluorescein angiography to test for retinal vasculitis. Second, defendants failed to state that their testing protocols were inadequate to detect that condition. The court then held, as a matter of law, that neither omission made the challenged statements misleading. The first omission was not actionable because the frequency of testing under the protocols was fully disclosed to investors in public statements well before the defendants made the challenged statements. The second was not actionable because it was rooted only in a disagreement about the adequacy of the scientific methodology employed in the studies, which under prevailing law cannot give rise to a securities fraud claim.

On appeal, the plaintiffs argue that the district court misunderstood and therefore did not address their material misrepresentation theory. That theory is, again, that the defendants' statements about the absence of occurrences of retinal vasculitis among OAKS and DERBY study participants during the class period, while literally true, were misleading half-truths because the defendants failed to disclose that the studies were not designed to test for that condition. In our view, the plaintiffs' theory fails to ground a viable securities fraud claim because, under the circumstances as alleged, the challenged statements are not actionable half-truths.

***4** "Half truths ... are 'representations that state the truth only so far as it goes, while omitting critical qualifying information.' " Macquarie Infrastructure Corp. v. Moab Partners, L.P., 601 U.S. 257, 263, 144 S.Ct. 885, 218 L.Ed.2d 214 (2024) (quoting Universal Health Servs., Inc. v. United States ex rel. Escobar, 579 U.S. 176, 188, 136 S.Ct. 1989, 195 L.Ed.2d 348 (2016)). Here, there was no omission of such information. Although the plaintiffs frame their appellate argument in terms of the omission being a statement regarding the intentions of the study designers, their theory of deception actually rests on two more specific omissions: (1) omitting a statement that the OAKS and DERBY protocols left to treating clinicians the decision whether to order a fluorescein angiogram upon the appearance of inflammation and ischemic neuropathy in study participants, rather than requiring one in all such cases; and (2) omitting a statement that the protocols did not require that participants who left

the studies to receive fluorescein angiograms until more than thirty days after their departures.

True, the defendants did not explicitly state that fluorescein angiograms were not automatically given to all sufferers of inflammation and ischemic neuropathy or that fluorescein angiograms were not given to those leaving the OAKS and DERBY studies within thirty days of their exits. Nevertheless, the defendants disclosed both facts by providing full and complete disclosures of when fluorescein angiograms would be given to trial participants. In other words, investors knew what the defendants were doing and the outcomes arising from those actions. [5] In this way, the present situation materially differs from SEC v. Lemelson, 57 F.4th 17 (1st Cir. 2023), and SEC v. Johnston, 986 F.3d 63 (1st Cir. 2021), two cases on which the plaintiffs rely.

5 The plaintiffs suggest that investors might not have had the scientific expertise to understand whether the protocols' testing procedures were sufficient to detect retinal vasculitis. We do not foreclose the possibility that, in some other case, the scientific details might be so complex that the hypothetical reasonable investor might be misled by a defendant's more accessible plain-English statements notwithstanding the public availability of technically dense documents describing the testing protocols.

Lemelson supports the premise that technically true but misleading "half-truths" can give rise to liability. See 57 F.4th at 23-25. In Lemelson, the defendant stated, inter alia, that a biopharmaceutical company did not intend to conduct clinical trials but failed to disclose that the company instead planned to hire a third party to conduct the trials. Id. at 24. This Court first determined that a reasonable jury could have concluded that the defendant's statement was a factual assertion, not a statement of opinion, because it "expressed certainty" and was not prefaced by "I think" or "I believe." Id. (citation modified). The Court then determined that the offending statement was "factually contradicted" by the company's plan to hire a third party to conduct the trials. Id. Thus, while it was true that the company would not conduct trials itself, that was an actionable half-truth because the company omitted to state that it was going to hire a third party to conduct the trials on its behalf.

Johnston is similar. Like Lemelson, it supports the premise that technically true but misleading half-truths can form the basis of a securities-fraud claim. 986 F.3d at 72. In Johnston, a company executive stated that he could not speculate whether the FDA would require the company to conduct a second clinical trial and that there had been no formal discussions with the FDA about a second trial. Id. at 72-73. But the executive did not disclose that the FDA had recommended a second trial. Id. As in Lemelson, the Court concluded that this omission rendered the statement made a misleading half-truth. Id. at 73-74.

***5** Here, in contrast, there were neither contradictions nor undisclosed facts. The defendants reported that their clinical studies found two side effects that are symptomatic of retinal vasculitis: retinal inflammation and ischemic neuropathy. The defendants then announced that there were no observed cases of retinal vasculitis. These facts provide some basis for reasonable investors to infer that the defendants were testing for retinal vasculitis. But they do not create a factual contradiction because both the OAKS and DERBY studies employed fluorescein angiography at set times and fluorescein angiography is the most common method used to test for retinal vasculitis.

In short, there is no actionable claim here because the information provided by the defendants was accurate and did not conceal material information. The trial protocols were public and followed, the tests used in the studies would detect retinal vasculitis, and no retinal vasculitis was detected in any study participant. Because everything disclosed was accurate and no "critical qualifying information" was withheld, Macquarie Infrastructure Corp., 601 U.S. at 263, 144 S.Ct. 885 (citation modified), the district court properly dismissed the complaint.

Affirmed.

All Citations

--- F.4th ----, 2026 WL 2425924

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