United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 10-3402

Public Pension Fund Group; Herman Unvericht; Norfolk County Retirement System; Joseph Mas; Building Trades United Pension Trust Fund; New Jersey Carpenters Pension Fund,	*	
	*	Appeal from the United States
Appellants,	*	District Court for the
	*	Eastern District of Missouri.
v.	*	
	*	
KV Pharmaceutical Company; Marc S. Hermelin; David A. Van Vliet; Rita E. Bleser,	*	
	*	
Appellees.	*	

Submitted: September 22, 2011
Filed: June 4, 2012

Before WOLLMAN, BYE, and SHEPHERD, Circuit Judges.

BYE, Circuit Judge.

Several groups of investors[1] who purchased the securities of KV Pharmaceutical Company (KV) brought this class action lawsuit alleging KV and some of its individual officers committed securities fraud. The investors alleged KV made false or misleading statements about its compliance with Food and Drug Administration (FDA) regulations governing the manufacture of pharmaceutical products, and made false or misleading statements about earnings resulting from pharmaceutical products allegedly manufactured in violation of FDA regulations. The district court dismissed the complaint for failure to state a claim for relief, concluding the investors failed to allege with sufficient particularity that KV's statements were false or misleading. The district court also dismissed the investors' separate claims for scheme liability against individual KV officers. Finally, the district court denied the investors' post-judgment motion to amend their complaint. We affirm in part, reverse in part, and remand for further proceedings.[2]

I

The primary issue before us is whether the investors' complaint[3] was sufficient to withstand a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Our factual recitation therefore tracks the allegations in the complaint, which "we are bound to accept as true for purposes of a Rule 12(b)(6) motion[.]"

---

[1]The Norfolk County Retirement System and the State-Boston Retirement System were appointed by the court as the lead plaintiffs in this class action on behalf of all investors. Hereinafter we will refer to all the plaintiffs collectively as "the investors."

[2]We grant the motions brought by both sides to file sur-reply briefs addressing the Supreme Court's recent decision in Matrixx Initiatives, Inc. v. Siracusano, 131 S.Ct. 1309 (2011).

[3]Unless otherwise indicated, references to the "investors' complaint" refer to the Consolidated Amended Complaint dated May 22, 2009.

Joyce v. Armstrong Teasdale, LLP, 635 F.3d 364, 365 (8th Cir. 2011) (internal quotation and punctuation marks omitted).

KV is a pharmaceutical company. KV publicly traded securities between June 15, 2004, and January 23, 2009, the "Class Period" alleged in the complaint. At all relevant times, KV had three operating segments: generic pharmaceutical products, branded pharmaceutical products, and specialty raw materials. KV marketed each of its segments through three subsidiary companies: ETHEX marketed the generic products, Ther-Rx marketed the branded products, and Particle Dynamics, Inc. marketed the specialty raw materials.

On five occasions during the Class Period (for KV's fiscal years 2004 through 2008), KV filed annual reports with the Securities and Exchange Commission (SEC) on Form 10-K. The first of the five Form 10-Ks was filed on June 14, 2004, and the last was filed on June 26, 2008. In the Form 10-Ks, KV explained in detail the extensive and complex governmental regulation of the pharmaceutical industry by the FDA. KV then made specific representations regarding its compliance with FDA regulations. In a section entitled "Manufacturing And Facilities," KV stated in all five of the applicable Form 10-Ks: "We believe that all of our facilities are in material compliance with applicable regulatory requirements." In the 2004 Form 10-K, in a section entitled "Risks Related To Our Industry," KV also represented: "We are currently in material compliance with cGMP[4] and are registered with the appropriate state and federal agencies." KV slightly modified this latter representation in its Form 10-Ks for fiscal years 2005 through 2008 by stating: "We believe that we are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies."

[4]Current Good Manufacturing Practices.

The investors' complaint alleges KV's statements regarding its material compliance with FDA regulations were false or misleading. The investors base this claim on KV's knowledge of the results of a series of inspections the FDA made of KV's facilities between 2003 and 2009. The FDA reported the results of its inspections to KV on Form 483s following inspections which concluded in April 2003, January 2004, January 2005, March 2006, April 2007, March 2008, and February 2009. Form 483s are issued pursuant to FDA regulations to notify a company's "top management in writing of *significant objectionable conditions*, relating to products and/or processes, or other *violations* of the [FDA] which were observed during the inspection" of a facility. FDA Investigations Operations Manual, Ch. 5, § 5.2.3 (2009) (emphasis added).

On March 2, 2009, after the last inspection which concluded on February 2, 2009, the United States filed a complaint (the FDA complaint) against KV, ETHEX, Ther-Rx, and four individual KV officers.[5] The government sought a permanent injunction to prevent KV from manufacturing and distributing pharmaceuticals due to irregularities in its manufacturing practices. In its complaint, the FDA stated KV had a "history of continuing . . . violations" of the FDA's current Good Manufacturing Practices (cGMP). FDA Compl. at ¶ 23. The FDA complaint stated the "deficiencies observed by the FDA at the most recent inspection in February 2009, are the same as, or similar to, prior violations observed by the FDA at several other inspections during the last eight years." Id. The government further alleged KV's "noncompliance has

[5]Three of the four individual KV officers sued by the United States are also individual defendants in this case: Marc S. Hermelin, KV's Chairman and Chief Executive Officer (CEO) at all relevant times until his termination for cause on December 5, 2008; David A. Van Vliet, who served as KV's Chief Administration Officer from September 2006 until September 2008, as the President and CEO of ETHEX from September 2008 until December 5, 2008, and as KV's Corporate President and interim CEO after Hermelin was fired for cause on December 5, 2008; and Rita E. Bleser, the President of KV's Pharmaceutical Manufacturing Division since April 2007.

continued despite repeated warnings from FDA regarding its cGMP violations." Id. at ¶ 24 (quoted in the investors' complaint at ¶ 8). The FDA complaint referred to six FDA inspections which took place between April 2003 and February 2009, in which

> FDA investigators prepared and issued a detailed List of Inspectional Observations, Form FDA-483, to [KV], notifying [KV] of the investigator's observations. The FDA investigators discussed the violations listed in the Form FDA-483s with [KV], who expressed a desire to correct the deficiencies. Nevertheless, FDA investigators have continued to observe cGMP violations at subsequent inspections.

Id. (quoted in the investors' complaint at ¶ 8).

The investors' complaint generally alleged KV's manufacturing, processing, packing, labeling, holding and distribution of drugs were not in compliance with cGMP, and further alleged the FDA investigators specifically documented thirty-five separate violations, including:

(a) Failure to follow the responsibilities and procedures applicable to the quality control unit;

(b) Failure to establish control procedures to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process materials and the drug product;

(c) Failure to make written records of investigations into unexplained discrepancies and the failure to make written records of investigations of a batch or any of its components to meet specifications;

(d) Failure to review and approve drug product production and control records by the quality control unit to determine

compliance with all established, approved written procedures before a batch is released or distributed;

(e) Failure to review and approve changes to written procedures by the quality control unit;

(f) Failure to clean, maintain, and sanitize equipment and utensils at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product; and

(g) Failure to follow written production and process control procedures in the execution of production and process control functions.

Investors' Compl. ¶ 35.

The investors alleged KV's manufacturing irregularities resulted in KV selling adulterated, unapproved, and misbranded drugs in violation of FDA regulations, and that KV knew since early 2003 it was selling adulterated and unapproved drugs in violation of FDA regulations. The investors alleged one of the violations "concerned KV's most important product in 2007 and 2008, Generic Metoprolol, responsible for the supposed explosive growth in [KV's] revenues and earnings, and sustained high stock prices." Id. at ¶ 41. The investors alleged KV's upper management gave instructions to violate Quality Control/Quality Assurance (QC/QA) procedures regarding the manufacture of generic Metoprolol. Id. The investors alleged the FDA found evidence that KV did not use the designed process for manufacturing 100mg tablets of generic Metoprolol during the Class Period between August 5, 2007, and October 17, 2008, by using "an active ingredient that resulted in smaller particle sizes than approved by FDA in the validation study." Id. at ¶ 43.

The investors further alleged another "flagrant violation" of FDA regulations involved KV's manufacture of pharmaceutical products which did not have the correct proportion of ingredients. Instead of discarding the defective products which

were out-of-specification, KV's upper management decided to "blend" production lots that had low assay values (which refer to the proportion of ingredients in a product) with production lots that had high assay values. Id. at ¶ 44. In addition, the investors alleged when KV identified the root cause of the problem during the Class Period on August 6, 2008, it nevertheless failed to correct the problem and continued to distribute pharmaceutical products using the faulty manufacturing process up until the FDA's February 2009 inspection. Id. at ¶ 45.

The investors also alleged KV ignored known and required modifications in the manufacturing process of Hydromorphone HC1 tablets. "In December 2005 and January 2006, several validation batches 'failed to demonstrate control and reproducibility' because 'blend uniformity and potency failures occurred.'" Id. at ¶ 51 (quoting from the 2009 Form 483). In other words, KV could not control the exact dosage in its pharmaceutical products due to deficient manufacturing processes. KV identified the problem during the Class Period in June 2006 and designed a new production process. Nonetheless, KV then ignored the new production process and reverted back to the old defective procedures that had resulted in the manufacture of dangerous drugs. Id.

The investors further alleged KV concealed from the FDA the production of oversized morphine sulfate tablets, which it had discovered during the Class Period on or about May 15, 2008. KV did not file a field alert with the FDA, as required, and did not notify the FDA until nearly five months later. At least two wrongful death lawsuits were filed against KV relating to the ingestion of oversized morphine sulfate tablets manufactured by KV. Id. at ¶ 54(a).

In addition to the specific violations outlined above, the investors alleged a number of other manufacturing irregularities which were noted by the FDA in the Form 483 from the February 2009 inspection. The investors attached a copy of the 2009 Form 483 as Exhibit 2 to their complaint. The 2009 Form 483 details a number

of manufacturing irregularities which occurred during the Class Period alleged in the investors' complaint, including: (a) KV's failure in 2007 to implement adequate corrective and preventative action in response to over 350 complaints of leaking capsules of a pharmaceutical product called PrimaCare One; (b) KV's failure to implement an adequate corrective action in response to several batches of Histinex HC Syrup packaged with incorrect closures which the FDA identified in inspections occurring in February 2007 and May 2007; (c) KV's failure to determine the exact source and nature of metal found in drug products manufactured between July 22, 2008, and December 25, 2008; (d) KV's conduct in June 2008 in restocking a lot of Metoprolol tablets initially processed in August 2007, and then returned without KV investigating the storage conditions of the product while out of its possession, in order to determine whether the safety, identity, strength, quality or purity of the tablets had been destroyed; and (e) KV's conduct, between September 11, 2008, and November 7, 2008, in using packaging components for six separate products (including 50 mg tablets of Metoprolol) which were disqualified on May 29, 2007.

The investors' complaint also alleged KV's violations of cGMP and FDA regulations rendered certain statements KV made about its earnings false and misleading. In November 2007, KV filed a press release with the SEC on Form 8-K announcing its second quarter fiscal 2008 financial results. Included in the press release was a statement attributing KV's improvements in net revenues in large part "to the July 2007 launch of the Company's generic . . . Metoprolol." In February 2008, KV filed a press release with the SEC on Form 8-K announcing its third quarter fiscal 2008 financial results. In the press release, KV attributed a 57.7% increase in revenue from the prior-year quarter "primarily . . . to sales of 100mg and 200mg strengths of metoprolol succinate extended release tablets launched in the second quarter of fiscal 2008." In May 2008, KV filed a Form 12b-25 reporting preliminary results for the fourth quarter fiscal 2008 financial results. KV again attributed its increase in net revenues "primarily [to] the launch in July 2007 of the 100mg and 200mg strengths of metoprolol succinate extended-release tablets." Finally, in

August 2008, KV filed a press release with the SEC on Form 8-K reporting its first quarter fiscal 2009 financial results. In the press release, KV stated "[r]evenue growth during the quarter was impacted by . . . a net sales gain of 52.6% over the prior year period at the Company's ETHEX generic/non-branded marketing subsidiary, contributed to by sales of 25mg, 50mg, 100mg, and 200mg strengths of metoprolol."

The investors alleged these four statements were false and misleading because KV knew and failed to disclose that its manufacturing process for generic Metoprolol violated FDA regulations, including cGMP. More specifically, the investors' complaint alleged KV's generic Metoprolol: (a) had not been developed in a scientifically sound manner with appropriate specifications and process controls; (b) the active pharmaceutical ingredient used in producing generic Metoprolol was different than the one used in the design process; and (c) the particle size of post-validation lots of generic Metoprolol was smaller than the particle sizes used in an August 5, 2007 validation study. Investors' Compl. ¶¶ 108, 110, 113, 116. The investors based these three allegations directly on statements the FDA made in the February 2009 Form 483.

The FDA's supervision of KV eventually affected its stock prices. On December 23, 2008, KV issued a press release disclosing that, effective December 19, it had "suspended all shipments of all FDA approved drug products in tablet form." The price of KV's shares fell from $5.39 to $1.99. On January 23, 2009, the end of the Class Period alleged in the investors' complaint, KV completely shut down its manufacturing activities. Three days later, KV announced it had "suspended the manufacturing and shipment of all of its products, other than products it distributes but does not manufacture." KV's stock price dropped to $0.51 per share. The investors allege they "lost approximately $1.5 billion in market capitalization" from the collapse in KV's stock price for Class A shares "from more than $30 at the height

of the Class Period, to 51 cents at the close of trading on January 26, 2009." Investors' Compl. ¶ 7.

After the investors filed their complaint, KV filed a motion to dismiss the complaint for failure to state a claim for relief. The district court granted the motion to dismiss. The district court determined the statements KV made in its Form 10-Ks about compliance with FDA manufacturing regulations were not false or misleading because the forms only listed "observations" rather than "violations" and were not the FDA's final agency determination on whether KV was compliant with regulations. The district court further determined the statements KV made attributing its financial success to the manufacture and sale of generic Metoprolol were not false or misleading because the statements were accurate reports of KV's financial performance, and KV did not have a duty to disclose its manufacturing issues with generic Metoprolol. The district court also dismissed the claims the investors brought against the individual KV officers concluding the investors failed to establish scheme liability. Finally, the district court denied a post-judgment motion to amend the complaint to supplement the investors' allegations primarily with information regarding ETHEX's guilty plea to criminal charges arising from the FDA's investigation. The investors filed a timely appeal.

II

The investors' complaint alleges securities fraud claims brought under Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and the SEC's Rule 10b-5, 17 C.F.R. § 240.10b-5. "Section 10(b) makes it unlawful '[t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors.'" Minneapolis Firefighters' Relief Ass'n v. MEMC Elec. Materials, Inc., 641 F.3d 1023, 1028 (8th Cir. 2011) (quoting 15 U.S.C. § 78j(b)).

Rule 10b-5 implements the provisions of Section 10(b). Matrixx Initiatives, Inc. v. Siracusano, 131 S.Ct. 1309, 1317 (2011). Rule 10b-5 makes it unlawful to "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading[.]" 17 C.F.R. § 240.10b–5(b). We employ de novo review to determine whether the district court properly dismissed the investors' securities fraud claims. In re NVE Corp. Sec. Litig., 527 F.3d 749, 751 (8th Cir. 2008).

A

The investors first argue the district erred when it determined their complaint did not allege with sufficient particularity that KV's statements about material compliance with FDA regulations or cGMP were false or misleading. The Private Securities Litigation Reform Act of 1995 (PSLRA), 15 U.S.C. § 78u-4(b)(2), "imposes a heightened pleading standard in cases alleging securities fraud." Lustgraaf v. Behrens, 619 F.3d 867, 873 (8th Cir. 2010). The heightened standard requires a plaintiff to "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading[.]" 15 U.S.C. § 78u-4(b)(1). The "circumstances of the fraud must be stated with particularity, including such matters as the time, place and contents of false representations, . . . [t]his means the who, what, when, where, and how." In re K-tel Int'l, Inc. Sec. Litig., 300 F.3d 881, 890 (8th Cir. 2002) (internal quotations and citations omitted). The PSLRA also requires a plaintiff to plead sufficient particular facts establishing scienter. See 15 U.S.C. § 78u-4(b)(2)(A) ("[T]he complaint shall, 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.").

In their complaint, the investors alleged KV made ten specific statements about its compliance with FDA regulations or cGMP which were false or misleading. KV made the statements in five annual Form 10-Ks it filed with the SEC between June

14, 2004, and June 26, 2008. In each Form 10-K, KV stated "[w]e believe that all of our facilities are in material compliance with applicable regulatory requirements." In each Form 10-K, KV also stated "[w]e believe that we are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies."[6] Based on these specific pleadings, we have no trouble concluding the investors satisfied the PSLRA's pleading standard with respect to the time, place, and contents of the allegedly false or misleading representations.

The crux is whether the investors' complaint adequately sets forth the reasons why KV's statements about its material compliance with FDA regulations or cGMP were false or misleading. The investors rely upon KV's knowledge of the results of the series of inspections performed by the FDA before, during, and after the Class Period, which were reported to KV on Form 483s. The final Form 483 issued by the FDA following its February 2009 inspection documented thirty-five separate significant objectionable conditions or other FDA violations which were observed during the inspection. The investors rely upon the fact that when the FDA filed its complaint seeking to permanently enjoin KV's operations, it alleged KV had a history of continuing cGMP violations, and the violations observed in the February 2009 inspection were "the same as, or similar to, prior violations observed by FDA at several other inspections conducted during the last eight years." The investors note the objectionable conditions observed by the FDA in February 2009 extended back into the Class Period, and thus contend the February 2009 Form 483 was relevant to the statements KV made during the Class Period. See, e.g., In re Merck & Co., Inc. Sec. Litig., 432 F.3d 261, 272 (3d Cir. 2005) ("[B]oth post-class-period data and pre-class data [can] be used to 'confirm what a defendant should have known during the class period,' [since] '[a]ny information that sheds light on whether class period

---

[6]As noted above, KV not only represented its *belief* that it was in material compliance in the 2004 Form 10-K, but affirmatively stated "[w]e are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies."

statements were false or materially misleading is relevant.'") (quoting In re Scholastic Corp. Sec. Litig., 252 F.3d 63, 72 (2d Cir. 2001)).

In response, KV argues allegations of a company's mere receipt of Form 483s can never satisfy the materiality requirements of a securities fraud claim because Form 483s simply do not implicate a company's compliant status with FDA regulations or cGMP, material or otherwise. KV refers to the explanatory language included on the face of all Form 483s, which informs recipients "[t]his document lists observations by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent final Agency determination regarding your compliance."

We reject KV's contention that the receipt of Form 483s can never render a company's statements about compliance with FDA regulations or cGMP false or misleading. The "fundamental purpose" of the Securities Exchange Act is to "implement[] a philosophy of full disclosure" in order "to protect investors against manipulation of stock prices." Basic Inc. v. Levinson, 485 U.S. 224, 230 (1988) (internal quotation marks and citations omitted). To accomplish that purpose, the Supreme Court has "explicitly . . . defined a standard of materiality" to determine when a statement or omission would be considered false or materially misleading by a reasonable investor. Id. at 231. "To fulfill the materiality requirement there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." Detroit Gen. Ret. Sys. v. Medtronic, Inc., 621 F.3d 800, 805 (8th Cir. 2010) (internal quotation marks and citation omitted). Under the circumstances present in this case, we conclude there is a substantial likelihood KV's disclosure of its receipt of Form 483s, during the same time period it was representing it was in material compliance with FDA regulations and cGMP, would have been viewed by the reasonable investor as having significantly altered the total mix of information made available.

Our rejection of KV's per se rule, holding a company's receipt of Form 483s never renders statements about material compliance with FDA regulations or cGMP false or misleading, is consistent with a number of district court decisions which have recognized the materiality of a company's receipt of Form 483s. See McGuire v. Dendreon Corp., 688 F. Supp. 2d 1239, 1241, 1244-45 (W.D. Wash. 2009) (Dendreon II) (granting leave to amend a complaint where a defendant stated his company had "hosted a good inspection" at a manufacturing plant without revealing the fact that the FDA issued a Form 483 following the inspection, concluding "the existence of the Form 483 might well have led his audience to conclude it was *not* a good inspection"); Yanek v. Staar Surgical Co., 388 F. Supp. 2d 1110, 1129 (C.D. Cal. 2005) (finding the FDA's issuance of a Form 483 material to a company's statements about the timing of FDA approval of an implantable contact lense (ICL) because issuance of the Form 483 was a "fact[] bearing on possible delays in FDA approval of the ICL"); Wilkof v. Caraco Pharm. Labs, Ltd., No. 09-12830, 2010 WL 4184465, at *6 (E.D. Mich. Oct. 21, 2010) (denying a motion to dismiss in a case where a company represented it was "substantially cGMP compliant" contemporaneously with receiving Form 483s noting serious manufacturing problems, including tablet size variation, failures to thoroughly investigate, and the company's general "inability to produce quality pills, *i.e.*, drug products that have the identity, strength, quality, and purity they purport or are represented to possess"); In re Able Labs. Sec. Litig., No. 05-2681, 2008 WL 1967509, at *16, 30 (D.N.J. March 24, 2008) (denying a motion to dismiss in a case involving a company's receipt of an FDA warning letter and Form 483 where the defendants represented the company was compliant with cGMP and all applicable FDA requirements); In re Cryolife, Inc., No. Civ.A.1:02CV1868-BBM, 2003 WL 24015055, at *8 (N.D. Ga. May 27, 2003) (denying a motion to dismiss in a case involving a company's receipt of a Form 483 noting twelve specific observations of regulatory violations at the same time it represented it in was "in compliance with all FDA regulations").[7]

[7]We are not persuaded by KV's reliance on Acito v. IMCERA Group, Inc., 47 F.3d 47 (2d Cir. 1995), which held a company was not obligated to disclose the

The issuance of a Form 483 represents a risk that the FDA may take corrective action against a company, and thus a company is obligated to assess the seriousness of the risk and disclose such information to potential investors if it also represents it is in compliance with FDA regulations and cGMP. See Gebhardt v. ConAgra Foods, Inc., 335 F.3d 824, 831 (8th Cir. 2003) ("We keep in the forefront of our minds [the] fact that '[j]ust because a hidden risk does not materialize doesn't mean its concealment cannot hurt investors.'") (quoting Rodney v. KPMG Peat Marwick, 143 F.3d 1140, 1144 (8th Cir. 1998)); see also In re SFBC Intern., Inc. Sec. & Derivative Litig., 495 F. Supp. 2d 477, 481 n.2 (D. N.J. 2007) ("While the observations contained in a Form 483 report do not constitute a final agency determination regarding the facility's compliance with applicable laws and regulations, corrective action by the inspected company is expected."); McGuire v. Dendreon Corp., No. CO7-800MJP, 2008 WL 5130042, at *6 (W.D. Wash. Dec. 5, 2008) (Dendreon I) ("One need not know the contents of an unfavorable report (a fair characterization of the Form 483 under the best of circumstances) to state with a high degree of certainty that the mere fact of its existence would have a negative impact on the hopes and expectations of investors, and thus upon the value of the stock.").

From our review of the caselaw we glean the following principle: for purposes of pleading a securities fraud claim, the issuance of Form 483s may render a defendant's statement about its compliance with FDA regulations or cGMP false, or at least misleading, in some circumstances. The FDA's issuance of Form 483s may be material depending on a number of factors, including the number, severity, and pervasiveness of objectionable conditions noted, as well as whether a company has failed to address or correct the deficiencies noted by the FDA. There is a substantial likelihood the presence of these factors would be viewed by a reasonable investor as

---

results of unfavorable FDA inspections to the investing public. Id. at 52. Acito did not involve allegations by investors that a company made false or misleading statements about its compliance with FDA regulations or cGMP, and thus the Second Circuit did not address the issue we face here.

significantly altering the total mix of information made available, irrespective of whether the Form 483 represents the FDA's final say on compliance issues.[8]

In this case, the investors' complaint pleads numerous, severe, and pervasive objectionable conditions which were outlined in the Form 483s. The investors alleged there was a lengthy history of KV manufacturing adulterated, unapproved, and misbranded drugs in violation of FDA regulations due to manufacturing irregularities. The manufacturing irregularities included KV's failure to manufacture pharmaceutical products with the correct proportion of ingredients, and the correct tablet sizes, during the Class Period. The investors also alleged KV failed to address or correct serious manufacturing problems during the Class Period (including the failure to investigate metal particles found in four different products, and the development of new design processes to correct problems but then a failure to implement them), incorporating the allegations in the FDA's March 2009 complaint which indicated KV's "noncompliance has continued despite repeated warnings from FDA regarding its cGMP violations." Finally, the investors' complaint indicates KV's operations were ultimately shut down as a result of its failure to comply with the FDA's requirements, and the stock market reacted to news of the shutdown with a

---

[8]We reject KV's contention that its statements about material compliance with FDA regulations and cGMP were not false or misleading because the Form 483s were publicly available through a Freedom of Information Act (FOIA) request. Having chosen to represent it was in material compliance with FDA regulations and cGMP, KV was obligated to make a full disclosure of any material facts. See K-tel, 300 F.3d at 898 (explaining that a party with no duty to speak on a particular topic must nevertheless make a full disclosure when it chooses to speak); see also Sailors v. N. States Power Co., 4 F.3d 610, 612 (8th Cir. 1993) ("A duty [to disclose] arises . . . if there have been inaccurate, incomplete or misleading disclosures."). If KV had chosen only to indicate that it was regulated by the FDA, the public availability of the Form 483s may have insulated it from a claim for securities fraud. See Sailors, 4 F.3d at 612-13. KV went a step farther, however, and affirmatively represented it was compliant with FDA regulations, giving rise to a duty to disclose material information.

significant drop in the price of KV's stock. See Medtronic, 621 F.3d at 807 ("A significant change in stock price upon disclosure of withheld information is strong evidence that the information was material.").

Under this set of facts,[9] we conclude the investors' complaint adequately set forth the reasons why KV's statements about its compliance with FDA regulations and cGMP were false, or at least misleading, at the time they were made.

B

The investors next argue the district court erred when it determined they did not sufficiently plead that KV made false or misleading statements about earnings tied to the manufacture of generic Metoprolol. The investors contend KV had a duty to disclose the manufacturing problems associated with generic Metoprolol because KV chose to publicly highlight the product's financial success. Although KV accurately reported its past financial figures, the investors claim the statements were nevertheless misleading because KV omitted the material fact that it could not

[9]The pleaded facts in this case are significantly different from those involved in Acito, where the results of unfavorable FDA inspections were found not to be material. Acito involved three FDA inspections which took place at just one plant among thirty of the company's business locations, a plant which produced just ten of one thousand products manufactured by the company in over thirty countries, 47 F.3d at 52, whereas here the investors allege the FDA violations covered the entire range of KV's operations and products, including generic Metoprolol, which the investors alleged was responsible for an explosive growth in KV's earnings and sustained high stock prices. In addition, the conditions in the plant at issue in Acito improved between the first and second inspections, id., whereas here the investors alleged there was an eight-year history of continuing cGMP violations which eventually led the FDA to completely shut down KV's operations. Moreover, as we stated above, Acito did not involve allegations that the company made false or misleading statements about its compliance with FDA regulations or cGMP. See ante at n.6.

manufacture generic Metoprolol within approved FDA guidelines and was violating cGMP in its production of generic Metoprolol.

The district court held KV did not have a duty to disclose its manufacturing problems with generic Metoprolol because

> KV did not attribute its financial success to its outstanding manufacturing processes or quality control measures associated with the production of the generic metoprolol. Moreover, the financial statements did not discuss KV compliance with the FDA regulations. Because KV chose only to speak about the financial status of the company, KV was not required to dump all known information about its manufacturing and regulatory issues.

Pub. Pension Fund Grp. v. KV Pharm. Co., 705 F. Supp. 2d 1088, 1102 (E.D. Mo. 2010) (internal quotation marks omitted). We agree with the district court. KV did not undertake a duty to speak about its manufacturing problems with generic Metoprolol solely by reporting historical financial results.

"Silence, absent a duty to disclose, is not misleading under Rule 10b-5." Basic Inc., 485 U.S. at 239 n.17. Even assuming KV's manufacturing problems with generic Metoprolol were material, "[m]ateriality alone is not sufficient to place a company under a duty of disclosure." K-tel, 300 F.3d at 898 (citation omitted). In the statements at issue, KV only reported past financial performance. The financial statements did not discuss compliance with FDA regulations, or tie KV's financial performance directly to manufacturing processes. As a result, KV's statements did not trigger a duty to disclose its compliance with FDA regulations, or to discuss its manufacturing problems with generic Metoprolol. While Rule 10b-5 requires "an actor to provide complete and non-misleading information with respect to the subjects *on which he undertakes to speak* . . . the requirement is not to dump all known information with every public announcement[.]" Id. (internal quotations and citation omitted).

The primary case cited by the investors, In re Gilead Sciences Securities Litigation, 536 F.3d 1049 (9th Cir. 2008), does not support their argument that KV had a duty to disclose the manufacturing problems associated with generic Metoprolol. The investors contend Gilead held a company's failure to disclose its off-label sale of a pharmaceutical product, contrary to FDA regulations, "was actionable because Gilead chose to tout the drug as a primary driver of its earnings." Appellants' Br. at 49. The investors rely upon the following quote from Gilead:

> Gilead issued a press release announcing that it anticipated its second quarter financial results would exceed analysts' expectations, and explaining that the company's success "was driven primarily by strong sales growth of Viread. . . . Increasing Viread sales reflect broader prescribing patterns in all commercial markets, as well as increases in U.S. wholesaler inventory levels in the second quarter in anticipation of a Viread price increase."
>
> These statements were materially false and misleading because Gilead and its Officers' "marketing and promotional activities for Viread were not in compliance with FDA approved guidelines, violated federal laws, and created serious public health and safety implications for Viread users."

Gilead, 536 F.3d at 1052. The above quote appears in the portion of the opinion where the Ninth Circuit merely summarized the allegations in the plaintiffs' complaint, however, and does not represent the court's holding. Indeed, Gilead did not even address whether a statement was misleading due to a duty to disclose, but rather dealt with the issue of loss causation. See id. at 1056-58.

The investors also rely upon the Supreme Court's recent decision in Matrixx, contending it stands for the broad proposition that a statement ascribing past financial success to a particular product is misleading unless the problems associated with the product are also disclosed. We disagree. Matrixx involved the cold remedy, Zicam, which allegedly accounted for 70% of Matrixx's sales. 131 S.Ct. at 1323. Matrixx

made public statements attributing a sizeable net sales increase to Zicam, and projecting future growth of the company due to the sale of Zicam. See Siracusano v. Matrixx Initiatives, Inc., 585 F.3d 1167, 1181 (9th Cir. 2009). The Supreme Court held the plaintiffs stated an actionable claim by pleading that Matrixx failed to disclose reports of a possible link between Zicam and loss of the sense of smell (anosmia). Matrixx, 131 S.Ct. at 1323. Significantly, however, the misleading statements upon which the Supreme Court focused were not the reports of past financial success attributing earnings to the sale of Zicam. Rather, the statements the Supreme Court held actionable were those in which Matrixx "stated that reports indicating that Zicam caused anosmia were 'completely unfounded and misleading' and that 'the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established.'" Id. Matrixx made these statements while at the same time projecting future growth in the sale of Zicam. See id. ("Matrixx told the market that revenues were going to rise 50 and then 80 percent.").

Thus, in Matrixx there was a direct connection between the information the company failed to disclose – the adverse reports of a link between the use of Zicam and anosmia – and the public statements the company made indicating the reports that Zicam causes anosmia were completely unfounded and misleading. In addition, the company made statements projecting future growth attributable to the product in issue. This case is distinguishable. KV's statements were accurate reports of its past financial success, and there was no direct connection between those statements and the alleged manufacturing problems associated with generic Metoprolol. In addition, the investors do not allege KV misled investors with projections regarding future performance, as KV only undertook to speak about its past financial success. We therefore conclude the district court did not err when it determined the investors' complaint did not sufficiently plead that KV made false or misleading statements about earnings tied to the manufacture of generic Metoprolol.

C

The investors next contend the district court improperly dismissed their claims brought pursuant to Rules 10b-5(a) and (c) against two individual KV officers: David A. Van Vliet, KV's Chief Administrative Officer from September 2006 until September 2008, the President and CEO of ETHEX from September 2008 until December 5, 2008, and KV's Corporate President and interim CEO after December 5, 2008; and Rita E. Bleser, the President of KV's Pharmaceutical Manufacturing Division since April 2007. Rule 10b-5(a) prohibits "any device, scheme or artifice to defraud." 17 C.F.R. § 240.10b-5(a). Rule 10b-5(c) prohibits "any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person[.]" 17 C.F.R. § 240.10b-5(c). Claims brought under Rules 10b-5(a) and (c) are generally referred to as "scheme liability" claims. See, e.g., In re DVI, Inc. Sec. Litig., 639 F.3d 623, 643 n.29 (3d Cir. 2011) ("We refer to claims under Rule 10b-5(a) and (c) as 'scheme liability claims' because they make deceptive conduct actionable, as opposed to Rule 10b-5(b), which relates to deceptive statements.").

The investors generally alleged Van Vliet and Bleser "carried out a plan, scheme, and course of conduct which was intended to and, throughout the Class Period, did . . . deceive the investing public . . . and . . . caused . . . members of the Class to purchase KV securities at artificially inflated prices." Investors' Compl. ¶ 163. To support this general allegation, the investors incorporated their allegations regarding the false and misleading statements about KV's compliance with FDA regulations and cGMP, and the allegations regarding the false and misleading statements about earnings tied to the production of generic Metoprolol, and then alleged Van Vliet and Bleser "had actual knowledge of the misrepresentations and omissions of material fact as set forth herein." Id. at ¶ 167. Other than incorporating the allegations regarding the misrepresentations and omissions, the investors only generally alleged Van Vliet and Bleser "employed devices, schemes, and artifices to defraud[,] . . . engaged and participated in a continuous course of conduct to conceal

adverse material information about the business [and] engaged in transactions, practices and a course of conduct that operated as a fraud and deceit upon the purchasers of KV securities." Id. at ¶¶ 164-66.

Based upon these allegations, the district court dismissed the scheme liability claims against Van Vliet and Bleser because the "plaintiffs fail to allege with sufficient particularity how the scheme operated and how Van Vliet and Bleser were actually involved. As such, the Court finds that lead plaintiffs' conclusory allegations fail to state claims under Rule 10b-5(a) and (c) against Van Vliet and Bleser." KV Pharm., 705 F. Supp. 2d at 1106. We agree with the district court.

The investors' conclusory allegations regarding Van Vliet and Bleser employing devices, schemes, and artifices to defraud do not satisfy the requirements of pleading fraud under Rule 9(b) of the Federal Rules of Civil Procedure. See, e.g., In re Parmalat Sec. Litig., 414 F. Supp. 2d 428, 432 (S.D.N.Y. 2006) ("Although the heightened pleading requirements of the PSLRA do not apply to claims under Rule 10b-5(a) and (c), such claims must be pleaded with specificity under Rule 9(b). Accordingly, a plaintiff . . . must specify, with particularity, what manipulative acts were performed, which defendants performed them, when the manipulative acts were performed and what effect the scheme had on the securities at issue.") (internal quotation marks and citations omitted). The investors do not allege what specific manipulative acts either Van Vliet or Bleser performed, or when the manipulative acts were performed.

The only scheme liability allegations in the investors' complaint which arguably are *not* merely conclusory are those which incorporate the allegations regarding the misrepresentations or omissions about FDA/cGMP compliance, and earnings tied to generic Metoprolol. The investors allege Van Vliet and Bleser had knowledge of those misrepresentations or omissions. The district court held, however, that misrepresentation claims under Rule 10b-5(b) cannot simply be recast

as scheme liability claims under Rules 10b-5(a) and (c) unless a plaintiff alleges a defendant "participated in a scheme that encompassed conduct beyond misrepresentation." KV Pharm., 705 F. Supp. 2d at 1104 (quoting In re Alstom SA Sec. Litig., 406 F. Supp. 2d 433, 475 (S.D.N.Y. 2005)).

We have not directly addressed this issue in our circuit, but "the two circuit courts that traditionally see the most securities cases [are] the Second and Ninth Circuits." Nicholas Fortune Schanbaum, Scheme Liability: Rule 10b-5(a) and Secondary Actor Liability after Central Bank, 26 Rev. Litig. 183, 197 (Winter 2007). Both the Second and the Ninth Circuits have held "[a] defendant may only be liable as part of a fraudulent scheme based upon misrepresentations and omissions under Rules 10b-5(a) or (c) when the scheme also encompasses conduct beyond those misrepresentations or omissions." WPP Luxembourg Gamma Three Sarl v. Spot Runner, Inc., 655 F.3d 1039, 1057 (9th Cir. 2011); Lentell v. Merrill Lynch & Co., 396 F.3d 161, 177 (2d Cir. 2005) ("[W]here the sole basis for such claims is alleged misrepresentations or omissions, plaintiffs have not made out a market manipulation claim under Rule 10b-5(a) and (c)[.]"). We join the Second and Ninth Circuits in recognizing a scheme liability claim must be based on conduct beyond misrepresentations or omissions actionable under Rule 10b-5(b). Because the investors do not allege with specificity (or otherwise) what conduct Van Vliet and Bleser engaged in beyond having knowledge of the misrepresentations and omissions regarding FDA/cGMP compliance and earnings tied to generic Metoprolol, the district court correctly dismissed the scheme liability claims against the two individual KV officers.

D

Finally, the investors contend the district court erred when it denied their post-judgment motion to amend the complaint. Because the motion to amend was filed post-judgment, we review the district court's decision for an abuse of discretion,

keeping in mind the district court was not at liberty to "ignore the Rule 15(a)(2) considerations that favor affording parties an opportunity to test their claim on the merits[.]" United States *ex rel*. Roop v. Hypoguard USA, Inc., 559 F.3d 818, 824 (8th Cir. 2009).

On appeal, the investors focus on two aspects of their proposed amended complaint. First, the proposed amended complaint alleged KV engaged in a criminal cover-up of its manufacturing problems starting in May 2008. The cover-up ultimately resulted in ETHEX pleading guilty in February 2010 to two felony counts of fraud "as a result of failing to report [to the FDA] the discovery of tablets that did not meet product specifications." Investors' Second Amended Compl. (SAC) ¶ 104. As part of the guilty plea, ETHEX agreed to pay $27 million in fines, restitution, and administrative forfeitures. Referring to the criminal information filed by the United States against ETHEX, the investors alleged the guilty plea resulted from two specific instances in May 2008 in which KV received reports of oversized morphine tablets from pharmacies. KV investigated the problem in May and June 2008 and discovered the problem was not limited to morphine tablets, but extended to additional products including Propanefone (an anti-arrhythmic drug used to treat heart disease) and dextroamphetamine sulfate (a drug marketed for use primarily by children to treat attention deficit hyperactive disorder). KV reported the discovery of the oversized morphine tablets to the FDA "more than a month late," which itself "violated FDA regulations," but more "[c]ritically, KV did not reference the discovery of other oversized tablets." Id. at ¶ 112.

In addition, a KV officer identified as "Corporate Executive A" in the criminal information directed the cover-up by choosing to "do nothing" in response to the problem and instructing "multiple KV employees to minimize written communications about KV's oversized tablet manufacturing problems, and limit distribution and discussion of any documents discussing these problems given the 'business risk' created by written materials." Id. at ¶ 115. The investors alleged Marc

Hermelin, one of the individual defendants in this case, was "Corporate Executive A" because Hermelin was subsequently "dismissed for cause," and "Hermelin's dismissal was a result of the Audit Committee's investigation into FDA regulatory compliance and management misconduct." Id. at ¶¶ 113, 149.[10]

In addition to alleging that this conduct violated FDA regulations (which would support the original complaint's allegation that the Form 10-K which KV filed on June 26, 2008, was false and misleading because it represented KV was FDA compliant), the proposed amended complaint alleged KV made an additional false statement. The investors alleged on August 11, 2008 (during the Class Period), KV filed a Form 10-Q with the SEC which stated: "Management is not aware of and does not believe that there has been any misconduct that would have a material impact on the Company's financial results." Id. at ¶ 147. The investors alleged this statement was false and misleading since KV (and Hermelin) knew the cover-up could have a material impact on KV's financial results because "the misconduct concerned overdosed tablets of multiple drugs, additional recalls, and 'business risk.'" Id. at ¶ 148(b).

Second, the proposed amended complaint included an expert report from a former FDA inspector who opined that the issuance of the Form 483s meant KV was not in compliance with cGMP. In their memorandum of law in support of the motoin to amend, the investors argued the expert report "cure[d] the deficiencies set forth" in the district court's order dismissing the original complaint, referring to the fact that the order "was largely based on the Court's finding that 'the Form 483s issued to KV

---

[10]On March 10, 2011, subsequent to the district court's denial of the motion to amend the complaint, Hermelin pleaded guilty to a criminal information charging him with misbranding drugs. The charges against Hermelin repeat the allegations against "Corporate Executive A" from ETHEX's criminal charges. Thus, by pleading guilty, Hermelin confirmed the investors' allegations that he was the "Corporate Executive A" referred to in the SAC. See Appellants' Supplemental App. at 6.

only contained observations – not a list of cGMP violations as alleged by lead plaintiffs.'" App. at 839 (quoting the district court's order). The investors argued the former FDA inspector's report established that the use of the term "observation" was interchangeable with the use of the term "violation." Id. at 839-40.

The district court denied the motion to amend for several reasons. First, it stated ETHEX's guilty plea merely added evidentiary support to the original allegations which the district court had determined were insufficient to state a cause of action. Second, the district court noted the cover-up conduct took place after May 2008, and therefore covered only a small portion of the relevant class period. Finally, the district court said there was nothing about the guilty plea that mentioned individual defendants to this action. The district court did not specifically address the expert report from a former FDA inspector in denying the motion to dismiss.

On appeal, the investors argue the district court erred in denying the motion to amend the complaint because ETHEX's guilty plea established felony violations of FDA regulations beginning in May 2008. The investors argue the new allegations regarding the guilty plea would have compelled the district court to view the criminal behavior as an undeniable violation of FDA regulations, not merely an observation. The investors contend their new allegations established a viable class period of at least May 2008 through January 2009, and that KV's August 2008 statement declaring its ignorance of material misconduct was false when made.[11]

Next, the investors argue the district court erred when it said the SAC did not mention individual defendants to this action, because the SAC specifically mentioned Hermelin and alleged he was the "Corporate Executive A" referred to in the criminal

[11] As we noted, the criminal conduct establishing FDA violations as early as May 2008 would also bear on whether KV's representation of FDA compliance on June 26, 2008, was false and misleading.

charges against ETHEX. On appeal, the investors note Hermelin's subsequent guilty plea to misbranding drugs confirms he was "Corporate Executive A."

Finally, the investors argue the district court erred when it denied the motion to amend the complaint on the grounds that the SAC merely added evidentiary support to the original allegations, pointing out the district court dismissed the original allegations precisely for lack of sufficient evidentiary support.

We conclude the district court abused its discretion in denying the motion to amend the complaint. The new allegations supported the investors' contention that KV made false and misleading statements during the Class Period, and we are unaware of any legal basis for discounting this relevant information simply because it covers only a portion of the relevant Class Period. See In re Scholastic Corp., 252 F.3d at 72 ("Any information that sheds light on whether class period statements were false or materially misleading is relevant.").

In addition, the SAC added allegations regarding a new statement KV made on August 11, 2008. The criminal behavior alleged in the SAC was relevant to determining whether this new statement was actionable in its own right, irrespective of whether the original allegations were insufficient. Yet, the district court never addressed this issue before denying the motion to amend.

The district court also relied upon an improper factor when it stated the guilty plea did not involve any individual defendants to this action. See Dunn v. Nexgrill Indus., Inc. 636 F.3d 1049, 1055 (8th Cir. 2011) (indicating a "district court abuses its discretion when it . . . considers and gives significant weight to an irrelevant or improper factor"). The SAC specifically mentioned Hermelin and specifically alleged he was the "Corporate Executive A" referred to in ETHEX's criminal charges. The allegations in the SAC were already sufficient to create the inference that Hermelin

was "Corporate Executive A," but even if they were not, Hermelin's subsequent guilty plea confirmed the SAC's allegations.

Given our preference for "affording parties an opportunity to test their claim on the merits," Roop, 559 F.3d at 824 , as well as our determination that some of the allegations in the original complaint already sufficiently pleaded the false or misleading nature of statements KV made during the Class Period, we direct the district court on remand to grant the investors' motion to amend their complaint.

III

For the reasons stated, we affirm in part, reverse in part, and remand to the district court for further proceedings consistent with this opinion.
