10-3402

United States Court of Appeals

FOR THE EIGHTH CIRCUIT

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

Plaintiffs-Plaintiffs,

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 DEFENDANT-APPELLEE MARC S. HERMELIN

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SUMMARY OF THE CASE

Plaintiffs' Complaint sought to hold Marc S. Hermelin, former CEO of KV Pharmaceutical Company ("KV" or "the Company"), liable for securities fraud based on allegations that the Company failed to disclose alleged material non-compliance with current Good Manufacturing Practices ("cGMP") regulations established by the Food and Drug Administration ("FDA"), the Company's alleged failure to predict and disclose years earlier the shutdown of its manufacturing operations in early 2009, and the Company's publication of accurate financial results that did not reference alleged regulatory issues.

The District Court dismissed the Complaint with prejudice, holding that 1) the Complaint failed to allege with particularity why the Company's compliance statements were false or misleading, 2) the Complaint failed to allege with particularity why the financial results were misleading, 3) Mr. Hermelin had no duty to disclose the FDA inspection reports in question, and 4) the Complaint failed to allege that Mr. Hermelin engaged in an actionable "scheme to defraud."

Plaintiffs challenge the first three of these holdings, but not the fourth. Plaintiffs also challenge the District Court's denial of their post-judgment motion requesting vacatur of the judgment and permission to amend.

Because of the number and complexity of the legal issues presented here, Mr. Hermelin respectfully requests 30 minutes per side for oral argument.

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STATEMENT OF FACTS

A. The Allegedly False Statements and Omissions.

The affirmative statements Plaintiffs allege to be materially false can be divided into two categories: 1) statements regarding the Company's compliance with cGMP ("Material Compliance Statements"); and 2) statements regarding the Company's financial performance ("Financial Performance Statements").

As to the former, Plaintiffs allege that statements in the Company's annual Form 10-K filings regarding the belief that the Company's facilities were, *at the time the statements were made*, "in material compliance with all applicable regulations," and that the Company was, *at the time the statements were made*, "in material compliance with cGMP" and "registered with appropriate agencies" were false and misleading.

Regarding the latter, the crux of these allegations appears to be that financial results reported for various quarters during the class period—specifically, November 20, 2007; February 15, 2008; May 30, 2008; and August 11, 2008—were materially false and misleading because, according to Plaintiffs, the reports should have included manufacturing process observations regarding the drug Metoprolol contained in an FDA inspection report (known as a "Form 483") issued

to the Company on **February 2, 2009**. Appendix ("App.") at A-103-08 (Complaint ¶¶ 107-110, 112-113, 115-116).[1]

As for material omissions, Plaintiffs allege that Defendants failed to disclose the Form 483s and the allegedly "foreseeable risk that [KV's] known – yet undisclosed – FDA violations would cause a complete shutdown of the Company's manufacturing operations." App. at A-71 (Complaint ¶ 12).

B. The District Court's Dismissal of the Complaint.

In his motion to dismiss, Mr. Hermelin argued to the District Court that Plaintiffs failed to state a claim under which relief could be granted for several reasons. First, he argued that Plaintiffs failed adequately to allege that the Material Compliance Statements were false because the Form 483s, which were the sole basis for Plaintiffs' falsity allegations, were merely "inspectional observations" made by the FDA and not findings of material non-compliance with cGMP.

Second, Mr. Hermelin argued that Plaintiffs inadequately pleaded falsity as to the Financial Performance Statements because such statements were merely reports of historical financial information regarding Metoprolol, the accuracy of

[1] *See* Exs. 1(a) and 2(a) to Defendant Marc S. Hermelin's Memorandum in Support of His Motion to Dismiss Plaintiff's Consolidated Amended Complaint ("Hermelin Mot. Dismiss") (setting forth the individual statements falling into each of these two categories).

which had not been challenged by Plaintiffs and did not relate to the Company's manufacturing processes regarding that drug.

Third, Mr. Hermelin argued that he had no duty to disclose the Form 483s because 1) as merely inspectional observations, the Form 483s and their content, as alleged in the Complaint, were not material as a matter of law, and 2) the Form 483s were publicly available from the FDA through the Freedom of Information Act ("FOIA"), and therefore were already part of the "total mix of information" in the market, *see Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988) (citation omitted).

Fourth, Mr. Hermelin argued that Plaintiffs' claim that he engaged in a "scheme to defraud" was not actionable because Plaintiffs failed to allege a scheme independent from the making of the alleged misstatements and omissions.

Fifth, Mr. Hermelin argued that Plaintiffs failed to allege facts giving rise to strong inference of scienter on his part under *Tellabs v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007).

Sixth, and finally, Mr. Hermelin argued that Plaintiffs failed to plead loss causation because the alleged corrective disclosures had no factual connection to the alleged misstatements and omissions.

After full briefing by the parties, the District Court granted Mr. Hermelin's motion in its entirety. *See Pub. Pension Fund Group v. KV Pharm. Co.*, 705

F. Supp. 2d 1088 (E.D. Mo. 2010). As set forth in its opinion, the District Court agreed that Plaintiffs' falsity allegations as to the Company's public statements were wanting because the allegations were based solely on the Form 483s, which—given both the Forms' clear language and the regulatory history of that language—indicate only that their findings are "inspectional observations" and not ones of material non-compliance with cGMP. *See id*. at 1100.

The court also concluded that the falsity allegations as to the Financial Performance Statements were inadequate because "KV chose only to speak about the financial status of the company" and therefore was "'not required to dump all known information'" about its manufacturing and regulatory issues and because, in any event, the Complaint did not allege that "the figures reported in the financial statements were false and misleading." *Id*. at 1102.

The court also held that the omission allegations against Mr. Hermelin were deficient, concluding that "[b]ecause the Form 483s that FDA issued to KV from 2003 through 2008 were readily accessible to the public by submitting a request to FDA, . . . KV and Hermelin were under no duty to disclose these documents." *Id*. at 1104.

The District Court further held that the "scheme" allegations against Mr. Hermelin were not actionable because "lead Plaintiffs have failed to allege that KV and Hermelin engaged in a scheme or course of conduct distinct and independent

from the alleged misrepresentations and omissions regarding KV's cGMP compliance and the Form 483s." *Id*. at 1105.

The District Court dismissed Plaintiffs' case with prejudice on these legal grounds and did not reach Mr. Hermelin's scienter and loss causation arguments.

C. The District Court's Denial of Plaintiffs' Post-Judgment Motion.

On March 18, 2010, approximately three weeks after the District Court entered its order of dismissal, Plaintiffs filed a post-judgment motion under Federal Rules of Civil Procedure 59(e) and 60(b)(2) requesting vacatur of the judgment and permission to file their proposed second amended complaint. They based this motion on what they characterized as "newly-discovered evidence." [2]

First, they argued that the criminal information and plea agreement relating to a recent guilty plea by ETHEX, a subsidiary of KV, showed that Mr. Hermelin was aware of instances of material non-compliance with cGMP and therefore knew of the falsity of the Material Compliance Statements, notwithstanding the fact that 1) the allegations in the information never once mention Mr. Hermelin's name and 2) the conduct in question occurred after all (but one) of the public statements at issue.

[2] Plaintiffs' proposed second amended complaint also added an additional allegedly false statement.

Plaintiffs also submitted with their motion affidavits from two purported experts offering opinions that, contrary to the District Court's decision, Form 483s in fact do constitute findings of non-compliance with cGMP and in fact are not publicly available through FOIA.

In a written opinion, the District Court denied Plaintiffs' motion, holding that the ETHEX information and plea agreement did not constitute "newly-discovered evidence" as required for relief under Rules 59(e) and 60(b)(2) and that the additional information presented by Plaintiffs in any event would not have altered the Court's decision. *See* App. at A-1052-53 (Order).

Plaintiffs here appeal both the District Court's judgment of dismissal and its denial of their post-judgment motion.

SUMMARY OF ARGUMENT

At its core, this is a pharmaceutical regulatory matter in the guise of a securities fraud class action. Indeed, Plaintiffs themselves admit that "[t]he central allegation in this securities class action is that Defendants knowingly manufactured adulterated drugs, despite FDA's continuous warnings of regulatory noncompliance." Plaintiffs-Appellants' Brief ("Aplts. Br.") at 3. That is not an allegation sounding in securities fraud.

Thus, as they tried and failed to do below, Plaintiffs seek to transform such an allegation into actionable securities fraud by pointing almost exclusively to the

issuance by the FDA of a series of Form 483s over a number of years containing observations from the FDA's inspection of KV's facilities and its manufacturing processes. Plaintiffs allege that the information contained in these Form 483 inspection reports rendered as false and misleading KV's and Mr. Hermelin's public representations regarding their belief that KV was in material compliance with cGMP, and further allege that KV and Mr. Hermelin should therefore have disclosed the reports to the public.

The fatal flaw in this attempted bootstrap may be found in the plain terms of the Form 483s themselves, all of which state:

> This document lists observations made by FDA representative(s) during the inspection of your facility. ***They are inspectional observations, and do not represent a final Agency determination regarding your compliance.***

App. at A-152 (emphasis added). Plaintiffs' distorted characterization of these Form 483s also flies in the face of clear evidence of the FDA's purpose in including the standard language above on all Form 483s: to avoid "inaccurate

conclusions about the compliance status of an inspected firm,"[3] and to "decrease[] the likelihood that inspectional observations will be misused or misunderstood."[4]

Simply stated, a putative securities fraud class action premised—like this one—on distorting and mischaracterizing the purpose and import of these inspection reports is precisely the kind of misuse the FDA sought to preclude. Moreover, all of these Form 483s were publicly available and therefore already within the total mix of information available to investors, thereby obviating any duty on the part of Mr. Hermelin to disclose these reports (again) to the public. The District Court aptly recognized these fatal pleading defects and correctly dismissed the Complaint with prejudice.

In a strained attempt to revive their case after its dismissal, Plaintiffs subsequently filed a post-judgment motion touting certain "newly-discovered evidence" as warranting a vacatur of the judgment, including 1) a criminal plea charging ETHEX, a subsidiary of KV, with two violations of an FDA filing requirement under the Food, Drug & Cosmetic Act and 2) affidavits from two

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[3] FDA, *Progress Report of the 483 Communications Working Group*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/QuestionsandAnswersonCurrentGoodManufacturingPracticescGMPforDrugs/ucm072012.htm (last visited Mar. 5, 2011).

[4] FDA, *Pharmaceutical cGMPs for the 21st Century: Questions and Answers*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/QuestionsandAnswersonCurrentGoodManufacturingPracticescGMPforDrugs/ucm072062.htm (last visited Mar. 5, 2011).

"experts" whose opinions regarding the import of the Form 483s and their public availability were somehow meant to show the District Court's decision to be in error. These facts, however, were not "newly discovered." Indeed, most of the facts underlying the ETHEX plea were included in the Complaint, and in any event none had any bearing on the basis for dismissal. Thus, the District Court rightly denied this motion as well.

This Court should thus affirm the District Court's judgment of dismissal for at least the three reasons addressed by the District Court:

First, as the District Court concluded, Plaintiffs' Complaint failed adequately to plead that the Material Compliance Statements were false or misleading. The Form 483s, the sole basis for Plaintiffs' falsity allegations, expressly disavow, consistent with the FDA's regulatory intent, any finding of material non-compliance with cGMP. This conclusion is bolstered by Plaintiffs' inability to allege that the FDA ever took any advisory or enforcement action in response to these Form 483s during the class period. And it is confirmed by the context in which such statements were made, including the cautionary language that surrounded them and the public availability of the Form 483s themselves.

Second, as the District Court also concluded, Plaintiffs' Complaint failed adequately to plead that the Financial Performance Statements (which reported revenue from Metoprolol sales) were false or misleading, because those statements

had nothing to do with the Company's *manufacturing practices* relating to Metoprolol, and thus were not rendered false by Mr. Hermelin's non-disclosure of inspectional observations purportedly relating to such practices. In addition, virtually all of the inspectional observations relating to Metoprolol implicated time periods that were months or years *after* the Financial Performance Statements were made, and therefore do not speak to the state of those practices, or any Defendant's knowledge of them, at the time those statements were made.

Third, as the District Court further concluded, Plaintiffs' Complaint failed to allege facts sufficient to establish that Mr. Hermelin had any duty to disclose the Form 483s, because they were already public available and therefore in the total mix of information available to investors. In addition, no such duty arose because, as the vast majority of courts addressing this issue have held, the Form 483s and their content as alleged in the Complaint are not material as a matter of law.[5]

There are also two bases for affirmance not addressed by the District Court. First, the allegations in the Complaint fail to satisfy the heightened standards for pleading scienter under *Tellabs v. Makor Rights & Issues, Ltd.*, 551 U.S. 308, 324 (2007). It alleges no specific facts that would raise a strong inference that Mr. Hermelin made the alleged false statements and omissions with actual knowledge

[5] Plaintiffs have not sought appeal of the District Court's dismissal of claims against Mr. Hermelin under Rule 10b-5(a) and (c). Accordingly, the Court should affirm the dismissal of those claims as well.

of, or recklessness in regard to, their falsity. Second, they also fail adequately to allege loss causation, because the purported "corrective disclosures" Plaintiffs have identified are not sufficiently related to the statements and omissions they allege to be false.[6]

The Court should also affirm the District Court's denial of Plaintiffs' post-judgment motion under Rule 59(e) and 60(b)(2), including its request for permission to amend pursuant to Rule 15, for at least two reasons.

First, the evidence on which Plaintiffs base their motion—the criminal information and plea agreement entered into by ETHEX, a subsidiary of KV, and affidavits from two purported experts—does not constitute newly-discovered evidence and in any event would not have affected the District Court's decision, as Rules 59(e) and 60(b)(2) require. Second, Plaintiffs' request to amend was properly denied as futile because none of the new allegations in the proposed complaint would have altered the District Court's legal conclusions, specifically that: 1) the Form 483s were not findings of material non-compliance with cGMP; 2) the Financial Performance Statements were not false or misleading; and 3) Mr. Hermelin had no duty to disclose information that was already publicly available.

[6] For these reasons, the Court should likewise affirm the district Court's dismissal of Plaintiffs' claims against Mr. Hermelin under Section 20 of the Exchange Act.

ARGUMENT

Securities and Exchange Commission Rule 10b-5, promulgated under Section 10(b) of the Securities Exchange Act of 1934, provides that it is unlawful for any person, directly or indirectly,

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,

in connection with the purchase or sale of any security. 17 C.F.R. § 240.10b-5 (2009). Accordingly, to plead an actionable private securities fraud claim under Section 10(b) and Rule 10b-5, Plaintiffs must sufficiently allege facts satisfying six requisite elements: "(1) a material misrepresentation (or omission); (2) scienter, *i.e.*, a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance, often referred to in cases involving public securities markets (fraud-on-the-market cases) as 'transaction causation'; (5) economic loss; and (6) 'loss causation,' *i.e.*, a causal connection between the material misrepresentation and the loss." *Horizon Asset Mgmt. Inc. v. H&R Block, Inc.*, 580 F.3d 755, 760 (8th Cir. 2009) (citations omitted); *see also Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008).

Allegations of securities fraud under Rule 10b-5 are subject to heightened pleading requirements under Rule 9(b) of the Federal Rules of Civil Procedure, the Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737 (1995) ("PSLRA"), and case law construing both. Rule 9(b) provides that, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Mere "'conclusory allegations' do not satisfy the pleading requirements of Rule 9(b)." *In re K-Tel Int'l, Inc. Sec. Litig.*, 300 F.3d 881, 894 (8th Cir. 2002) (citations omitted). Instead, the Rule demands that "the claim must identify who, what, where, when, and how." *United States ex rel. Costner v. United States*, 317 F.3d 883, 888 (8th Cir. 2003).

In addition, such allegations are also subject to the even more exacting standards of the PSLRA, which was enacted by Congress in 1995 to curb the abuses of meritless securities fraud litigation. *See In re K-Tel Int'l*, 300 F.3d at 889; *In re Navarre Corp. Sec. Litig.*, 299 F.3d 735, 741 (8th Cir. 2002); *see also* 15 U.S.C. § 78u-4(b) (2006). The PSLRA demands that, to survive dismissal, a complaint must "specify each statement alleged to have been misleading" and identify "the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1) (2006).

Finally, although well-pleaded factual allegations must be presumed true for purposes of a motion to dismiss, *see, e.g.*, *Katun Corp. v. Clarke*, 484 F.3d 972, 975 (8th Cir. 2007), "unwarranted inferences and conclusory or catch-all assertions of law" cannot shield a complaint from dismissal. *Elam v. Neidorff*, 544 F.3d 921, 926 (8th Cir. 2008) (citation omitted).

I. THE DISTRICT COURT CORRECTLY HELD THAT PLAINTIFFS FAILED ADEQUATELY TO ALLEGE FALSITY.

Plaintiffs' primary challenge on appeal is that the District Court erred in dismissing the Complaint because it incorrectly held that the Complaint failed adequately to allege that the Material Compliance Statements and Financial Performance Statements were false or misleading at the time they were made. For the reasons set forth below, Plaintiffs' arguments are unavailing, and the District Court's dismissal of the Complaint should be affirmed.

A. Plaintiffs Fail Adequately to Allege that the Material Compliance Statements Were Materially False or Misleading.

As the District Court correctly concluded, Plaintiffs' falsity allegations as to the Material Compliance Statements—which are based solely on the premise that the Form 483s contemporaneously issued by the FDA uncontrovertibly demonstrate material cGMP non-compliance—simply do not satisfy the strict pleading requirements under Rule 9(b) and the PSLRA. *See KV Pharm. Co.*, 705 F. Supp. 2d at 1100. Nor could those allegations ever do so because, for at least

four independent reasons, there exists no set of facts that could render the statements false or misleading.

1. Form 483s Are Not Evidence of Non-Compliance with cGMP, Material or Otherwise.

Plaintiffs' entire theory of liability hinges on a series of Form 483s issued to the Company on a periodic basis throughout the class period, which they assert were evidence of material cGMP non-compliance and thus render the Material Compliance Statements false or misleading when made. As the District Court recognized, however, the problem with this theory is that the Form 483s—both on their face and as a matter of law—are not findings of material non-compliance with cGMP and therefore cannot establish that Material Compliance Statements were false or misleading at the time they were made. *See KV Pharm. Co.*, 705 F. Supp. 2d at 1100.

One need only read the explanatory language included on the face of all Form 483s, including the report attached to the Complaint, to conclude that the Form 483s *do not* implicate a company's compliance status:

> This document lists observations by the FDA representative(s) during the inspection of your facility. ***They are inspectional observations, and do not represent a final Agency determination regarding your compliance.*** If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above.

App. at A-152 (emphasis added). In light of this clear and unambiguous language, nothing about the observations in these inspection reports renders false or misleading the Company's Material Compliance Statements. Plaintiffs' bald assertions to the contrary must therefore be rejected outright on this ground alone.

The regulatory history behind the language only reinforces this conclusion. As emphasized by the District Court, the standard language on all Form 483s disavowing any conclusion of non-compliance is the result of an effort by the FDA nearly a decade ago to bring increased transparency to the pharmaceutical industry's manufacturing practices. *See KV Pharm. Co.*, 705 F. Supp. 2d at 1100. In 2002, the FDA taskforce charged with this mission made clear its basis for adding this standard language to all Form 483s:

> A conclusion was that the purpose and legal intent of the 483 as well as the Agency's process for developing and issuing it may be unclear to some inspected entities and the public. ***Because such perceived ambiguity may result in inaccurate conclusions about the compliance status of an inspected firm,*** both by the firm itself and by those seeking information through the FOI process, the group developed additional standard language to be provided to a sponsor along with the form.

FDA, *supra* note 3 (emphasis added).

In response, the FDA adopted the relevant language in its Form 483s to clarify that Form 483s do not address the compliance status of the recipient company. *See id*. Indeed, a "Q&A" guidance document issued by the FDA after the adoption of the new language provides further insight into its purpose:

> 13. What reaction does FDA anticipate in response to the added language clarifying the status of observations on the FDA Form 483?
>
> We anticipate a positive reaction because it clarifies what the document represents. For the firm undergoing inspection, it illustrates that the Agency has a regulatory process and the FDA-483 is only one aspect of that process. ***Further, it decreases the likelihood that inspectional observations will be misused or misunderstood.***
>
> 14. Is this effort in response to industry complaints about how the press and public perceive the FDA Form 483 they obtain through the FOIA process?
>
> The external and internal interviews we conducted ***demonstrated a general lack of understanding as to what the FDA Form 483 represents. It is only one piece of the overall inspection process that the Agency employs to make its decisions on the compliance status of the inspected firm.***

FDA, *supra* note 4 (emphases added). The imposition of liability proposed by Plaintiffs here is precisely the kind of "misuse or misunderstanding" the FDA sought to foreclose by adding this clarifying language in 2003.

In keeping with the express regulatory purpose of this language, federal courts have consistently held that Form 483s are merely inspectional observations and are not determinations by the FDA as to a company's compliance status.[7]

[7] *See, e.g.*, *McGuire v. Dendreon Corp.*, No. C07-800MJP, 2008 U.S. Dist. LEXIS 65436, at *23-24 (W.D. Wash. Apr. 18, 2008) ("*Dendreon I*") ("Plaintiffs inappropriately conflate the [] inspection and issuance of a Form 483 with a finding of non-compliance" because "the Form 483 is not a final agency determination of non-compliance"); *Plus, LLC v. Arch Pers. Care Prods., L.P.*, No. 10-3089 (WJM), 2010 U.S. Dist. LEXIS 124055, at *9 n.2 (D.N.J. Nov. 23, 2010) ("FDA Form 483s are essentially forms completed by the FDA upon an inspection of a facility. These forms identify the agency's 'observations' and concerns that result from a given inspection and/or audit. An inspected company

Indeed, we have found no case, and Plaintiffs fail to cite any authority, holding that Form 483s constitute an official finding of non-compliance by the FDA in any respect, much less *material* non-compliance.

Nevertheless, Plaintiffs persist on appeal in their insupportable view that the Form 483 observations at issue were actually formal "violations" and accuse the District Court of making unsupported "semantic distinctions." Aplts. Br. at 31. But the distinction here is neither semantic nor of the District Court's making. Rather, it is a distinction appearing on the face of the Form 483s themselves in express terms and one deliberately drawn by the FDA itself to "avoid inaccurate conclusions about the compliance status of an inspected firm."

Plaintiffs' selective and misleading citation to the FDA's Investigations Operations Manual ("IOM"), if anything, provides further support for the District

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has an opportunity to respond to a FDA Form 483.") (internal record citations omitted); *United States v. Utah Med. Prods., Inc.*, 404 F. Supp. 2d 1315, 1318 (D. Utah 2005) ("A Form FDA-483 is a list of concerns observed by an FDA inspector during the course of an inspection. The investigator's observations are subject to review and response by the Company and are further reviewed by other FDA personnel before the FDA makes a decision whether it believes the Company complies with applicable law and regulations."); *Fujisawa Pharm. Co. v. Kapoor*, 16 F. Supp. 2d 941, 943 (N.D. Ill. 1998) ("Form 483s list observations made by an FDA inspector during an inspection of a plant. When a company receives a 483, it usually submits a written response to the FDA disputing or explaining the inspector's observations, or promising to correct the problem if the company agrees that it exists. Ordinarily, if the FDA finds the company's response acceptable, the FDA will take no further action."); *United States v. Union Cheese Co.*, 902 F. Supp. 778, 780 n.1 (N.D. Ohio 1995) ("A Form 483 is a written summary of observations made by the inspector.").

Court's conclusion. Their excessive dissection of a single statement in the IOM purporting to equate observed "conditions" identified in Form 483s with "violations" is belied by clear language appearing elsewhere in the IOM. For example, the IOM expressly directs that Form 483 observations should include observations indicating not only actual problems but also "potential" problems. *See* App. at A-514 (IOM § 5.2.3.1.4) (noting that reportable observations "should be significant and relate to an observed *or potential* problem with the facility, equipment, processes, controls, products, employee practices, or records") (emphasis added); *accord id.* at A-513 (IOM § 5.2.3) (noting that Form 483 observations are made "when in the Investigator's 'judgment' conditions or practices observed indicate that any . . . drug . . . [is] being prepared, packed or held under conditions whereby they *may* become adulterated or rendered injurious to health") (emphasis added).

And, more critically, the IOM expressly directs the FDA inspectors not to characterize conditions as "violative" in Form 483s because "[t]he determination of whether any condition is violative ***is an agency decision made after considering all circumstances, facts and evidence***." *Id.* at A-516 (IOM § 5.2.3.3) (emphasis added). Plaintiffs' transparent attempts to sidestep the limited reach of the Form 483s cannot withstand even minimal scrutiny.

Plaintiffs also argue that it does not matter whether the Form 483s constituted a final determination of the Company's compliance status because the Company "expressed a desire to correct the deficiencies" noted in the inspection reports and therefore "accepted the Form 483s as violations" and effectively waived any future objection that their findings were not violations. Aplts. Br. at 34. This argument is absurd. An expressed desire by the Company to correct any deficiencies observed during routine inspections does not magically transform the Company's or Mr. Hermelin's state of mind into an awareness of material non-compliance with cGMP any more than it transforms the observations contained in the Form 483s themselves into findings of material non-compliance by the FDA, especially given that the FDA itself expressly stated following each inspection that the reports *do not* represent such a finding.

Finally, and in troubling fashion, Plaintiffs attempt to mislead this Court by citing language from the FDA Complaint (filed in 2009) to suggest that KV was, in fact, "informed of its 'noncompliance'" during years before the FDA Complaint was actually filed. Aplts. Br. at 29 ("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.") (emphasis added). Of course, it is not only implausible, but impossible, that any of the Material Compliance Statements made from 2004 through 2008 were made

"subsequent" to the filing of the FDA Complaint in 2009, and Appellant's shameless suggestion to the contrary should be rejected out of hand. The bottom line remains—and Plaintiffs know full well—that Defendants were *never* advised by the FDA that they were out of material compliance following the FDA's inspections throughout the class period for the simple fact that the KV was *never* out of material compliance.

2. There Is No Allegation That the FDA Took Any Action in the Wake of Any Particular Form 483 During the Class Period.

Beyond their *ipse dixit* that "observations" are really "violations," Plaintiffs fail to allege any actual fact to establish that these observations rose to the level of material violations of cGMP, let alone that Mr. Hermelin was aware of or recklessly disregarded any such material violation. In particular, there is a glaring absence of any allegation in the Complaint that the FDA took any advisory or enforcement action against the Company during the class period as a result of these observations. That is because the FDA never took any such action. The Complaint's ringing and inescapable silence as to any advisory or enforcement actions by the FDA in the face of six Form 483s over a span of five years only strengthens the strong inference that the FDA's inspectional observations did not constitute findings of material cGMP non-compliance and that the Form 483s

cannot support Plaintiffs' allegations that the Material Compliance Statements were false and misleading.

When FDA inspections result in the issuance of a Form 483, the subject company has the option to respond to the observations contained in the Form. If the FDA "finds the company's response unacceptable, the FDA may take further action such as the issuance of a regulatory letter." *Fujisawa Pharm.*, 16 F. Supp. 2d at 943; *see also Utah Med. Prods.*, 404 F. Supp. 2d at 1318 ("A Form FDA-483 is a list of concerns observed by an FDA inspector during the course of an inspection. The investigator's observations are subject to review and response by the Company and are further reviewed by other FDA personnel before the FDA makes a decision whether it believes the Company complies with applicable law and regulations."). Only when issues rise to the level of "*regulatory significance*" does the FDA issue a "warning letter," which constitutes "advisory action" and is "the agency's principal means of achieving prompt voluntary compliance." App. at A-653 (FDA Regulatory Procedures Manual (Ch. 4) at 4-1, 4-2 (March 2009)).

Despite its exclusive reliance on six different Form 483s received by the Company during the class period, Plaintiffs do not—and cannot—allege that the FDA took *any action whatsoever* in response to the inspectional observations. The FDA never issued a warning letter or pursued more formal enforcement action against the Company during the class period, and the Complaint does not allege

otherwise. Plainly, the fact that the FDA did not consider the observations in the Form 483s as having sufficient "regulatory significance" to require any enforcement or even advisory action against KV negates any inference drawn from the Form 483s that the Material Compliance Statements were false or misleading when made.

3. Plaintiffs Fail to Plead Facts Establishing That the Conditions Identified in the Form 483s Persisted at the Time the Material Compliance Statements Were Made.

Even assuming *arguendo* that the Form 483s somehow signaled that the Company was out of material compliance with cGMP at the time of each Report's issuance, Plaintiffs have failed to allege any contemporaneous facts supporting an inference that the Company remained out of compliance *at the time the Material Compliance Statements were made*, which in every case was several months after the preceding Form 483. This temporal disconnect is itself fatal to Plaintiffs' falsity claims. *See In re K-Tel Int'l*, 300 F.3d at 891 ("[The] Appellant must set forth . . . an explanation as to why the disputed statement was untrue or misleading *when made*.") (citations omitted & emphasis added); *In re Cerner Corp. Sec. Litig.*, 425 F.3d 1079, 1083 (8th Cir. 2005) ("[T]he complaint must indicate why the alleged misstatements 'would have been false or misleading at the several points in time in which it is alleged they were made.'") (quoting *Navarre*, 299 F.3d at 743).

Rather than pointing to any specific facts at or even around the time that each Material Compliance Statement was made, Plaintiffs instead seek to impute falsity upon the statements solely on the basis of a preceding Form 483, which in all instances was issued several months prior.[8] As the District Court concluded, Plaintiffs' non-contemporaneous allegations are insufficient to establish that the Material Compliance Statements were false *when made*. *See KV Pharm. Co.*, 705 F. Supp. 2d at 1100.

Plaintiffs attempt to bridge this temporal gap by asserting in boilerplate fashion that in each of these instances, "[d]espite Defendants' assurances to FDA that the cGMP violations would be rectified after each of the Forms 483 were issued, the Defendants had not resolved the cGMP violations by the time" each of the subsequent Material Compliance Statements was issued. App. at 101-08 (Complaint ¶¶ 104-06, 111, 114). But these conclusory recitations are unsupported by any factual allegations, and the more likely inference to be drawn from the facts alleged—particularly in light of the absence of any corresponding FDA advisory or enforcement actions—is that the Company subsequently discussed with the observations with the FDA and resolved the issue promptly, thereby avoiding any

[8] The Complaint reveals that for each of the cGMP Compliance Statements, the Form 483s nearest in time were 13 months and five months prior, six months prior, three months prior, 11 months prior, and three months prior, in chronological order. App. at A-100-108 (Complaint ¶¶ 102-14).

enforcement action. *See* App. at A-653-54 (FDA Regulatory Procedures Manual); *see also Fujisawa Pharm.*, 16 F. Supp. 2d at 943; *Utah Med. Prods.*, 404 F. Supp. 2d at 1318. Indeed, Plaintiffs acknowledge that the Company sought immediately to remedy any potential deficiencies observed during the inspections (Aplts. Br. at 34), yet fail to set forth any allegations demonstrating that the potential deficiencies were still in existence months later when the Material Compliance Statements were made.

Unarmed with any facts supporting the inference that material cGMP violations were occurring at KV at the time the Material Compliance Statements were made, Plaintiffs attempt to distort the findings in each referenced Form 483 by taking the FDA's findings in February and March of 2009 and extrapolating them backward in time over a six-year period. Specifically, Plaintiffs point to the FDA Complaint and Consent Decree executed in February and March 2009, respectively. *See* Aplts. Br. at 29-32, 37; App. at A-78-79, 99 (Complaint ¶¶ 38-39, 98-99). But these documents do not begin to demonstrate, with the particularity required under the PSLRA, that the Material Compliance Statements were false or misleading at the time they were made.

As to the FDA Complaint, Plaintiffs focus on the statement that the Company's regulatory issues as of February 2009 were "the same as, or similar to, prior violations observed by FDA at several other inspections conducted during the

last eight years." App. at A-78-79 (Complaint ¶ 38). But such a self-serving, vague, conclusory, and retrospective statement sheds no light on the truth or falsity of the Company's Material Compliance Statements at the time they were made. This statement does not identify with specificity what the prior violations were, whether and when they were previously resolved and had recurred in 2009, or whether any of the violations constituted *material* non-compliance with FDA regulations.

As to the Consent Decree, Plaintiffs point to the provision requiring that "Defendants report to FDA in writing the actions they have taken to: (1) Correct the cGMP *deviations* brought to Defendants' attention by FDA since January 1, 2005." App. at A-99 (Complaint ¶ 99) (emphasis added). Again, this statement adds nothing to Plaintiffs' allegations as to the falsity of the Material Compliance Statements. Rather, the statement refers only to "cGMP *deviations*" that the Defendants agreed to remedy as part of the Consent Decree. The fact that the signatories to the Decree had agreed to remedy these deviations does not establish that those "deviations" are *material cGMP violations* let alone that any other such deviation existed or was ongoing at the time the Material Compliance Statements were made.

Finally, Plaintiffs' reliance on Mr. Hermelin's signing the Consent Decree as an admission by him is flatly contradicted by an express provision stating that the

signatories to the Decree do not "admit[] or deny[] the allegations in the Complaint," App. at A-191, as well as the provision stating that "the provisions of this Decree . . . shall not apply to Defendant Marc S. Hermelin." App. at A-212; *see also KV Pharm. Co.*, 705 F. Supp. 2d at 1100.

Simply stated, Plaintiffs' retroactive extrapolation of the FDA's statements in 2009 backwards in time over a six-year period is classic "fraud by hindsight," which is never actionable under the federal securities laws. *See In re K-Tel Int'l*, 300 F.3d at 891; *Navarre*, 299 F.3d at 742.[9] The reason for this prohibition is clear—even if it could be shown that in early 2009 the FDA concluded that the Company had failed adequately to correct various observations from the FDA inspections, that conclusion has no bearing on whether the Company's statements of belief that it was in material compliance were false or misleading *at the time those statements were made*.[10]

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[9] *See also Florida State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 645, 662 (8th Cir. 2001) ("we cannot countenance pleading fraud by hindsight"); *Elam*, 544 F.3d at 927 (finding no fraud where allegations lacked contemporaneous reports).

[10] *See, e.g., Reding v. Goldman Sachs & Co.*, 382 F. Supp. 2d 1112, 1124 (E.D. Mo. 2005) (holding that consent order involves alleged rule violations, not fraud, and "cannot be used to demonstrate knowledge by hindsight or by psychic ability"); *see also In re Discovery Labs. Sec. Litig.*, No. 06-1820, 2007 U.S. Dist. LEXIS 18163, at *17 (E.D. Pa. Mar. 15, 2007) ("The fact that, more than two years later Discovery has not been able to remedy the problems [in the 483], also does not make the earlier statements false or misleading . . . . This is what Judge Friendly memorably referred to as 'fraud by hindsight.' . . . We cannot hold

4. The Material Compliance Statements Were Not False or Misleading in Light of the Cautionary Context in Which They Were Made.

It is a well-settled principle of securities law that a statement is not false or misleading as a matter of law "if no reasonable investor could conclude public statements, *taken together and in context*, were misleading." *In re K-Tel Int'l*, 300 F.3d at 897 (citation omitted) (emphasis added). In other words, the "central issue is . . . whether defendants' representations, *taken together and in context*, would have misled a reasonable investor." *In re NVE Corp. Sec. Litig.*, 551 F. Supp. 2d 871, 881 (D. Minn. 2007) (alteration in original) (quotation marks and citation omitted) (emphasis added), *aff'd*, 527 F.3d 749 (8th Cir. 2008); *accord In re Trex Co., Inc. Sec. Litig.*, 454 F. Supp. 2d 560, 588-89 (W.D. Va. 2006) (concluding that, when presented with allegedly false statements "read in context with other statements and information made available to the investing public, no reasonable investor could have been misled").

In addition to the multiple deficiencies in Plaintiffs' falsity allegations as to the Material Compliance Statements discussed above, the context in which those statements were made further confirms that they were not false or misleading to the reasonable investor. That context includes both a) the cautionary language

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defendants liable because they read that report in much the same way as the FDA did and remained optimistic that the problems could be timely resolved. Statement 178 is, therefore, not materially false or misleading.") (citation omitted).

accompanying the statements in the SEC filings, and b) the Form 483s themselves, which were also publicly available.

a. Accompanying Statements in the Company's SEC Filings Warned of the Potential for Future Findings of cGMP Problems.

No reasonable investor could interpret the Material Compliance Statements to exclude or to minimize the risk of non-compliance with cGMP because such risk was clearly disclosed in language accompanying those statements. In each 10-K filing, alongside the Company's statement regarding cGMP compliance, the Company disclosed the risks associated with non-compliance and that it could not guarantee compliance going forward:

> All pharmaceutical companies, including us, are subject to extensive, complex, costly and evolving regulation by the federal government, principally the FDA . . . . Failure to comply with applicable FDA or other regulatory requirements may result in criminal prosecution, civil penalties, injunctions, recall or seizure of products and total or partial suspension of production, as well as other regulatory actions against our products and us.
>
> * * *
>
> We are currently in material compliance with cGMP and are registered with the appropriate agencies. Non-compliance with applicable cGMP requirements or the rules and regulations of these agencies can result in fines, recall or seizure of products, total or partial suspension of production and/or distribution, refusal of government agencies to grant pre-market approval or other product applications and criminal prosecution. Despite our ongoing efforts, cGMP requirements and other regulatory requirements, and related enforcement priorities and policies may evolve over time and we may not be able to remain continuously in material compliance with all of these requirements.

App. at A-267 (excerpt from 2004 Form 10-K).

Each of the Form 10-Ks in which the Material Compliance Statements appear contains virtually identical cautionary language. *See* App. at A-270-325 (Forms 10-K for 2005-2008). This language informed the reasonable investor in no uncertain terms of the inherent risks of non-compliance that exist when operating in an industry subject to "extensive, complex, costly, and evolving regulation" by the FDA. App. at A-267 (excerpt from 2004 Form 10-K).

In light of these cautionary statements accompanying each of the Material Compliance Statements, Plaintiffs cannot claim that the Material Compliance Statements misled investors into believing that there was no risk of future cGMP violations or of regulatory action resulting in a shut-down of some or all of the Company's operations years later. *See In re K-Tel Int'l*, 300 F.3d at 897.[11]

[11] Thus, Plaintiffs' assertion that Defendants "failed to disclose the foreseeable risk that its known – yet undisclosed – FDA violations would cause a complete shutdown of the Company's manufacturing operations," App. at A-71 (Complaint ¶ 12), must also fail. Beyond the risks fully disclosed as set forth above, there is no duty to disclose the unknown and unknowable, and failure to speculate is not fraud. *See Elam*, 544 F.3d at 927 ("Corporate officials need not be clairvoyant; they are only responsible for revealing those material facts reasonably available to them.") (internal quotation marks and citation omitted). Indeed, directly analogous caselaw instructs otherwise. *See Acito v. IMCERA Grp.*, 47 F.3d 47, 53 (2d Cir. 1995) (holding that despite dozens of deficiencies noted during two previous FDA inspections, "one cannot infer that it was a 'foregone conclusion' that the [] plant would fail the inspection and adverse consequences would ensue"); *Discovery Labs.*, 2007 U.S. Dist. LEXIS 18163, at *17 ("[w]e cannot hold defendants liable because they read that report in much the same way

b. The Form 483s Were Publicly Available at the Time the Material Compliance Statements Were Made.

Any analysis of the context in which the Material Compliance Statements were made must necessarily consider all information publicly available to investors at the time. *See In re K-Tel Int'l*, 300 F.3d at 897. This necessarily includes the Form 483s themselves, given that, as discussed in more detail below (*see supra* Section II.A), all Form 483s issued to companies are available to the public through the FDA, including all reports issued to KV. *See In re Discovery Labs. Sec. Litig.*, No. 06-1820, 2006 U.S. Dist. LEXIS 79823, at *34-35 (E.D. Pa. Nov. 1, 2006) (acknowledging that Form 483s are readily available to the public through the FDA). Because the Form 483s became part of the public domain at the time of their issuance and were readily accessible by any reasonable investor from that time forward, Plaintiffs' claims for actionable omissions cannot stand. *See Sailors v. N. States Power Co.*, 4 F.3d 610, 613 (8th Cir. 1993) (noting that "securities laws require disclosure of information that *is not otherwise* in the public domain" and "could have easily been obtained by any investor") (emphasis in original).

Given the public availability of the Form 483s themselves, the Material Compliance Statements here, when read in the broader context of all of the information publicly available to investors—and to both analysts following the

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as the FDA did and remained optimistic that the problems could be timely resolved").

Company and the broader pharmaceutical industry—cannot possibly be construed as misleading to the reasonable investor. At a minimum, the express disclaimer on each Form 483 that it does not represent "a final Agency determination regarding [the Company's] compliance," App. at A-152, would have informed a reasonable investor or analyst that the Material Compliance Statements were affirmations regarding the Company's *material* compliance with cGMP and other applicable regulations at that point in time, notwithstanding any of the inspectional observations contained in the Form 483s.

B. Plaintiffs Insufficiently Allege that the Financial Performance Statements Were Materially False or Misleading.

Plaintiffs' allegations regarding the falsity of the Financial Performance Statements based on the purported cGMP violations relating to the manufacture of the drug Metoprolol were also properly dismissed. These allegations, as the District Court held, likewise fail to satisfy the requirements for pleading falsity under Rule 9(b) and the PSLRA. *See KV Pharm. Co.*, 705 F. Supp. 2d at 1102.

Plaintiffs do not allege that the reported financial results themselves were false or inaccurate. At most, Plaintiffs appear to suggest that these financial results, however truthful and accurate they may have been, were somehow misleading because of the alleged undisclosed manufacturing problems associated with Metoprolol at the time these results were announced. Like Plaintiffs' Material Compliance Allegations, however, the effort to plead Mr. Hermelin's

contemporaneous knowledge of such problems at the time the Financial Performance Statements were made quickly devolves into another exercise of fraud by hindsight.

First, and as explained by the District Court, the Financial Performance Statements did not attribute the success to manufacturing processes or quality control, and thus did not implicate KV's compliance with FDA regulations. *See id.* In addition, the statements reported only *past* financial performance related to Metoprolol. Plaintiffs do not allege that those results were false, and do not identify any alleged misrepresentation regarding the Company's *projected* revenue related to its sales of Metoprolol or its prospects for future success. And to the extent that Plaintiffs have alleged that these results were misleading because they suggested that there would not be a future shutdown of production of Metoprolol, *see* Aplts. Br. at 48, KV's Form 10-K's repeatedly disclosed this very risk to investors, *see, e.g.*, App. at A-267 (2004 Form 10-K).

Moreover, for all of the reasons set forth in Section I.A.3, *supra*, Plaintiffs cannot establish that the manufacture of Metoprolol was materially out of cGMP compliance in years prior to the February 2009 Form 483 simply by invoking the statement in the FDA Complaint that "[t]he 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." This statement does not specify which of the 35 observations in the February 2009 Form 483 (of which only 16 relate to Metoprolol) are "the same as, or similar to" the prior observations, nor does it shed light the nature of the purported similarities. And even if the 2009 Metoprolol-related observations somehow "related back" to prior years, the Complaint fails to allege that such observations were more than mere inspectional observations.

The cases on which Plaintiffs rely are readily distinguishable. They focus primarily on a Ninth Circuit decision, *In re Gilead Sciences Sec. Litig.*, 536 F.3d 1049 (9th Cir. 2008), for the proposition that attributing strong earnings primarily to one drug is misleading when the drug sales were in contravention of FDA regulations. The reasoning in *Gilead Sciences* in inapposite, however, because the court held that the financial statements were actionable only because illegal off-label marketing created the false impression of high demand. *Id.* at 1052. Here, the reporting of high sales of Metoprolol, which could imply high demand, was not misleading because the demand was legitimate—*i.e.*, alleged manufacturing issues had no bearing on the legitimacy of the sales and the demand for the drug.

Similarly, Plaintiffs' reliance on *Steiner v. MedQuist Inc.*, a case involving an improper billing scheme with fraudulent revenue attribution, is equally unavailing because the court held that potential liability arose strictly because the "statements putting the source of the company's revenue at issue [were] false or

misleading." No. 04-5487 (JBS), 2006 U.S. Dist. LEXIS 71952, at *48 (D.N.J. Sept. 29, 2006). The Financial Performance Statements, on the other hand, accurately attributed the revenue numbers, in part, to legitimate sales of Metoprolol, and Plaintiffs do not allege that the revenue reported in these statements was improperly recognized.

Plaintiffs also raise the argument—for the first time on appeal—that failure to disclose Metoprolol's manufacturing problems was required because "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." Aplts. Br. at 48. Even assuming that this proposition applied here,[12] it is based on

[12] It does not, and the cases Plaintiffs cite here are inapposite. The alleged misstatements regarding the company's financial success in Plaintiffs' cases, unlike the Financial Performance Statements here, disguised the true source of that success. *See In re Providian Fin. Corp. Sec. Litig.*, 152 F. Supp. 2d 814, 825 (E.D. Pa. 2001) (statement attributing company's "good fortunes" to "customer focused approach" required disclosure of fraudulent business practices as true source of success); *Kapur v. USANA Health Servs., Inc.*, 2008 WL 2901705, at *13 (D. Utah July 23, 2008) (statement attributing company's success to retail demand required disclosure of "recruitment of new associates" as true source of success); *In re Van der Moolen Holding N.V. Sec. Litig.*, 405 F. Supp. 2d 388, 400-01 (S.D.N.Y. 2005) (statement attributing revenue success to trading by specialty traders required disclosure of traders' NYSE trading violations as true source of revenue). Moreover, in *Freudenberg v. E-Trade Fin. Corp.*, the failure of the defendant to disclose its exposure to subprime risk in light of its representation that its loan portfolio was "superprime" rendered that statement literally false, rather than incomplete, as Plaintiffs argue here. 712 F. Supp. 2d 171, 182 (S.D.N.Y. 2010).

the same presumption of contemporaneous knowledge that fails for the reasons set forth above.

II. THE DISTRICT COURT CORRECTLY HELD THAT MR. HERMELIN HAD NO DUTY TO DISCLOSE THE FORM 483s.

Plaintiffs also challenge the District Court's holding that the failure to disclose the information contained in the Form 483s was not actionable because Mr. Hermelin and the other Defendants had no obligation to disclose something that was already publicly available. *See KV Pharm.*, 705 F. Supp. 2d at 1103. In the face of unambiguous FDA regulations recognizing the public availability of Form 483s, and turning their own control person liability allegations on their head, Plaintiffs appear to argue that Mr. Hermelin was nonetheless required to disclose the Form 483s because *he himself* had not made them publicly available. *See* Aplts. Br. at 45. For the reasons that follow, these arguments are unavailing.

A. The Form 483s Were Publicly Available as a Matter of Law.

As the District Court correctly observed, "[b]ecause the Form 483s that FDA issued to KV from 2003 through 2008 were readily accessible to the public by submitting a request to the FDA," *KV Pharm.*, 705 F. Supp. 2d at 1103, Mr. Hermelin was under no duty to disclose them. Federal securities laws require only the "disclosure of information *that is not otherwise* in the public domain" or information that cannot be "easily obtained by any investor" because, where the omitted information is in the public domain or readily accessible by investors, the

information would already be part of the "total mix." *Sailors*, 4 F.3d at 613 (internal quotation marks and citations omitted) (emphasis in original).[13]

The FDA has expressly recognized that Form 483s are available under FOIA following inspection. Indeed, federal regulations actually *require* that the FDA make inspection-related and other regulatory reports available to the public, including Form 483s. *See* 21 C.F.R. § 20.101(a). To this effect, the FDA's website explains that FDA records, including Form 483s, are readily accessible to the public under FOIA.[14] According to Annual FOIA reports published by the FDA, in 2006 alone the FDA processed over 15,000 FOIA requests with a median processing time of 30 days.[15]

Indeed, at least one court has recognized the public availability of Form 483s through FOIA. *See Discovery Labs.*, 2006 U.S. Dist. LEXIS 79823, at *34-35. For that very reason, the court in *Discovery Labs* held that the failure to disclose

[13] *See also City Nat'l Bank v. Vanderboom*, 422 F.2d 221, 231 (8th Cir. 1970) (a company has no duty to disclose if investors have "ready access to the information involved"); *Myzel v. Fields*, 386 F.2d 718, 736 (8th Cir. 1967) (Rule 10b-5 does not protect "nondisclosed facts equally known *or available* to both parties.") (emphasis added); *see also In re Marion Merrell Dow Inc. Sec. Litig. II*, No. 93-0251-CV, 1994 U.S. Dist. LEXIS 10062, at *23 (W.D. Mo. July 18, 1994) ("information [that] was already within the public domain . . . is not actionable as a material omission").

[14] *See* FDA website, *Freedom of Information*, at http://www.fda.gov/RegulatoryInformation/FOI/default.htm (last visited Mar. 5, 2011).

[15] *See* FDA website, FOIA Annual Reports, at http://www.fda.gov/RegulatoryInformation/FOI/FOIAAnnualReports/default.htm (last visited Mar. 5, 2011).

Form 483s, as well as Warning Letters, could not be a materially misleading omission because they were "publicly available." *See id.* at *34. The court so concluded by pointing out that the plaintiffs actually "learned of the Form 483s from 'a former analyst,'" and noting that this was "a concession to efficient markets that are quickly informed by specialists who make it their business to dig through publicly available sources to inform the investing community." *Id.* at *35 n.22 (citation omitted). Explaining that "prior public disclosure negates a finding that material information was withheld," the court noted that Form 483s "were readily available . . . from the FDA." *Id*. at *34.

Plaintiffs complain that the securities laws envision "full disclosure" by companies and that investors should not be required to seek out information, even where it already exists in the public domain. Aplts. Br. at 44. But such a requirement would turn the disclosure framework of the federal securities laws on its head. "[T]he requirement is not to dump all known information with every public announcement," *K-Tel Int'l*, 300 F.3d at 898, and because pharmaceutical companies "engage [] in heavily regulated businesses," it "would be unduly burdensome and impractical to publicly disseminate the results of every inspection of every plant," especially where companies are fully aware of the fact that FDA inspection reports are required to be disclosed to the public by law. *Acito*, 47 F.3d at 52-53. Furthermore, as stressed by the court in *Discovery Labs.*, the securities

laws do not envision that "*any* investor should be capable of finding the information and understanding its significance based on a single click for a simple Web search" because "[w]e deal here with *reasonable* investors, those who we can assume exercise due investment diligence." *Discovery Labs.*, 2006 U.S. Dist. LEXIS 79823, at *35 (emphasis added).

In confusing fashion, Plaintiffs also argue against the importance of the information being available to the public through the FDA by suggesting that analyst reports or news stories do not cite to FOIA as their source for information. *See* Aplts. Br. at 44. Although it is unclear what Plaintiffs are attempting to convey here, the lack of any analyst reports citing to the Form 483s at issue in this case, if anything, is a strong indication that the analyst community did not view the Form 483s as material. This is not surprising because, as discussed above, in the pharmaceutical industry FDA inspections and resulting Form 483s are a routine occurrence. Despite being publicly available through the FDA, the lack of analyst coverage of the Form 483s is demonstrates that they are largely irrelevant and do not "assume[] actual significance in the deliberations of reasonable shareholders." *TSC Indus. Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976).

Accordingly, even assuming that the Form 483s themselves were material—which, as discussed in Section II.B, *infra*, they were not—Defendants' non-disclosure of the Form 483s could never have been a materially misleading

omission based on the simple fact that it could never have "altered" the "total mix" because *it was already part of that total mix*. *See Basic*, 485 U.S. at 231-32; *see also In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1115 (9th Cir. 1989) ("We conclude that in a fraud on the market case, the defendant's failure to disclose material information may be excused where that information has been made credibly available to the market by other sources.").

B. The Form 483s and Their Content, as Alleged, Are Not Material as a Matter of Law.

Although the District Court based its dismissal of Plaintiffs' omission claims based on the public availability of the Form 483s, affirmance of this dismissal is warranted for an additional reason raised below: the Form 483s and their content, as alleged in Plaintiffs' Complaint, were not material to the investing public as a matter of law.

In general, "materiality depends on the significance the reasonable investor would place on the withheld or misrepresented information." *Basic*, 485 U.S. at 240. Statements or omissions are not material where the allegedly concealed information "would simply not matter to a reasonable investor." *In re Stellent Inc. Sec. Litig.*, 326 F. Supp. 2d 970, 984 (D. Minn. 2004) (quoting *Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 546 (8th Cir. 1997)). The information contained in the Form 483s at issue in this case falls short of this standard.

As previously noted, the Forms themselves make clear that the "inspectional observations" they contain do not "represent a final Agency determination regarding [the Company's] compliance." App. at A-152. Rather, the issuance of Form 483s following routine FDA inspections are commonplace in the heavily regulated pharmaceutical industry. *See, e.g.*, *Acito*, 47 F.3d at 52-53 (noting that pharmaceutical companies "engage [] in heavily regulated businesses," and that it "would be unduly burdensome and impractical to publicly disseminate the results of every inspection of every plant," even in cases where a warning letter is eventually issued); *Robbins v. Moore Med. Corp.*, 894 F. Supp. 661, 674 (S.D.N.Y. 1995) (the "mere fact of an FDA inspection is not material" because "such inspections represent a routine aspect of business" even with resulting deficiencies).

Thus, courts reaching this very issue, often in contexts resembling the case *sub judice*, have expressly found that Form 483s are generally not, by themselves, material as a matter of law. Most recently, in *Plumbers & Pipefitters Local Union 719 Pension Fund v. Zimmer Holdings, Inc.*, the court expressly rejected the notion that the mere issuance of Form 483s following routine FDA inspections, without more, is material to investors:

> Even if we were to assume that the Complaint successfully pleads that the 483 Observations had actually been issued by January 29, 2008, Plaintiff has not included any averment as to the materiality of the FDA inspection and Observations. *Observations are by no means*

> *inherently adverse or material.* They may be issued based on a wide variety of conditions, including record-keeping deficiencies and a host of other inadequacies, clerical and otherwise.

673 F. Supp. 2d 718, 735 (S.D. Ind. 2009) (citations omitted) (emphasis added); *see also Acito*, 47 F.3d at 52-53; *Anderson v. Abbott Labs.*, 140 F. Supp. 2d 894, 902 (N.D. Ill. 2001), *aff'd sub nom. Gallagher v. Abbott Labs.*, 269 F.3d 806 (7th Cir. 2001); *Discovery Labs.*, 2006 U.S. Dist. LEXIS 79823, at *33-34; *Robbins*, 894 F. Supp. at 674.

For example, in *Acito*, the court concluded that two 483 inspection reports from the FDA, both of which resulted in dozens of identified "deficiencies," were "not material to the average investor" because "no materially adverse action was taken by the FDA as a result of the first two inspections," even though the FDA did take adverse action after a third inspection. *Acito*, 47 F.3d at 52.

In *Robbins*, the court held that the "mere fact of an FDA inspection is not material," and even with costly inspectional deficiencies, "it was neither false nor materially misleading to state . . . it was in material compliance." 894 F. Supp. at 674.

In *Discovery Labs.*, a case involving warning letters and Form 483s, the court held that even warning letters are "not the sort of information that would form the basis for a reasonable investment decision" because they "are a reality of doing business." 2006 U.S. Dist. LEXIS 79823, at *33-34.

Finally, in *Anderson*, which dealt with actual warning letters from the FDA to a company that had been "in, and out, of an FDA monitoring plan" due to ongoing compliance problems, the court held that the warning letter in question—an enforcement action that in the cGMP context is reserved only for those observations in Form 483s that are of "regulatory significance," *see* App. at A-653 (FDA Regulatory Procedures Manual (Ch. 4) at 4-1, 4-2 (March 2009))—was not material because the FDA had never taken enforcement action in the past against the company, and Plaintiffs failed to establish that the FDA was "serious" this time. 140 F. Supp. 2d at 902.

Against this great weight of authority, the cases upon which Plaintiffs rely are largely off the mark. In fact, the two cases that Plaintiffs place front and center in support of the proposition that Form 483 cases are inherently material—*McGuire v. Dendreon Corp.*, No. C07-800MJP, 2008 U.S. Dist. LEXIS 98773 (W.D. Wash. Dec. 6, 2008) ("*Dendreon II*"), and *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110 (C.D. Cal. 2005)—only serve to illustrate why Plaintiffs have failed to adequately plead materiality as to the Form 483s at issue here.

Notably, in both decisions, the court found that materiality was sufficiently pleaded as to the FDA inspections and resulting reports *only because they had a direct bearing on the potential delay of critical drug approvals*. *See Dendreon II*, 2008 U.S. Dist. LEXIS 98773, at *19 n.4 ("Although the observations in the Form

483 are not final agency determinations and although Plaintiffs have failed to plead how serious the observations were, the disclosure of 'significant objectionable conditions' would significantly alter the total mix of information available to the reasonable investor because it bears on potential delays in the approval of Dendreon's only near-commercial status product."); *Yanek*, 388 F. Supp. 2d at 1129-30 (finding that the Form 483s were relevant to investors strictly because "[a]ny facts bearing on possible delays in FDA approval of the ICL are [] material because STAAR's entire strategy depended on the timely approval and commercial launch of the ICL.").

Further highlighting this point, the court in *Dendreon* expressly rejected numerous allegations of misleading statements relating to the Form 483s, permitting only one alleged misstatement by the company to proceed: "Of the statements made during this phone conference [regarding the status of the drug approval], the Court finds only one that is actionable: the 'good inspection' statement by Defendant Urdal." 2008 U.S. Dist. LEXIS 98773, at *13. Unlike the allegations of materiality in *Dendreon*, Plaintiffs do not allege here that Defendants made any statements regarding the outcomes of the routine inspections that were regularly conducted by the FDA during the class period.

Moreover, in contrast to virtually all of the cases cited by Plaintiffs, the FDA's routine inspections of KV and the resulting Form 483s *never* resulted in any

adverse action taken against the Company during the class period, and such action was never even threatened by way of a warning letter. It thus cannot be said that the mere existence of the Form 483s "would have assumed actual significance in the deliberations of the reasonable shareholder." *K-Tel Int'l*, 300 F.3d at 897 (quoting *TSC Indus., Inc.*, 426 U.S. at 449); *see also Basic*, 485 U.S. at 234 ("The role of the materiality requirement is not to attribute to investors a child-like simplicity . . . but to filter out essentially useless information that a reasonable investor would not consider significant, even as part of a larger 'mix' of factors to consider in making his investment decision.") (internal quotation marks and citation omitted). If Form 483s are immaterial to investors under circumstances in which the subject company has received warning letters (as in *Anderson*) or other adverse action (as in *Acito*), they are clearly not material under the circumstances here, where they did not bear on the delay of any drug approvals (as in *Dendreon* and *Yanek*) and the FDA never so much as warned the Company during the class period of possible adverse regulatory consequences stemming from the routine inspections.

Finally, and once again, to say that the FDA took action in early 2009 says nothing about the materiality of information in any of the Form 483s at the time they were issued. Whether that information was material "should not be judged with the advantage of hindsight." *Gebhardt v. ConAgre Foods, Inc.*, 335 F.3d 824,

830 (8th Cir. 2003); *id.* at 831 ("This requires us to look at the information from the perspective of a reasonable investor at the time of the misrepresentation, not from the perspective of a reasonable investor looking back on how events unfolded.").

III. THE DISTRICT COURT CORRECTLY DISMISSED PLAINTIFFS' CLAIMS FOR ADDITIONAL REASONS.

Because the District Court correctly held that Plaintiffs failed sufficiently to plead that the alleged misstatements were false or misleading, and that Plaintiffs failed to plead facts supporting a duty to disclose on the part of Mr. Hermelin, the court did not need to reach the elements of scienter and loss causation. Nevertheless, the District Court's dismissal of the Complaint can be affirmed on these additional grounds as well. *See Sipe* v. *Workhorse Custom Chassis, LLC*, 572 F.3d 525, 531 n.4 (8th Cir. 2009) (quoting *Jackson* v. *United Parcel Serv., Inc*., 548 F.3d 1137, 1143 n.2 (8th Cir. 2008)) (affirming district court's judgment on basis not addressed by district court and noting that the court "'may affirm the judgment of the district court on any basis supported by the record").[16]

[16] *See also Moore v. Forrest City Sch. Dist.*, 524 F.3d 879, 885 (8th Cir. 2008) ("This court may affirm the judgment of the district court on any basis supported by the record.") (citing *Robinson v. Brandtjen & Kluge, Inc.*, 500 F.3d 691, 694 (8th Cir. 2007)); *accord Pro Service Auto., LLC v. Lenan Corp.*, 469 F.3d 1210, 1213 (8th Cir. 2006) ("We may affirm the district court's grant of summary judgment on any ground supported by the record.") (citing *White v. Moulder*, 30 F.3d 80, 82 (8th Cir. 1994)).

A. The Complaint Fails to Plead the Requisite Scienter as to Mr. Hermelin.

As Mr. Hermelin argued below, Plaintiffs' Complaint does not, and cannot, plead facts giving rise to a strong inference that Mr. Hermelin made any fraudulent statements or omissions with the requisite state of mind. Under the PSLRA's heightened pleading standard, a complaint must state with particularity facts giving rise to a strong inference of 1) motive and opportunity, 2) "a mental state embracing intent to deceive, manipulate, or defraud," or 3) conduct that rises to the level of severe recklessness, which "is limited to 'highly unreasonable omissions or misrepresentations' involving 'an extreme departure from the standards of ordinary care, and . . . presenting a danger of misleading buyers or sellers which is either known to the defendant or is so obvious that the defendant must have been aware of it.'" *K-Tel Int'l*, 300 F.3d at 893-94 (alteration in original) (citations omitted).

"[T]he inference of scienter must be more than merely 'reasonable' or 'permissible' – it must be cogent and compelling, thus strong in light of other explanations." *Tellabs*, 551 U.S. at 324. Indeed, a court must determine whether "all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Id.* at 323. Furthermore, the PSLRA's heightened pleading standard requires a court to "disregard 'catch-all' or 'blanket' assertions that do not live up

to the particularity requirements of the statute." *K-Tel Int'l*, 300 F.3d at 889 (quoting *Green Tree Fin. Corp.*, 270 F.3d at 660). For the reasons set forth in support of Mr. Hermelin's Motion to Dismiss (*see* Hermelin Mot. Dismiss at 34-39), and summarized here, Plaintiffs' attempts to plead scienter fall far short of the *Tellabs* standard in all respects.

First, Plaintiffs' sole allegation of motive—Mr. Hermelin's purported desire to "maintain [his] executive and directorial positions at KV and the profits, power and prestige that [he] enjoyed as a result of those positions," App. at A-125 (Complaint ¶ 158)—does not, under settled law in this Circuit, constitute a "concrete and personal" benefit under the PSLRA. *See* Hermelin Mot. Dismiss at 34-35 (discussing cases).

Second, Plaintiffs fail to allege with particularity that Mr. Hermelin acted with knowledge or recklessness, as they rely only on the following facts: 1) Mr. Hermelin's position as Chief Executive Officer of KV; 2) KV's termination of Mr. Hermelin's employment; 3) the FDA Complaint and subsequent Consent Decree entered into by the Defendants; 4) the February 2009 Form 483; and 5) generalized allegations that the Defendants "knowingly" misrepresented KV's compliance with cGMP. Such allegations, however—which must be "particularly strong in order to meet the Reform Act standard" absent a particularized motive, *Green Tree Fin. Corp*, 270 F.3d at 660—are insufficient as a matter of law. *See* Hermelin Mot.

Dismiss at 37 (arguing that the fact of Mr. Hermelin's corporate position does not raise a strong inference of scienter); *id*. at 36 (arguing that allegations regarding the basis for Mr. Hermelin's alleged termination from KV do not raise a strong inference of scienter because they fail to link his termination to the alleged misrepresentations regarding its compliance with cGMP); Defendant Marc S. Hermelin's Reply in Support of His Motion to Dismiss Plaintiff's Consolidated Amended Complaint at 21-22 (arguing that neither the FDA Complaint nor the Consent Decree raise a strong inference of scienter because neither alleges that Mr. Hermelin was ever told by FDA that KV was not in material compliance with cGMP); *id*. at 23-24 (arguing that the February 2009 Form 483 does not raise a strong inference of scienter because it fails to establish that Mr. Hermelin knew or was reckless in not knowing that KV was not in material compliance with cGMP during the preceding six years); Hermelin Mot. Dismiss at 37-38 (arguing that Plaintiffs' other generalized and conclusory allegations of scienter fail to cite any specific fact giving rise to a strong inference of scienter).

B. The Complaint Fails to Plead Loss Causation.

As Mr. Hermelin also argued below, Plaintiffs failed sufficiently to plead loss causation. *See* Hermelin Mot. Dismiss at 29-33. Under the PSLRA, the plaintiff has "the burden of proving that the act or omission of the defendant . . . caused the loss for which the plaintiff seeks to recover damages." 15 U.S.C.

§ 78u-4(b)(4) (2006). The Supreme Court has held that this proof requirement carries with it a pleading requirement, such that a complaint seeking relief under Section 10(b) must allege a causal connection between the alleged fraud and the losses the plaintiff claims to have suffered or else face dismissal. *See Dura Pharm. v. Broudo*, 544 U.S. 336, 345-46 (2005). It is not sufficient to allege that the misstatements or omissions at issue resulted in the artificial inflation of the market price of the issuer's stock. Rather, properly to allege loss causation, a plaintiff must also plead facts establishing that the alleged material misstatements or omissions were the proximate cause of his losses. *See id.*; *see also Schaaf v. Residential Funding Corp.*, 517 F.3d 544, 550 (8th Cir. 2008) ("In a securities case, th[e] [loss causation] standard requires the plaintiff to show that the defendant's fraud – and not other events – caused the security's drop in price."). For this reason, the PSLRA requires that pleadings establish that the alleged misrepresentations or omissions in question "*cause[d]* a loss, not just merely 'touch[ed] upon' a loss." *Reding*, 382 F. Supp. 2d at 1126 (quoting *Dura Pharm.*, 544 U.S. at 343) (emphasis added).

Plaintiffs' cobbling together of various public statements that purport to reveal the truth behind the alleged misstatements and omissions fails to demonstrate any connection between the alleged misstatements/omissions and these "corrective" disclosures. *See* Hermelin Mot. Dismiss at 30-31 (arguing that

$5.5 million write-off disclosed in May and June 2008 had nothing to do with failure to comply with cGMP); *id*. at 31 (arguing that August 2008 disclosure regarding an inquiry into "management misconduct" generally made no reference to any of alleged misstatements or omissions); *id*. at 32-33 (arguing that November 2008 disclosure of the Company's investigation into "FDA regulatory and other compliance matters and management misconduct" makes no mention of cGMP compliance issues or of time period being investigated); *id*. at 33 (arguing that December 2008 and January 2009 disclosures have no relation to state of cGMP compliance at time the alleged misstatements and omissions were made).

IV. THE DISTRICT COURT CORRECTLY DENIED PLAINTIFFS' POST-JUDGMENT MOTION.

In addition to affirming the dismissal of Plaintiffs' first amended Complaint, this Court should also affirm the District Court's denial of Plaintiffs' post-judgment motion to vacate under Rules 59(e) and 60(b)(2), as well as its request for permission to amend under Rule 15(a)(2) because 1) Plaintiffs have offered no new evidence warranting a vacatur of the judgment of dismissal, and 2) Plaintiffs' proposed second amended complaint would have been futile.

A. Plaintiffs' Post-Judgment Motion Offered No New Evidence Requiring the Court to Vacate Its Dismissal as to Mr. Hermelin.

The District Court correctly held that Plaintiffs' post-judgment motion failed to offer any new evidence sufficient to vacate the order of dismissal. The "primary

basis for [Appellant's] motion" was a criminal information and plea agreement involving ETHEX, a subsidiary of KV, regarding ETHEX's failure to comply with FDA reporting requirements upon the discovery of oversized tablets of the drugs Propafenone and Dextramphetamine in September 2008. App. at A-1053 (Order).

Conspicuously absent from Plaintiffs' motion, however, was that ETHEX's failure to report such oversized tablets was not "newly-discovered" evidence at all; indeed, ***it was cited in the February 2009 Form 483 attached to Plaintiffs' Complaint*** and quoted at length in its allegations. Not only did the February 2009 Form 483 explicitly state that oversized tablets were found on several products, including Propafenone and Dextramphetamine, and that "[n]o field alert was ever filed and FDA was not notified until 10 Oct 2008," App. at A-171, Plaintiffs also cited that specific observation in their Complaint as evidence of purported non-compliance with cGMP. *See* App. at A-83-84 (Compl. ¶ 54). The factual predicate—known by and relied upon by the District Court—underlying both the criminal information and the plea agreement by ETHEX therefore does not constitute newly-discovered evidence that could serve as a basis to vacate the Court's dismissal of the Complaint.[17]

[17] For that same reason, the criminal information and plea agreement by ETHEX would not "probably produce a different result." *Harris v. Potter*, No. 4:08-CV-1191 CAS, 2009 U.S. Dist. LEXIS 35580, at *5-6 (E.D. Mo. April 20, 2009).

Moreover, Plaintiffs' submission of two affidavits by purported "experts," who "opine" that the Forms 483 constitute findings of cGMP violations and were not publicly available, similarly cannot be considered newly-discovered evidence.[18] The vast majority of the materials underlying those affidavits—the Forms 483 issued to KV, KV's securities filings and press releases, news articles, and analyst reports about KV—were both already known to Plaintiffs and expressly cited in the Complaint. Under such circumstances, courts have consistently rejected attempts to classify expert opinions which are based upon facts available to the movant prior to the entry of judgment as "newly-discovered" evidence. *See, e.g., United States v. Metro. St. Louis Sewer Dist.*, 440 F.3d 930, 934-35 (8th Cir. 2006) (affirming refusal to consider an expert report as newly-discovered evidence where the report was "merely a newly created opinion based on facts known to or accessible by [the movant] at the time of the Consent Decree hearing").[19]

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[18] Plaintiffs misleadingly assert that the "District Court never [sic] failed to consider or analyze whether [one of the] expert report[s] cured the dismissal of the Complaint." Aplts. Br. at 58. To the contrary, in denying Plaintiffs' motion to vacate the order of dismissal, the District Court specifically cited the two expert reports that, "according to Plaintiffs, will 'cure the deficiencies set forth in the Court's Memorandum and Order.'" App. at A-1052 (Order).

[19] *See also Cranmer v. Tyconic Inc.*, 278 F. App'x 744, 746-47 (9th Cir. 2008) (affirming district court's denial of Rule 60(b) relief where, although the expert report "did not actually exist until eight days after the district court signed the order granting summary judgment, the evidence on which [it was] based had

Furthermore, neither expert report would have probably produced a different result, because an expert simply may not substitute his own opinions for a court's legal conclusions. *See, e.g.*, *Schmidt v. Magyari*, 557 F.3d 564, 570 (8th Cir. 2009) (affirming exclusion of expert testimony where, *inter alia*, "a number of opinions offered [] were improper legal conclusions"); *Kinder v. Acceptance Ins. Cos.*, 423 F.3d 899, 905 (8th Cir. 2005) ("[E]xpert opinions . . . meant to substitute the judgment of the district court" are properly excluded). The District Court held that, as a matter of law, "the Form 483s issued to KV only contained observations—not 'a list of cGMP violations' as alleged by lead plaintiffs." *KV Pharm. Co.*, 705 F. Supp. 2d at 1100. The District Court similarly held that "the Form 483s that FDA issued to KV from 2003 through 2008 were readily accessible to the public by submitting a request to the FDA." *Id.* at 1103.

Because both expert reports are intended directly to contradict the District Court's findings of law, they would almost certainly be inadmissible and thus would not have probably produced a different result.

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been in the possession of [the movant's former counsel and therefore] . . . cannot be considered 'newly discovered'") (citation omitted); *accord Provident Life & Accident Ins. Co. v. Goel*, 274 F.3d 984, 999-1000 (5th Cir. 2001) (expert report that could have been proffered prior to summary judgment did not constitute newly-discovered evidence under Rule 60(b)); *Webber v. Mefford*, 43 F.3d 1340, 1345 (10th Cir. 1994).

B. Plaintiffs' Amendment Would Have Been Futile as to Mr. Hermelin.

The District Court correctly denied Plaintiffs' request to file a second amended complaint because the proposed amendment would have been futile as to Mr. Hermelin. Plaintiffs erroneously assert that amendment would not have been futile based upon 1) the proposed Second Amended Complaint's citation of a new, allegedly false statement made by KV on August 11, 2008, and 2) the criminal information and plea agreement entered into by ETHEX.[20] Yet neither of these asserted bases would cure the fundamental defects in Plaintiffs' Complaint.

Plaintiffs' extensive reliance on KV's August 11, 2008 statement—that "[m]anagement 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," Aplts. Br. at 57 (quoting App. at A-895)—is misplaced. This new allegation does nothing to address the deficiency upon which the District Court's dismissal of the Complaint was based—*i.e.*, the failure of the Form 483s to establish the falsity of the alleged misstatements and omissions at issue and the absence of any duty to disclose the Form 483s given their public availability. Nor does it allege any additional fact that would otherwise establish that the misstatements at issue were

[20] Plaintiffs also assert that the two newly-submitted expert reports demonstrate that amending the Complaint would not be futile. But as explained in Section IV.A, *supra*, those reports improperly seek to overrule the District Court's legal conclusions and therefore would almost certainly be inadmissible.

false. It likewise fails to alter the conclusion that Mr. Hermelin had no duty to disclose the Form 483s and adds nothing to the deficiencies in Plaintiffs' allegations regarding Mr. Hermelin's scienter and loss causation.

Nor can the proposed allegations concerning the ETHEX Information and plea agreement revive Plaintiffs' Complaint. Neither of these documents references any misconduct—by Mr. Hermelin or anyone else—that occurred at or before the time any of the alleged misstatements were made except one statement concerning the reporting of Metoprolol, which has nothing to do with the information or plea agreement. Moreover, the FDA regulation on which ETHEX's plea was based—21 C.F.R. § 314.81—relates to a filing requirement, and is not part of the regulations governing compliance with cGMP. *See generally* 21 C.F.R. §§ 210-211.

Finally, Plaintiffs' purely speculative assertion that "the only reasonable inference is that the 'Corporate Executive A'" referenced in the criminal information as having knowledge of the finding of oversized tablets in July 2008 is Mr. Hermelin, *see* Aplts. Br. at 59, is insufficient to rectify the Complaint's failure to allege a strong inference of scienter. As an initial matter, neither the criminal information nor the plea agreement identifies Mr. Hermelin as "Corporate Executive A." Thus, Plaintiffs' proposed Second Amended Complaint cannot establish that Mr. Hermelin knew, or was reckless in not knowing, that KV was

allegedly not in material compliance with cGMP throughout the class period based upon a criminal information and plea agreement entered into by a third party and wholly unrelated to cGMP compliance.

CONCLUSION

For the reasons set forth above, the Court should affirm the District Court's judgment of dismissal of Plaintiffs' claims as to Mr. Hermelin and its denial of Plaintiffs' motion to vacate the judgment under Rules 59(e) and 60(a)(2) of the Federal Rules of Civil Procedure.

DATED: March 8, 2011

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C)(i), I hereby certify that the foregoing Brief for Defendant-Appellee Marc S. Hermelin complies with Fed. R. App. P. 32(a)(7)(B)(i) because it contains 13,913 words, excluding the parts of the brief exempted by Fed. R. App. P. 32 (a)(7)(B)(iii). I also certify that this brief complies with the typeface and style requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared using Microsoft Word with a proportionally-spaced 14-point font in Times New Roman.

DATED: March 8, 2011

/s/ *Jeffrey E. McFadden*

Jeffrey E. McFadden

CERTIFICATE OF SERVICE (CM/ECF)

The undersigned certifies that on March 8, 2011, the foregoing Brief for Defendant-Appellee Marc S. Hermelin was filed with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit using the appellate CM/ECF filing system. The brief was scanned for viruses using Symantec Antivirus 10.1.7 (updated June 16, 2010) and no viruses were detected.

DATED: March 8, 2011

/s/ *Jeffrey E. McFadden*

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