IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

TWIN MASTER FUND, LTD., TWIN OPPORTUNITIES FUND, LP, and TWIN SECURITIES, INC.,	)	
Plaintiffs,	)	
vs.	)	**Case No. 19 C 3648**
AKORN, INC., RAJAT RAI, DUANE PORTWOOD, ALAN WEINSTEIN, RONALD JOHNSON, and BRIAN TAMBI,	)	
Defendants.	)	
MANIKAY MASTER FUND, LP, and MANIKAY MERGER FUND, LP,	)	
Plaintiffs,	)	
vs.	)	**Case No. 19 C 4651**
AKORN, INC., RAJAT RAI, DUANE PORTWOOD, ALAN WEINSTEIN, RONALD JOHNSON, and BRIAN TAMBI,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

In 2017, Akorn, Inc., a pharmaceutical company, announced that it would be acquired by Fresenius, an international healthcare company. Before the merger closed, however, a whistleblower alerted Fresenius to possible regulatory compliance problems at Akorn facilities. Fresenius investigated these allegations, found substantial compliance problems, and subsequently announced that it was terminating the merger.

After the termination announcement, the price of Akorn's stock dropped precipitously.

Twin Master Fund, Ltd., Twin Opportunities Fund, LP, and Twin Securities, Inc. (collectively "Twin") purchased Akorn securities shortly after it announced the merger with Fresenius. Manikay Master Fund, LP and Manikay Merger Fund, LP (collectively "Manikay") also purchased Akorn securities around this time. Twin and Manikay have each sued Akorn and several corporate officers and board members, alleging that they made misrepresentations regarding Akorn's regulatory compliance that were fraudulent and violated the Securities Exchange Act of 1934. The defendants have moved to dismiss all of the plaintiffs' claims.

Background

Akorn is a pharmaceutical company that produces and sells generic drugs. At all times relevant to this suit, the individual defendants had the following roles at Akorn: Rajat Rai was the Chief Executive Officer, Duane Portwood was the Chief Financial Officer, and Alan Weinstein, Ronald Johnson, and Brian Tambi were board members.

Akorn is subject to U.S. Food and Drug Administration (FDA) regulations that set forth "current good manufacturing practices" for production of drugs. These regulations require manufacturers to meet certain data integrity standards, such as ensuring that data is backed-up and periodically reviewed for accuracy. Akorn's Vice President of Global Quality is in charge of ensuring that the company complies with the FDA's current good manufacturing practices.

To enforce compliance with its good manufacturing practices, the FDA periodically inspects drug manufacturing facilities. After inspection, the FDA may issue a "Form 483," which lists the observed violations and gives the manufacturer fifteen

days to respond with a corrective action plan. Once the manufacturer submits this plan, the FDA informs the facility whether the agency is satisfied with the proposed changes or plans to take enforcement action.

Akorn, like all generic drug manufacturers, must receive FDA approval of its generics prior to releasing them on the market. To gain approval, a manufacturer submits an Abbreviated New Drug Application (ANDA) to the FDA. An ANDA must include data demonstrating that the generic drug performs in the same manner as the analogous brand-name drug, and this data is subject to the FDA's data integrity standards. If the data submission in the ANDA is inadequate, the FDA will issue the company a "complete response letter," which lists the deficiencies and the action needed to overcome them. The applicant can then address the issues and resubmit the ANDA.

A. Data integrity issues at Akorn

In January 2016, an Akorn employee reported to Rai, Portwood, and other executive officers that Akorn’s then-Vice President of Global Quality was providing misleading information to the FDA and thwarting Akorn’s internal investigations of data integrity. In April 2016, Akorn's Global Quality Compliance team investigated data practices at the company's headquarters in Lake Forest, Illinois and found that it was not meeting data integrity standards. The team also investigated Akorn's research facility in Vernon Hills, Illinois and concluded that the data practices there were not meeting standards either. An independent data-integrity consulting company, Cerulean, inspected Akorn's manufacturing facility in Decatur, Illinois and found that its data practices did not meet FDA standards.

In mid-2016, the FDA also inspected Akorn's Decatur facility and issued a Form 483. Rai reported the Form 483 to investors. In December 2016, following up on the Form 483, the FDA reinspected the Decatur facility. Akorn passed the inspection, and agency informed the company that it would not take further enforcement action.

B. Akorn's merger agreement with Fresenius

In April 2017, Akorn accepted a buyout bid from Fresenius, and the two companies executed a merger agreement. A provision in the agreement allowed Fresenius to terminate the merger if Akorn's representations in the agreement were not "true and correct" as of both the signing date and closing date of the merger. Among Akorn's representations was a regulatory compliance statement stating that, "to the [k]nowledge of Akorn":

> [Akorn] and its Subsidiaries are[,] and . . . since July 1, 2013 . . . have been[,] in compliance with . . . all applicable Laws (including all rules, regulations, guidance and policies) relating to or promulgated by the U.S. Food and Drug Administration . . . and other Healthcare Regulatory Authorities . . . .

Merger Agr., Ex. 4, Akorn's Mot. to Dismiss, dkt. no. 29-6, at 33.[1] Another provision allowed Fresenius to terminate if Akorn breached its commitment to operate "in the ordinary course of business" during the pendency of the merger. *Id.* at 40.

After the companies executed the merger agreement, Akorn filed a Form 8-K—announcing the merger and attaching the agreement—with the U.S. Securities and Exchange Commission (SEC). Twin and Manikay first purchased Akorn securities shortly thereafter, in April 2017 and August 2017, respectively.

[1] In deciding this motion, the Court is generally limited to the complaint, but it may also consider the merger agreement and other documents referenced in and central to the complaint. *See Adams v. City of Indianapolis*, 742 F.3d 720, 729 (7th Cir. 2014).

In October 2017, Fresenius received a whistleblower complaint alerting it to issues with Akorn's product development and quality control processes. Both Akorn and Fresenius retained independent counsel to concurrently investigate the whistleblower's allegations. On February 26, 2018, Fresenius issued a press release announcing it was investigating "alleged breaches of FDA data integrity requirements . . . at Akorn" and that the "consummation of the [merger] may be affected" if the findings revealed that Akorn was not in compliance with the agreement conditions. Twin Compl., No. 19-cv-3648, dkt. no. 1, ¶ 130. [2] The same day, Akorn released a statement in which is said that its investigation "investigation has not found any facts that would result in a material impact on Akorn's operations and the Company does not believe this investigation should affect the closing of the [sale] with Fresenius." *Id.* ¶ 131. After these announcements, Akorn's stock price dropped from $30.28 per share on February 26, 2018 to $18.65 per share on February 27.

Fresenius's investigation resulted in a determination that Akorn was not in compliance with data integrity standards, and on April 22, 2018, Fresenius informed Akorn that it was terminating the merger. Fresenius issued a press release stating that it planned to pull out, in part, because Akorn had breached FDA data integrity requirements. Akorn issued its own release, stating that its investigation had not uncovered any facts that would compromise the merger. Akorn's stock price fell from $19.70 per share on April 22, 2018, to $13.05 per share on April 23, the day after the companies' announcements.

[2] Manikay's complaint and Twin's complaint contain the same allegations of the defendants' conduct, and for convenience, this opinion cites to Twin's complaint only.

On April 23, 2018, Akorn sued Fresenius in Delaware chancery court, seeking an order requiring consummation of the merger, and the court held a five-day trial. In October 2018, it issued a decision concluding that Fresenius's termination was valid on two independent grounds: the inaccuracy of Akorn's regulatory compliance statement and its failure to operate in "the ordinary course of business." First, the court concluded that Akorn's regulatory compliance statement was inaccurate because it had "widespread regulatory violations and pervasive compliance problems . . . [that] existed at signing and got worse." *Akorn, Inc. v. Fresenius Kabi AG*, No. 2018-300, 2018 WL 4719347, at *66 (Del. Ch. Oct. 1, 2008). Second, the court found that Akorn had breached its commitment to operate in ordinary course of business because it cancelled internal audits and failed to address data integrity deficiencies. *Id.* at *88.

In May 2019, Twin sued the defendants, asserting three fraud-based claims: (1) violation of section 10(b) the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5 (count 1); (2) violation of section 18 of the Act, 15 U.S.C. §§ 78r(a) (count 3); and (3) common law fraud (count 4).[3] In July 2019, Manikay also sued, alleging the same misconduct by the defendants and asserting identical claims.

Discussion

The defendants have moved to dismiss all of the plaintiffs' claims. First, they

[3] The complaint also includes a claim against the individual defendants under section 20(a) of the Securities Exchange Act, 15 U.S.C. § 78t(a), which holds "controlling persons" jointly and severally liable for violations of the Act. It does not provide an independent cause of action, and "to state a claim under § 20(a), a plaintiff must first adequately plead a primary violation of securities laws." *Pugh v. Tribune Co.*, 521 F.3d 686, 693 (7th Cir. 2008). The fate of this claim therefore depends on the section 10(b) and 18(a) claims.

argue that the section 18 claim is time-barred. Second, the defendants contend that Twin and Manikay failed to adequately plead two elements common to all of their claims: material misrepresentation and causation. Additionally, the defendants have moved to dismiss the section 18 claim, arguing that the plaintiffs did not adequately plead actual reliance. Finally, defendant Portwood has separately moved for dismissal from the common law fraud and section 10(b) claims, arguing that the plaintiffs' allegations were insufficient to establish the requisite mental state for these claims.

A. Timeliness of the Section 18 claim

Section 18 imposes civil liability for false statements knowingly made in any SEC filing and sets a one-year limitations period from the time a "reasonably diligent plaintiff" would have discovered—or did discover—conduct actionable under this provision. 15 U.S.C § 78r(a), (c); *see Merck & Co. v. Reynolds,* 559 U.S. 633, 653 (2010). The Sarbanes-Oxley Act extended to two years the limitations period for "claim[s] of fraud, deceit, manipulation, or contrivance in contravention of . . . securities laws." 28 U.S.C. § 1658(b)(1).

Preliminarily, the parties dispute whether the Sarbanes-Oxley Act extension applies to section 18(a) claims. The defendants argue that because section 18(a) does not include a fraudulent intent element, these are not fraud-based claims for which the Sarbanes-Oxley Act extended the limitations period. The Seventh Circuit has not yet ruled on the issue.

The Second Circuit held, in *Dekalb County Pension Fund v. Transocean Ltd.*, 817 F.3d 393 (2d Cir. 2016), that the two-year limitations period established by the Sarbanes-Oxley Act does apply to section 18 claims. *Id.* at 407. It explained that

although section 18(a) does not expressly set forth a scienter requirement, the Supreme Court has "strongly indicated" that it includes one. *Id.* at 406. In *Ernst & Ernst v. Hochfelder,* 425 U.S. 185 (1976), the Court observed that civil liability provisions of the Securities Exchange Act all include "a state-of-mind requiring something more than negligence." *Id.* at 209 n.28. And later, in *Musick, Peeler & Garrett v. Employers Insurance of Wausau*, 508 U.S. 286 (1993), the Court stated that section 18 imposes liability on defendants who violate securities laws "with scienter." *Id.* at 296.

This Court agrees with the Second Circuit's reading of *Ernst & Ernst* and *Musick* and concludes that the two-year limitations period applies to the plaintiffs' section 18 claims, rendering them timely. The parties dispute the date on which the limitations period began to run. The plaintiffs contend that it was May 2, 2018, when a news article reported that Fresenius had accused Akorn of fraud in the Delaware court proceedings; the defendants contend that it was October 1, 2018, when the chancery court issued its decision. Even if the two-year limitations period began to run on the earlier May 2, 2018 date, the plaintiffs' claims were timely: Twin filed its complaint on May 31, 2019, and Manikay filed its on July 10, 2019.

B. Sufficiency of fraud allegations

The defendants have moved to dismiss the plaintiffs' claims under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim and for failure to plead fraud with particularity under Rule 9(b) and the Private Securities Litigation Reform Act of 1995 (PSLRA), 15 U.S.C. § 78u-4(b)(1). In deciding a motion to dismiss for failure to state a claim, the Court must accept as true all well-pleaded factual allegations in the complaint and must draw all reasonable inferences in the plaintiffs' favor. *NewSpin Sports, LLC v.*

Arrow Elecs., Inc., 910 F.3d 293, 299 (7th Cir. 2019). To survive a motion to dismiss, the plaintiff must allege facts sufficient for a court to draw a plausible inference that the defendant is liable for the alleged misconduct. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

All of the plaintiffs' claims are based on fraud and are therefore subject to heightened pleading standards. Federal Rule of Civil Procedure 9(b) requires a plaintiff to allege "with particularity" the circumstances that constitute fraud, which is the "who, what, when, where, and how" of the deceptive conduct. *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 776 (7th Cir. 2016). The particularity standard requires plaintiffs to plead fraud with precision and "some measure of substantiation." *Id.* (quoting 2 James W. Moore et al., Moore's Federal Practice § 9.03[1][b], at 9-22 (3d ed. 2015)).

The plaintiffs' securities fraud claims must also meet the even more stringent standard set forth in the PSLRA, which requires that plaintiffs plead with particularity:

> each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and the basis for the belief that the defendants' statements were misleading, and, if an allegation regarding the statement or omission is based on information and belief, the complaint shall state with particularity all facts on which that belief is formed.

15 U.S.C. § 78u-4(b)(1)(B); *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 437 F.3d 588, 594 (7th Cir. 2006) *vacated and remanded on other grounds*, 551 U.S. 308 (2007). Unlike Rule 9(b), the PSLRA also requires plaintiffs to "state with particularity facts giving rise to a strong inference that the defendant acted with the requisite state of mind." 15 U.S.C. § 78u-4(b)(2)(A).

The defendants argue that the plaintiffs have failed to allege facts sufficient under

these standards to support any of their fraud claims. To state a securities fraud claim under section 10(b) and Rule 10b-5, a plaintiff must sufficiently allege (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) justifiable reliance by the plaintiff; (5) economic loss; and (6) loss causation. *See Pension Tr. Fund for Operating Eng'rs v. Kohl's Corp.*, 895 F.3d 933, 936 (7th Cir. 2018) (quoting *Pugh v. Tribune Co.*, 521 F.3d 686, 693 (7th Cir. 2008)); *Caremark, Inc. v. Coram Healthcare Corp.*, 113 F.3d 645, 648 (7th Cir. 1997) (reliance must be justifiable). Section 18(a) creates civil liability for misrepresentations made in SEC filings, and the elements of this claim track those of a section 10b-5 claim. *See* 15 U.S.C. § 78r. The elements of common law fraud in Illinois are also analogous to those for a claim under Rule 10b-5. *See Cohen v. Am. Sec. Ins. Co.*, 735 F.3d 601, 613 (7th Cir. 2013) (applying Illinois law).[4]

1. Material misrepresentations

The defendants argue that Twin and Manikay failed to adequately allege that they made any misrepresentation of material fact, an element common to all of the fraud claims.

For claims under the Securities Exchange Act, a statement or omission must be materially misleading from the perspective of a reasonable investor. *Omnicare, Inc. v.*

[4] The parties agree, for the purposes of this motion, that Illinois law applies to the common law fraud claim. The elements of a common law fraud under Illinois law are: (1) a false statement of material fact; (2) defendant's knowledge of falsity; (3) defendant's intent to induce the plaintiff to act; (4) plaintiff's reasonable reliance; and (5) damages. *See Cohen*, 735 F.3d at 613 (stating elements); *Pack v. Maslikiewicz*, 2019 IL App (1st) 182447, ¶ 105 (reliance must be reasonable).

Laborers Dist. Council Constr. Indus. Pension Fund, 575 U.S. 175, 186 (2015). A misrepresentation is material if a reasonable investor would view it as "significantly alter[ing]" the “total mix” of information available and important to deciding whether to buy or sell a security. *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011); *Appert v. Morgan Stanley Dean Witter, Inc.*, 673 F.3d 609, 616 (7th Cir. 2012). For forward-looking statements, materiality depends on "a balancing of both the indicated probability that the event will occur and the anticipated magnitude of the event in light of the totality of the company activity." *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988). And under Illinois law, a misrepresentation is material if the plaintiff "would have acted differently had he been aware of it, or if it concerned the type of information upon which he would be expected to rely when making his decision to act." *Miller v. William Chevrolet/GEO, Inc.*, 326 Ill. App. 3d 642, 649, 762 N.E.2d 1, 7 (2001).

The plaintiffs have alleged that the defendants misrepresented Akorn's (1) compliance with FDA regulations, (2) manufacturing facilities' attributes, (3) volume of pending ANDA applications, (4) commitments to regulatory compliance, (5) internal data integrity investigations, and (6) SEC disclosure procedures. The Court will review the adequacy of the complaint regarding each of these alleged misrepresentations.

a. Regulatory compliance

The plaintiffs have alleged that the defendants fraudulently misrepresented Akorn's compliance with FDA regulations through: (1) statements and omissions in Akorn's Forms 8-K (annual reports) and 10-Q (quarterly reports) filed with SEC between March 2017 and February 2018; (2) Akorn's regulatory compliance statement in the Fresenius merger agreement; and (3) statements on Akorn's website.

i. Forms 8-K and 10-Q

The allegedly false statement that Akorn made in its Forms 8-K and 10-Q was that the company is "subject to extensive government regulations which if . . . we are not in compliance with, could increase our costs, subject us to various obligations and fines, or prevent us from selling our products or operating our facilities." Twin Compl., No. 19-cv-3648, dkt. no. 1, ¶ 144. As the defendants correctly observe, this statement is not misleading—it is true. The plaintiffs argue that it was misleading for the defendants to suggest that adverse consequences were only a possibility "if" Akorn was not in regulatory compliance, contending that the defendants internally knew there were serious compliance issues. But no reasonable investor would have understood Akorn's statement to represent anything about the status of its regulatory compliance; it was "nothing more than a boilerplate statement of what the government regulates." *See Anderson v. Abbott Labs.*, 140 F. Supp. 2d 894, 905 (N.D. Ill. 2001). Because the plaintiffs have failed to allege—with sufficient particularity to satisfy even the Rule 9(b) standard—the reasons this statement was misleading, it does not support their claim that the defendants misrepresented Akorn's regulatory compliance.

The plaintiffs argue, alternatively, that omissions from Akorn's Forms 8-K and 10-Q regarding the company's data integrity issues amounted to material misrepresentations. "Mere silence about even material information is not fraudulent absent a duty to speak." *Stransky v. Cummins Engine Co.*, 51 F.3d 1329, 1331 (7th Cir. 1995). Securities laws do not impose an "absolute duty to disclose all information material to stock prices," and firms are "entitled to keep silent (about good news as well as bad news) unless positive law creates a duty to disclose." *Gallagher v. Abbott Labs.*,

269 F.3d 806, 808 (7th Cir. 2001). Similarly, for a common law fraud claim under Illinois law, an omission is not actionable unless the defendant had a duty to speak. *See Henderson Square Condo. Ass'n v. LAB Townhomes, L.L.C.*, 2014 IL App (1st) 130764, ¶ 99, 16 N.E.3d 197, 216.

The plaintiffs contend that Item 303 of Regulation S-K, which sets forth disclosure requirements for Forms 8-K and 10-Q, created a duty to disclose regulatory noncompliance at Akorn's facilities. Item 303 requires disclosure of "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." 17 C.F.R. § 229.303(a)(3)(ii). The SEC has issued guidance explaining Item 303's materiality standard. It requires the following two assessments:

> (1) Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required.
>
> (2) If management cannot make that determination, it must evaluate objectively the consequences of the known trend . . . on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur.

Management's Discussion and Analysis of Financial Condition and Results of Operations, 54 Fed. Reg. 22427, 22430 (May 24, 1989) (hereafter "*SEC Guidance*"). The SEC has clarified that Item 303 materiality is "inapposite" with regard to the materiality standard for securities fraud claims articulated in *Basic*, 485 U.S. at 238. *See SEC Guidance*, 54 Fed. Reg. at 22430 n.27. The *Basic* standard, which governs whether a forward-looking misrepresentation is material, requires a balancing of the probability of occurrence of an event and the magnitude of its effect. *See* 485 U.S. at

238.

The Seventh Circuit has not yet decided whether Item 303 imposes a duty to disclose that, when violated, can give rise to fraud liability under the Securities Exchange Act. Other circuits are divided on the issue. *See, e.g.*, *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 104, 108 (2d Cir. 2015); *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1056 (9th Cir. 2014). The Second Circuit considered the matter most recently, in *Stratte-McClure*, and held that Item 303 does impose a duty to disclose for the purposes of securities fraud claims, because silence as to Item 303 conditions in an SEC filing has the potential to mislead investors. *Stratte-McClure*, 776 F.3d at 102. The court concluded that a reasonable investor, familiar with Item 303's "obligatory nature," would understand a company's nondisclosure of Item 303 conditions as a representation that no such condition exists. *Id.* The court clarified, however, that a violation of Item 303's duty to disclose is not automatically actionable as securities fraud; an actionable securities violation also requires the plaintiff to meet the materiality standard under *Basic*. *Id.*

The Second Circuit in *Stratte-McClure* rejected the Ninth Circuit's conclusion that Item 303 does not impose a duty to disclose because it has a different materiality standard than the one that applies to a claim for securities fraud. *See id.* at 103-4; *INVIDIA*, 768 F.3d at 1055. The Second Circuit explained that the Item 303 and *Basic* standards are not truly in tension: "a violation of Item 303's disclosure requirements can only sustain a [securities fraud] claim . . . if the allegedly omitted information satisfies *Basic*'s test for materiality." *Stratte-McClure*, 776 F.3d at 103. In sum, the Second Circuit set forth a two-step approach to determining whether an omission that violates

Item 303's duty to disclose is actionable as securities fraud: (1) does Item 303 require disclosure of the condition; and if so, then (2) does the omission meet the *Basic* materiality standard?

The Court finds the Second Circuit's reasoning in *Stratte-McClure* compelling and more persuasive than that of the Ninth Circuit. Further, the Court concludes that the plaintiffs have alleged, with sufficient particularity to satisfy the PSLRA standard, actionable material omissions in Akorn's SEC filings. First, the silence regarding Akorn's regulatory noncompliance in its Forms 8-K and 10-Q violated Item 303's duty to disclose. Akorn's noncompliance with FDA data integrity standards was a "known trend": Rai and Portwood had received an employee report that the Vice President of Global Quality was thwarting data integrity investigations; Akorn's Global Quality Compliance team had found data integrity issues at Akorn's headquarters in Lake Forest and research facility in Vernon Hills; and the FDA had issued a Form 483 for its Decatur facility. Furthermore, these conditions could have "reasonably" been expected to materially impact Akorn's revenues by compromising the approval of their ANDA applications or subjecting them to FDA fines or other sanctions.

The plaintiffs have also sufficiently alleged that the Item 303 omissions meet the materiality standard under *Basic* for forward-looking statements, measured by "the size [of the impact] if the worst happens, multiplied by the probability that it will happen." *Wielgos v. Commonwealth Edison Co.*, 892 F.2d 509, 517 (7th Cir. 1989) (explaining the *Basic* standard). "Even very improbable events may be material if the injury is great enough." *Id.* The plaintiffs' allegations reflect that Akorn's data integrity issues were widespread across many of the company's facilities and thus that any impact—FDA

enforcement action or compromise of merger execution conditions—would be substantial. And there was some non-zero probability of adverse effects arising out of Akorn's data integrity problems: the FDA had already found noncompliance with its standards at one of Akorn's facility and the buy-out by Fresenius was contingent on Akorn's regulatory compliance. These allegations are sufficient to meet the materiality standard under *Basic* at the pleading stage.

The Item 303 omissions also satisfy the materiality requirement for an Illinois common law fraud claim, because they involve is the "type of information upon which [a plaintiff] would be expected to rely when making his decision to act." *Miller*, 326 Ill. App. 3d at 649, 762 N.E.2d at 7. As explained above, investors like Manikay and Twin Securities rely on disclosures of Item 303 conditions to understand a company's risk exposure and whether to buy its securities. *See Stratte-McClure*, 776 F.3d at 102. And because the Court has concluded that the plaintiffs' allegations regarding this omission were sufficient to meet the heightened particularity standard of the PSLRA, they are likewise sufficient to satisfy Rule 9(b).

ii. Merger agreement

The plaintiffs have sufficiently alleged that Akorn's regulatory compliance statement in the merger agreement was a material misrepresentation. They contend that the defendants are precluded from arguing otherwise because the Delaware chancery court concluded that the compliance statements were inaccurate. *See Akorn*, 2018 WL 4719347, at *47, *64-66.

Issue preclusion, or collateral estoppel, bars relitigation of facts that were already decided by another court. *See Valbruna Slater Steel Corp. v. Joslyn Mfg. Co.*, 934 F.3d

553, 563 (7th Cir. 2019). The Court's application of issue preclusion is governed by the law of the state that issued the earlier decision, in this case Delaware. *See id.* at 560; *see also* 28 U.S.C. § 1738. Under Delaware law, issue preclusion requires: (1) the same factual issue was presented in a prior case; (2) the issue was litigated and decided in the prior suit; and (3) the finding was essential to the prior judgment. *See Rogers v. Morgan*, 208 A.3d 342, 346 (Del. 2019).

Even if the chancery court's finding regarding Akorn's regulatory compliance statement is the same issue in this case, which the parties dispute, issue preclusion does not apply because the falsity finding was not essential to the chancery court's judgment. A finding is not essential to a judgment if it could have been "grounded . . . upon an issue other than that which [a party] seeks to foreclose from consideration." *See Taylor v. State*, 402 A.2d 373, 375 (Del. 1979). The chancery court concluded that the inaccuracy of Akorn's regulatory compliance statement was one of two breaches of the merger agreement by Akorn and that either breach independently entitled Fresenius to terminate. *See Akorn*, 2018 WL 4719347, at *45, 101. Thus, the chancery court's finding on Akorn's regulatory compliance statement does not preclude the defendants from litigating the accuracy of the statement in this proceeding.

The Court concludes, however, that the plaintiffs have adequately alleged that Akorn's regulatory compliance statement was a material misrepresentation. Specifically, they allege that by the time the merger agreement was executed in April 2017, Akorn's Global Quality Compliance team and Cerulean had identified severe noncompliance with FDA data integrity standards at several Akorn sites. Twin Compl., No. 19-cv-3648, dkt. no. 1, ¶¶ 86, 88, 90, 150. These allegations are sufficiently

particularized, within the meaning of the PSLRA, to support an inference that Akorn falsely stated that it was then in compliance with "all applicable Laws (including all rules, regulations, guidance and policies) relating to or promulgated by the U.S. Food and Drug Administration." Merger Agr., Ex. 4, Akorn's Mot. to Dismiss, dkt. no. 29-6, at 33.

The Court turns next to whether this alleged false statement meets the materiality standard for securities fraud claims. The defendants argue that the regulatory compliance statement is not actionable securities fraud because no reasonable investor would view such provisions in a merger agreement as statements of material fact. They point out that the Form 8-K to which the merger agreement was attached included disclaimers alerting the investing public that representations in the agreement were made only for purposes of the merger transaction. The defendants add that the disclaimer explained that the regulatory compliance statement's role in the merger agreement involved risk allocation, not communication of facts.

The Seventh Circuit has not yet addressed whether representations in a merger agreement representations can be actionable as securities fraud, but in *Glazer Capital Management, LP v. Magistri*, 549 F.3d 736 (9th Cir. 2008), the Ninth Circuit held that representations in a merger agreement may be actionable. *Id.* at 741. In *Glazer*, the defendant moved to dismiss section 10(b) claims based on a representation of regulatory compliance made in a merger agreement. *Id.* It argued that the representation was not actionable because no reasonable investor would interpret statements in a merger agreement—representations directed only to parties to the agreement—as factual communications directed to the investing public. *Id.* The Ninth Circuit rejected this argument, concluding that "the mere context of the statements" was

not sufficient to "render these statements inactionable *as a matter of law*." *Id.* The court reasoned that because the merger was a "very significant event" for the company, there would have been significant investor interest in the details of the agreement. *Id.* Thus, a reasonable investor might rely on the agreement's terms. *Id.*

The Court finds the Ninth Circuit's reasoning in *Glazer Capital Management* persuasive and concludes that plaintiffs have alleged with particularity sufficient to satisfy the PSLRA that the regulatory compliance statement was a material misrepresentation. Like the merger in *Glazer*, the Fresenius merger was a very significant event for Akorn, and the company should have anticipated high investor interest in the details of the agreement. Reviewing the agreement, an investor would have seen not only the regulatory compliance statement but also the provision making the merger contingent on the truth of its regulatory compliance statement. A reasonable investor could conclude that Akorn would not have agreed to this condition if it had serious regulatory compliance problems. Thus, plaintiffs' allegations regarding Akorn's merger-agreement representation of compliance with all FDA regulations meets the materiality requirement, because one could reasonably find that a reasonable investor would deem this information important to a decision to buy or sell Akorn securities. *See Appert*, 673 F.3d at 616.

This statement likewise meets the materiality standard for common law fraud, because the plaintiffs have alleged with particularity that it was "the type of information upon which [investors] would be expected rely" when deciding to buy or sell Akorn securities, for the reasons just discussed. *See Miller*, 326 Ill. App. 3d at 649, 762 N.E.2d at 7.

iii. Statements on Akorn's website

Finally, the plaintiffs have alleged that several statements on Akorn's website asserting that it had internal policies to ensure regulatory compliance were material misrepresentations. But the plaintiffs have not alleged, with particularity, the "who, what, when, where, and how" regarding these statements and therefore have not satisfied either the Rule 9(b) pleading standard or the more stringent PSLRA standard. *See Presser*, 836 F.3d at 776. There are no allegations in the complaint about when these statements were posted to the website. Nor have the plaintiffs alleged that Akorn lacked regulatory compliance or quality assurance policies, which is what would be needed to render the website statements false. Rather, the plaintiffs have alleged only that there were widespread noncompliance and quality issues at Akorn. This supports, at most, a reasonable inference that whatever policies Akorn had failed, not that it lacked compliance policies in the first place. Thus, the plaintiffs cannot rely on Akorn's website statements as the basis for their fraud claims.

b. Qualities of Akorn's manufacturing facilities

Twin and Manikay have alleged that the defendants misrepresented particular qualities of Akorn's manufacturing facilities through the following statements: (1) its facilities were approved by the FDA; (2) Akorn had "expertise" in research and development and manufacturing; and (3) the FDA had determined, after its December 2016 reinspection of the Decatur facility, that Akorn did not need to take any further action to comply with FDA standards. None of these qualify as material misrepresentations.

First, the plaintiffs have not alleged with particularity sufficient for Rule 9(b) or the

PSLRA their basis for contending that it was deceptive for Akorn to characterize its facilities as "Food and Drug Administration . . . approved" and "in good standing with the FDA." Twin Compl., No. 19-cv-3648, dkt. no. 1, ¶¶ 154, 155. They have not alleged any facts setting forth the requirements for FDA approval for a pharmaceutical manufacturing facility or even that the FDA makes any such facility-wide designation. Rather, the plaintiffs have alleged only that Akorn is generally subject to FDA regulations and that the agency conducts inspections of facilities to enforce compliance with its current good manufacturing practices. The FDA's Form 483 process, as described in the complaint, does not involve any "approval" or "good standing" facility designation by the FDA. Rather, at least as alleged in the plaintiffs' complaints, it involves the FDA giving facilities notice of compliance issues at a facility and following up with its approval or disapproval of any proposed corrective action. Thus, because the plaintiffs' allegations do not describe with particularity any FDA approval process for facilities, the purported misstatements that Akorn's facilities are "FDA approved" or "in good standing" with the agency do not support the plaintiffs' fraud claims.

Second, the statements touting Akorn's expertise are not actionable because they are not material—rather, they amount to puffery. For the purposes of a securities fraud claim, statements of "vague aspiration or unspecific puffery" are not material. *Makor Issues & Rights*, 437 F.3d at 596. Puffery consists of an "empty superlative[]" that is not actionable as fraud because no reasonable person would rely on such a statement when deciding to buy a security. *See United States v. Burns*, 843 F.3d 679, 684 (7th Cir. 2016). Similarly, Illinois courts define puffery as a seller's "exaggerations" or "subjective descriptions" about the quality of its products or services, which sellers

are "reasonably expected" to make. *Avery v. State Farm Mut. Auto. Ins. Co.*, 216 Ill. 2d 100, 173-74, 835 N.E.2d 801, 847 (2005). The Court concludes that Akorn's assertions regarding its expertise are nonactionable puffery under both Illinois and federal securities law. *See id.* at 174 (noting that claim of "expert workmanship" is puffery); *see also Assocs. in Adolescent Psychiatry, S.C. v. Home Life Ins. Co. of N.Y.*, 751 F. Supp. 727, 733 (N.D. Ill. 1990) (holding that statement of "expertise" was puffery).

Finally, the plaintiffs have failed to adequately allege that the defendants' statements—made in November 2016, December 2016, and March 2017—regarding a Form 483 and follow-up inspection of Akorn's Decatur facility amounted to material misrepresentations. The Decatur facility had received a Form 483 in mid-2016, and in December 2016, after reinspecting the facility, the FDA notified Akorn that there were no outstanding compliance issues. The plaintiffs have alleged that it was misleading for the defendants to report the results of the reinspection because other data integrity issues—undetected by the FDA—still existed at the Decatur site. But the fact that there were other compliance problems does not undermine or render misleading the assertion that Akorn had addressed, to the FDA's satisfaction, the issues cited in the Form 483.

In sum, the plaintiffs have not alleged with particularity sufficient to satisfy Rule 9(b) or the PSLRA that any of the defendants' statements about their manufacturing facilities amounted to material misrepresentations.

c. Volume of pending ANDA applications

The plaintiffs have alleged that the defendants made two statements that fraudulently misrepresented the volume of Akorn's pending ANDA applications. First, the defendants allegedly stated that they had "a large pipeline" of pending ANDA

applications. This statement is not actionable, however, because, again, it amounts to mere puffery—a subjective exaggeration on which no reasonable investor would rely. *See Burns*, 843 F.3d at 684; *Avery*, 216 Ill. 2d at 173-74, 835 N.E.2d at 847.

Next, Rai is alleged to have misled investors on an earnings call in February 2017, when he stated: "We have received . . . our first ANDA approval from the Decatur facility since the [FDA] reinspection. This implies we should now expect to receive approvals for other [applications] . . . from our Decatur facility that was delayed due to compliance status." Twin Compl., No. 19-cv-3648, dkt. no. 1, ¶ 164. The plaintiffs contend that this was misleading because the defendants knew about Akorn's widespread data compliance issues, which would compromise further ANDA application approvals.

The defendants argue that Rai's statement is not actionable as fraud because it is protected under the PSLRA's safe harbor, which forecloses liability for forward-looking statements that are accompanied by "meaningful cautionary statements." 15 U.S.C. § 78u-5(c)(1)(A)(i); *Asher v. Baxter Int'l Inc.*, 377 F.3d 727, 729 (7th Cir. 2004). Illinois law recognizes this same principle as the "bespeaks caution" doctrine. *Rasgaitis v. Waterstone Fin. Grp., Inc.*, 2013 IL App (2d) 111112, ¶ 34, 985 N.E.2d 621, 632. "[T]he *most* helpful caution" is not necessary to protect against liability for forward-looking statements—sellers need only "point to the principal contingencies that could cause actual results to depart form the projection." *Asher*, 377 F.3d at 734; *see Rasgaitis*, 2013 IL App (2d) 111112, ¶ 36, 985 N.E.2d at 632 (explaining that adequate cautionary language must note specific risks). Sufficient cautionary language renders a misrepresentation immaterial as a matter of law. *Harden v. Raffensperger, Hughes &*

Co., 65 F.3d 1392, 1404 (7th Cir. 1995); *Lagen v. Balcor Co.*, 274 Ill. App. 3d 11, 19, 653 N.E.2d 968, 974 (1995).

Although Rai's statements were forward-looking, they are not protected under the PSLRA safe harbor, because they lacked sufficient cautionary language. The defendants point out that Rai indicated that it is "hard to project and predict the timing of the approvals." Defs.' Mot. to Dismiss, Ex. 8, No. 19-4651, dkt. no. 29-10, at 6. But this statement did not meaningfully alert investors to the principal contingencies arising from data integrity problems at the Decatur site, which posed a significant risk to approval of Akorn's ANDA applications. Although the Decatur facility did pass the FDA's December 2016 inspection, there were still substantial data integrity compliance issues at the site, and the defendants allegedly knew this. And Cerulean's report identified significant problems that FDA missed during its December 2016 inspection. Additionally, Fresenius's investigation revealed that there was "no data integrity" at the Decatur site, so data integrity problems reemerged after FDA's December 2016 inspection. Twin Compl., No. 19-cv-3648, dkt. no. 1, at ¶¶ 113, 115.

These allegations regarding data integrity problems at Akorn's Decatur facility meet the PSLRA's particularity requirements and support a reasonable inference that Rai's projection of additional ANDA approvals was misleading.

d. Commitment to operating "in the ordinary course of business," SEC disclosure procedures, and internal data integrity investigations

None of the remaining statements cited in the complaint are sufficient to support the plaintiffs' fraud claims. The plaintiffs have not adequately alleged that Akorn's merger-agreement commitment to operate "in the ordinary course of business" was an

actionable misrepresentation vis-à-vis a potential investor. There are no allegations in the complaint explaining what exactly a reasonable investor would have understood this representation to mean, beyond Akorn's commitment to simply continue to operate as a going concern. The plaintiffs assert only that Akorn's obligations under the "ordinary course" provision "included investigating and remediating . . . data-integrity violations." Twin Compl., No. 19-cv-3648, dkt. no. 1, ¶ 107. But the merger agreement did not define the "ordinary course of business," and the plaintiffs' unsupported allegation that this term included data-integrity remediation lacks the particularity necessary to satisfy even Rule 9(b). *See Presser*, 836 F.3d at 776.

The plaintiffs point out that the Delaware chancery court interpreted the "ordinary course" provision as requiring Akorn to address data integrity problems during the pendency of the merger. *See Akorn*, 2018 WL 4719347, at *19. But assuming the chancery court's reading adequately establishes the meaning of "ordinary course of business," the plaintiffs have not sufficiently alleged that a reasonable investor would regard this statement as material. *See Appert*, 673 F.3d at 616; *Miller*, 326 Ill. App. 3d at 649, 762 N.E.2d at 7. The chancery court's reading of the contractual provision was based on trial testimony from Rai and another witness rather than on a common understanding of the term "ordinary course." *See id.* at *19 n.223. And the plaintiffs have not alleged that any such common understanding exists. Thus, they have failed to adequately allege a factual basis for their contention that a reasonable investor would understand the "ordinary course" provision as anything more than boilerplate but rather as a specific commitment by Akorn to internally investigate data integrity problems.

The plaintiffs likewise have not sufficiently alleged that statements that Akorn had

"effective" controls and procedures governing its SEC disclosures were material misrepresentations. The plaintiffs have not described Akorn's SEC disclosure policies, assuming it had any. Nor have they described the claimed features of "effective" SEC disclosure policies. Instead, the plaintiffs cite to deficiencies in Akorn's SEC filings, such as the Item 303 omissions, to support their allegation that the company's policies were not effective. But merely pointing to the failure of a policy is not adequate to support the allegation that the policy was deficient. *Cf. Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 760 (7th Cir. 2007) (holding that allegation of control process failure did not support strong inference of scienter required for securities fraud claim) ("[B]y definition, *all* frauds demonstrate the 'inadequacy' of existing controls, just as all bank robberies demonstrate the failure of bank security and all burglaries demonstrate the failure of locks and alarm systems).

Finally, the plaintiffs have failed to allege that a reasonable investor would have viewed Akorn's February 2018 press release, denying accusations of data integrity problems, as significantly altering the total mix of information about Akorn. *See Matrixx*, 563 U.S. at 38. Investors understand a statement "in its full context," not in a vacuum, and this context includes "apparently conflicting information." *Omnicare,* 575 U.S. at 190. Akorn's press release was a response to an earlier press release from Fresenius, which alleged that serious data integrity problems at Akorn could compromise the merger. Given this context, the plaintiffs have not allege facts sufficient to support an inference that, a reasonable investor would have viewed Akorn's denials as important to a decision to buy or sell Akorn securities. *See Appert*, 673 F.3d at 616.

2. Loss causation

To recap, the plaintiffs have adequately alleged that the following were material misrepresentations actionable as fraud: the Item 303 omissions, the regulatory compliance statement in the merger agreement, and Rai's statement regarding anticipated ANDA approvals out of the Decatur facility. The defendants argue that the Court should nevertheless dismiss the plaintiffs' claims because they have not adequately alleged causation.

The loss causation element of securities fraud claims requires plaintiffs to "tether . . . directly" the fraudulent conduct to the harm. *Menzies v. Seyfarth Shaw LLP*, 943 F.3d 328, 335 (7th Cir. 2019). A plaintiff can make this connection by alleging that a defendant's misrepresentations artificially inflated its stock price and that once the market learned of the deception, the stock value declined. *Ray v. Citigroup Glob. Mkts., Inc.*, 482 F.3d 991, 995 (7th Cir. 2007). An Illinois common law fraud claim similarly requires that a defendant's misrepresentation caused the plaintiff's damages. *Clinton Imperial China, Inc. v. Lippert Mktg., Ltd.*, 377 Ill. App. 3d 474, 484, 878 N.E.2d 730, 739 (2007).

The plaintiffs have adequately alleged losses caused by the defendants' actionable misrepresentations regarding Akorn's regulatory compliance. Both Twin and Manikay owned Akorn stock before significant stock-price drops that followed the market's discovery of the company's data integrity problems. Specifically, the day after Fresenius announced that it was investigating data integrity issues that could compromise the merger, Akorn's stock price dropped to $18.65 per share from $30.28 the previous day. And the day after Fresenius announced that it was terminating the

merger due to these data integrity issues, Akorn's stock price dropped to $13.05 per share, down from $19.70 the day before. This close connection between the market revelations about Akorn's data compliance issues and the drops in stock prices are sufficient, at this stage, to properly allege loss causation.

3. Reliance for section 18 claim

The defendants have moved to dismiss the section 18 claim, arguing that the plaintiffs have failed to adequately allege reliance. The defendants argue that the allegations do not support a connection between any specific securities purchase and a misrepresentation by the defendants. For federal securities claims, reliance is a "synthetic" concept: "it is the confluence of materiality and causation." *Stark Trading v. Falconbridge Ltd.*, 552 F.3d 568, 572 (7th Cir. 2009). The Court has already concluded that the plaintiffs have adequately alleged materiality and loss causation with respect to the defendants' claimed misrepresentations of Akorn's regulatory compliance and anticipated ANDA approvals. Consequently, they have also adequately alleged reliance. The Court declines to dismiss the section 18 claim.

4. Portwood's scienter

Portwood asks the Court to dismiss him from the section 10(b) and common law fraud claims, arguing that the plaintiffs have not adequately alleged that he had the requisite mental state for either claim. For a section 10(b) claim, scienter is “knowledge of the statement's falsity or reckless disregard of a substantial risk that the statement is false.” *Pugh*, 521 F.3d at 693. As noted earlier, the PSLRA's pleading standard requires the plaintiffs' allegations to support a "strong inference" of scienter. 15 U.S.C. § 78u-4(b)(2)(A). Pleading "collective scienter" for a group of defendants does

not meet the PSLRA's particularity standard, and a plaintiff must plead a defendant's scienter as to each statement or omission underlying a section 10(b) claim. *Cornielsen v. Infinium Capital Mgmt., LLC*, 916 F.3d 589, 600 (7th Cir. 2019).

The plaintiffs' fraud claims are all based in part on the allegedly fraudulent Item 303 omissions on the Forms 8-K and 10-Q—all of which Portwood signed. They have adequately pled scienter as to Portwood with respect to this omission. In January 2016, Portwood received an employee complaint alleging that Akorn's Vice President of Quality Assurance was thwarting internal investigations regarding data integrity and sending misleading information to FDA. Twin Compl., No. 19-cv-3648, dkt. no. 1, ¶ 187. That officer's role was to ensure that Akorn complied with the FDA's data integrity standards, and—for pleading purposes at least—the employee complaint put Portwood on notice that there were serious compliance problems at the company. The plaintiffs' allegations are therefore sufficient to support a strong inference that Portwood's failure to note the risk of compliance issues in Akorn's SEC filings, in violation of Item 303, amounted to omissions made with reckless disregard for the truth. *See Pugh*, 521 F.3d at 693-94.

Similarly, under Illinois law, reckless disregard satisfies the knowledge element of a fraud claim. *See Bunting v. Progressive Corp.,* 348 Ill. App. 3d 575, 588, 809 N.E.2d 225, 236 (2004). And because the plaintiffs' allegations of Portwood's scienter satisfy the PSLRA's heightened pleading standard for the section 10(b) claim, they are likewise sufficient for the common law fraud claim.

For these reasons, the Court denies Portwood's request for dismissal from the section 10(b) and common law fraud claims.

Conclusion

For the foregoing reasons, the Court denies the defendants' motions to dismiss Twin's complaint [No. 19-cv-3648, dkt. nos. 27, 29] and Manikay's complaint [No. 19-cv-4651, dkt. nos. 29, 31]. Defendants are directed to answer both complaints within 21 days of this order.

MATTHEW F. KENNELLY
United States District Judge

Date: February 5, 2020