# United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
**FILED**
September 10, 2021
Lyle W. Cayce
Clerk

No. 20-20487

PAUL E. CALLINAN; JORGE RIVERA,

*Plaintiffs—Appellants*,

*versus*

LEXICON PHARMACEUTICALS, INCORPORATED; LONNEL COATS; JEFFREY L. WADE; PABLO LAPUERTA,

*Defendants—Appellees*.

Appeal from the United States District Court
for the Southern District of Texas
USDC No. 4:19-CV-301

Before DENNIS and ENGELHARDT, *Circuit Judges*, and HICKS, *Chief District Judge*.*

PER CURIAM:*

Investors in Lexicon Pharmaceuticals, Inc. brought this class-action suit alleging securities fraud against the company and certain of its current

* Chief Judge of the Western District of Louisiana sitting by designation.

* Pursuant to 5TH CIRCUIT RULE 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIRCUIT RULE 47.5.4.

and former executives.[1] Lexicon is a publicly traded biopharmaceutical company that develops new drugs to treat serious diseases. This case involves one of its drugs that ultimately failed to obtain regulatory approval by the Food and Drug Administration ("FDA").

Sotagliflozin is an oral therapy intended for use in conjunction with insulin therapy to improve blood sugar control in adults with diabetes. Like many drugs, sotagliflozin bestows benefits encumbered by risks, and its regulatory approval depended, in part, on whether the former outweighed the latter. On the benefit side of the scale, the drug improves control of blood sugar by functioning as an inhibitor, preventing proteins in the body from absorbing glucose. On the risk side of the scale, it is associated with increased incidences of one of the most well known and serious health risks for people who have diabetes: diabetic ketoacidosis ("DKA"). If left untreated, DKA is a life-threatening condition that results when the body produces excess acids in the bloodstream.

When sotagliflozin successfully completed all three phases of clinical trials, the FDA convened a public advisory committee meeting. The committee put to a vote the question of whether "the available data suggest that the benefits outweigh the risks and support the approval of sotagliflozin." That question produced a deadlocked vote by the committee, an impasse driven largely by concerns about the risk of DKA. Later, the FDA determined not to approve sotagliflozin. After both the committee vote and the FDA rejection, Lexicon's stock price declined precipitously.

Appellants claim that Lexicon made materially false and misleading statements and omissions about sotagliflozin, violating Section 10(b) of the

[1] For purposes of this opinion, the investor-plaintiffs are collectively referred to as "Appellants" and defendants are collectively referred to as "Lexicon."

Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and Rule 10b–5 promulgated thereunder, 17 C.F.R. § 240.10b–5. As relevant here, they advanced three theories in the district court. First, they alleged that Lexicon had minimized the risk of DKA posed by sotagliflozin. Second, they alleged that the FDA had warned Lexicon about its use of a particular endpoint in its Phase 3 trials and that Lexicon had failed to disclose that warning to investors. Third, they alleged that Lexicon failed to disclose that it had not prepared a meaningful DKA risk management program for sotagliflozin.

In a careful and thorough opinion spanning 114 pages, the district court granted Lexicon's motion to dismiss and rejected each of Appellants' theories of liability. First, it concluded that Appellants had not alleged any actionable misrepresentations or omissions. Second, it found that, even assuming Appellants' allegations were actionable, the facts alleged do not support a strong inference that the misrepresentations were made with scienter. Finally, the district court determined that Appellants failed to plead loss causation. The district court also disallowed Appellants' request to amend their complaint. It resolved that any additional attempt to amend would be futile given that they had already filed an amended complaint, argued strenuously that it stated claims, and failed either to submit a proposed second amended complaint or to describe any additional facts that could be alleged in it. This appeal followed.

Attentive to the arguments advanced on appeal, we have reviewed the district court's extensive opinion *de novo*. *See Masel v. Villarreal*, 924 F.3d 734, 742–43 (5th Cir. 2019). For the reasons stated more fully by the district court, *see Callinan v. Lexicon Pharms., Inc.*, 479 F. Supp. 3d 379 (S.D. Tex. 2020), we agree that Appellants failed to state a claim with sufficient particularity to survive a motion to dismiss under the stringent pleading requirements imposed by the Private Securities Litigation Reform Act, 15 U.S.C. § 78u–4. *See Owens v. Jastrow*, 789 F.3d 529, 535 (5th Cir. 2015).

Moreover, the district court considered the relevant factors in determining not to grant leave to amend, and we cannot say that it abused its discretion in doing so. *See Schiller v. Physicians Res. Grp. Inc.*, 342 F.3d 563, 566 (5th Cir. 2003).

Accordingly, the judgment of the district court is AFFIRMED.