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)

BRIEF OF PLAINTIFFS-APPELLANTS

CHRISTOPHER J. KELLER
JAVIER BLEICHMAR
JOSEPH A. FONTI
STEPHEN W. TOUNTAS
ALAN I. ELLMAN
LABATON SUCHAROW LLP
140 Broadway
New York, New York 10005
(212) 907-0700

TED R. OSBURN
JASON G. CROWELL
MICHAEL D. MURPHY
OSBURN, HINE, YATES & MURPHY, L.L.C.
3071 Lexington Avenue
Cape Girardeau, Missouri 63701
(573) 651-9000

Attorneys for Plaintiffs-Appellants

SUMMARY OF THE CASE AND REQUEST FOR ORAL ARGUMENT

This is a securities class action pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and Rule 10b-5 thereunder, on behalf of investors who purchased the securities of Defendant KV Pharmaceutical Company ("KV" or the "Company"). Norfolk County Retirement System and State-Boston Retirement System are court-appointed Lead Plaintiffs ("Plaintiffs"). Defendants include the Company and three of its senior officers.

Plaintiffs allege that Defendants made materially false and misleading statements and omissions, and engaged in a fraudulent scheme, while systematically and knowingly violating manufacturing regulations issued by the United States Food & Drug Administration ("FDA"). As a result of these violations, the FDA forced KV to shut down all of its manufacturing operations.

The District Court dismissed this action without leave to replead. It also denied Plaintiffs' subsequent motion pursuant to Federal Rules of Civil Procedure ("Rules") 59(e) and 60(b)(2) to alter the judgment. Plaintiffs filed this motion after KV's manufacturing subsidiary entered a criminal guilty plea to two felony counts of defrauding the FDA, just days after the District Court's dismissal here.

Plaintiffs appeal (i) the dismissal and (ii) denial of their Rules 59(e) and 60(b)(2) motion. Because this appeal presents a complex, fact-intensive inquiry, Plaintiffs respectfully request 20 minutes of oral argument per side.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure ("FRAP"), Plaintiffs state that they do not have any parent corporations nor any stockholders.

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JURISDICTIONAL STATEMENT

This is an appeal from a final order of the United States District Court for the Eastern District of Missouri, Honorable Carol E. Jackson, which disposes of all claims and is timely brought. This case arises under Exchange Act Sections 10(b) and 20(a), 15 U.S.C. §§ 78j(b) and 78t(a). The District Court had subject matter jurisdiction under 15 U.S.C. § 78aa and 28 U.S.C. § 1331.

On February 22, 2010, the District Court entered an order granting Defendants' motions to dismiss the Complaint pursuant to Rule 12(b)(6) (the "Order"). (ADDM-1-29).[1] On March 18, 2010, Plaintiffs timely filed a Notice of Appeal of the Order, pursuant to Rule 4(a)(1)(A) of the FRAP. (A-1047-1050). Also on March 18, 2010, Plaintiffs moved pursuant to Rules 59(e) and 60(b)(2) for alteration of the Order to allow Plaintiffs to file an amended pleading. (A-833-1046). Plaintiffs included a proposed Second Amended Complaint with the filing (the "SAC"). (A-842-1043).

On October 20, 2010, the District Court entered an order denying Plaintiffs' motion pursuant to Rules 59(e) and 60(b)(2). (ADDM-30-33). The District Court did not transmit to this Court Plaintiffs' Notice of Appeal of the Order until

[1] This Brief cites to the Joint Appendix as "A-___" and to the Addendum as "ADDM-___". The Joint Appendix is submitted on behalf of Plaintiffs and Defendant Rita E. Bleser. References to the Consolidated Amended Complaint for Violations of the Federal Securities Laws (the "Complaint") also include paragraph references denoted by "¶". References to paragraphs in the proposed Second Amended Complaint are denoted by "SAC ¶".

October 21, 2010. (A-1055). On November 1, 2010, Plaintiffs timely filed an Amended Notice of Appeal, also appealing the October 20 order, pursuant to Rule 4(a)(1)(A) of the FRAP. (A-1064-1067).

This Court has jurisdiction pursuant to 28 U.S.C. § 1291. On appeal, Plaintiffs request reversal of (i) the Order, and (ii) the order denying Plaintiffs' motion under Rules 59(e) and 60(b)(2).

STATEMENT OF ISSUES

1. Whether the District Court erred in dismissing the Complaint for failure to state a claim under Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5(b) thereunder, because Plaintiffs failed to adequately plead the falsity of the alleged statements and omissions concerning (i) KV's material compliance with FDA regulations, and (ii) KV's financial results. *See Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988); *In re K-Tel Int'l, Inc. Sec. Litig.*, 300 F.3d 881, 890 (8th Cir. 2002); *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1052 (9th Cir. 2008); *Wilkof v. Caraco Pharm. Labs.*, 2010 WL 4184465, at *2 (E.D. Mich. Oct. 21, 2010).

2. Whether the District Court erred in dismissing the Complaint for failure to state a claim under Rules 10b-5(a) and (c) because Plaintiffs failed to adequately plead that certain Defendants engaged in a fraudulent scheme. *Stoneridge Inv. Partners LLC v. Scientific Atlanta, Inc.*, 552 U.S. 148, 158 (2008); *In re Able Labs. Sec. Litig.*, 2008 WL 1967509, at *8 (D.N.J. Mar. 24, 2008).

3. Whether the District Court erred in denying Plaintiffs' motion pursuant to Rules 59(e) and 60(b)(2) requesting permission to amend the pleadings. *Amrine v. Brooks*, 522 F.3d 823, 833 (8th Cir. 2008); *In re Merck & Co., Inc., Sec., Derivative & ERISA Litig.*, 493 F.3d 393, 402-03 (3d Cir. 2007).

STATEMENT OF THE CASE

The central allegation in this securities class action is that Defendants knowingly manufactured adulterated drugs despite the FDA's continuous warnings of regulatory noncompliance, which Defendants then concealed from the public. (A-76-84, A-99; ¶¶32-54, 98-100). These continuous violations were ultimately revealed when the FDA forced KV to shut down all its manufacturing operations. (A-68; ¶2). As a result of the FDA violations and subsequent shutdown, the Company's stock price plummeted from more than $30 to $0.51 per share. Investors lost more than $1.5 billion. (A-70; ¶7).

Plaintiffs' allegations are supported by documents filed by the United States Attorney in federal court, which assert that Defendants knowingly made false statements. (A-70; ¶8). Specifically, on March 2, 2009, the United States filed a complaint on behalf of the FDA seeking a permanent injunction against all Defendants in this Action (the "FDA Complaint"). (*Id.*). The FDA explained that, starting in 2003, Defendants systematically and knowingly violated FDA manufacturing regulations known as "current Good Manufacturing Practices" ("cGMP"). (*Id.*). These violations of cGMP were not limited to a few products, or a few manufacturing issues. **Rather, the violations covered the entire range of KV's operations and products, leaving the FDA with no option but to shut down all of KV's production**. (A-76-84; ¶¶33-54).

The FDA Complaint stated in unequivocal terms that Defendants knowingly failed to comply with cGMP for years: "Defendant [KV] has a history of continuing cGMP violations." (A-78-79; ¶38). Significantly, this history of violations continued despite repeated warnings. (A-70; ¶8). The repeated warnings were specifically made to all Defendants here, all of whom were named defendants in the FDA Complaint. (*Id.*) ("FDA investigators discussed the violations listed in the Form FDA-483s with Defendants").

As a result of this systematic disregard of FDA regulations, KV terminated its Chief Executive Officer ("CEO"), Defendant Marc S. Hermelin ("Hermelin"), **for cause**. (A-69; ¶5). **Termination for cause under Hermelin's employment agreement required improper conduct "with full knowledge of all pertinent facts."** (*Id.*) (emphasis supplied throughout unless otherwise stated). Hermelin was unable to prevent his own termination despite owning a controlling block of KV's voting stock, more than 66% of the Class B shares, which had super voting rights. (*Id.*).

In light of the fraud, KV investors filed a number of securities class actions, which were consolidated by order of the District Court on April 15, 2009. (A-48). Plaintiffs then filed the operative complaint on May 22, 2009, on behalf of a class of all purchasers of KV publicly-traded securities between June 15, 2004 and January 23, 2009 (the "Class" and the "Class Period"). (A-68; ¶1).

Ultimately, in February 2010, KV's main subsidiary, ETHEX, **pled guilty to two felony counts of fraud** on the FDA, paid $27 million in fines, and subsequently ceased all operations. (A-880; SAC ¶104).

STATEMENT OF FACTS

A. Overview Of The Defendants

Defendant KV is a pharmaceutical company that developed, manufactured and marketed prescription drugs. (A-75; ¶25). The Company had three divisions: ETHEX (generic products), Ther-Rx (branded products) and Particle Dynamics, Inc. (specialty raw materials). (*Id.*). ETHEX was the division responsible for the Company's failure to comply with FDA regulations, and ultimately pled guilty to two felony counts of fraud on the FDA. It accounted for approximately 60% of the Company's net revenues during the Class Period. (A-75; ¶26).

Defendant Hermelin served as Vice-Chairman of the Board of Directors and CEO of the Company from 1975 until August 2006. (A-72-73; ¶18). In August 2006, he became Chairman of the Board in addition to CEO until his termination for cause on December 5, 2008. (*Id.*).

Defendant David A. Van Vliet ("Van Vliet") served as Chief Administrative Officer beginning in September 2006 until September 5, 2008, when he was appointed President and CEO of ETHEX. (A-73; ¶20). At all times since

September 2006, Defendant Van Vliet served as an executive officer of the Company. (*Id*.).

Defendant Rita E. Bleser ("Bleser") was the President of KV's Pharmaceutical Manufacturing Division since April 2007 through the end of the Class Period. (A-74; ¶22) She also served as an executive officer of the Company during this time. (*Id*.)

Defendants Hermelin, Van Vliet, and Bleser are referred to collectively as the "Individual Defendants." The Individual Defendants were also named defendants in the FDA Complaint. (A-76; ¶32).

B. KV And Hermelin Made False And Misleading Statements Concerning Material Compliance With FDA Regulations, Including Current Good Manufacturing Practices

KV and Hermelin regularly made false and misleading statements concerning compliance with FDA regulations. Every year of the Class Period, KV was required to file an annual report with the Securities and Exchange Commission ("SEC") on Form 10-K (the "10-Ks"). (A-100-109; ¶¶102-118). In each of these 10-Ks, KV falsely and misleadingly stated that it complied with the requisite regulations. In a section entitled "Manufacturing And Facilities," the 10-K said:

> We believe that all of our facilities are in material **compliance** with applicable regulatory requirements.

Further, in a section entitled "Risks Related To Our Industry," KV also said:

> We believe that we are currently in material **compliance** with cGMP and are registered with the appropriate state and federal agencies.

(A-101-103, A-105-108; ¶¶105, 106, 111, 114; *see also* similar language in A-101; ¶104 for the 2004 10-K).[2]

1. The FDA Informed Defendants Repeatedly That KV Was Not In Compliance

The FDA Complaint filed by the Department of Justice and U.S. Attorney's Office demonstrates that the statements in the 10-Ks purporting compliance were false. The FDA concluded that Defendants had a history of the same or similar violations over eight years:

> Defendant 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**.

(A-78-79; ¶38).

The FDA also concluded that KV's violations continued despite repeated, consistent, and explicit warnings to Defendants:

> Defendant's **noncompliance has continued** despite repeated warnings from FDA regarding cGMP violations.

[2] Defendant Hermelin is liable for the statements in KV's 10-Ks because he signed the documents. *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1061-62 (9th Cir. 2000) ("a corporate official … who, acting with scienter, signs an SEC filing containing misrepresentations 'make[s]' a statement so as to be liable as a primary violator under § 10(b)"). Defendant Hermelin did not contest this issue below.

> 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.

(*Id*.).

The FDA expressly stated that it had discussed each of the violations with Defendants, who failed to remedy the violations.

> The FDA investigators discussed the violations listed in the Form FDA-483s with Defendants, who expressed a desire to correct the deficiencies. Nevertheless, FDA investigators have continued to observe cGMP violations at subsequent inspections.

(*Id*.).

Based on the dates on which the FDA informed KV that it was not in compliance, KV's statements in the 10-Ks publicly proclaiming compliance were false at the time they were made – not in hindsight. The following table shows each date on which the FDA informed KV of its non-compliance, next to the date that same year in which KV publicly filed its 10-K falsely stating otherwise. (A-100-101; ¶¶102, 104).

Date FDA Informed KV Of Non-Compliance[3]	Date KV Filed 10-K Falsely Claiming Compliance[4]
January 2004	June 2004
January 2005	June 2005
March 2006	June 2006
April 2007; March 2008	March 26, 2008;[5] June 26, 2008

In addition to its investors, Defendants' flagrant disregard of the FDA's continuous and repeated warnings that KV was violating cGMP had serious consequences to the patients ingesting the drugs. "The [FDA's] inspections of Defendant KV['s] facilities **have established** that the drugs manufactured by Defendants are **adulterated** .... " (A-144; FDA Complaint ¶13).

2. The FDA Informed Defendants Of KV's Non-Compliance By Issuing A Form 483 After Each Inspection

The allegations in the FDA Complaint were largely predicated on the underlying evidence documented in the last Form 483 issued by FDA to KV in February 2009. This Form 483 was attached as an exhibit to Plaintiffs' Complaint. (A-108; ¶116).

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[3] A-78-79; ¶38.

[4] A-100-103, A-105-108; ¶¶102, 105, 106, 111 and 114, respectively.

[5] KV did not file its 2007 10-K until March 26, 2008, and its 2008 10-K until June 26, 2008. (A-105-107; ¶¶111, 114).

Form 483s are issued pursuant to FDA regulations to notify companies "of significant objectionable conditions, relating to products and/or processes, or **other violations** of the [Food Drug & Cosmetics Act] ... which were observed during the inspection" of a facility. (A-421).[6] The Form 483 issued on February 2009 evidenced the seriousness of the violations by KV. It consists of 37 pages and portrays a company whose upper management routinely and knowingly disregarded critical manufacturing procedures designed to protect the safety of consumers. (A-79-84; ¶¶40-54). Some of the more egregious violations are set forth below.

Violations Concerning Hydromorphone HCl Tablets. KV ignored modifications in the manufacturing process of Hydromorphone HCl ("HCl") tablets by continuing to produce and distribute defective drugs for years. (A-82; ¶51). In December 2005 and January 2006, several batches "failed to demonstrate control and reproducibility" because "blend uniformity and potency failures occurred." (*Id*.). In other words, KV could not control the exact dosage in each tablet. KV identified the problem in June 2006 and designed a new production process. (*Id*.). Nonetheless, KV then ignored the new process and reverted back to

[6] *See also* FDA Investigations Operations Manual, Ch. 5, § 5.2.3 (2009) (A-513).

the old defective procedures that had resulted in dangerous drugs. (A-82-83; ¶¶51-53).

Violations Concerning Morphine Sulfate Tablets. KV concealed from the FDA the production of oversized Morphine Sulfate tablets, which it had discovered on or about May 15, 2008. (A-83; ¶54(a)). KV did not file a field alert, as required, and did not notify the FDA until nearly five months later. (*Id*.). Several wrongful death lawsuits were filed against KV relating to the ingestion of oversized Morphine Sulfate tablets. (*Id*.).

Violations Due To Lack Of Acceptable Quality Limits. KV ignored quality control. One of the usual procedures used in the pharmaceutical industry to assess quality control is known as Acceptable Quality Limit ("AQL"). (A-81; ¶47). AQL is determined by statistically sampling production defects and setting maximum limits of acceptable defects. (*Id*.). The February 2009 Form 483 makes clear that KV ignored the AQL results.

> [KV has] failed to adequately study causes for the acceptable quality limit (AQL) failures which occur across product lines.... This brings into doubt the validation of this process step for all coated and quality of products on the market.... **None of these issues is [sic] adequately investigated** [by KV]....

(*Id*.).

The recurring theme in all of these violations is not only the danger to the public, but the utter disregard of manufacturing defects by Defendants.

C. KV And Hermelin Made False Statements Concerning The Company's Earnings

KV's violations of cGMP and other FDA regulations also rendered certain Company statements about its earnings false and misleading. During the Class Period, KV launched a new product, with much fanfare, causing its earnings to increase dramatically. The Company touted the earnings from the release of this drug and Wall Street labeled it a "breakout opportunity." (A-85-86; ¶59). The reality, however, was far different. KV had never been able to manufacture the drug within FDA regulations, and the manufacturing process had been rampant with deficiencies and a dangerous lack of controls. (A-84-96; ¶¶55-86).

More specifically, in July 2007, KV launched Generic Metoprolol to treat hypertension. (A-84-85; ¶¶55-56). The branded product had total sales of $1.71 billion prior to the launch of KV's generic version. (A-85; ¶57). Total net revenues for KV in 2006 were $368 million. (*Id*.). Accordingly, if KV obtained even a modest percentage of the $1.71 billion market, it would dramatically increase net revenues. (*Id*.).

In light of the potential windfall, Wall Street analysts closely followed the launch and reacted positively as sales of Generic Metoprolol drove KV's financial results skyward: "[w]e continue to see continued share gains for [Metoprolol] as a key focal point for KV shares" (A-86; ¶61); "[we] continue to recommend purchase of KV shares based upon the large earnings contribution for the launch of

generic [Metoprolol]" (A-87; ¶ 64); "[Metoprolol] was an earnings 'breakout' opportunity" (A-85; ¶59); "[s]ales for the recent quarter came in slightly above our projections, aided by generic [Metoprolol]." (A-87; ¶66).

Wall Street closely followed the sales of Generic Metoprolol because KV trumpeted the importance of this new drug for the Company's financial performance. In KV's earnings releases for each of the four quarters ending September 30, 2007 through June 30, 2008, the Company specifically tied its increased revenues to Generic Metoprolol. (A-103-104, A-106, A-108; ¶¶107, 109, 112, 115). For the quarter ending September 30, 2007, KV's earnings press release stated:

> The improvement in net revenues [of 61% from $108 million to $175 million] was due to the July 2007 launch of [Generic Metoprolol]…. Net revenue contribution from [Generic Metoprolol] was $50.4 million.

(A-104; ¶107).

The next quarter, ending December 31, 2007, KV's earnings press release stated:

> ETHEX ... contributed approximately $102.1 million of revenue, up 57.7% from the prior-year quarter, primarily due to sales of [Generic Metoprolol].

(A-104-105; ¶109).

In the first quarter of 2008, ending March 31, 2008, KV's earnings press release stated:

> [N]et revenues for [the fiscal year] will increase $158.8 million ... due primarily to sales growth of 56.4% in its [generics segment]. The increase in the [generics segment] resulted primarily from the launch in July 2007 of [Generic Metoprolol] which generated net revenues of $119.1 million.

(A-106; ¶112). In other words, **virtually all financial growth that year, or $119 million out of $158 million (75%), was the result of Generic Metoprolol**. (*Id.*).

Finally, in the second quarter of 2008, ending June 30, 2008, KV's earnings press release stated:

> Net revenues ... increased 30.2% ... Revenue growth during the quarter was impacted by: ... a net sales gain of 52.6% over the prior year period ... contributed to by sales of [Generic Metoprolol].

(A-108; ¶115).

While KV focused its public disclosures on Generic Metoprolol's substantial and dramatic financial contribution to the Company's bottom line, unbeknownst to investors KV had violated numerous manufacturing regulations that would end the earnings bonanza. In the first instance, the FDA had found that KV had never been able to properly manufacture the tablets:

> It does not appear the [Generic Metoprolol] product line (25mg, 50mg, 100mg, 200mg) was developed in a scientifically sound manner with appropriate specifications and process controls. All strengths have historically resulted in drug product of variable quality ... at all manufacturing stages.

(A-80; ¶42).

A critical manufacturing defect was that KV simply had not followed the "designed process." (A-80; ¶43). Since August 5, 2007 (ten days after the launch), the active ingredient used by KV had resulted in smaller particle sizes than approved by the FDA in the validation study. (*Id.*). Yet, KV had "continued to manufacture and distribute ... these tablets until October 17, 2008." (*Id.*).

Another problem was the dissolution of the tablets caused by out-of-spec assay values. (A-80; ¶44). (Assay values refer to the proportion of ingredients.) (*Id*.). Instead of simply rejecting and discarding these defective drugs, "upper management" decided to "blend" lots that had low assay values with lots that had appropriate or high assay values. (*Id.*). Yet there was no justification, documentation, or, more importantly, approved procedure for this blending. (*Id.*). Put another way, "upper management" disregarded all procedures and simply ordered employees to mix together defective batches with good batches, hoping that the mix would turn out better. (*Id*.). KV then sold these mixed batches regardless of their quality.

Indeed, the FDA also found evidence that even after KV identified the cause of the dissolution problem, KV simply failed to correct it. On August 6, 2008, KV had identified "excessive press speed" as the root cause of the dissolution failures. (A-80-81; ¶45). Nonetheless, KV continued to operate at excessive press speeds until the FDA put a stop to it in 2009. (*Id*.).

In sum, KV had never been able to manufacture Generic Metoprolol in any acceptable or safe manner, let alone within FDA regulations. (A-80; ¶42). Yet KV never disclosed this. Instead, KV touted the tens of millions of dollars in sales of this defective product. (A-86-87; ¶¶62-66). While the financial results were accurately reported, and Plaintiffs do not allege that they were false, it was misleading not to disclose that these results were based on sales of a product that violated FDA regulations.

D. The FDA Forced KV To Shut Down All Manufacturing Operations

After years of continuous and repeated violations, the FDA escalated its inspections in 2008. It increased its number of annual inspections of KV facilities from one to three, in March, August, and December of 2008. (A-78; ¶38). The last inspection began on December 15, 2008. (A-72; ¶32). Eight days later, KV made the first of two announcements that would lead to the complete shut down of KV's manufacturing plants.

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." (A-97; ¶91). The price of KV's shares fell from $5.39 to $1.99. (A-98; ¶95).

On January 26, 2009, KV announced that it had "suspended the manufacturing and shipment of **all** its products, other than products it distributes

but does not manufacture." (A-98; ¶96). The stock price dropped to $0.51 per share. (A-99; ¶97).

E. ETHEX Pled Guilty To Criminal Charges Relating To The FDA Violations

On February 25, 2010, KV announced that ETHEX had pled guilty to two felony counts of fraud and agreed to pay $27 million in fines, restitution, and administrative forfeitures. (A-880; SAC ¶104). This announcement came three days after the District Court issued the Order dismissing this Action on February 22. The allegations concerning this guilty plea were included in the SAC, which the District Court did not allow Plaintiffs to file.

The guilty plea was the result of two specific instances in which ETHEX had received reports of oversized drugs from pharmacies, concealed the reports from the FDA, and instructed employees to "minimize written communications." (A-883; SAC ¶115). Simply put, ETHEX got caught in a cover up.

The cover up was continuous, systematic, and egregious. According to the Criminal Information, "Corporate Executive A" directed the cover up. (A-880, A-882-883; SAC ¶¶105, 113). Corporate Executive A was informed in May and June 2008 that oversized morphine tablets had been reported by two pharmacies, in sizes exceeding 60% to 100% of the acceptable limit. (A-881; SAC ¶¶106-107). In July 2008, Corporate Executive A was presented with a number of options to address the problem, but instead chose to "do nothing." (A-883; SAC ¶114).

Then, this same executive "instructed 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." (A-883; SAC ¶115). Corporate Executive A "was worried that communicating problems to FDA could lead to FDA insisting on additional recalls, and also wanted to limit the Audit Committee's investigation." (*Id.*).

Corporate Executive A was not even deterred by reports of painful consequences to patients. On July 12, 2008, this executive had been informed that a patient had suffered "adverse health effects" after ingesting a "crumbly, differently textured, bigger, and thicker than usual 60mg strength morphine tablet." (A-883-884; SAC ¶117). It was not until the Audit Committee instructed Corporate Executive A to begin taking remedial action on September 25, 2008, that KV informed the FDA. (A-884; SAC ¶118).

On December 5, 2008, Defendant Hermelin was terminated for cause. (A-112; ¶129). As explained above, under Hermelin's employment contract he could not be terminated for cause unless he had "full knowledge of all pertinent facts." (*Id.*). Accordingly, the Second Amended Complaint alleges that the only reasonable inference is that Corporate Executive A was Hermelin.

SUMMARY OF ARGUMENT

A. The District Court Erred In Dismissing The Complaint

The District Court committed three errors in dismissing the complaint. **First**, the District Court erroneously held that Plaintiffs failed to plead the falsity of the alleged misstatements with particularity. (ADDM-16-17; ADDM-19-20). The District Court did not explain why particularity was lacking, nor did it cite to any supporting case law. (*Id.*). Contrary to the District Court's conclusion, the Complaint sets forth a series of detailed allegations explaining the "who, what, when, where, and how," which amply satisfy the applicable pleading standard. *K-Tel*, 300 F.3d at 390.

Second, the District Court erred in finding that the Complaint failed to allege an actionable omission under Section 10(b). (ADDM-21-23). "[T]he law requires 'an actor to provide complete and non-misleading information with respect to the subjects ***on which he undertakes to speak.***'" *K-Tel*, 300 F.3d at 898 (emphasis in original). Here, by undertaking to speak about KV's compliance with cGMP, and the financial success of Generic Metoprolol, Defendants had a duty to disclose all material facts that could have rendered their statements misleading. Such material facts unquestionably include the Form 483s—and the violations identified therein—particularly considering that the ***same violations*** prompted the

FDA to shut down all of KV's manufacturing operations at the end of the Class Period.

Third, the District Court erred in finding that the Complaint failed to allege scheme liability under Rules 10b-5(a) and (c) with respect to Van Vliet and Bleser. (ADDM-26-27). The Order overlooks the Complaint's well-pled allegations that: (i) Van Vliet and Bleser were informed of the violations identified in the Form 483s; (ii) as President of ETHEX (which manufactured Generic Metoprolol) and President of Manufacturing, Van Vliet and Bleser, respectively, concealed numerous reports of defective products from the FDA; and (iii) "upper management" gave the order to violate quality control procedures concerning Generic Metoprolol. (A-73-74, A-78-79, A-83-84; ¶¶21-22, 38, 41, 54).

B. The District Court Erred In Denying Leave To Amend

The District Court also erred in finding that any amendment to the Complaint would be futile. (ADDM-32). This Court "reviews the findings of futility *de novo* [and] should freely give leave when justice so requires." *Amrine*, 522 F.3d at 833. The District Court committed reversible error by failing to address the new allegations proposed in the SAC, as well as a new false statement, arising from ETHEX's guilty plea. (*Id.*). Moreover, the District Court erred in failing to consider an expert report attached to the SAC, which cured one of the stated reasons for dismissal. (ADDM-31-32). Finally, while the District Court

endeavored to explain why an amended pleading would be futile, its logic does not withstand scrutiny.

STANDARD OF REVIEW

A. Dismissal Of The Complaint

This Court reviews *de novo* the dismissal of a securities fraud complaint for failure to state a claim under Rule 12(b)(6). *In re NVE Corp. Sec. Litig.*, 527 F.3d 749, 751 (8th Cir. 2008).

B. Denial Of Leave To Amend

Denial of an amendment to the pleadings is reviewed *de novo* where it is based on "futility," as is the case here. *Detroit Gen. Ret. Sys. v. Medtronic, Inc.*, 621 F.3d 800, 809 (8th Cir. 2010); *NVE*, 527 F.3d at 752. In assessing "futility," the District Court must apply the same standard of legal sufficiency as applied under Rule 12(b)(6). *See In re Acceptance Ins. Cos. Sec. Litig.*, 423 F.3d 899, 904 (8th Cir. 2005).

Similarly, where a denial of a motion under Rules 59(e) or 60(b) is based on a determination that newly discovered evidence would still be legally insufficient, the standard of review is *de novo*. *Jones v. Swanson*, 512 F.3d 1045, 1048 (8th Cir. 2008). That is the case in this instance as a result of ETHEX's criminal guilty plea of February 25, 2010.

Accordingly, the standard of review is *de novo* for all issues.

ARGUMENT

A. Plaintiffs Adequately Allege That Defendants Made Materially False And Misleading Statements And Omissions

Pursuant to Rule 12(b)(6), the Court must accept all factual allegations in the complaint as true and consider the complaint in its entirety. *NVE*, 527 F.3d at 751. Plaintiffs are also entitled to all reasonable inferences that may be drawn from the allegations of the complaint. *Lustgraaf v. Behrens*, 619 F.3d 867, 873 (8th Cir. 2010).

1. Legal Standards For Pleading Falsity Pursuant To The Exchange Act

When alleging Section 10(b) claims, the Private Securities Litigation Reform Act ("PSLRA") requires Plaintiffs to "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." *Lustgraaf*, 619 F.3d at 873. The "circumstances of the fraud must be stated with particularity, including such matters as the time, place and contents of false representations, as well as the identity of the person and what was obtained or given up thereby.... This means the who, what, when, where, and how." *K-Tel*, 300 F.3d at 890.

While Plaintiffs must allege falsity with particularity, the pleading standard for falsity remains "plausibility" as articulated in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Aschroft v. Iqbal*, 129 S. Ct. 1937 (2009). When the allegations of falsity are plausible, "even if it strikes a savvy judge that actual proof

of those facts is improbable, and that a recovery is very remote and unlikely," the Complaint must still be sustained. *Twombly*, 550 U.S. at 556. Accordingly, the "plausibility of a complaint turns on whether the facts alleged allow us to 'draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Lustgraaf*, 619 F.3d at 873 (asserting Exchange Act claims) (quoting *Iqbal*, 129 S. Ct. at 1949).

With this pleading standard in mind, a statement is false or misleading if it "affirmatively creates an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). "Some statements, although literally accurate, can become, through their context and manner of presentation, devices which mislead investors. For that reason, the disclosure required by the securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers." *McMahan & Co. v. Wherehouse Entm't, Inc.*, 900 F.2d 576, 579 (2d Cir. 1990). "[T]he law requires an actor to provide complete and non-misleading information with respect to the subjects *on which he undertakes to speak*." *K-Tel*, 300 F.3d at 898 (emphasis in original). Similarly, an omission is also actionable when a defendant "omit[s] to state a material fact necessary in order to make statements made, in light of the circumstances in which

they were made, not misleading." *In re Charter Commc'ns, Inc. Sec. Litig*., 443 F.3d 987, 990 (8th Cir. 2006).

2. KV And Hermelin Made Materially False And Misleading Statements And Omissions Concerning KV's Non-Compliance With cGMP And FDA Regulations

KV and Hermelin made false and misleading statements every year by representing that KV complied with cGMP, when, in fact, the FDA had told Defendants that KV was in violation and not in compliance with FDA regulations. In addition, KV and Hermelin failed to disclose that the FDA had issued seven Form 483s to KV during the Class Period.

(a) False And Misleading Statements Concerning KV's Non-Compliance With cGMP And FDA Regulations

(i) Plaintiffs Amply Satisfy Particularity

Plaintiffs properly pled the false and misleading statements in the Complaint with particularity. During the Class Period, KV filed its annual reports with the SEC on Form 10-K. *See* A-100-103, A-105-108; ¶¶102-106, 111-114. Each 10-K filed by KV was signed by Hermelin, and included the following two statements:

In a section entitled "Manufacturing and Facilities," KV stated:

> **[W]e are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies**.

In a section entitled "Risks Related to our Industry," KV stated:

> **We believe that all of our facilities are in material compliance with applicable regulatory requirements**.

(A-101-103, A-105-108; ¶¶104-106, 111, 114).

The Complaint alleges that KV repeatedly made these two statements during the Class Period in each 10-K filed on: (1) June 14, 2004 (the first day of the Class Period) (A-101; ¶104); (2) June 14, 2005 (A-101-102; ¶105); (3) June 14, 2006 (A-102-103; ¶106); (4) March 26, 2008 (A-105-106; ¶111); and (5) June 26, 2008 (A-107-108; ¶114).

Having set forth each allegedly false and misleading statement, the date each statement was made, and identified the authors of each statement, the Complaint then explains exactly why these statements were false and misleading: because prior to the date of each statement, the FDA had found numerous violations of, and noncompliance with, cGMP, and communicated the violations and noncompliance verbally and in writing to all Defendants. (A-78-79, A-101-103, A-106-108; ¶¶38, 104(a), 105(a), 106(a), 111(a), 114(a)).

The Complaint specifically alleged this in the body of the document itself (A-76-79; ¶¶32-39). As alleged at ¶38: "**Defendant KV Pharmaceutical has a history of continuing cGMP violations. The deficiencies observed by FDA at the most recent inspection in February 2009 are the same as, or similar to, prior violations observed by FDA at several other inspections conducted during the last eight years.**" (A-78-79, ¶38, quoting A-146-147, FDA Complaint ¶23).

The Complaint then reiterates that KV continuously "violated" cGMP and was therefore non-compliant: "Defendant's **noncompliance has continued** despite repeated warnings from FDA regarding its cGMP **violations**." (A-78-79, ¶38, quoting A-147, FDA Complaint ¶24). These violations and noncompliance were communicated by the FDA to all Defendants in this action: "The FDA investigators discussed the **violations** listed in the Form FDA-483s with Defendants...." (*Id.*).

There is no way to read these allegations, which have the imprimatur of the FDA, other than as directly, and squarely, contradicting KV's and Hermelin's statements that KV complied with cGMP. This goes way beyond pleading a plausible inference of falsity, which is all that Plaintiffs must do at this juncture. *Twombly*, 550 U.S. at 545. Indeed, the language used by the FDA Complaint could not be more at odds with the false statements alleged here. While KV and Hermelin said in the 10-Ks that KV was in "compliance," the FDA had told KV that the Company was in "noncompliance" because of "cGMP violations." (A-78-79; ¶38) ("Defendant's noncompliance has continued despite repeated warnings from FDA regarding its cGMP violations"). Compliance and noncompliance are polar opposites, not shades of gray, and do not allow any room for ambiguity. Simply put, KV and Hermelin lied to the public by saying KV was in compliance with cGMP and applicable regulatory requirements.

Accordingly, having specified the time, place and contents of Defendants' false statements, as well as facts more than sufficient to support a plausible inference that those statements were false at the time they were made, Plaintiffs satisfy the standard for particularity required to allege fraud, "the who, what, when, where, and how." *K-Tel*, 300 F.3d at 890; *see also Lustgraaf*, 619 F.3d at 874.

(ii) The District Court Erred In Finding That The Alleged False And Misleading Statements Were Not Pled With Particularity

a) The District Court Did Not Explain Why The Complaint Lacked Particularity

The District Court held that Plaintiffs "failed to allege with sufficient particularity that the compliance statements in the Form 10-K that the FDA issued to KV in 2004, 2005, 2006, 2007, and 2008 were false and misleading."[7] (ADDM-16-17). The District Court did not explain why particularity was lacking, nor did it cite to any cases that supported its conclusory finding. (*Id.*). The District Court's unsupported holding is contradicted by the detailed allegations in the Complaint and the case law set forth above. Even Defendant Bleser admitted in her opening

[7] The District Court mistakenly stated that the statements in the 10-K were issued by the FDA to KV (ADDM-16) ("statements in the Form 10-K **that the FDA issued to KV**"). That is factually inaccurate because the 10-K was not issued by the FDA. KV filed the 10-K with the SEC. Nevertheless, Plaintiffs understand the District Court to mean that the false and misleading statements made in the 10-K by KV were not alleged with sufficient particularity. The Order subsequently states that "plaintiffs plead no specific facts that show that KV was not in compliance when KV filed each of the Form 10-Ks." (ADDM-17).

brief in support of her motion to dismiss that particularity was satisfied: "Plaintiff describes **in detail** the financial statements made by the Company **and how** these were allegedly misleading." (A-237).

Moreover, the District Court's decision is demonstrably wrong in view of the FDA's statement that KV's "noncompliance has continued despite repeated warnings from FDA regarding its cGMP violations." (A-78-79; ¶38). Once the FDA informed KV of its "noncompliance" due to "cGMP violations," it is "plausible" (to say the least) that KV's subsequent, repeated statements of "compliance" were false. *Iqbal*, 129 S. Ct. at 1940. The District Court simply ignored this. (ADDM-15-17).

The District Court similarly ignored additional specific allegations that provided even more particularity. The Complaint pled exactly the reasons that led the FDA to conclude that KV was noncompliant. In paragraphs 32 through 54, the Complaint included the following violations identified by the FDA:

- "Upper management" gave specific instructions to violate quality control procedures to continue manufacturing Generic Metoprolol. (A-79; ¶41).
- "Upper management" ordered the "blending" of defective drugs with non-defective drugs in order to sell the defective drugs, violating all procedures. (A-80; ¶44).
- In 2005, KV determined that its hydromorphone tablets lacked "blend uniformity" and suffered "potency failures." KV did not rectify these problems and continued to manufacture the defective tablets until KV was shut down in 2009. (A-82-83; ¶¶51-53).

- KV purposely failed to investigate Generic Metoprolol's manufacturing problems and metal particles in four different products. (A-81, A-84; ¶¶47, 54(c)).

- KV received 980 complaints and 46 ADEs in 2007 and 2008 from leaking capsules of a prenatal vitamin. The FDA concluded that quality control had completely failed and yet KV continued to sell the product. (A-82; ¶¶49-50).

- KV ignored the "designed process" for manufacturing Generic Metoprolol by using an active ingredient that caused incorrectly sized particles. KV knew this in August 2007 but continued to use the improper active ingredient until October 2008. (A-80; ¶43).

- On May 15, 2008, KV discovered that it had sold tablets with oversized doses of morphine. KV did not file a Field Alert with the FDA until October 10, 2008, despite the fact that it knew that it had sold oversized tablets in ten additional products. In the interim, on June 26, 2008, KV had issued its 10-K falsely representing compliance with cGMP. (A-83; ¶54(a)).

As if these well-pled facts, alone, were not sufficiently particularized, Plaintiffs also submitted the 37-page Form 483 that the FDA issued to KV in February 2009, setting forth every single violation. (A-151-188; Compl. Ex. 2). Indeed, the FDA Complaint explained that this Form 483 listed the "same as, or similar to, prior violations observed by FDA at several other inspections conducted during the last eight years." (A-78-79; ¶38). This is more than sufficient to meet the element of particularity set forth in the PSLRA, as Plaintiffs are not required to plead evidence. *See Mississippi Pub. Emps.' Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75, 90 (1st Cir. 2008) ("in determining the adequacy of a complaint ... we cannot hold plaintiffs to a standard that would effectively require them, pre-

discovery, to plead evidence."); *In re Cabletron Sys. Inc.*,, 311 F.3d 11, 33 (1st. Cir 2002) ("the rigorous standards for pleading securities fraud do not require a plaintiff to plead evidence").

b) The Form 483s Report "Violations," Not Just "Observations"

While the lack of particularity was one of the stated reasons for which the District Court dismissed the Complaint, the discussion on particularity actually turned on the District Court's disbelief as to the falsity of the alleged misstatements. (ADDM-16-17). According to the District Court, the Form 483s did not establish KV's "violations" or "noncompliance," but merely set forth "observations." (ADDM-16) ("[T]he Form 483s issued to KV only contained observations – not 'a list of cGMP violations' as alleged by lead plaintiffs").

The District Court's semantic distinction is unsupportable. As Plaintiffs argued below, FDA regulations state that Form 483s are issued to notify companies "of significant objectionable conditions, relating to products and/or processes, **or other violations** of the FDCA." (A-421). Accordingly, KV's failure to disclose the "significant objectionable conditions ... or other violations" listed in the Form 483s rendered KV's statements of "material compliance" with cGMP to be materially false and misleading. The District Court ignored this.

In addition, the District Court's reading of Form 483s as merely setting forth "observations" or "deficiencies" instead of "violations" is textually wrong. The

FDA said that the Form 483s established that KV "violated" cGMP and was "noncomplian[t]:"

> Defendant 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 FDA at several other inspections conducted during the last eight years.
>
> Defendant's **noncompliance has continued** despite repeated warnings from FDA regarding its 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. The FDA investigators discussed the **violations** listed in the Form FDA-483s with Defendants, who expressed a desire to correct the deficiencies. Nevertheless, FDA investigators have continued to observe cGMP violations at subsequent inspections.

(A-78-79; ¶38).

While it is true that the FDA also uses the terms "deficiency" in addition to "violation," the most that can be said is that these terms are used interchangeably.

> 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 FDA at several other inspections conducted during the last eight years.

(*Id.*).

In other words, "deficiencies observed by the FDA" are the same as "prior violations." Likewise, while the Form 483 lists "observations," these "observations" are also "violations," and the two terms are not mutually exclusive:

> FDA investigators prepared and issued a detailed List of Inspectional Observations, Form FDA-483, to Defendants, **notifying them of the investigators' observations**. The FDA investigators discussed **the violations listed in the Form FDA-483s** with Defendants ....

(*Id.*).

Indeed, "observation" merely describes the two nouns that the FDA inspectors could find and include in a Form 483: "significant objectionable conditions ... or other violations of the FDCA." (A-421). Plainly, everything that the FDA inspectors observed is an observation, and everything that they observed and included in a Form 483 was, by definition, a violation or a significant objectionable condition, since that is how the FDA defined the contents of Form 483. (*Id.*). *See also supra* n.6.

c) Whether Form 483s Are Final Agency Determinations Is Not Relevant To Pleading Falsity

The District Court further compounded its error by introducing facts not pled in the Complaint. (ADDM-16). It cited to the FDA's website where, at some point in time, the FDA had added language to Form 483s to supposedly clarify that those forms do not represent a final agency determination. (*Id.*). But the fact that a Form 483 may not represent a "final FDA determination" does not mean it need not be disclosed under the securities laws: "Although the observations in the Form 483 are not final agency determinations ... the disclosure of 'significant

objectionable conditions' would significantly alter the total mix of information available to the reasonable investor...." *McGuire v. Dendreon Corp.*, 2008 WL 1791381, at *4 (W.D. Wash. Apr. 18, 2008) ("*Dendreon I*"). Rather than wait until a final FDA determination is made, Defendants were required to "permit an investor to appreciate the risk that the future sanction may arise." *In re Indep. Energy Holdings PLC Sec. Litig.*, 154 F. Supp. 2d 741, 760 (S.D.N.Y. 2001), *abrogated on other grounds by In re Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281 (S.D.N.Y. 2003). As this Court previously held: "[w]e keep in the forefront of our minds ... that just because a hidden risk does not materialize doesn't mean its concealment cannot hurt investors." *Gebhardt v. ConAgra Foods, Inc.*, 335 F.3d 824, 830 (8th Cir. 2003).

Indeed, the District Court's suggestion that only a final determination would have rendered the statements of compliance with cGMP false makes no sense in light of the facts. Defendants did not object to the violations and did not seek to overturn the violations: "The FDA investigators discussed the violations listed in Form FDA-483s with Defendants, who expressed a desire to correct the deficiencies." (A-78-79; ¶38). Having accepted the Form 483s as violations, there was no need for the FDA to engage in a long and expensive process to reach a formal final determination. Accordingly, Defendants cannot now argue that the Form 483s did not constitute an agency determination after waiving objections and

forestalling the process. *See, e.g.*, 21 C.F.R. § 17.45(d) ("Unless the initial decision or the decision granting summary decision of the presiding officer is appealed, the initial decision or the decision granting summary decision shall constitute the final decision of FDA;" in the context of hearings concerning monetary penalties).

Closely related, while the District Court concluded that the statements of compliance were not false, in part, because Form 483s did not constitute the FDA's "final determination," no court has held that "only" an administrative agency's "final determination" triggers disclosure. In doing so, however, the District Court divorced its Order from the content and context of Form 483s, and ignored the parameters of an FDA final determination. As an administrative agency, the FDA may make final determinations only after providing sufficient due process, including notice, an opportunity for a hearing, a reasoned basis for the determination, and opportunity for appellate administrative review.[8] But requiring a formal and final FDA determination for disclosure is contrary to decades of securities case law, and ignores the reality of what constitutes a fact that "would

[8] "A regulatory hearing is initiated by a notice of opportunity for hearing from FDA." 21 C.F.R. § 16.22(a). "On the basis of the administrative record of the hearing, the Commissioner shall issue a written decision stating the reasons for the Commissioner's administrative action and the basis in the record." 21 C.F.R. § 16.95(b)(2). "[T]he Commissioner's final decision constitutes final agency action" (reviewable in courts under 5 U.S.C. 701). 21 C.F.R. § 10.45(d).

have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic*, 485 U.S. at 231-32.

(iii) The District Court Erred By Failing To Find That The False And Misleading Statements Concerning KV's Non-Compliance With cGMP Were Material And Had To Be Disclosed

Plaintiffs argued below that the Form 483s and the information therein was material and should have been disclosed. (A-441-453). The District Court erred by ignoring this argument and effectively ruling that the information concealed was not material.

For a fact to be material it must have "significantly altered the 'total mix' of information made available." *Medtronic*, 621 F.3d at 805 (quoting *Basic*, 485 U.S. at 231-32). The materiality requirement poses a very low burden on a motion to dismiss: "[o]rdinarily, materiality is a question of fact for the jury." *Gebhardt*, 335 F.3d at 829. For this reason, "a complaint may not properly be dismissed ... on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 162 (2d Cir. 2000). *See also Basic*, 485 U.S. at 240 (materiality is inherently an intensely "fact-specific inquiry" that "depends on the significance the reasonable investor would place on the withheld or misrepresented information").

Here, KV's noncompliance was material because the cGMP violations were sufficiently egregious and important that KV was forced to suspend all shipments of products in tablet form on December 23, 2008, and all products on January 26, 2009. (A-69-70; ¶6). The FDA Complaint, as alleged by Plaintiffs here, is unequivocal on this point: "**Defendant KV Pharmaceutical has a history of continuing cGMP violations**. **The deficiencies observed by FDA at the most recent inspection in February 2009, are the same as, or similar to, prior violations observed by FDA at several other inspections conducted during the last eight years**." (A-78-79; ¶38). In other words, the "prior violations" in "the last eight years" were the "same" as or "similar" to those observed in January 2009, which caused a complete manufacturing shutdown.

There can hardly be more material information than that which could lead, and did lead, to the cessation of all operations. *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp*., 320 F.3d 920, 935 (9th Cir. 2003) ("[A] reasonable investor would consider the potential effects of each of these facts [concerning compliance with FAA regulations] on the overall economic health of the company as 'significantly alter[ing] the 'total mix' of information available."). Indeed, a reasonable investor would have undoubtedly regarded such serious cGMP violations as having "significantly altered the total mix of information." *K-Tel*, 300 F.3d at 897. *See also In re Priceline.com Inc. Sec. Litig.*,

342 F. Supp. 2d 33, 53 (D. Conn. 2004) ("Statements regarding the viability of Priceline's business model and the feasibility of applying the business model to different markets are material information"); *In re Williams Sec. Litig.*, 339 F. Supp. 2d 1206, 1227 (N.D. Okla. 2003) (deteriorating liquidity condition threatening bankruptcy was material even though any one particular fact may not have been).

The materiality of KV's noncompliance was also demonstrated by the market's reaction to the news about the shutdown in December 2008 and January 2009. In *Medtronic*, this Court recently held that a "significant change in stock price upon disclosure of withheld information is strong evidence that the information was material." *Medtronic*, 621 F.3d at 807.

Here, investors immediately sold-off KV stock. The stock price dropped 50% on December 23, 2008, from $5.39 to $2.71 per share, and from $2.13 to $0.51 per share on January 26, 2009. (A-118, A-119; ¶¶138(a), 139(a)). Volume swelled ten times on both days. (*Id.*). Similarly, on November 13, 2008, and prior to the shutdown, details had begun to emerge disclosing the Audit Committee's 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 per share in response. (A-117; ¶137(d)).

(b) The Failure To Disclose The Form 483s Was An Actionable Omission

(i) The Omission Of The Form 483s Was Material

KV's failure to disclose the existence of the Form 483s is actionable under Section 10(b). Pursuant to the FDA's internal regulations, Form 483s are issued to notify companies "of **significant objectionable conditions**, relating to products and/or processes, or other **violations** of the FDCA." (*See supra* n.6). For this reason, numerous courts have held that a company's receipt of one or more Form 483s is *per se* material and must be disclosed. Here, the FDA issued seven different Form 483s, all alerting Defendants of the "same as, or similar ... violations." (A-78-79; ¶38). Yet, Defendants never disclosed that the FDA had issued even one of these seven Form 483s.

In *McGuire v. Dendreon Corp*., 2008 WL 5130042, at *7 (W.D. Wash. Dec. 5, 2008) ("*Dendreon II*"), the court held that "the mere fact that this document [Form 483] was issued is 'material.'" The *Dendreon II* court reasoned that "[o]ne 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." *Id*. at *6. Similarly, *Yanek v. Staar Surgical Co*., 388 F. Supp. 2d 1110 (C.D. Cal. 2005) held

that "[t]he facts related to the issuance of the Form 483 and the problems described therein were material." *Id.* at 1129.

The Form 483s should also have been disclosed not only because the issuance itself of the Forms was material, but also because of the materiality of the information contained therein – namely, that KV was not in compliance with cGMP. (A-78-79; ¶38). In another recent case, with facts nearly identical to those in this Action, the company had publicly stated that it was "substantially cGMP compliant." *Wilkof*, 2010 WL 4184465, at *2. Like here, plaintiff in *Wilkof* alleged that that statement had been false because "the FDA had found 'continuing and significant violations of cGMP.'" *Id.* The Court concluded that the allegedly false statements concerning compliance with cGMP were material: "The statements Plaintiffs identify in their Amended Complaint would not have been so obviously unimportant to a reasonable investor." *Id.* at *3. *See also In re Cryolife, Inc. Sec. Litig.*, 2003 WL 24015055, at *2, *8 (N.D. Ga. May 27, 2003) (sustaining claims against company that issued press release claiming that it "was in compliance with all FDA regulations" after the "FDA issued a Form 483 ... containing twelve specific observations of regulatory violations").

(ii) Defendants Had A Duty To Disclose The Form 483s

The District Court erred in finding that KV and Hermelin were under no duty to disclose the Form 483s. (ADDM-22). This finding not only

misapprehends the applicable law, but hinges upon the flawed premise that Form 483s were "readily accessible to the public" and, therefore, Defendants had no duty to disclose them.

In the Eighth Circuit, it is well-settled that "[a] duty [to disclose] arises ... if there have been inaccurate, incomplete or misleading disclosures." *K-Tel*, 300 F.3d at 898. Further, "the law requires 'an actor to provide complete and non-misleading information with respect to the subjects ***on which he undertakes to speak.***'" *Id.* (emphasis in original). "[E]ven 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 topics." *Id.*

As explained above, every 10-K that KV filed during the Class Period contained two affirmative misrepresentations: (1) "We are currently in material compliance with cGMP"; and (2) "We believe that all of our facilities comply with applicable regulatory requirements." (A-101-103, A-105-108; ¶¶104-106, 111, 114). By undertaking to speak on these topics, Defendants had a duty to speak fully and truthfully, and to disclose all material facts—including the Form 483s and the myriad violations identified therein—that could have rendered their statements inaccurate, incomplete or misleading. It is simply indisputable that Defendants failed to disclose the full truth given that the FDA specifically informed every Defendant—verbally and in writing—that KV had numerous

violations of, and noncompliance with, cGMP. (A-37, A-101-103, A-106-107; ¶38; 104(a); 105(a); 106(a); 111(a); 114(a)).[9]

These particularized allegations are more than sufficient to state a claim that Defendants' non-disclosure of the Form 483s violated Section 10(b). *America West* is directly on point. In *America West*, the Federal Aviation Agency ("FAA") repeatedly warned the company that its substandard maintenance was unsafe and in violation of FAA regulations. *America West*, 320 F.3d at 927-29. When news of the warnings leaked out via the press, the company dismissed them as "routine," similar to Defendants' argument below. *Id.* at 929. The Ninth Circuit, however, held that plaintiffs adequately alleged that defendants had a duty to disclose possible sanctions stemming from adverse FAA warnings because, like here, "[a] reasonable investor would find significant the information regarding a company's ... unsafe maintenance practices, and possible sanction." *Id.* at 935; *cf. Indep. Energy*, 154 F. Supp. at 760 ("While ... the securities laws may not require disclosure of possible future sanctions, ... they certainly require disclosure of

[9] The sufficiency of these well-pled allegations is underscored by this Court's reasoning in *Medtronic*, 621 F.3d at 806-07, a decision issued after the dismissal of this Action. *Medtronic* held that plaintiffs failed to establish defendants' duty to disclose because, unlike here, plaintiffs "failed to allege facts showing Medtronic possessed the [omitted] information at the time the supposedly inconsistent statements were made." *Id.* at 806.

information that would permit an investor to appreciate the risk that the future sanction may arise.").[10]

Another similar case is *Apollo Group, Inc. Securities Litigation*, 395 F. Supp. 2d 906 (D. Ariz. 2005), in which the University of Phoenix "failed to disclose a report from the Department of Education ["DOE Report"] that seriously criticized" its payments to recruiters. As in *America West*, and as Defendants argued below, the *Apollo* defendants downplayed the DOE Report as "routine." Nevertheless, the *Apollo* court held that plaintiffs adequately alleged that defendants had a duty to disclose the DOE Report because "[a] reasonable investor would 'find significant' the specifics of the DOE investigation, including the report that outlined a substantial failure to comply with Title IV." *Id.* at 919. Alternatively, the *Apollo* court reasoned that "even if Defendants ... had no duty to disclose the report when it was issued, ... at the point Defendants chose to speak about the DOE investigation, they had a duty to speak fully and truthfully and such full disclosure would have included the negative DOE Report." *Id.* at 919-20.

[10] *See also In re Amylin Pharms., Inc. Sec. Litig.*, 2003 WL 21500525, at *8 (S.D. Cal. May 1, 2003) ("A company seeking FDA approval of a new drug clearly is not under any obligation to disclose every single issue raised by the FDA throughout the process. However, ***if the FDA expresses significant concerns*** regarding the sufficiency of the trials, ***the company cannot make affirmative representations regarding the completeness or sufficiency of the trials without full disclosure.***").

Rather than address the applicability of the above-referenced case law, the District Court held that because the Form 483s were "available" to investors by virtue of a Freedom of Information Act ("FOIA") request, Defendants had no duty to disclose them. (ADDM-22). Affirming this holding would be tantamount to turning the federal securities laws on their head. The Supreme Court "repeatedly has described the 'fundamental purpose' of the [Exchange Act] as implementing a 'philosophy of ***full disclosure***.'" *Basic*, 485 U.S. at 230. To that end, it is not the investors' burden to disregard a company's public representations of compliance with the FDA, initiate an investigation of fraud on their own, and issue a series of speculative FOIA requests to "double-check" the veracity of what the company is saying. Indeed, it is telling that, in briefing this issue below, Defendants were unable to point to a single Wall Street analyst report, newspaper article, or other public disclosure indicating that anyone used FOIA to obtain this information during the Class Period. Nor is that surprising given that no one knew the Form 483s existed until they were ultimately disclosed by KV.[11]

[11] Defendants' motions to dismiss also relied upon these facts to argue that the truth was on the market and, therefore, that Plaintiffs are not entitled to a presumption of reliance based on the fraud-on-the-market doctrine. However, it is widely accepted that the truth-on-the-market defense "is intensely fact-specific and is rarely an appropriate basis for dismissing a § 10(b) complaint." *Ganino*, 228 F.3d at 167. Indeed, in a recent case involving the omission of Form 483s, the court "decline[d] to dismiss ... based on Defendants' argument that documents such as the FDA Form 483s were public and could be accessed by shareholders." *Wilkof*, 2010 WL 4184465, at *4. No Court has adopted a contrary view.

Plaintiffs are not aware of a single case, nor have Defendants been able to find one, to have ever held that merely because information is known to an administrative agency, but not in the public domain, it need not be disclosed.

In support of its flawed reasoning, the District Court relied upon *B.L. Sailors v. N. States Power Co.*, 4 F.3d 610 (8th Cir. 1993) ("*Sailors*"), for the proposition that "Rule 10b-5 does not protect 'nondisclosed facts equally known or available to both parties.'" (ADDM-22, quoting *Sailors*, 4 F.3d at 613). To the contrary, *Sailors* actually supports Plaintiffs' argument here. In *Sailors*, the Court considered at summary judgment whether the company had a duty to disclose the step-by-step developments of a regulatory proceeding. *Sailors*, 4 F.3d at 613. In contrast to Defendants' non-disclosure of the Form 483s, the *Sailors* defendants ***had disclosed*** the regulatory proceedings. Thus, the *Sailors* Court held that "***having alerted the market to the existence of regulatory proceedings***, [the company] had no duty to inform them of each of the steps required in that process." *Id*. The *Sailors* court also emphasized "the vast amount of publicity" concerning the regulatory proceeding in noting that "all of the information [plaintiff] [alleges] should have been disclosed ... was public information that could have easily been obtained by any investor." *Id.* Of course, KV's investors could not have "easily" done the same, as Defendants omitted all information concerning the existence of the Form 483s. *Compare with id*. ("We observe,

however, that the mass media and the specialized press made repeated references to the general concerns about [defendant's regulatory] application and to some of the specific problems about which [plaintiff] complains.").

3. KV's Materially False And Misleading Statements Concerning Earnings Based On Generic Metoprolol

(a) Having Chosen To Publicly Highlight The Financial Success Of Generic Metoprolol, Defendants Had A Duty To Disclose The Drug's Manufacturing Problems

In similar fashion to the statements concerning KV's regulatory compliance, Plaintiffs also pled with particularity the falsity of the statements attributing the Company's financial success to Generic Metoprolol. The four statements in this category are specifically identified. (A-103-106, A-108; ¶¶107, 109, 112 and 115). Each of these four statements is substantially identical for purposes of the motion to dismiss, and consists of KV's quarterly earnings announcement in which the stellar results touted by the Company are largely, if not entirely, ascribed to Generic Metoprolol.

For example, the first earnings statement after the launch of Generic Metoprolol occurred on November 20, 2007. The Company said that net revenues had increased by 61%, from $108 million to $175 million, and that "the improvement in net revenues was due to the July 2007 launch of [Generic Metoprolol]." (A-103-104; ¶107). The next quarter, on February 15, 2008, KV

again announced significant net revenue growth of 38.7%, "primarily due to the sales of 100mg and 200mg strengths of [Generic Metoprolol]." (A-104-105; ¶109). And the next two quarters after that, KV again announced net revenue growth exceeding 30% also resulting "primarily from the launch in July 2007 of the 100mg and 200mg strengths of Generic [Metoprolol]." (A-106; ¶112).

The Complaint further alleged that the launch of Generic Metoprolol "mark[ed] a major milestone" for KV and constituted the central focal point for Wall Street analysts and investors. (A-84-88; ¶¶55-66). Analysts issued research reports stating that: generic Metoprolol was an "earnings breakout opportunity" (A-85-86; ¶59); "[w]e see continued share gains for generic [Metoprolol] as a key focal point for KV shares" (A-86; ¶61); "[we] continue to recommend purchase of KV shares based upon the large earnings contribution for the launch of generic [Metoprolol]" (A-87; ¶64); "sales for the recent quarter came in slightly above our projections, aided by generic [Metoprolol]." (A-87-88; ¶66).

Having alleged each specific statement and explained the importance of Generic Metoprolol to KV, the Complaint then explains exactly why these statements were false and misleading: because the FDA had concluded that KV's manufacturing process was so flawed and replete with regulatory deficiencies that KV had never been able to manufacture Generic Metoprolol safely and pursuant to cGMP. (A-80-81, A-104-108; ¶¶42-46, 108, 110, 113 and 116). Specifically:

- The [Generic Metoprolol] product line was not "developed in a scientifically sound manner with appropriate specifications and process controls. All strengths have historically resulted in drug product of variable quality." (A-80; ¶42).

- KV used an active ingredient in Generic Metoprolol outside FDA regulations from August 5, 2007 through October 2008 – the entire time it manufactured the product. (A-80; ¶43).

- Because the proportion of Generic Metoprolol ingredients kept falling outside acceptable parameters, "upper management" ordered the "blending" of lots that met specifications with those that did not, in the hope that the final product would be within the acceptable range. There was no approved procedure for this. (A-80; ¶44).

- KV ignored already-identified manufacturing problems and continued to manufacture Generic Metoprolol improperly until stopped by the FDA in 2009. (A-80; ¶45).

Defendants had a duty to disclose these deep-seated manufacturing issues that ultimately led to the shutdown of production of Generic Metoprolol. A long line of cases holds that when a company links its financial success to a specific line of business, it must disclose all information about that business that would alter the total mix of information. "Material misrepresentations include those 'concerning a segment or other portion of the [company's] business that has been identified as playing a significant role in the [company's] operations or **profitability**.'" *Freudenberg v. E*Trade Fin. Corp.*, 712 F. Supp. 2d 171, 181 (S.D.N.Y. 2010). *See also In re Providian Fin. Corp. Sec. Litig.*, 152 F. Supp. 2d 814, 825 (E.D. Pa. 2001) ("Were [sic] Providian engaged in a series of illegal or fraudulent business practices and were those practices responsible for inflating revenue, profit, and the

customer base, such information would clearly alter the mix of information available to the public as to the source of Providian's success and the viability of full realization of Providian's reported profits"); *Kapur v. USANA Health Servs., Inc*., 2008 WL 2901705, at *13 (D. Utah July 23, 2008) ("[B]ecause, in several cited press releases, Defendants chose to reveal the source of their financial success, they had a duty under the law to ensure that the revelation was complete and accurate."); *In re Van der Moolen Holding N.V. Sec. Litig.*, 405 F. Supp. 2d 388, 400-01 (S.D.N.Y. 2005) (holding that if a company "puts the topic of the cause of its financial success at issue, then it is obligated to disclose information concerning the source of its success …").

A decision by the Ninth Circuit is also on point. In *In re Gilead Sciences Securities Litigation*, 536 F.3d 1049, 1052 (9th Cir. 2008), the company also attributed strong earnings "primarily" to one drug. *Id.* at 1052. The company, however, failed to disclose that it was selling the drug for off-label use contrary to FDA regulations – perhaps less egregious than manufacturing the drug in contravention of cGMP. *Id.* The Ninth Circuit held that the failure to disclose off-label sales was actionable because Gilead chose to tout the drug as a primary driver of its earnings:

> 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 of Viread" .... These statements were materially false and misleading because Gilead's 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.

Id. Although Plaintiffs discussed *Gilead* in their papers below, the District Court did not address, or let alone distinguish, the case.

Similarly, in *Steiner v. MedQuist Inc.*, 2006 WL 2827740 (D.N.J. Sept. 26, 2006), the defendant failed to disclose an improper billing scheme, and instead attributed its revenues to legitimate businesses. *See id.* at *16. These statements put the source of MedQuist's revenue at issue and, as a result, the failure to disclose a major source of that revenue—the improper billing scheme—was misleading. *Id.* The court held as much: "[S]ection 10(b) liability can arise when defendants know that statements putting the source of the company's revenue at issue are false or misleading, even though the financials themselves are otherwise accurate." *Id*. at *15; *see also Schultz v. Applica Inc.*, 488 F. Supp. 2d 1219, 1226-27 (S.D. Fla. 2007) (defendant "knew of the product's defects and slow sales but failed to disclose this information when commenting on Applica's new products and expected growth, creating an overlying optimistic view of their success.").

Accordingly, although KV's financial figures in the challenged statements are true, the earnings statements discussing Generic Metoprolol are false and misleading because they consist of half-truths that omit the most critical facts

about Generic Metoprolol: that the Company was violating cGMP and could not manufacture the drug within approved guidelines.

(b) The District Court Erred In Finding That Defendants Had No Duty To Disclose Generic Metoprolol's Manufacturing Issues

Nevertheless, the District Court erroneously held that Defendants had no duty to disclose the manufacturing problems of Generic Metoprolol because KV's disclosures had been limited to the financial results. (ADDM-17-20). The District Court stated:

> 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. Moreover, lead plaintiffs do not allege that the figures reported in the financial statements were false and misleading.

(ADDM-19-20). The District Court did not cite any supporting precedent or case law on point, other than the general standard that there is no requirement "to dump all known information" under *K-Tel*, 300 F.3d at 898. But the Order never addressed the critical distinction between the duty to disclose "all information" and material information, nor did it analyze whether the fact that KV could not manufacture Generic Metoprolol within FDA regulations was material information.

There is no question that there is no duty to disclose "all information." But the case law cited by Plaintiffs above makes clear that material information must

be disclosed, and that the manufacturing problems of Generic Metoprolol were material after KV so heavily emphasized the drug's financial success. Surely investors would have wanted to know that the financial success of the drug (and, as a result, the Company) was premised on violations of FDA manufacturing regulations. Accordingly, the District Court's cursory analysis does not withstand scrutiny and should be reversed.

B. The Complaint Properly Pleads Scheme Liability Against Van Vliet And Bleser

A violation of Rule 10b-5 is not limited to a false statement or material omission; it extends to "conduct itself [which] can [also] be deceptive." *Stoneridge Inv. Partners LLC v. Scientific Atlanta, Inc.*, 552 U.S. 148, 158 (2008). Rules 10b-5(a) and (c) make it unlawful "to employ any device, scheme, or artifice to defraud," or "to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person," respectively. 17 C.F.R. §240.10b-5(a) & (c).

Accordingly, to state a primary liability claim under Rules 10b-5(a) and (c), plaintiffs must allege conduct that is deceptive under either of those subsections, and also establish the other elements of Section 10(b), namely, scienter and reliance. *In re Alstom Sec. Litig.*, 406 F. Supp. 2d 433, 474 (S.D.N.Y. 2005).

The Complaint alleges that the conduct of Van Vliet and Bleser met the elements for scheme liability under Rules 10b-5(a) and (c). (A-125-127; ¶¶162-

171). Both Van Vliet and Bleser are defendants in the FDA Complaint. (A-70; ¶8).

"Plaintiffs [are] not required to allege that [Defendant was] the architect or mastermind of the scheme to defraud investors" to plead scheme liability. *In re Able Labs. Sec. Litig.*, 2008 WL 1967509, at *21 (D.N.J. Mar. 24, 2008). Nonetheless, the Complaint alleges that **all** Defendants sued by the FDA, including Van Vliet and Bleser, were responsible for KV's violations and noncompliance:

> 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. The FDA investigators discussed the violations listed in the Form FDA-483s with **Defendants**, who expressed a desire to correct the deficiencies. Nevertheless, FDA investigators have continued to observe cGMP violations at subsequent inspections.

(A-78-79; ¶38).

The Complaint further points to the FDA Complaint's revelation that "upper management" gave the order to violate quality control procedures concerning the manufacturing of Generic Metoprolol. (A-79; ¶41). Generic Metoprolol was manufactured by the ETHEX division, and Van Vliet was President of the ETHEX division. (A-73; ¶20) Bleser was the President of Manufacturing. (A-74; ¶22). *See Able Labs.*, 2008 WL 1967509 at *7 (sustaining scheme liability claims

because defendants' "hir[ed] inexperienced and poorly trained bench chemists and foster[ed] a culture of dishonesty to conceal adverse quality control results").

In their roles as heads of ETHEX and Manufacturing, Van Vliet and Bleser also concealed from the FDA numerous reports of defective products that regulations required them to disclose. (A-83-84; ¶54). For example, "KV concealed from FDA the production of oversized Morphine Sulfate tablets" and did not file a "field alert" with the FDA within days of such finding. (*Id.*). *See Able Labs.*, 2008 WL 1967509, at *20 (sustaining scheme liability claims because of defendant's "fail[ure] to report adverse drug events to the FDA throughout [defendant's] tenure at the Company").

Put simply, Plaintiffs sued Van Vliet and Bleser under scheme liability because the above-referenced facts demonstrate that they both participated in systemic and continued violations of FDA regulations. *See also New York City Emps. Ret. Sys. v. Berry*, 616 F. Supp. 2d 987, 996 (N.D. Cal. 2009) (sustaining scheme liability claims in option-backdating scheme against individual defendant "responsible for overseeing [company's] stock option granting process"); *In re Bristol Myers Squibb Co. Sec. Litig.*, 586 F. Supp. 2d 148, 170 (S.D.N.Y. 2008) (sustaining scheme liability against company's general counsel who "knowingly withheld information about the negotiations, the terms of the settlement, and the

oral side agreements from shareholders, the Board of Directors, and the federal monitor").

Nonetheless, the District Court dismissed the claims pursuant to Rules 10b-5(a) and (c) on the basis that the allegations against Van Vliet and Bleser lacked sufficient particularity. (ADDM-26-27). The Court below did not explain why that was the case, and cited only to two paragraphs in the **counts section** of the Complaint, which paraphrase the statutory language of Rules 10b-5(a) and (c). (*Id.*, citing A-126; ¶¶164, 166). The District Court, however, then ignored all the specific factual allegations (A-76-84; ¶¶32-54), which explain that Defendant**s**, plural, all participated in the scheme violating FDA regulations, including Van Vliet and Bleser. Accordingly, the District Court should be reversed. *See Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 196 (4th Cir. 2009) (reversing District Court which failed to consider allegations).

C. The District Court Erred In Denying Leave To Amend The Complaint Because It Would Be Futile

The District Court denied Plaintiffs' motion under Rules 59(e) and 60(b)(2) to amend the pleadings on the basis that it would be futile. (ADDM-30-33). This Court "review[s] the finding of futility de novo [and] should freely give leave [to amend the pleadings] when justice so requires." *Amrine v. Brooks*, 522 F.3d 823, 833 (8th Cir. 2008). *See Phillips v. Allegheny*, 515 F.3d at 245 ("[A] district court **must** permit a curative amendment unless such an amendment would be

inequitable or futile."). For the reasons set forth below, the District Court should be reversed.

Plaintiffs respectfully submit, however, that this Court should not rule in the alternative and should reverse (i) the Order, and (ii) the Rules 59(e) and 60(b)(2) motion. The errors of law in the Order cannot stand as precedent.

1. Amendment Would Not Be Futile Because Plaintiffs Pled New False Statements Arising From New Allegations

The SAC included new allegations based on the guilty plea entered by ETHEX on February 25, 2010, which occurred after the District Court had dismissed the Complaint on February 22, 2010. (ADDM-31). Specifically, the SAC alleged for the first time that KV engaged in a criminal cover-up of its manufacturing problems starting in May 2008. (A-880-884; SAC ¶¶105-118).

The cover-up was principally carried out by an unnamed "Corporate Executive" who, (i) "instructed multiple KV employees to minimize written communications about KV's oversized tablet manufacturing problems ... given the 'business risk' created by written material" (A-883; SAC ¶115); (ii) "was worried that communicating problems to the FDA could lead to the FDA insisting on additional recalls, and also wanted to limit the Audit Committee's investigation" (*Id.*); and (iii) "thought it was better to leave the drug products 'on the market.'" (A-883; SAC ¶116). This Corporate Executive then instructed KV employees "to do nothing," and refused to inform the FDA. (A-883; SAC ¶114). All these

instructions were given in June and July 2008, and form the basis for ETHEX's guilty plea to defraud the FDA.

Based on these new facts, which had not been alleged in the Complaint, the SAC then pled a new false statement that KV had made 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). Yet, contemporaneously, ETHEX and Corporate Executive A were in the midst of intentionally defrauding the FDA, as now admitted to in the guilty plea. (A-885; SAC ¶125). The District Court did not mention or consider this new alleged false statement and new facts when it denied leave to amend. That constitutes reversible error. *In re Merck & Co., Inc., Sec., Deriv. & ERISA Litig.*, 493 F.3d 393, 402-03 (3d Cir. 2007) (holding failure to consider information discovered after filing initial complaint was reversible error; reversing denial of leave to amend).

2. Amendment Would Not Be Futile Because The SAC Attached An Expert Report That Cured Certain Supposed Deficiencies Set Forth In The Order

The SAC also attached an expert report that cured one of the reasons for which the District Court had dismissed the Complaint. The District Court held that Plaintiffs failed to allege that the statement that KV was in regulatory compliance was false. (ADDM-16-17). The District Court erroneously concluded that

Plaintiffs only alleged that the FDA had made "observations" and not found "violations." (*Id.*).

As set forth above, these semantic distinctions are irrelevant. But putting that aside, the SAC attached an expert report from a former FDA inspector who opined that the "deviations" and "observations" communicated by the FDA to KV meant that KV was not in compliance with cGMP. (A-902-903, A-1027-1035; SAC ¶170-172, England Decl.). The District Court never failed to consider or analyze whether the expert report cured the dismissal of the Complaint. (ADDM-31-32). *See Matrix Capital Mgmt. Fund*, 576 F.3d at 196 (reversing denial of leave to amend pleading in PSLRA case where district court failed to consider new allegations in amended pleading).

3. The Order Is Erroneous On Its Face

In addition to the allegations that the District Court ignored, even the three reasons provided for finding that amendment of the Complaint would be futile do not withstand scrutiny. (ADDM-32).

The District Court first held that the SAC's new allegations about KV's cover-up and criminal conduct occurred only after May 2008, "which covers only a small portion of the relevant class period." (*Id.*). Without explanation, but presumably because the new allegations did not cover the entire Class Period, the District Court thus found the amendment futile. However, even if the new

allegations do cover a small portion of the Class Period, from May 2008 through January 2009, that is still a viable class period, with viable claims. Nothing in the District Court's analysis says otherwise. *Jurimex v. Case Corp*., 65 F. App'x. 803, 807 (3d Cir. 2003) ("The District Court committed legal error by failing to consider the effects of certain factual pleadings" in denying leave to file amended complaint).

Second, the District Court held that the cover-up allegations do not "mention[] the individual defendants to this action, and it is highly questionable whether the second amended complaint would survive similar motions to dismiss filed by those defendants." (ADDM-32). But the new allegations do cover an individual defendant, Hermelin. The SAC alleges that the only reasonable inference is that the "Corporate Executive A" who ordered the criminal misconduct was Hermelin. (A-882-883; SAC ¶113). Accordingly, the District Court made a factual error that should be reversed. *Northstar Indus., Inc. v. Merrill Lynch & Co., Inc.* 576 F.3d 827 (8th Cir. 2009) (all factual allegations must be accepted as true on motion to dismiss; reversing dismissal).

Third, the District Court claimed that the new allegations had already been pled in the Complaint and that all that Plaintiffs added in the SAC was "evidentiary support" – not new allegations. (ADDM-32). But the District Court had dismissed the Complaint precisely for this reason – because the allegations lacked "sufficient

particularity," adding: "[L]ead Plaintiffs plead no specific facts that show that KV was not in compliance when KV filed each of the Form 10-Ks." (ADDM-16-17). The "evidentiary support" added in the SAC adds the particularity the District Court held was wanting. (A-880-884; SAC ¶¶105-118). Indeed, the new "evidentiary support" shows that, while in May, June, and July 2008 KV's Corporate Executive A engaged in criminal conduct and a cover-up, KV intentionally and falsely stated in its August 11, 2008 Form 10-K that management was not aware of any "misconduct." (A-896-897; SAC ¶151). *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1435 (3d Cir. 1997) (leave to replead is favored when dismissal is based on lack of particularity because courts are hesitant to dismiss potential meritorious claims due to inadequate pleadings).

Further, this additional "evidentiary support" about the cover-up undercuts the Order's erroneous holding that all the information was "public and available." (ADDM-22). The Order held that the allegedly omitted information was "public and available" based on the factual predicate alleged in the Complaint that the FDA knew about the manufacturing violations. (*Id.*). That, however, was no longer the factual predicate for all the facts pled by the SAC. The SAC now alleged that at least some information had **not** been provided to the FDA (the cover-up allegations), and that that information had also been concealed from the FDA and the public. (A-880-886, A-899-902; SAC ¶¶104-126, 161-169).

Accordingly, the fraud on the FDA concerning a portion of the Class Period in 2008, as now alleged in the SAC, contradicts one of the fundamental bases for which the District Court dismissed the Complaint: that Defendants had no duty to disclose because the information had been made available to the FDA. (ADDM-22). The District Court did not consider this in denying leave to amend. (ADDM-32). *Jurimex*, 65 F. App'x at 807 ("District Court committed legal error by failing to consider the effects of certain factual pleadings" in denying leave to file amended complaint). Accordingly, the Court below erred in denying leave to replead on the basis that it would be futile.

4. Plaintiffs Had Never Sought Leave To Amend Before

The District Court also should be reversed because Plaintiffs had never sought leave to amend prior to filing the SAC. The Order was the first decision on the sufficiency of the pleadings. *See Bryant v. Dupree*, 252 F.3d 1161, 1163 (11th Cir. 2001) (in securities class action, "the Amended Complaint was filed as a matter of course, and until the renewed motion to dismiss came before the court, the plaintiffs had not asked for leave to amend. Therefore, it cannot be said that the plaintiffs already had been given an opportunity to amend or that the plaintiffs repeatedly had failed to cure deficiencies through previously allowed amendments").

CONCLUSION

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

Dated: January 6, 2011

Respectfully submitted,

LABATON SUCHAROW LLP

By /s/ Javier Bleichmar
Christopher J. Keller
Javier Bleichmar
Joseph A. Fonti
Stephen W. Tountas
Alan I. Ellman
140 Broadway
New York, New York 10005
(212) 907-0700

OSBURN, HINE, YATES & MURPHY, L.L.C.

By /s/ Ted R. Osburn
Ted R. Osburn
Jason G. Crowell
Michael D. Murphy
3071 Lexington Avenue
Cape Girardeau, Missouri 63701
(573) 651-9000

Attorneys for Plaintiffs-Appellants

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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 13,742 words (excluding, as permitted by Fed. R. App. P. 32(a)(7)(B), the corporate disclosure statement, table of contents, table of authorities, and certificate of compliance), as counted by the Microsoft Word program used to produce this brief.

Dated: January 6, 2011

/s/ Javier Bleichmar
Javier Bleichmar

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/s/ Javier Bleichmar
Javier Bleichmar