UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 18-2415

CHARLES CRAIG JANIES; ROBERT F. COLWELL, JR.; JENNIFER COLWELL,

Plaintiffs - Appellants,

and

JOHNATHAN HIRTENSTEIN; DONALD B. HALLOWES,

Plaintiffs,

v.

CEMPRA, INC.; PRABHAVATHI B. FERNANDES; MARK W. HAHN; DAVID W. OLDACH,

Defendants - Appellees.

Appeal from the United States District Court for the Middle District of North Carolina, at Greensboro. Thomas D. Schroeder, Chief District Judge. (1:16-cv-01303-TDS-JEP)

Argued: December 11, 2019 Decided: May 28, 2020

Before WILKINSON, KEENAN, and DIAZ, Circuit Judges.

Affirmed by unpublished per curiam opinion.

ARGUED: Steven Francis Hubachek, ROBBINS GELLER RUDMAN & DOWD LLP, San Diego, California, for Appellants. Michael S. Hines, SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP, Boston, Massachusetts, for Appellees. **ON BRIEF:** Trig R. Smith, ROBBINS GELLER RUDMAN & DOWD LLP, San Diego, California; Michael I. Fistel, Jr., JOHNSON FISTEL, LLP, Marietta, Georgia, for Appellants. Lee M. Whitman, Samuel A. Slater, WYRICK ROBBINS YATES & PONTON LLP, Raleigh, North Carolina; James R. Carroll, Emily M. Jennings, SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP, Boston, Massachusetts, for Appellees.

Unpublished opinions are not binding precedent in this circuit.

PER CURIAM:

Plaintiffs Charles Janies, Robert Colwell, Jr., and Jennifer Colwell appeal the dismissal of their suit alleging securities fraud, which was filed as a putative class action against Cempra, Inc. and its former officers and directors (collectively, the defendants). For the reasons stated in the district court's well-reasoned opinion, we affirm.

I.

Cempra was a publicly traded pharmaceutical company focused on the development of new antibiotics.[1] In 2015 and 2016, Cempra became a popular choice for investors based on the hope that its lead drug, solithromycin, would receive approval from the Food and Drug Administration (FDA) for treatment of community-acquired bacterial pneumonia (CABP).[2] The plaintiffs represent shareholders who invested in Cempra in the sixteen months preceding the FDA's review of solithromycin in November 2016. The shareholders incurred significant losses when Cempra's stock price decreased sharply after the FDA expressed safety concerns regarding the drug's impact on the liver.

[1] After the events that gave rise to the litigation in this case, Cempra was merged with another bio-pharmaceutical company, Melinta Therapeutics, Inc. (Melinta). Melinta has since filed for Chapter 11 bankruptcy. Upon motion of the parties, the bankruptcy court lifted the automatic stay to allow resolution of this appeal.

[2] At the time, solithromycin was also undergoing clinical trials for chronic obstructive pulmonary disease (COPD) and non-alcoholic steatohepatitis. However, Cempra's FDA application in 2016 was solely for treatment of CABP.

The plaintiffs filed suit seeking to recoup their losses under Sections (10)(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j, 78t. In their putative class-action complaint, the plaintiffs averred that the defendants were aware that solithromycin's chances for FDA approval were contingent on Cempra's ability to differentiate solithromycin from Ketek, a similar drug. Ketek initially was approved by the FDA but later was found to cause severe liver injury, ultimately prompting congressional investigations. As alleged by the plaintiffs, the defendants fraudulently induced them to purchase stock in Cempra by misrepresenting solithromycin's clinical data and by overstating the likelihood that solithromycin would be reviewed favorably by the FDA.

The defendants filed a motion to dismiss, which the district court granted in a comprehensive 83-page opinion. The district court determined that, contrary to the plaintiffs' allegations, many of Cempra's alleged misrepresentations were factually accurate, and that Cempra adequately had informed the public of the risk of unfavorable FDA review, given the well-known history of Ketek. More broadly, the court concluded that the plaintiffs' complaint, viewed as a whole and in context, did not contain factual allegations sufficient to give rise to the "strong inference" of scienter required by the Private Securities Litigation Reform Act of 1995 (PSLRA), 15 U.S.C. § 78u-4(b)(2)(A), and applicable precedent. The plaintiffs appealed from the district court's judgment.

II.

We review de novo the district court's determination that the plaintiffs' complaint failed to state a claim for securities fraud. *Maguire Fin., LP v. PowerSecure Int'l, Inc.*,

876 F.3d 541, 545 (4th Cir. 2017). To be actionable, fraud claims brought under Section 10(b) must satisfy six elements: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Singer v. Reali*, 883 F.3d 425, 438 (4th Cir. 2018) (citation omitted). Here, the foundation of the district court's opinion dismissing the complaint and, therefore, the focus of this appeal, is the element of scienter. The requirements for pleading scienter in a securities fraud claim are set forth in the PSLRA. 15 U.S.C. § 78u–4(b)(2).

The PSLRA was enacted by Congress "[a]s a check against abusive litigation by private parties" in securities fraud actions. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007). Congress sought to achieve this "check," at least in part, by imposing a heightened pleading requirement for the element of scienter. *Id.* at 313-14. Thus, the PSLRA mandates that any prospective plaintiff, "with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2) (emphasis added).

The "required state of mind" under Section 10(b) is "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 319 (citation omitted). To satisfy this standard at the motion to dismiss stage, a complaint must include allegations of "intentional or severely reckless conduct." *Maguire Fin.*, 876 F.3d at 547 (citation omitted). "Severe recklessness" is "a slightly lesser species of intentional misconduct,"

id., and is satisfied only by allegations demonstrating "such an extreme departure from the standard of ordinary care" that the danger of misleading the plaintiff must have been "either known to the defendant or so obvious that the defendant must have been aware of it." *Zak v. Chelsea Therapeutics Int'l, Ltd.*, 780 F.3d 597, 606 (4th Cir. 2015) (citations omitted).

In assessing whether a securities-fraud complaint contains sufficient allegations of scienter to withstand a motion to dismiss, courts must examine the complaint "in its entirety" and avoid evaluating statements in isolation. *Tellabs*, 551 U.S. at 322-23. Moreover, under the PSLRA's heightened standard of scienter, "the court must take into account plausible opposing inferences." *Id.* at 323. Although no "smoking-gun" evidence is required, the inference of scienter must be "cogent and compelling." *Id.* at 324. Ultimately, dismissal is proper unless "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*

III.

On appeal, the plaintiffs argue that their complaint satisfies the heightened standard for scienter under the PSLRA based on the factual context of the alleged misrepresentations. The plaintiffs contend that several of the defendants' misrepresentations were made when the defendants had actual knowledge that the statements were false, which, according to the plaintiffs, is "classic evidence of scienter" under our precedent in *S.E.C. v. Pirate Investor LLC*, 580 F.3d 233, 243 (4th Cir. 2009) (citation omitted). Thus, the plaintiffs assert that they adequately alleged scienter,

particularly when considered in the context of the "[d]efendants' motivation to maintain a high share price for Cempra."

In advancing this argument, the plaintiffs focus on three statements and one omission made by the defendants: (1) the representation, made more than once, that elevated levels of ALT,[3] a liver enzyme, observed during clinical trials were "generally asymptomatic" and "reversible;" (2) the related suggestion, also repeated, that the elevated ALT in the trials was not indicative of "liver toxicity;" (3) the statement, made on a single occasion, that across "all of our trials" "nobody has had any of those same types of issues that the folks had experienced with Ketek;" and (4) the failure to disclose that the drug protocol for one of the clinical trials was altered based on an observed liver injury. The plaintiffs assert that these statements and omissions, taken together, are sufficient to conclude at the pleading stage that the defendants acted at least with "severe recklessness."

These arguments were rejected by the district court. First, the court thoroughly reviewed the record and determined that the defendants' statements regarding the "generally asymptomatic" and "reversible" nature of the observed ALT elevations "closely track[ed] the reported clinical data." Thus, the court concluded that those statements could not support any inference of scienter.

Second, the district court determined that the defendants' statements that elevated ALT was not indicative of "liver toxicity" also did not support an inference of scienter, because the defendants plainly had defined and explained their use of that term. As the

[3] ALT stands for alanine aminotransferase.

court observed, the defendants repeatedly informed the public that they were defining "liver toxicity" by reference to "Hy's Law," a model used by the FDA to predict the likelihood of severe, drug-induced liver injury. And, as the plaintiffs conceded, none of the patients in Cempra's clinical trials satisfied the criteria for Hy's Law. Accordingly, the court found that the defendants' statements regarding liver toxicity were true in the context in which they were made and, therefore, did not constitute evidence of scienter.

The district court was more troubled by the defendants' statement, made in September 2016, that no participant in Cempra's clinical trials "had any of those same types of issues that the folks had experienced with Ketek." As the court noted, by that time, one patient in Cempra's COPD trial had suffered drug-induced hepatitis, a recognized liver injury. Thus, viewing the facts in the plaintiffs' favor, the court reasoned that the statement could be viewed as misleading because such an injury is of the same *type* as those caused by Ketek. Nevertheless, the court concluded that this statement was insufficient to establish a "strong inference of scienter," given the context of all the other statements and Cempra's repeated disclosure that it was using "Hy's Law" as its barometer for assessing the risk of liver injury. The court also noted that the patient at issue had been receiving solithromycin for a longer duration and as treatment for a different disease than CABP, the subject of Cempra's FDA application. The court determined that, evaluated in this context, the most compelling inference that could be drawn from the statement was that the defendants thought that the patient's adverse reaction to solithromycin was distinguishable from the problems that patients suffered from Ketek and, thus, would not preclude favorable FDA review.

Finally, the district court concluded that no inference of scienter could be drawn from the defendants' alleged failure to disclose that the drug protocol for one of Cempra's clinical trials was altered based on the single drug-induced liver injury. As the district court noted, the full context of the defendants' statements regarding the change in drug protocol show that the defendants disclosed that the change was due, in part, to safety concerns. Shortly after Cempra's chief medical officer allegedly misrepresented that the change in protocol was for efficacy reasons, the CEO clarified that the "driver" behind the decision was "efficacy as well as safety." Given this disclosure, the district court concluded that the defendants' alleged failure to make a more complete disclosure did not support a "strong inference of scienter."

We discern no error in the district court's thorough analysis. As stated above, to withstand a motion to dismiss, a complaint alleging securities fraud must contain facts supporting an inference of scienter that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314. The plaintiffs did not do so here. At most, the allegations supporting scienter in the complaint consist of one or two misleading statements highlighted in isolation, together with the defendants' purported "motivation to maintain a high share price for Cempra." However, as the district court observed, "the motivations to raise capital or increase one's own compensation are common to every company and thus add little to an inference of fraud." *Cozzarelli v. Inspire Pharm. Inc.*, 549 F.3d 618, 627 (4th Cir. 2008). And "[t]he inquiry . . . is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not

whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 322-23 (emphasis added).

Here, viewing the facts alleged collectively, we agree with the district court that the most cogent inference arising from the complaint is that the defendants had great confidence in solithromycin's prospects and in their interpretation of the clinical data, and that the FDA simply disagreed with the defendants' assessment. This inference strongly is supported by the FDA's own documents, which largely "did not conclude that Cempra's statements were factually inaccurate but simply determined that more data should be obtained before drawing those same positive interpretations."

Moreover, the defendants repeatedly warned investors about the risk that the FDA would adopt such a position. For example, in a January 2016 prospectus, Cempra informed investors that solithromycin was "likely to be carefully scrutinized by the FDA" in light of Ketek's history, and cautioned investors that although Cempra thought it had "all the clinical trials necessary to support the [application] for solithromycin for CABP," "the FDA may disagree with our assessment and may require additional clinical data." These public disclosures further undermine the plaintiffs' contention that the defendants acted with the intent to deceive, or that their alleged misstatements represent "such an extreme departure from the standard of ordinary care" that the danger of misleading the plaintiff "was either known . . . or so obvious that the defendant[s] must have been aware of it." *Zak*, 780 F.3d at 606 (citation omitted).

For these reasons, we conclude that the inference that the defendants acted with fraudulent intent or severe recklessness is not as cogent or compelling as the opposing

inference that they acted with a genuine confidence in solithromycin's prospects and ultimately were mistaken. *Tellabs*, 551 U.S. at 314. As the district court recognized, such a mistaken belief does not support a claim for securities fraud. *See, e.g.*, *Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016) (dismissing complaint under similar circumstances); *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 470-72 (S.D.N.Y. 2008) (same). Accordingly, we affirm the court's dismissal of the plaintiffs' complaint.[4]

IV.

For these reasons, which are stated in greater detail by the district court in its opinion, we affirm the district court's judgment.

AFFIRMED

[4] Having concluded that the district court did not err in dismissing the plaintiffs' securities fraud claim under Section 10(b), we also affirm the dismissal of the claim against the individual defendants brought under Section 20(a) for the same reasons. *Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc*., 576 F.3d 172, 192 (4th Cir. 2009).