

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION

PUBLIC PENSION FUND GROUP, et al.,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	
	)	No. 4:08-CV-1859 (CEJ)
KV PHARMACEUTICAL COMPANY, et al.,	)	
	)	
Defendants.	)	

**MEMORANDUM AND ORDER**

This matter is before the Court on the motion filed by lead plaintiffs seeking a ruling on issues that remain unresolved in the motion to dismiss filed by defendant Marc S. Hermelin.

**I. Background**

Lead plaintiffs are two pension plans for the public employees of Norfolk County Massachusetts and the City of Boston. KV Pharmaceutical Company (KV) is a publicly-traded entity, which develops, manufactures, and markets prescription drug products. Hermelin is KV's former Chief Executive Officer and member of the Board of Directors. Several groups of investors who purchased securities of KV brought a class action alleging that KV and some of its individual officers, including Hermelin, committed securities fraud.

This Court previously granted Hermelin's motion to dismiss the consolidated amended complaint for failure to state a claim for relief, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. The United States Court of Appeals for the Eighth Circuit reversed the dismissal of plaintiffs' claim that KV and Hermelin made false and

misleading statements regarding compliance with the regulatory requirements of the United States Food and Drug Administration (FDA) and cGMP, in violation of § 10(b) of the Securities Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 of the Securities Exchange Commission, 17 C.F.R. § 240.10b-5. Public Pension Fund Group v. KV Pharmaceutical Co., 679 F.3d 972 (8th Cir. 2012). The court of appeals determined that the consolidated amended complaint adequately pled that the statements regarding regulatory compliance were false or misleading. However, in order to survive a motion to dismiss on this claim, the complaint must also properly plead scienter and loss causation. See Horizon Asset Mgmt. Inc. v. H&R Block, Inc., 580 F.3d 755, 760 (8th Cir. 2009) (listing the elements required to state a private securities fraud claim under § 10(b) and Rule 10b-5).

The court of appeals did not rule on the issue of whether the consolidated amended complaint adequately pleads the elements of scienter and loss causation. Lead plaintiffs now seek a ruling on that issue.

## II. Discussion

### A. Scienter

In order to properly plead scienter, “the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2)(A). Scienter can be established in one of three ways: “(1) from facts demonstrating a mental state embracing an intent to deceive, manipulate, or defraud; (2) from conduct which rises to the level of severe recklessness; or (3) from allegations of motive and opportunity.” Detroit Gen. Ret. Sys. v. Medtronic, Inc., 621

F.3d 800, 805 (8th Cir. 2010). “The inquiry . . . is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.” Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322-23 (2007).

Plaintiffs rely on the following allegations to establish that Hermelin acted with the required state of mind: (1) defendants knew of the FDA violations, the continuous nature of the violations, the Forms 483, and had discussions with the FDA concerning those violations as evidenced by the government’s preliminary injunction complaint against KV; (2) Hermelin signed a consent decree with the government that reflects that he knew of the FDA violations since January 1, 2005; (3) Hermelin was terminated for cause “with full knowledge of all pertinent facts;” and (4) the ongoing fraudulent scheme could not have been perpetrated over a substantial period of time without the knowledge, participation, and complicity of the executives at the highest level of the company.

These facts, taken collectively, give rise to a strong inference of scienter. During the relevant period, Hermelin signed various Form 10-Ks, stating that “[w]e believe that all our facilities are in material compliance with applicable regulatory requirements” and “we believe that we are currently in material compliance with cGMP.” Plaintiffs also cite to the government’s March 2, 2009 complaint for permanent injunction, which sought to enjoin KV from manufacturing, packaging, labeling, holding, and/or distributing any of its products. The government complaint alleged that the defendants had notice of KV’s non-compliance with FDA regulations:

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, 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.

(United States Comp., Doc. #66-1, at 85, para. 24).

In attempting to satisfy the scienter requirement, it is relevant that plaintiffs "compare (1) an allegedly false or misleading statement with (2) [d]efendants' prior receipt of information demonstrating that the statement would be false or misleading." In re 2007 Novastar Financial, Inc., Securities, 2008 WL 2354367, at \*4 (W.D. Mo. June 4, 2008). "Factual allegations indicating 'that defendants made statements when they knew or had access to information suggesting these public statements to be materially inaccurate' create a strong inference of scienter." In re MoneyGram Intern., Inc. Securities Litigation, 626 F.Supp.2d 947, 981 (D. Minn. 2009).

The Eighth Circuit wrote that "[t]he issuance of a Form 483 represents a risk that the FDA may take corrective action against a company, and thus a company is obliged to assess the seriousness of the risk and disclose such information to potential investors if it also represents it is in compliance with FDA regulations and cGMP." Public Pension Fund Group, 679 F.3d at 982. The Form 483s were issued to KV prior to the issuance of each Form 10-K. It seems extremely unlikely that Hermelin did not have access to the information contained in the Forms 483 prior to signing the Forms 10-K. Therefore, representing regulatory compliance while being issued written FDA non-compliance observations shows a strong inference of scienter.

The complaint also alleges that Hermelin's knowledge of the fraud is evidenced by his forced termination "for cause." The complaint references his employment agreement, which states:

Employers may terminate this Agreement at any time for Cause. For purposes of this Agreement, "Cause" shall mean that (I) Employee has committed a breach of a fiduciary duty . . . or has wilfully failed to perform his duties to Employer, and in doing so has acted with knowledge of all pertinent facts; and (ii) such act has a had a material and demonstrable adverse effect on Employer.

The complaint also addresses KV's press release announcing Hermelin's termination:

The Board of Directors . . . as a result of its investigation with respect to a range of specific allegations involving, among other things, FDA regulatory and other compliance matters and management misconduct, terminated . . . Hermelin . . . 'for cause.'

Plaintiff rationalizes that KV could not have fired him for cause unless he had knowledge of the non-compliance. Hermelin argues that the documents announcing his termination did not reference the violations or suggest that he had knowledge of the violations at the time they were occurring. The Court agrees that the employment agreement and the press release, standing alone, do not sufficiently allege scienter. However, in conjunction with the Form 483s issued to defendants outlining the observations of non-compliance by the FDA and the assertion of the government that these observations were discussed with defendants, a reasonable person could find Hermelin's knowledge of the fraud "cogent and as plausible as defendant's opposing nonfraudulant narrative." See In re MoneyGram Intern., Inc. Securities Litigation, 626 F.Supp.2d 947, 983 (citing Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. at 313-314).

Plaintiffs also attempt to use the consent decree signed by Hermelin as evidence of scienter, noting that it affirmatively states that the FDA first informed defendants of the non-compliance issues on January 1, 2005. The Court will decline to consider the consent decree as evidence of scienter. The decree expressly provides that its adoption does not function to admit or deny any aspects of plaintiffs' complaint.

After a consideration of the totality of the circumstances, the Court finds that the complaint's factual allegations permit a strong inference of scienter.

### **B. Loss Causation**

"To adequately plead loss causation, the complaint must state facts showing a causal connection between the defendant's misstatements and the plaintiff's losses." McAdams v. McCord, 584 F.3d 1111, 1114 (8th Cir. 2009). "The plaintiff must show 'that the loss was foreseeable and that the loss was caused by the materialization of the concealed risk.'" Id. (quoting Schaaf v. Residential Funding Corp., 517 F.3d 544, 550 (8th Cir. 2008)). "'Where the alleged misstatement conceals a condition or event which then occurs and causes the plaintiff's loss, a plaintiff may plead that it is 'the materialization of the undisclosed condition or event that causes the loss.'" Heller v. Golden Restructuring Fund, L.P., 590 F. Supp. 2d 603, 623-24 (S.D.N.Y. 2008).

Plaintiff's amended complaint alleges that defendants "engaged in a course of conduct that artificially inflated the price of KV securities." The conduct includes:

[M]aking materially false and misleading statements and failing to disclose that KV (i) had been systematically violating FDA regulations, including cGMP, ignoring the corrective requirements of the several Forms 483 issued to it throughout the Class Period, and (ii) manufactured and sold Generic Metoprolol in violation of FDA regulations. Defendants also made materially false and misleading statements that operated as a fraud or deceit when they failed to disclose that KV had manufactured and

distributed, and continued to manufacture and distribute, defective pharmaceutical drugs that were dangerous to the public.

Plaintiffs go on to allege that once this conduct became public, the price of KV securities could no longer remain artificially inflated and that the price substantially declined. Plaintiffs argue that the decline was “a direct result of the nature and extent of [the] materially false and misleading statements and omissions.” In order to support these allegations, plaintiffs cite to various disclosures that KV issued between May 30, 2008 and January 26, 2009.

The Court finds that plaintiffs have sufficiently pled that the monetary losses suffered by investors of KV securities were foreseeable and were caused by the materialization of the concealed risk. Plaintiffs allege that KV’s failure to inform the market about their continuing non-compliance created an artificial stock price which plummeted when the undisclosed condition became known. This allegation is supported by the fact that the per share price for KV’s Class A shares collapsed from more than \$30 at the height of the class period, to \$0.51 at the close of trading on January 26, 2009. Plaintiffs conclude that this decline in stock price was the direct result of each fraud revealed to the market.

\* \* \* \* \*

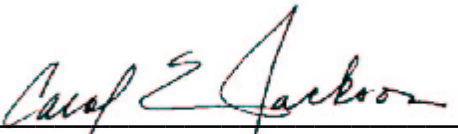
For the reasons discussed above,

**IT IS HEREBY ORDERED** that lead plaintiffs’ motion for a ruling on the issues in the pending motion to dismiss that have not been ruled on by the court of appeals [Doc. # 162] is granted.

**IT IS FURTHER ORDERED** that the motion to dismiss filed by defendant Marc S. Hermelin [Doc. # 95] is denied as to lead plaintiffs’ claims that he made materially

false and misleading statements and omissions concerning KV Pharmaceutical's noncompliance with cGMP and FDA regulations.

**IT IS FURTHER ORDERED** that defendant Hermelin shall have until **May 20, 2013**, to file an answer to the consolidated amended complaint.

  
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CAROL E. JACKSON  
UNITED STATES DISTRICT JUDGE

Dated this 30th day of April, 2013.