10-3402

United States Court of Appeals

FOR THE EIGHTH CIRCUIT

NORFOLK COUNTY RETIREMENT SYSTEM, STATE-BOSTON RETIREMENT SYSTEM, PUBLIC PENSION FUND GROUP,

Plaintiffs-Appellants,

JOSEPH MAS, HERMAN UNVERICHT,

Consolidated Plaintiffs,

—v.—

KV PHARMACEUTICAL COMPANY, MARC S. HERMELIN, DAVID A. VAN VLIET, RITA E. BLESER,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI (ST. LOUIS)

REPLY BRIEF OF PLAINTIFFS-APPELLANTS

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INTRODUCTION

Defendants fundamentally misapprehend the nature of this lawsuit by ignoring Plaintiffs' most critical allegation: that the complaint filed by FDA in 2009 (the "FDA Complaint") alleged that FDA had informed KV Pharmaceutical Company ("KV") between 2003 and 2008 that KV was violating current good manufacturing practices ("cGMP"). (A-78-79; ¶38). Plaintiffs thus allege that the public statements KV made between 2003 and 2008 claiming material compliance with cGMP were false and misleading. *Id.* The statements were false and misleading **at the time** because, **at the time**, FDA had told KV that it was noncompliant.

Nevertheless, one of Defendants' central themes is that Plaintiffs are alleging fraud by hindsight. Fraud by hindsight occurs when plaintiffs allege that defendants must have known of the fraud without any allegations of contemporaneous knowledge of falsity. *Konkol v. Diebold, Inc.*, 590 F.3d 390, 403 (6th Cir. 2009). That is not the case here. Plaintiffs rely on the FDA Complaint to allege contemporaneous knowledge. The fact that the FDA Complaint was filed after the Class Period is of no consequence: "Contrary to the defendants' argument, the plaintiff's partial reliance on alleged facts dating from the post-class period does not amount to 'fraud by hindsight.'" *Lormand v. US Unwired, Inc.*, 565 F.3d 228, 254 (5th Cir. 2009).

Defendants also argue that Plaintiffs' allegations are not sufficiently particularized because the allegations are not based on the seven Form 483s issued between 2003 and 2008 that listed the cGMP violations. But those Form 483s are not the only source of particularity. The FDA Complaint and the Form 483 issued in 2009, which were both attached to the Complaint (A-140-188), provide sufficient particularity.

Finally, Defendants contend that the Form 483s did not include cGMP "violations," only "observations," and therefore did not need to be disclosed. Defendants are raising an issue of fact directly contradicted by Plaintiffs' allegations. Plaintiffs quoted the FDA Complaint, which alleged that the "FDA investigators discussed **the violations listed in the Form-483s** with Defendants…." (A-78-79; ¶38).[1]

In sum, Plaintiffs rely on the FDA to allege that KV had been told that it was violating cGMP at the same time that KV was telling the public otherwise. Defendants raise factual questions by contending that the allegations in the FDA complaint are not true. On a motion to dismiss, Defendants' arguments are inapposite and should be rejected.

[1] Emphasis added and internal quotations and citations omitted unless otherwise specified.

Defendants ask this Court to dismiss the Complaint on two alternative grounds not ruled on by the Court below: scienter and loss causation. Plaintiffs agree that the Court should reach these issues, but respectfully submit that it should rule in Plaintiffs' favor.

ARGUMENT

I. PLAINTIFFS ADEQUATELY PLED FALSITY

A. Plausibility Is The Pleading Standard

No other Defendant except KV contests that the pleading standard for falsity is plausibility. KV argues, however, that the standard is particularity pursuant to the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. §78u-4(b)(1). (KV 18-21).[2] But particularity and plausibility are not mutually exclusive. They are complementary.

Indeed, Plaintiffs do not contest that falsity must be pled with particularity pursuant to the PSLRA. Plaintiffs said that in their opening brief (Pltf. 23), despite KV's claim that Plaintiffs did not. (KV 20). However, particularity requires alleging the "who, what, when, where, and how," as well as "why" a statement is false. *In re K-Tel Int'l, Inc. Sec. Litig.*, 300 F.3d 881, 890 (8th Cir. 2002). It is a requirement about the type of information that Plaintiffs must allege that goes to

[2] Previously filed briefs are cited as follows: (i) Brief of Defendants-Appellees KV and David Van Vliet "(KV __);" (ii) Brief of Defendant-Appellee Marc Hermelin "(Hermelin __);" and (iii) Brief of Defendant-Appellee Rita Bleser "(Bleser __)." Plaintiffs' opening brief is cited as "(Pltf. __)."

the breadth of the allegations. Particularity does not concern the degree of the inference–which must be strong with respect to scienter and only plausible with respect to the other elements of a Section 10(b) claim. In other words, after providing the who, what, when, where, how, and why of the alleged statement, the inference to be drawn from all of **that particularized information** must be one of plausible falsity: "To surmount a motion to dismiss, the investors must thus plead facts sufficient to **plausibly** articulate with particularity the circumstances constituting fraud." *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1108 (9th Cir. 2010).

The latest Supreme Court decision in a PSLRA case confirms this. *See Matrixx Initiatives, Inc. v. Siracusano*, 2011 WL 977060, at *12 (U.S. Mar. 22, 2011) ("Assuming the complaint's allegations to be true, as we must, Matrixx received information that **plausibly** indicated a reliable causal link between [the drug] and [the adverse event]"). While *Matrixx* primarily concerned materiality, materiality is part of the falsity analysis because false statements must be material to be actionable. *See Cutera*, 610 F.3d at 1108.

B. Plaintiffs Pled Falsity With Particularity

1. The Allegations Based On The FDA Complaint Establish Particularity

Defendants argue that Plaintiffs do not allege with particularity that KV failed to comply with cGMP. (KV 26-29; Hermelin 25-26). Plaintiffs do meet the

particularity requirement, however, in large measure based on the following allegations from the FDA Complaint:

- "KV Pharmaceutical Company has a **history of continuing** cGMP violations."
- "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."
- "Defendants' **noncompliance has continued despite repeated warnings** from FDA regarding cGMP violations."
- "At the conclusion of each FDA inspection in 4/2003, 1/2004, 1/2005, 3/2006, 4/2007, 3/2008, 8/2008 and 2/2009, FDA investigators prepared and issued a **detailed List** of Inspectional Observations, Form FDA-483, to Defendants, notifying them of the investigators' observations."

(A-78-79; ¶38).

These allegations satisfy the particularity requirement. "FDA" told "Defendants" (*who*); on seven specific dates between 2003 and 2008 (*when*); that KV was committing "continuing cGMP violations" (*what*); at KV's plants (*where*); with a "detailed" list of violations (*how*); which contradicted the public statements of material compliance (*why*). Particularity need not be long and repetitive, as Defendants seem to suggest. It must simply be precise. Moreover, despite KV's protestations that the FDA allegations are "untested," (KV 22), these facts must be accepted as true on a motion to dismiss. *Matrixx*, 2011 WL 977060, at *4.

Indeed, Plaintiffs' particularized allegations that KV received seven Form 483s between 2003 and 2008 stand in stark contrast with the classic fraud by hindsight cases cited by Defendants. *Cf. Elam v. Neidorff*, 544 F.3d 921, 927 (8th Cir. 2008) (fraud by hindsight when "[t]he pleading fails to point to any contemporaneous reports, witness statements, or information that had actually been provided to defendants…."); *In re Navarre Corp. Sec. Litig.*, 299 F.3d 735, 742 (8th Cir. 2002) ("The investors fail to plead the existence of any facts or further particularities that, if true, demonstrate that the defendants had access to, or knowledge of, information contradicting their public statements when made").

Defendants nonetheless argue that Plaintiffs do not provide sufficient particularity as to how the violations in prior years were "the same as" the subsequent violations. (KV 22-23). The allegations, however, could always be more precise. The dates could include the year, month, day, and hour. The violations could list not only the processes violated, but also the specific drug, machine, and operator.

Here, the level of particularity is commensurate with the alleged false statement. The false statement here stated that KV was "in material compliance with cGMP." (A-101-109; ¶¶104-118). Plaintiffs then allege falsity because FDA said that KV was, *inter alia*, noncompliant and committing continuing cGMP violations. *Id.* That is sufficient. If KV had disclosed the specific cGMP with

which it purportedly complied, then perhaps Plaintiffs may have needed to specify the cGMP violated. But that is not the case and, even if it were, Plaintiffs do provide such specificity. *See infra* 8-10.

Defendants then argue that "the more likely inference" is that KV promptly "resolved" the violations listed in each Form 483 before it issued any false statements about material compliance with cGMP. (Hermelin 24). That is pure speculation and not what the FDA Complaint said. It said that the (i) "noncompliance has continued despite repeated warnings"; (ii) "deficiencies observed by the FDA at the most recent inspection in February 2009, are the same as, or similar to, prior violations"; and (iii) "FDA investigators have continued to observe cGMP violations at subsequent inspections." (A-78-79; ¶38).

Moreover, even if there was a "more likely inference" in KV's favor, that is not the pleading standard for falsity. The standard is whether it is plausible that KV made false statements and did not resolve the cGMP violations–which is what Plaintiffs alleged and exactly what the FDA said. The Court cannot weigh inferences of falsity to determine which inference is "more likely"; only with respect to scienter can the Court weigh competing inferences. *Tellabs, Inc. v. Makor Issues & Rights Ltd.*, 551 U.S. 308, 314 (2007).

Finally, Hermelin accuses Plaintiffs of "misleading" the Court, in "troubling fashion," based on the "shameless suggestion" that "KV was, in fact, informed of

its noncompliance during years before the FDA Complaint was actually filed." (Hermelin 20-21). That is exactly what Plaintiffs are explicitly alleging, not merely suggesting. The FDA Complaint filed in 2009 says that FDA informed Defendants between 2003 and 2008 that KV was noncompliant and in violation of cGMP. (A-78-79; ¶38).

2. Plaintiffs Also Allege The Violations Prior To 2009 With Particularity

Defendants further argue that Plaintiffs did not include allegations from the specific Form 483s issued between 2003 and 2008, and only allege that KV committed "the same violations" throughout the years, without specifying which ones. (KV 22; Hermelin 33-34).

Plaintiffs do specify the violations that occurred prior to 2009. Plaintiffs' Complaint attached the Form 483 issued in February 2009, which raised 37 different issues, many of which existed before 2009. (A-151-188). The Complaint then discussed these at length in twenty different paragraphs and subparagraphs.[3] (A79-84; ¶¶40-54(f)). For example,

- "In **December 2005 and January 2006**, several validation batches of HCl Tablets "failed to demonstrate control and reproducibility"

[3] The cases KV cites at 29 n.7 actually support Plaintiffs because these cases sustained complaints when plaintiffs listed "12 specific [Form 483] observations," and the "complaint devoted 17 paragraphs describing the Form 483 observations in detail." *Id.*

because "blend uniformity and potency failures occurred.'" (A-82; ¶51).

- "The Company received 350 complaints **in 2007** and 26 adverse event reports" concerning a pre-natal drug. "[KV] **continued distribution** of this product **despite continued complaints** of leaking capsules." (A-82; ¶¶49-50).

- "The dissolution methods…used for analysis of Metoprolol Succinate …were not properly transferred to the Quality Control Laboratory from Analytical Research department after a significant change to the preparation of dissolution control medium occurred **in November of 2006**." (A-180).

- "Since your **05Aug2007** IR pellet validation study…in the production of 100mg and 200mg tablets, you have had approximately [redacted in original] NCRs [non conformance reports] relating to particle size ….You **continued to manufacture and distribute** approximately [redacted in original] lots of these tablets until 17Oct2008, when you ceased production." (A-156).

Plaintiffs thus alleged with particularity the violations predating 2009 which led to the shutdown of KV's entire operations. Yet, KV claims that "there are no particularized factual allegations at all that inform KV–or this Court–why the compliance statements for any given year were false." (KV 22). KV is wrong. At bottom, KV's point is that Plaintiffs did not include all Form 483s, and based their allegations on the 2009 Form 483 and the 2009 FDA Complaint that say that the violations in 2009 were the same as in years past. This is not lack of particularity.

KV then says that it is "conclusively" "impossible" for the 2009 violations to have occurred in "earlier years" because "many of the observations" relate to one product not introduced until 2007. (KV 23). This argument is flawed.

Violations in 2007 still render false the 2008 statements of professed compliance with cGMP. And even if many of the violations arose in 2007, many others arose before that, such as those in 2005 and 2006 listed above.

Finally, Hermelin argues that "Plaintiffs cannot establish that the manufacture of Metoprolol was materially out of cGMP compliance in years prior to the February 2009 Form 483 simply" by relying on the FDA Complaint. (Hermelin 33). Plaintiffs actually can rely solely on the FDA Complaint for the reasons explained above. Regardless, Plaintiffs also rely on the 2009 Form 483, which said that: "All strengths have historically resulted in drug product of variable quality when[] the designed processes are executed as evidenced by the high numbers of batch rejects, out-of-specification (OOS) test results and non-conformance reports (NCRs) at all manufacturing stages." (A-80; ¶42). Plaintiffs thus alleged that "FDA concluded that KV was **never** able to properly manufacture Generic Metoprolol." *Id*.

C. KV Had A Duty To Disclose The Material Information In The Form 483s

Defendants argue that the Form 483s issued to KV did not list cGMP violations, but mere observations, and then claim that mere observations do not trigger a duty to disclose. (KV 28; Hermelin 15-20). They are wrong on both counts.

First, while Form 483s in the abstract may or may not list violations, in this case, FDA stated that the information in the Form 483s did actually list violations: "FDA investigators discussed the violations listed in the Form-483s with Defendants…." (A-78-79; ¶38). The FDA Complaint also adds: "Defendants' **noncompliance** has continued despite repeated warnings from FDA regarding its **cGMP violations**." *Id.* It is these allegations in the 2009 FDA Complaint stating that the Form 483s issued between 2003 and 2008 included violations—that continued for years and led to KV's shutdown—which establish that, in this case, the Form 483s included violations.[4]

Second, Defendants still had a duty to disclose the facts included in the Form 483s, even if they were observations, because they were material under *Matrixx* and *Basic Inc. v. Levinson*, 485 U.S. 224 (1988). Indeed, even if FDA never informed KV about its noncompliance, as KV submits (KV 24), KV still had a duty to disclose the information in the Form 483s. *Matrixx* held that reports of a drug's adverse effect must be disclosed, even if not statistically significant, because a "reasonable investor would have viewed the nondisclosed information

[4] Hermelin's argument that the boilerplate language in the Form 483s states that Form 483s include observations is similarly inapposite. (Hermelin 15-16). The boilerplate language applies to Form 483s generally. But here, the FDA Complaint goes beyond the general use of Form 483 to explain that, in this instance, Defendants were informed of "violations" and "noncompliance." (A-78-79; ¶38).

'as having significantly altered the 'total mix' of information.'" *Matrixx*, 2011 WL 977060, at *11.

The information in the Form 483s, whether observations or violations, was akin to the adverse event reports in *Matrixx*, whether statistically significant or not. *Matrixx* required disclosure because the adverse event reports, like the Form 483s, would have provided the information necessary for investors to assess the risk on their own. *Id.* Having chosen to speak, and represent that KV was in material compliance with cGMP, it was false and misleading for KV not to fully disclose the information in the Form 483s.

Indeed, KV ignores that it chose to affirmatively state that it was in material compliance with cGMP. KV argues that there is no duty to disclose material information and cites repeatedly to *K-Tel*, 300 F.3d at 898. (KV 26-27, 35). But there is no duty to disclose material information **only** if KV had not made any prior statements on the subject. *K-Tel* is clear that, having chosen to speak, KV had to speak fully: "even absent a duty to speak, a party who discloses material facts in connection with securities transactions assume[s] a duty to speak fully and truthfully on those subjects." 300 F.3d at 898.

Further, the information in the Form 483s was material because, for example, it would have warned investors that KV had serious manufacturing problems in 2005, well before the shutdown in 2008. In 2005, KV had identified

problems with its tablet-manufacturing processes, particularly the compression of tablets and press speed, which led to defective Hydromorphone tablets. (A-82; ¶51). In 2008, the same problem, excessive press speed, led to defective Generic Metoprolol tablets, which by then had become KV's flagship product. (A-80; ¶¶42-46). On December 23, 2008, KV shut down all manufacturing of products in tablet form, causing its stock price to fall 50%. (A-117-118; ¶138). Accordingly, on these facts, Plaintiffs have established plausibility: a plausible inference that a reasonable investor would have viewed the violations listed in the Form 483s, such as those concerning the tablet-manufacturing process, as significantly altering the total mix of information. *Matrixx*, 2011 WL 977060, at *11.

Nevertheless, KV argues that Form 483s do not constitute a final agency determination and only include minutiae that would flood investors with "the results of every inspection of every plant." (KV 29 n.8; Hermelin 41). It is true that the securities laws do not require disclosure of every detail. Here, however, the violations in the Form 483s issued between 2003 and 2008 led to the cessation of all operations by the Company in 2009, causing the stock price to approach zero. This is hardly minutiae. These allegations suffice "to 'raise a reasonable expectation that discovery will reveal evidence' satisfying the materiality requirement, and to 'allo[w] the court to draw the reasonable inference that the

defendant is liable for the misconduct alleged.'" *Matrixx*, 2011 WL 977060, at *12.

Defendants then argue that there is no *per se* requirement that Form 483s be disclosed. (KV 28; Hermelin 40-46). But it is the importance of the information in the Form 483s that make them material, not the forms themselves. Under *Matrixx*, materiality "is a fact-specific inquiry that requires consideration of the source, content, and context of," in that instance, "the adverse event reports," to determine whether those reports should have been disclosed. *Matrixx*, 2011 WL 977060, at *10. Here, the fact-specific inquiry establishes materiality. It points to the FDA as the source of the Form 483s; the Form 483s listed "continuing cGMP violations" according to FDA; and the violations were "the same as" the violations that led to the shutdown. (A-78-79; ¶38). Moreover, whether the disclosure of one form is *per se* mandatory is not the point because FDA issued seven such forms to KV between 2003 and 2008. (Pltf. 39-40). Nevertheless, some courts have adopted that *per se* holding. *Id*.

Matrixx also refutes the argument that KV had no duty to disclose the information in the Form 483s because FDA took no enforcement action until 2009. (Hermelin 21). There is no *per se* rule that absolves KV of its duty to disclose absent an enforcement action. Even before *Matrixx*, courts held that enforcement or sanctions were not necessary to trigger materiality: "A reasonable investor

would find significant the information regarding a company's deferred maintenance costs, unsafe maintenance practices, and **possible sanction**." *No. 84 Emp'r Teamster Trust Fund v. Am. West*, 320 F.3d 920, 935 & n.13 (9th Cir. 2003) (finding material the failure to disclose "two FAA letters" concerning "the results of incident investigations").[5]

D. The Availability Of Form 483s Through FOIA Does Not Abrogate KV's Duty To Disclose

Defendants then contend that KV did not need to disclose Form 483s because KV disclosed "the nature and scope of FDA's oversight of KV." (KV 31; Hermelin 31-32). They then argue that, armed with this understanding, investors could have obtained the Form 483s through a Freedom of Information Act ("FOIA") request, relieving KV of any duty to disclose the information. (KV 30-32; Hermelin 40-46). In KV's world, investors should routinely make FOIA requests of each and every company in which they invest.

This is an extraordinary proposition. It would place upon all investors the continuing burden of submitting FOIA requests for all pharmaceutical companies

[5] KV also contends that because compliance with cGMP is required before approval of new drugs, and KV received such approval, KV must have been compliant. (KV 7). But KV omits that the statute it cites only precludes new drug approvals if there is a final agency determination—if the Secretary of Health and Human Services finds non-compliance. *See* 21 U.S.C. § 355(j)(4)(A). Here, that was not the case, although that does not matter because the risk of noncompliance also needed to be disclosed, not just a formal finding of noncompliance.

because of the hypothetical possibility that one company may have received an undisclosed Form 483. This burden would also extend to other industries. For this reason, courts have declined to impose such a burden, and no court, other than the District Court below, has held that information obtainable through FOIA abrogates the duty to disclose under the securities laws. Courts instead consistently require disclosure by the company of information necessary to assess the risk of governmental actions. *See In re Indep. Energy Holdings PLC Sec. Litig.*, 154 F. Supp. 2d 741, 760 (S.D.N.Y. 2001) (securities laws "certainly require disclosure of information that would permit an investor to appreciate the risk that the future sanction may arise"), *abrogated on other grounds sub nom. In re Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281 (S.D.N.Y. 2003).

The recent decision in *Matrixx* controls on this point. There, the Supreme Court held that a pharmaceutical company had to disclose adverse event reports even when the adverse events were known outside the company. *Matrixx*, 2011 WL 977060, at *4-5. The reports linked a medication called Zicam to the loss of the sense of smell, a condition called anosmia. *Id.* at *12. That information, however, already existed outside the company. Nine plaintiffs had already commenced public lawsuits alleging that Zicam caused anosmia. *Id.* A presentation at the American Rhinologic Society described in detail the condition found in more than ten patients who had ingested Zicam. *Id.* at *4. And there

were multiple studies that linked anosmia to Zicam's active ingredient. *Id.* at *12. Accordingly, here, even if the Form 483s were available through FOIA, KV still had an independent duty to disclose the violations listed in the Form 483s.

Relatedly, KV's contention that the Form 483s had been requested by a handful of individuals and therefore were known to the public is of no moment. (KV 32). The fact that a handful of people requested the Form 483s is no different from *Matrixx*, where some members of the public also knew that Zicam caused anosmia. This is also consistent with the cases that require disclosure of information **by the company**, even when available through other sources, because the truthful information must be "conveyed to the public with a degree of intensity and credibility sufficient to counter-balance effectively any misleading information created by the alleged misstatements." *Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 167 (2d Cir. 2000); *see also In re Citigroup, Inc. Bond Litig.*, 723 F. Supp. 2d 568, 590 (S.D.N.Y. 2010) (rejecting argument that bank had no duty to disclose subprime portfolio simply because details of subprime portfolio were known and "determinable from public information").

KV, however, continues to rely on *B.L. Sailors v. N. States Power Co.*, 4 F.3d 610 (8th Cir. 2003), to argue that there is no duty to disclose. (KV 31). But *Sailors* is distinguishable because the company there had alerted the public about the existence of regulatory proceedings. *Sailors* merely held that there was no duty

to disclose the ins-and-outs of those already-disclosed proceedings. *Id.* at 613 ("[H]aving alerted the market to the existence of regulatory proceedings, NSP had no duty to inform them of each of the steps required in that process"). That is very different from here, where KV said nothing about the seven Form 483s it received that listed continuing cGMP violations over five years.

The other cases Hermelin cites are also inapposite. (Hermelin 41-42). *In re Discovery Laboratories Securities Litigation* held that FDA notification was not material because it had been issued to the prior owner of the plant, three years before, not to the defendant. 2006 WL 3227767, at *10 (E.D. Pa. Nov. 1, 2006). *Discovery* then clarified that, had the FDA notification been issued to the defendant, "[i]t seems incontrovertible that this information would be material to investors in the company who received [them]." *Id.* at *10 n.20. *Anderson v. Abbott Laboratories* is also distinguishable because Abbott never made any affirmative disclosures about compliance with regulations, as KV did here. 140 F. Supp. 2d 894, 904 (N.D. Ill. 2001).

Finally, Hermelin argues that the risk of noncompliance had been adequately disclosed in generic, boilerplate risk disclosures in KV's public filings. (Hermelin 29). Hermelin then quotes the following disclosure: "failure to comply with applicable FDA or other regulatory requirements **may** result in…recall or seizure of products and total or partial suspension of production." *Id.* But even "warnings

of specific risks...do not shelter defendants from liability if they fail to disclose hard facts critical to appreciating the magnitude of the risks described." *In re Bear Stearns Inc. Sec. Litig.*, 2011 WL 223540, at *56 (S.D.N.Y. Jan. 19, 2011).

E. KV's Financial Results From Metoprolol Were False And Misleading Because They Failed To Disclose The Drug's Manufacturing Problems

Defendants contend that because the alleged false statements concerning sales of Metoprolol were limited to financial results, and did not directly concern manufacturing, KV had no duty to tell investors that the stellar earnings were based on a product that violated cGMP. (KV 32-36; Hermelin 32-36).

Neither KV nor Hermelin cite a single case directly on point–where earnings were ascribed to a product or practice with underlying problems and the question was whether the earnings were misleading because the problems were not disclosed. *Id.* Not only is Defendants' position here not the law, but if it had been, *Matrixx* conclusively overruled it. The facts there are nearly identical as here, as the false statements also concerned earnings results and not manufacturing or safety issues.

> Matrixx's first allegedly misleading statement was its October 22, 2003, press release announcing the 163% net sales increase, attributed to Zicam, and stating that the Zicam brand was "poised for growth." The second statement was the conference call on October 23, 2003, again attributing the company's positive results to Zicam and projecting further growth.

Siracusano v. Matrixx, 585 F.3d 1167, 1181 (9th Cir. 2009), *aff'd sub nom. Matrixx Initiatives, Inc. v. Siracusano*, 2011 WL 977060 (U.S. Mar. 22, 2011). Here too KV said: "the improvement in net revenues [of 61%] was due to the July 2007 launch of [Metoprolol]." (A-103-104; ¶107).

The Supreme Court held that the failure to disclose Zicam's links to anosmia rendered false and misleading the statements attributing the company's financial results to Zicam's success. "Importantly, Zicam Cold Remedy allegedly accounted for 70 percent of Matrixx's sales. Viewing the allegations of the complaint as a whole, the complaint alleges facts suggesting a significant risk to the commercial viability of Matrixx's leading product." *Matrixx*, 2011 WL 977060, at *12. Similarly, "Matrixx told the market that revenues were going to rise 50 and then 80 percent. Assuming the complaint's allegations to be true, however, Matrixx had information indicating a significant risk to its leading revenue-generating product." *Id.*

Plaintiffs' opening brief cited a line of cases that fall squarely within *Matrixx*. (Pltfs. 48-50). KV's only response was that those cases were non-binding, out-of-circuit decisions, whose principles need not be applied here. (KV 35). Even if previously correct, that is no longer the case after *Matrixx*.

II. PLAINTIFFS' SCHEME LIABILITY CLAIMS AGAINST VAN VLIET AND BLESER WERE PROPERLY PLED

Van Vliet and Bleser argue that they could not have been part of the scheme starting in 2003 because Van Vliet did not start with KV until 2006 and Bleser until April 2007. (Bleser 4; KV 38-39). This is a red-herring because both are being sued only for their actions after they joined KV. *See* A-73-74; ¶¶20, 22.

Bleser then states, in passing, that Plaintiffs have failed to adequately plead reliance. (Bleser 4-5). She does not explain why. Plaintiffs adequately pled reliance on Bleser's deceptive conduct because Plaintiffs relied on KV's statements concerning compliance with cGMP, and Bleser was directly responsible for compliance as head of manufacturing. (A-79-80; ¶¶ 41, 44). *See In re Bristol Myers Squibb Co. Sec. Litig*., 586 F. Supp. 2d 148, 170 (S.D.N.Y. 2008) (sustaining scheme liability claims against general counsel who did not make any statements but negotiated the settlement agreement at the heart of the fraud).

III. SCIENTER AND LOSS CAUSATION

A. Because Defendants Invite A Ruling On Scienter And Loss Causation, Plaintiffs Respectfully Submit That The Court Should Rule In Plaintiffs' Favor

Defendants urge dismissal on the alternative grounds of scienter and loss causation. Plaintiffs agree that the Court should rule on these issues, but respectfully submit that it should do so in Plaintiffs' favor. There has been enough delay and the resolution of these issues is beyond doubt: "there are circumstances

in which a federal appellate court is justified in resolving an issue not passed below, as where the proper resolution is beyond any doubt, or where 'injustice might otherwise result.'" *Singleton v. Wulff*, 428 U.S. 106, 121 (1976); *see also Wiser v. Wayne Farms*, 411 F.3d 923, 927 (8th Cir. 2005) (quoting *Singleton*: "we have corrected errors raised for the first time on appeal in civil cases, observing among other things that we may do so when proper resolution of the issue is 'beyond any doubt.'").

B. Plaintiffs Adequately Pled Scienter

The PSLRA requires that the Complaint "give rise to a strong inference of scienter," which "must be cogent and at least as compelling as any opposing inference of non-fraudulent intent." *Tellabs*, 551 U.S. at 310. Critically, "a tie goes to the Plaintiff[] in terms of competing inferences." *Teamsters Local 617 Pension and Welfare Funds v. Apollo Group, Inc.*, 633 F. Supp. 2d 763, 792 (D. Ariz. 2009). The question then is "whether **all** of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 310. (emphasis in original).

The facts here are overwhelming. First, the FDA Complaint names each Defendant in this action and unequivocally states that "FDA investigators discussed the violations listed in the Form FDA-483s with Defendant**s**." (A-79;

¶38). For this reason, Hermelin's argument that scienter is merely based on Defendants' corporate position is wrong. (Hermelin 48). Plaintiffs allege scienter because the **FDA told** Defendants of the violations, not because of their position. *See Florida State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 645, 665 (8th Cir. 2001) (finding scienter because "defendants published statements when they knew facts or had access to information suggesting that their public statements were materially inaccurate.").

While Van Vliet and Bleser argue that they were not at KV from the beginning of the Class Period, the only inference from the FDA Complaint (not just the strongest) is that, once they were at KV, the FDA informed them of KV's violations. (A-73-74; ¶¶20, 22).

Second, with respect to Hermelin, his scienter is also evidenced by his termination "for cause." (A-96-97; ¶¶87-90). Termination for cause required "knowledge" under his employment contract. *Id*. Hermelin, however, argues that there was no link between his termination and this case. (Hermelin 49). Hermelin ignores that KV directly linked his termination for cause to the regulatory violations: "The Board of Directors…as a result of its investigation with respect to a range of specific allegations, [including], FDA regulatory and other compliance matters and management misconduct, terminated…Hermelin…'for cause.'" (A-96; ¶88) *See In re Alstom SA Sec. Litig.*, 406 F. Supp. 2d 433, 505-06 (S.D.N.Y. 2005)

("Plaintiffs thus link the suspensions to the alleged fraud, and defendants offer no contrary explanation for [the employees'] departures. Under these circumstances, the suspensions support a strong inference of scienter.").

Third, all Defendants except Hermelin admit that FDA informed them of the cGMP issues starting in 2005. KV, Bleser, and Van Vliet signed a consent decree in which they agreed to "[c]orrect the cGMP deviations **brought to Defendants' attention by FDA since January 1, 2005**." (A-111; ¶128).

Fourth, a strong inference of scienter is further supported by the massive and pervasive nature of the fraud. Because all of KV's operations ultimately violated regulations, the stronger inference is that senior officers had knowledge: "While the size of the fraud and an individual's position, standing alone, are insufficient to create a strong inference of scienter, they are factors that may be considered in light of the totality of the circumstances." *In re Royal Ahold N.V. Sec. Litig.*, 351 F. Supp. 2d 334, 376 (D. Md. 2004).

Fifth, the 2009 Form 483 states that "upper management" gave specific instructions to violate cGMP. (A-79-80; ¶¶41, 44). While "upper management" is not identified, a holistic analysis requires that this allegation be read together with the FDA Complaint, Hermelin's termination for cause, and other allegations of scienter. The more compelling inference, and perhaps the only inference, is that "upper management" includes Defendants.

Defendants' main counterargument is that there was no scienter because FDA did not notify them of "violations," but of "observations." Accordingly, they contend, Defendants could not have known that KV was noncompliant. (Hermelin 49; KV 43). This argument is not about scienter but, again, about falsity. Defendants are not arguing, because they cannot, that the FDA did not tell them about the Form 483 violations/observations (regardless of the term). The FDA did. That is all scienter requires. Having established that Defendants knew about the FDA's violations/observations, whether those are actionable is an issue of falsity and materiality, not scienter. *Green Tree*, 270 F.3d at 665 (scienter properly pled when defendants had information contradicting public statements).

The other remaining arguments are improper because they raise factual issues. (KV 41-42). KV argues that although the FDA Complaint says that the Form 483 violations were "continuing," there is another form called "EIR," which presumably "close[d] each inspection," and that that form is the really important one. (KV 42). Similarly, KV contends that FDA issued no warning letters and approved other KV drugs, and extrapolates that to mean that when the FDA Complaint says that Defendants' "noncompliance has continued," it is simply wrong. *Id.* KV cannot introduce new facts that contradict the allegations of the Complaint on a motion to dismiss. *Matrixx*, 2011 WL 977060, at *4.

C. Plaintiffs Adequately Pled Loss Causation

Hermelin alone argues that Plaintiffs have failed to demonstrate any connection between KV's alleged misstatements and KV's corrective disclosures. (Hermelin 50). He asserts that the corrective disclosures do not relate to, or mention, cGMP compliance specifically. *Id*. at 51.

Hermelin's argument has no merit. First, KV's disclosures expressly mention KV's regulatory compliance. *See, e.g.*, A-116; ¶137(a) (announcing investigation into "FDA regulatory and other compliance matters and management misconduct"); *see generally* A-112-120; ¶¶132-141.

Second, it is simply not a requirement for pleading loss causation that the disclosures explicitly mention cGMP compliance. Loss causation is properly pled when the loss was foreseeable and the drop in price of the stock is "caused by the materialization of the concealed risk." *Schaaf v. Residential Funding Corp.*, 517 F.3d 544, 550 (8th Cir. 2008). Thus, "[when] the alleged misstatement conceals a condition or event which then occurs and causes the plaintiff's loss, a plaintiff may plead that it is the materialization of the undisclosed condition or event that causes the loss." *Heller v. Golding Restructuring Fund, L.P.*, 590 F. Supp. 2d 603, 623-24 (S.D.N.Y. 2008). Accordingly, pleading loss causation does not require that a corrective disclosure "precisely mirror [an] earlier misrepresentation." *See Alaska Elec. Pension Fund v. Flowserve Corp.*, 572 F.3d 221, 230 (5th Cir. 2009).

Materialization of the risk is precisely what happened here. When the foreseeable risk that the undisclosed violations of FDA regulations materialized through each corrective disclosure, KV's stock price plummeted. For example, on November 13, 2008, KV announced that it was delaying the public filing of its financial statements because of an investigation into "FDA regulatory and other compliance matters and management misconduct." (A-116; ¶137(a)). KV's stock price dropped 58%, from $14.26 to $5.90. (A-117; ¶137(d)). On December 23, 2008, KV announced the suspension of all shipments of products in tablet-form and the recall of one drug. (A-117-118; ¶138). The stock price fell about 50%, from $5.39 to $2.71. *Id.* And on January 26, 2009, KV announced the suspension of the manufacturing and shipment of all its products. (A-119; ¶139). The stock price dropped more than 75%, from $2.13 to $0.51. (A-119; ¶139(a)).

IV. THE DISTRICT COURT ERRED IN DENYING LEAVE TO AMEND BASED ON FUTILITY

A. The Standard Of Review Is *De Novo*

The District Court denied leave to amend based on futility. (ADDM-31-32). "We review the denial of leave to amend for abuse of discretion and questions of futility *de novo*." *U.S. ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 822 (8th Cir. 2009) (Pltf. 55). Although KV contends that Plaintiffs set forth the incorrect standard, it is KV who is mistaken. (KV 44). KV only cites to *Drobnak*

v. Andersen Corp., 561 F.3d 778, 787 (8th Cir. 2009), which did not concern futility.

KV then suggests that the Court should adopt the minority view that the PSLRA restricted Rule 15(a). (KV 54-55). However, the majority view in the First, Ninth, and D.C. Circuits is that "the PSLRA does not itself modify the liberal amendment policy of Rule 15(a)." *ACA Fin. Guaranty Corp. v. Advest, Inc.*, 512 F.3d 46, 56-57 (1st Cir. 2008) (citing cases). Rather than restricting Rule 15(a)'s liberal amendment policy, "[a]dherence to these principles is **especially important** in the context of the PSLRA" because of the "unprecedented degree of specificity and detail" required. *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003).

This liberal amendment standard is even more appropriate where, as here, Plaintiffs had not sought leave to amend prior to the proposed Second Amended Complaint ("SAC"), and the District Court's dismissal constituted the first review of the pleadings. *See Bryant v. Dupree*, 252 F.3d 1161, 1164 (11th Cir. 2001).

B. The Court Should Grant Leave To Amend

The SAC added new allegations principally based on the criminal Information and guilty plea concerning KV's subsidiary ETHEX. This occurred after the dismissal of the Complaint but before Plaintiffs filed the SAC. (Pltf. 18-19). Based on the guilty plea and criminal Information, Plaintiffs alleged in the

SAC that KV engaged in a criminal cover-up of its manufacturing problems executed by "Corporate Executive A" starting in May 2008. (A-880-884; SAC ¶¶105-118).

Relying on this new fact, the SAC then added a false statement issued on August 11, 2008: "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." (A-895; SAC ¶148). This statement was false because ETHEX and Hermelin were in the midst of intentionally defrauding the FDA, as now revealed in the Information. (A-885; SAC ¶125). The District Court ignored these new allegations added to the SAC in denying leave to amend.

Defendants argue that this new evidence was not new, was cumulative, and would not have affected the District Court's decision. (KV 48-51; Hermelin 51-52). They are mistaken. Even assuming *arguendo* that the Court below was correct that the conditions listed in the Form 483s were observations and not regulatory violations, ETHEX's guilty plea shows that ETHEX committed felony violations of FDA regulations. The ETHEX guilty plea would have compelled the District Court to view this felony plea as an undeniable form of misconduct, not merely an observation, and the August 11, 2008 statement regarding the absence of misconduct as false when made. Tellingly, Defendants do not address Plaintiffs'

argument that the ETHEX guilty plea establishes a viable class period of May 2008 through January 2009, an argument that the District Court also ignored.[6]

Hermelin then argues futility based on scienter grounds, labeling as "purely speculative" Plaintiffs' assertion that "the only reasonable inference is that 'Corporate Executive A' is Hermelin." (Hermelin 56). Yet Hermelin raises no competing inference as to the identity of "Corporate Executive A"—nor could he, because **Hermelin pled guilty on March 10, 2011 and confirmed that he is "Corporate Executive A."** *See* Information ¶19, *United States v. Hermelin*, 11-cr-00085-ERW (E.D. Mo. Mar. 10, 2011) (attached to Plaintiffs' Supplemental Appendix, SA-6). Echoing the ETHEX Information, the Hermelin Information reveals that Hermelin himself led the cover-up. (A-883; SAC ¶115).

ETHEX's guilty plea also contradicts one of the District Court's reasons for dismissing the Complaint: that Defendants had no duty to disclose regulatory information that had been **provided to FDA** because once it had been provided it was "public and available." (ADDM-22). That is no longer the case. ETHEX's guilty plea shows that ETHEX had not provided all the information to the FDA.

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[6] Plaintiffs did not waive the argument that the ETHEX guilty plea demonstrates the falsity of the August 11, 2008 statement because Plaintiffs expressly alleged this in the SAC. (A-895; SAC ¶148). KV's cases are thus inapposite. (KV 46-47). *See, e.g., Travelers Prop. Cas. Co. of Am. V. Hillerich & Bradsby Co., Inc.*, 598 F.3d 257, 275 (6th Cir. 2010) ("Arguments raised only in reply, and **not in the original pleadings**, are not properly raised before the district court, and so are not properly preserved for appeal").

The District Court did not consider this in denying leave to amend, even though Plaintiffs argued it below. (ADDM-30-32).

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court reverse the District Court.

Dated: April 12, 2011

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)(7)

I hereby certify pursuant to Fed. R. App. P. 32(a)(7)(C) that the attached brief is proportionally spaced, has a typeface (Times New Roman) of 14 point, and contains 6,939 words (excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)), as counted by the Microsoft Word program used to produce this brief.

Dated: April 12, 2011

/s/ Javier Bleichmar
Javier Bleichmar

CERTIFICATE OF SERVICE
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I, Javier Bleichmar, hereby certify that on April 12, 2011, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the appellate CM/ECF system.

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Dated: April 12, 2011
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