

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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Fort Worth Employers' Retirement :
Fund, On Behalf of All Others Similarly :
Situating, :
Plaintiff, :
-against- :
Biovail Corporation, *et al.*, :
Defendants. :
-----x

08 Civ. 8592 (CM) (KNF)

DECISION GRANTING DEFENDANTS' MOTION TO DISMISS THE COMPLAINT

McMahon, J.:

This is a securities fraud class action. Plaintiff's Amended Complaint, dated December 17, 2008 (the "Amended Complaint"), asserts a single claim under Section 10(b) of the Securities Exchange Act of 1934 against Biovail Corporation ("Biovail") and four of its current and former officers (collectively, "Defendants"). It also asserts a related "controlling person" claim under Section 20 of the 1934 Act against the four individual defendants.

In enacting the Private Securities Litigation Reform Act ("PSLRA"), Congress sought "to deter strike suits wherein opportunistic private plaintiffs file securities fraud claims of dubious merit in order to exact large settlement recoveries." Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 171 (2d Cir. 2005). Plaintiff's Amended Complaint is a prime exemplar of a legally baseless securities "strike suit."

The Amended Complaint alleges that three statements by Biovail about its new drug, "BVF-033," did not adequately disclose the risk that the U.S. Food and Drug Administration ("FDA") either might not approve BVF-033, or might delay its approval. The statements are:

- March 15, 2007: “[T]he product [BVF-033] *hopefully* gets approved at the end of July” (Am. Compl. ¶ 53 (emphasis added));
- May 10, 2007: “[W]e are in active discussions with partners and *we hope* to be able to announce something in the relative near term on that, *but that’s about the most I can say at this point in time*” (id. ¶ 56 (emphasis added)); and
- May 23, 2007: The “FDA *is expected to* respond to our NDA [New Drug Application] in late July 2007” (id. ¶ 59(emphasis added)).

The Amended Complaint alleges that these statements are actionable because they did not disclose that Biovail’s New Drug Application (NDA) for BVF-033—submitted to the FDA in September 2006 and affirmatively accepted by the FDA for review in November 2006—used a certain method of showing the drug’s “bioequivalence” called a “multiple-dose” study. According to the Amended Complaint, Defendants knew that Biovail’s reliance on a multiple-dose study, instead of a “single-dose” study, increased the risk that the FDA would not approve BVF-033 or might delay such approval.

In making this charge, Plaintiff mischaracterizes a publicly available letter from the FDA to Biovail—dated December 14, 2006, the first day of the putative class period. The letter states that a single-dose study was the “preferred approach” for a different type of application—an *Abbreviated* New Drug Applications (ANDA)—that had been submitted by Biovail competitors who were seeking FDA approval of generic versions of Wellbutrin, a drug developed by Biovail and approved by the FDA years earlier. The December 14 letter does not address Biovail’s BVF-033 NDA at all.

Plaintiff nonetheless contends that, after receiving the FDA’s letter concerning ANDAs for generic versions of Wellbutrin, Defendants knew that there was a greater risk that the FDA would not approve Biovail’s NDA for BVF-033, because Biovail had relied on a multiple-dose study. The pleading alleges that Biovail and the individual defendants should have disclosed that

risk, but instead kept their knowledge secret until July 20, 2007—the last day of the putative class period—when Biovail announced that the FDA had declined to approve BVF-033.

The Amended Complaint's allegations of securities fraud, however, are self-refuting. Plaintiff's premise is that Defendants knew, but failed to disclose, that the FDA would not likely approve BVF-033 unless the NDA relied on a single-dose study. But the Amended Complaint's own allegations confirm that such a single-dose study was not necessary, because it acknowledges that Biovail resubmitted the NDA for BVF-033 *without including a single-dose study or any other new clinical data*, and the FDA *approved* BVF-033 based on Biovail's resubmission, *without ever requiring submission of data from a single-dose study*. Thus, the Amended Complaint's own allegations fatally undermine the premise on which plaintiff's theory of securities fraud rests.

Furthermore, the ostensibly negative information about single-dose study date was no secret. The supposedly damning letter on which plaintiff's theory rests was publicly available on the FDA's website throughout the putative class period, where it could have been read and assessed by any investor.

The Amended Complaint fails to plead with particularity fact that give rise to a strong inference of scienter, as required by Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 127 S. Ct. 2499 (2007). It fails to plead loss causation in a manner consistent with the rule announced in Dura Pharm. Inc. v. Broudo, 544 U.S. 336 (2005). And the statements identified as misrepresentations are both immaterial as a matter of law and fall squarely within the PSLRA's safe harbor for forward looking statements.

For these reasons, as explained more fully below, the Amended Complaint is dismissed in its entirety, with prejudice.

ALLEGATIONS OF THE AMENDED COMPLAINT

Biovail is a pharmaceutical company headquartered in Mississauga, Canada. (Am. Compl. ¶ 2.) The four individual defendants are current and former officers of Biovail. (Id. ¶ 25.)

In 2001, Biovail developed Wellbutrin, which became a popular medication for treating depression. (Id. ¶¶ 3, 4.) More recently, Biovail developed another depression medication called Aplenzin, which has the same uses as Wellbutrin, but has several improvements (including that this drug can be taken with alcohol). (Id. ¶ 6.) Aplenzin was called “BVF-033” during the relevant time period. It was approved by the FDA in April 2008. (Id. ¶ 6.)

1. “Abbreviated New Drug Applications” for Generic Drugs and the Separate “New Drug Application” for BVF-033

The Amended Complaint alleges that, in 2005, several of Biovail’s competitors began filing ANDAs seeking FDA approval of generic versions of Wellbutrin. (Id. ¶ 4.) An ANDA is an application to the FDA for approval of a generic version of an existing approved drug. To qualify its product as a generic, the applicant, must show, among other things, that the generic version is “bioequivalent” to the approved drug. (Id. ¶ 4.) Once approved, a generic version of Wellbutrin could be used to fill a prescription written for Wellbutrin. (Id. ¶ 6.)

In December 2005, Biovail filed a petition with the FDA (called a “Citizen Petition”) asking that the FDA require ANDAs for generic versions of Wellbutrin to demonstrate bioequivalence to Wellbutrin by using a certain method of testing called “multiple-dose” testing. (Id. ¶ 5.) The FDA did not respond to Biovail’s Citizen Petition until one year later, on December 14, 2006. (Id. ¶ 8.)

In September 2006, Biovail filed with the FDA its NDA in which it sought approval of BVF-033. (*Id.* ¶ 6.) Biovail’s NDA for BVF-033 included various analyses and studies, including multiple-dose bioequivalence studies. (*Id.* ¶ 9.)

Biovail filed an NDA—not an ANDA—for BVF-033 because BVF-033 was a *new* drug, rather than a generic version of an already approved drug. It was a different formulation than Wellbutrin, using a different active ingredient. An FDA-approved generic version of Wellbutrin could *not* be used to fill a prescription written for BVF-033. (*Id.* ¶¶ 3, 6.) It is not disputed that approval was sought for BVF-033 to stave off competition from Wellbutrin generics.

The FDA accepted the NDA for BVF-033 for review in November 2006. (*Id.* ¶ 7.) The FDA gave Biovail a “PDUFA” date—the date by which the FDA was to issue its decision on the NDA—of July 28, 2007. (*Id.* ¶¶ 16 n.2, 48.)

On December 14, 2006, the FDA issued its response to Biovail’s Citizen Petition concerning ANDAs for generic versions of Wellbutrin (the “December 14 FDA Letter”). (*Id.* ¶ 8.) In its response (which was not even cited in Plaintiff’s initial Complaint), the FDA declined to require ANDAs for generic versions of Wellbutrin to include data from multiple-dose bioequivalence studies. (*Id.* ¶ 8.) The December 14 FDA Letter stated that a single-dose study was the preferred method for assessing bioequivalence between generic versions of Wellbutrin and the name-brand drug:

With regard to a bioequivalence study comparing generic bupropion HCl extended release tablets to Wellbutrin XL, we conclude, based on our experience and expertise, that a single dose study is the preferred approach—not a multiple dose study. . . . It has been the FDA’s experience that for a generic drug, single dose studies are more sensitive at detecting small differences in formulation performance For generic versions of modified-release products including sustained-release or extended-release products such as Wellbutrin XL, the Agency generally recommends a single dose, cross-over, nonreplicate bioequivalency study.

(Robert J. Giuffra, Jr. Decl. (“Giuffra Decl.”), Ex 1 at 12 (December 14 FDA Letter) (emphasis added).)¹

Nothing in the December 14 FDA Letter, on which Plaintiff rests its amended pleading, discussed the data supporting Biovail’s then-pending NDA for BVF-033, because the December 14 FDA Letter did not concern BVF-033. Instead, it dealt with applications by Biovail competitors for generic versions of Wellbutrin, and the type of data that the FDA would require when it assessed those applications. The letter addressed the type of bioequivalence studies that would be required of applicants who sought to prove that their products were bioequivalent to Wellbutrin—not what types of data were needed for Biovail to obtain approval of an entirely new drug, BVF-033, which was not the bioequivalent of Wellbutrin or anything else. (See *id.*)

2. Challenged Public Statements Concerning the BVF-033 NDA

According to the Amended Complaint, Defendants made the following allegedly actionable public statements about the NDA for BVF-033 during two conference calls with securities analysts and in one filing with the Securities and Exchange Commission (“SEC”):

- March 15, 2007 Call: “I’m not really able to comment on whether [BVF-033] is going to allow us to do different formulations or higher strengths . . . we’ll disclose that as we get a partnership and the product *hopefully* gets approved at the end of July.” (Am. Compl. ¶ 53 (quoting Dr. Squires) (emphasis added).)
- May 10, 2007 Call: “[BVF-033] has a PDUFA date of end of July, July 28, I believe. As you know, we are in active discussions with partners and *we hope* to be able to announce something in the relevant near term on that, *but that’s about the most I can say at this point in time.*” (*Id.* ¶ 56 (quoting Dr. Squires) (emphasis added).)
- May 23, 2007 SEC Form 20-F/A: “The FDA accepted our New Drug Application (‘NDA’) for BVF-033 for review in November 2006. The FDA *is expected to* respond to our NDA in late July 2007.” (*Id.* ¶ 59 (emphasis added).)

¹ Because the Amended Complaint quotes and relies on the December 14 FDA Letter, the Court may properly consider the letter in its entirety on this motion to dismiss, without converting the motion into one for summary judgment. See *Ingrassia v. Cty. of Sullivan*, 262 F. Supp. 2d 116, 119-20 (S.D.N.Y. 2003).

On July 20, 2007, Biovail announced that the FDA had declined to approve BVF-033 on July 19. Biovail revealed that the FDA had taken issue with the studies contained in the NDA. (Id. ¶ 12.) The agency took the position that Biovail should have provided single-dose study data. (Id. ¶ 66).

The Amended Complaint alleges that Biovail's stock price dropped from \$25.51 per share to \$20.03 per share on July 20, 2007. (Id. ¶ 12.) According to the Amended Complaint, the announcement of the FDA's initial disapproval of BVF-033 was the supposed "corrective disclosure" that brought the proposed class period to an end. (Id. ¶¶ 1, 12.)

The Amended Complaint does not point to any earlier statement from the FDA in which the agency expressed a preference for data from a single-dose study in connection with its assessment of the NDA for BVF-033.

3. The FDA Approves BVF-033 Without Requiring a Single-Dose Study

Biovail disagreed with the FDA's decision, because it improperly treated Biovail's NDA for the new drug BVF-033 as if it had been an ANDA for a generic drug. (Id. ¶ 66.) As defendant Dr. Squires publicly explained during a conference call with securities analysts on August 8, 2007: "The nonapproval letter states that a single-dose comparative study should have been conducted instead of a multiple dose study, as if this were an abbreviated new drug application. Biovail completely disagrees with this position." (Id. ¶ 66.) Dr. Squires also pointed out that the bioequivalence method used for the BVF-033 NDA was consistent with those previously used in Biovail's FDA-approved application for Wellbutrin and several other drugs. He reiterated Biovail's "strong view" that the method it had used was "consistent with FDA published guidance and the code of federal regulations." (Id. ¶ 66.) The Amended

Complaint does not allege that these post-putative class period statements were inaccurate in any way.

In fact, as the Amended Complaint acknowledges, Biovail not only maintained its position that a multiple-dose study was proper for the BVF-033 NDA, but also resubmitted BVF-033 for FDA approval without including a single-dose study in the application. (*Id.* ¶¶ 70, 71, 76.) Thus, for example, a Biovail press release on October 24, 2007 stated: “Based on Biovail’s discussions with the FDA in an August 14, 2007 meeting, and in accordance with FDA feedback, the submission includes new analyses of the [original]data included in the original New Drug Application (NDA) for BVF-033, but does not include results from any new studies.” (*Id.* ¶ 70; *see also id.* ¶¶ 71, 76.)

On April 23, 2008, the FDA approved BVF-033 without requiring a single-dose study. (*See id.* ¶ 84 (FDA approval); ¶¶ 70, 71, 76 (no new studies).)

Almost six months later, and more than a year after the FDA initially declined to approve BVF-033, Plaintiff commenced this action. It filed the Amended Complaint on December 12, 2008.

STANDARD ON THIS MOTION

Pursuant to Rule 12(b)(6), a court must dismiss a complaint if it fails to plead “enough facts to state a claim to relief that is plausible on its face.” Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 127 S. Ct. 1955, 1974 (2007). Stated differently, to survive a motion to dismiss, a complaint must “provide the grounds upon which [its] claim rests through factual allegations sufficient to raise a right to relief above the speculative level.” *Id.* at 1965 (internal quotation marks omitted). Moreover, “a plaintiff’s obligation to provide the grounds of his entitlement to

relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” Id. at 1964.

To state a claim under Section 10(b), a plaintiff “must allege that [Defendants] (1) made misstatements or omissions of material fact; (2) with scienter; (3) in connection with the purchase or sale of securities; (4) upon which plaintiffs relied; and (5) that plaintiffs’ reliance was the proximate cause of their injury.” Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 172 (2d Cir. 2005) (internal quotation and citation omitted).

The PSLRA requires “that securities fraud complaints specify each misleading statement; that they set forth the facts on which [a] belief that a statement is misleading was formed; and that they state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit, 547 U.S. 71, 81-82 (2006) (internal quotation and citation omitted; alteration in original).

DISCUSSION

I. The Amended Complaint Does Not Plead with Any Particularity Facts Giving Rise To The Required Strong Inference of Scienter.

Under Section 10(b), the required state of mind is “a mental state embracing intent to deceive, manipulate, or defraud.” Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 127 S. Ct. 2499, 2507 (2007) (quotation and citation omitted). As the Supreme Court held in Tellabs: “To determine whether the plaintiff has alleged facts that give rise to the requisite ‘strong inference’ of scienter, a court must consider plausible nonculpable explanations for the defendant’s conduct, as well as inferences favoring the plaintiff.” Id. at 2510. The Supreme Court further held: “A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.” Id.

In the Second Circuit, a plaintiff may plead a strong inference of scienter only by alleging particularized facts that “(1) show[] that the defendants had both motive and opportunity to commit the fraud or (2) constitute strong circumstantial evidence of conscious misbehavior or recklessness.” ATSI Commc’ns Inc., v. Wolfson, 493 F.3d 87, 99 (2d Cir. 2007). Regardless of the manner in which a plaintiff attempts to plead scienter, at the end of its evaluation, this Court must be convinced that the inference of scienter is “at least as compelling” as any competing inferences. Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc., 531 F.3d 190, 197 (2d Cir. 2008).

The Amended Complaint’s scienter allegations are woefully deficient.

A. The Amended Complaint Contains No Legally Cognizable Motive Allegations.

In the Second Circuit, the requirements for pleading motive as a basis for an inference of scienter are well established:

Motive entails concrete benefits that can be obtained as a result of the alleged misstatements or omissions. . . . The Second Circuit has held that a “generalized motive, one which could be computed to any publicly owned, for-profit endeavor” is not enough. Chill v. Gen. Elec. Co., 101 F.3d 263, 267 (2d Cir. 1996). Thus, arguing that the motive for defrauding investors was to increase the company’s profits or to increase officer compensation is not sufficient.

In re AstraZeneca Sec. Litig., 559 F. Supp. 2d 453, 468 (S.D.N.Y. 2008). Indeed, where there “is no allegation of any insider trading by any of the defendants, nor is there any allegation of pecuniary gain . . . [Second Circuit precedent] does not permit mere conclusory allegations of motive to satisfy the requirements of Rule 9(b) and the Reform Act.” See Kalnit v. Eichler, 85 F. Supp. 2d 232, 243 (S.D.N.Y. 1999). And where a plaintiff “has failed to demonstrate that defendants had a motive to defraud . . . he must produce a *stronger* inference of recklessness” or intentional misconduct. Kalnit v. Eichler, 264 F.3d 131, 143 (2d Cir. 2001) (emphasis added).

Plaintiff's Amended Complaint does not allege that Defendants engaged in any insider trading during the alleged period of fraud, or otherwise stood to reap personal benefits from allegedly misleading the public about BVF-033's prospects for FDA approval or from "concealing" the fact that Biovail's NDA for BVF-033 used a multiple-dose study. The only motive for fraud identified in either the Amended Complaint or the plaintiff's opposition to the motion to dismiss is Defendants' desire to get BVF-033 approved and marketed before competitors' generic versions of Wellbutrin were launched. (See Am. Compl. ¶¶ 6, 91.) As plaintiff argues in its opposition brief, "Defendants would not have wanted to disclose any information that would embolden competitors' efforts." (Pl. Opp'n at 16). But this is nothing more than a "generalized motive" of increasing corporate profits, which has uniformly been deemed insufficient. The Second Circuit has held that the alleged motives to maintain a company's stock price or "sustain [] the appearance of corporate profitability" do not constitute sufficient evidence of motive to support a securities fraud claim. Chill, 101 F.3d at 268. This rule is well founded, because the desire to improve corporate performance is a perfectly proper motive for executives of for-profit enterprises. "If scienter could be pleaded on that basis alone, virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions" Acito v. IMCERA Group, 47 F.3d 47, 57 (2d Cir. 1995), and "the motive requirement [would become] meaningless," Chill, 101 F.3d at 268 n.5. Furthermore, plaintiff does not explain how non-disclosure of information would have "emboldened" Biovail's competitors; they were already sufficiently "emboldened" to have submitted ANDA applications to the FDA.

Plaintiff asserts that it has adequately pled scienter simply by alleging that Defendants failed to disclose that the BVF-033 application used a multiple-dose study and therefore had a

greater risk of non-approval or delay, stating: “The fact that Defendants failed to inform the investing public that the Company was taking such risk constitutes strong circumstantial evidence of scienter.” (Am. Compl. ¶ 92.) Plaintiff’s reasoning is a classic example of “fraud by hindsight.” The mere allegation that Defendants failed to disclose a risk does not in and of itself constitute strong evidence that they did so with scienter.

As stated previously, under the Supreme Court’s decision in Tellabs, 551 U.S. 308, 127 S. Ct. at 2510, the Amended Complaint cannot survive this motion to dismiss unless its inference of scienter is “cogent and at least as compelling as any opposing inference one could draw from the facts alleged.” Id. at 2510. The Amended Complaint does not pass muster.

Plaintiff’s own allegations acknowledge the following facts and support the following resulting inferences:

First, plaintiff does not allege that Defendants wanted BVF-033 to be disapproved; to the contrary, plaintiff contends that Biovail desperately wanted to get an entirely new product into the marketplace before competitors were able to offer generic versions of Wellbutrin. Nor does plaintiff allege that Defendants believed their NDA application was deficient at the time it was submitted to the FDA; again to the contrary, plaintiff takes the position that Biovail had no reason to believe otherwise until it received the December 14 FDA Letter. That is the moment when the allegedly fraudulent non-disclosure commenced. (See Am. Compl. ¶ 50.) The only fair inference to be drawn from the Amended Complaint is that Defendants reasonably believed that their application was supported by sufficient and acceptable data and would be approved.

Second, the December 14 FDA Letter did not diminish Defendants’ hopes of BVF-033’s approval, because this letter addressed the different context of *Abbreviated* NDAs for *generic* versions of a *different* drug (Wellbutrin). (See id.) As plaintiff concedes, the FDA Letter did not

address Biovail's NDA for BVF-033 at all, although the FDA had already accepted the BVF-033 NDA for review with its multiple-dose study. (See *id.* ¶ 47.) Plaintiff argues, in effect, that Defendants should have inferred from a letter addressing ANDAs that the FDA would express the same preference in connection with an application relating to an entirely new drug. But plaintiff alleges nothing that would have caused Biovail to draw such an inference. And the Amended Complaint reveals several reasons why defendant quite logically would not have reached any such conclusion.

First and foremost, as Biovail publicly announced (see *id.* ¶¶ 66, 68), Biovail's use of a multiple-dose study in the BVF-033 NDA was expressly supported by the applicable FDA regulation setting forth the basis for determining bioequivalency, which provides: "Two drug products will be considered bioequivalent drug products if they . . . do not show a significant difference when administered . . . under similar experimental conditions, *either single dose or multiple dose.*" 21 C.F.R. § 320.23(b) (emphasis added). Indeed, Biovail's NDA for the FDA-approved Wellbutrin (and several other drugs) had also included a multiple-dose bioequivalence study. (See Am. Compl. ¶ 66.)

Consistent with this regulation, neither the December 14 FDA Letter nor the FDA authority cited and relied on therein *required* that an NDA applicant use a single-dose study. The December 14 FDA Letter used the words "preferred approach" and "recommendation" to describe its views about bioequivalence studies for generic versions of Wellbutrin. (See *id.* ¶ 50.) The December 14 FDA Letter cites and relies on an FDA publication entitled "Guidance for Industry: Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations," which bears the bold legend "***Contains Nonbinding Recommendations***" on the top of every page. (See Giuffra Decl. Ex. 1, at 5, n.21 (December 14

FDA Letter); Ex. 2 (FDA “Guidance for Industry”).) That March 2003 publication also states in a large bolded box on the first page: “This guidance represents the [FDA’s] current thinking on this topic. . . . An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.” (See Giuffra Decl., Ex. 2, at 1.)

The significance of these matters cannot be overstated. All of the cases cited by plaintiff in its opposition to the motion to dismiss are cases in which the defendants’ public statements about their pending drug applications were directly contradicted by contrary evidence known to the defendants. In In re Genta, Inc. Sec. Litig., No. Civ. A. 04-2123 (JAG), 2005 WL 2416970, at *4-5 (D.N.J. Sept. 30, 2005), defendants stated that drug “did not appear to be associated with serious . . . adverse reactions,” even though they knew that drug *was* associated with increased toxicity and adverse reactions in significant numbers of patients. In In re Regeneron Pharm., Inc. Sec. Litig., 03 Civ. 3111, 2005 WL 225288, at *19-20 (S.D.N.Y. Feb. 1, 2005), defendants made numerous statements about the efficacy of the drug, which were expressly refuted by 20 confidential sources, who reported problems “far beyond the statistical levels disclosed after the Phase II clinical trial”). In In re Cell Pathways, Inc. Sec. Litig., No. 99-752, 2000 WL 805221, at *3-4 (E.D. Pa. June 20, 2000), defendants publicly stated that pharmaceutical study was proceeding as planned despite knowledge that the study was fatally flawed, because the medical records needed to evaluate patient suitability for testing were not obtained until *after* the study had been completed. Even in In re Amylin Pharm., Inc. Sec. Litig., No. 01CV1455 BTM (NLS), 2002 WL 31520051, at *4 (S.D. Cal. Oct. 12, 2002), defendants made numerous statements about efficacy of studies and prospects of approval despite explicit FDA warning that the key study submitted in connection with their NDA was “inconsistent with clinical practice” and “not considered pivotal data for an NDA.”

Here, by contrast, the most that can be said is that, after Biovail submitted an NDA for BVF-033, defendants knew that, despite the FDA's published regulations, which permitted either single or multiple-dose studies, the agency expressed a non-binding preference for single-dose rather than multiple-dose trial data in the context of ANDAs (not NDAs). There is not a single allegation in the Amended Complaint that the FDA ever explicitly warned defendants that they were proceeding with an insufficiently supported application. Nor could the pleading so allege, since plaintiff admits that Biovail had more than 30 interactions with the FDA after submission of the BVF-033 NDA, and that the agency never once mentioned the inappropriateness of relying on multiple-dose studies in support of NDAs. (See Am. Compl. ¶ 66.)

The last nail in the coffin for plaintiff's theory of scienter is that Defendants' continued belief that BVF-033 would be approved based on a multiple-dose study was demonstrably reasonable, since the FDA ultimately *approved* BVF-033 based on a multiple-dose study and without requiring the submission of data from any single-dose study. (See *id.* ¶ 84 (FDA approval); ¶¶ 70, 71, 76 (no new studies).) Plaintiff argues that this is irrelevant because the issue is not whether BVF-033 was approved, but rather when it was approved. But there is nothing in the Amended Complaint or the December 14 FDA Letter or the FDA's published regulations, or even its non-binding guidelines, suggesting that it will take longer to approve an NDA that relied on a multiple-dose study rather than a single-dose study. The only support for plaintiff's assertion that BVF-033 could be approved without a single-dose study, but that approval would be delayed, is the fact that this is what occurred. Once again, plaintiff is relying on fraud by hindsight.

All of these "non-culpable explanations" point to a single inference: Defendants did not know, and had no reason to know, that the FDA would initially (and erroneously) reject its NDA

for BVF-033 because it submitted data from a multiple-dose study rather than a single-dose study. Furthermore, this inference is not simply “as compelling” as any inferences raised by plaintiff’s conclusory and self-refuting allegations of fraud; it is far, far more plausible than the inference plaintiff would have the trier of fact draw. The Amended Complaint must be dismissed for this reason alone. Tellabs, 551 U.S. at ---, 127 S. Ct. at 2510.

II. The Amended Complaint Does Not Adequately Plead Loss Causation.

The Amended Complaint must also be dismissed for failure to state a claim for the independently sufficient reason that it does not plead the required element of loss causation.

To plead loss causation under Section 10(b), a complaint must allege a direct causal connection between defendants’ allegedly actionable statements or conduct and plaintiffs’ alleged damages. See Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 346-47 (2005). As the Supreme Court has made clear, private securities fraud actions are not meant “to provide investors with broad insurance against market losses.” Id. at 345. Rather, they allow recovery only where the plaintiff pleads facts that support an inference that the allegedly fraudulent act or omission is “the proximate causal link between the alleged misconduct and the plaintiffs’ economic harm.” ATSI Commc’ns Inc., v. Wolfson, 493 F.3d 87, 106 (2d Cir. 2007) (citing Dura, 544 U.S. at 346; Lentell, 396 F.3d at 172). To this end, a plaintiff must plead that any alleged loss was “caused by the materialization of the risk concealed by the fraudulent statement” Id. at 106-07 (citing Lentell, 396 F.3d at 173). In other words, a complaint must plead that plaintiff’s losses were caused by the disclosure of the truth that Defendants had previously allegedly misrepresented. Dura, 544 U.S. at 342-43.

As the Supreme Court held in Dura, simply alleging that a stock’s price was inflated during the putative class period is not sufficient. Instead, the alleged inflation must also be

eliminated upon disclosure of the relevant fraud—either by a “corrective disclosure” or because the “truth” entered the market in some other way. Dura, 544 U.S. at 347.

Here, the Amended Complaint does not (and cannot) identify any “corrective disclosure” that revealed the existence of some prior alleged misrepresentation by Defendants and so caused Biovail’s stock price to decline.

The all-but-inevitable decline in the price of Biovail’s stock price following the company’s announcement that the FDA had not approved the BVF-033 application by late July 2007 was caused by the agency’s failure to approve the drug—not by any “corrective” disclosure of some prior untruth. Nothing in the July 20, 2007 announcement that the FDA had declined to approve BVF-033 “corrected” or otherwise revealed the “actual truth” behind any prior alleged misrepresentation by Defendants, or otherwise tied the resulting stock price decline to any prior alleged fraud.

If, as Plaintiff contends, the alleged fraud was Defendants’ failure to inform investors of their supposed belief that the NDA for BVF-033 was unlikely to be approved by the FDA because the application improperly relied on a multiple-dose study, no corrective disclosure ever occurred. To the contrary: as the Amended Complaint itself acknowledges, after the FDA’s initial rejection of BVF-033, Biovail maintained its public stance that a single-dose study was not required for the BVF-033 NDA, and that the original multiple-dose study was proper. (Am. Compl. ¶¶ 70, 71, 76.) So defendants persisted in their purported “misstatements” after the expiration of the class period. The Amended Complaint also acknowledges that Biovail informed the public that it was going to seek FDA approval of BVF-033 again, without including a single-dose study or any other new clinical data. (Id.) That is precisely what Biovail did—and the FDA approved the drug despite the absence of a single-dose study.

Thus, Plaintiff has failed to plead loss causation. For this reason, too, the complaint must be dismissed.

III. The Amended Complaint Fails To Plead Any Actionable Misrepresentations.

Section 10(b) requires the plaintiff in a case like this one to allege, *inter alia*, a material misstatement or omission in a public disclosure. See 15 U.S.C. § 78(j). The meaning of materiality in the context of securities litigation is long settled—the key to the inquiry is whether there is a “substantial likelihood” that the alleged misstatement or omission would be deemed significant by a reasonable investor in light of the “total mix” of information available at such time about the investment. Basic, Inc. v. Levinson, 485 U.S. 224, 231-32 (1988) (quoting TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976)). The Amended Complaint here fails to state a claim because it does not adequately plead any actionable misrepresentation (by way of alleged misstatement or omission).

The three allegedly actionable statements challenged by the Amended Complaint are all soft, forward-looking statements that are immaterial on their face as a matter of law. The first two statements were merely expressions of “hope” that the FDA would approve BVF-033:

- March 15, 2007 Analyst Call: “I’m not really able to comment on whether [BVF-033] is going to allow us to do different formulations or higher strengths . . . we’ll disclose that as we get a partnership and the product *hopefully* gets approved at the end of July.” (Am. Compl. ¶ 53 (emphasis added).)
- May 10, 2007 Analyst Call: “[BVF-033] has a PDUFA date of end of July, July 28, I believe. As you know, we are in active discussions with partners and *we hope* to be able to announce something in the relevant near term on that, *but that’s about the most I can say at this point in time.*” (*Id.* ¶ 56 (emphasis added).)

Far from being worded as guarantees, these statements made no predictions whatsoever about the likelihood of FDA approval. Indeed, these statements reflected only the slightest degree of optimism—if any—and Dr. Squires (the speaker) was conservative and cautious in

advising the audience that Biovail would not comment any further than that on the subject of potential FDA approval. The Amended Complaint does not identify a single statement in which Biovail indicated that the drug would definitely be approved by its PDUFA date. And it nowhere alleges (nor could it) that Biovail and Dr. Squires did not in fact “hope” that BVF-033 would be approved.

The third purported misstatement merely recites the historical fact—not alleged to be false—that the FDA had “accepted . . . the NDA for BVF-033 for review” back in November 2006, and (like the second statement) indicates that the “FDA is expected to respond to [the BVF-033] NDA in late July 2007.” (*Id.* ¶ 59 (citing May 23, 2007 SEC Form 20-F/A).) This statement of expectation about the FDA’s timing is soft and immaterial on its face as a matter of law. In addition, it merely referred to the historical fact—also not alleged to be false—that the FDA gave Biovail a “PDUFA” date for its response to the NDA of July 28, 2007. (*Id.* ¶¶ 16 n.2, 48.) In fact, the FDA ultimately gave Biovail its response on July 20, 2007, eight days earlier than expected. (*Id.* ¶ 12.) The challenged statement says nothing about what the FDA’s response was expected to say.

All three of these statements “are in all relevant respects identical to those that the [Second Circuit] Court of Appeals has repeatedly held to be nonactionable expressions of corporate optimism.” *In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 557 (S.D.N.Y. 2004) (citations omitted; collecting cases). As the court observed in *Bristol-Myers*:

It is well settled that a complaint alleging violations of the securities laws may not rely upon statements that are true, or constitute puffery or ordinary expressions of corporate optimism. . . . Further, statements regarding future performance are actionable only if they are worded as guarantees or are supported by specific statements of fact, or if the speaker does not genuinely or reasonably believe them.

Id.; see also In re Int'l Bus. Machs. Corp. Sec. Litig., 163 F.3d 102, 108 (2d Cir. 1998)

(statement that “we fully expect our cash flow [to be] sufficient to cover the dividends in 1992,” as well as other opinions regarding future dividends, was “plainly an expression of optimism that is too indefinite to be actionable under the securities laws”).

The Bristol-Myers case is particularly instructive here. There, defendants had made various statements about potential FDA approval of the cancer drug Erbitux. Id. at 554-55. The complaint challenged the following statements made by defendants during a conference call with securities analysts: (i) “[W]e think that [Erbitux] is a tremendous strategic opportunity;” (ii) “We think [Erbitux] is real blockbuster potential, has the potential to be one of the most exciting, if not the most exciting, oncology compound introduced over the next several years;” (iii) [Erbitux is] a compound with an 18-year patent life, ready to go to market hopefully next year;” (iv) “[Erbitux] is a late-stage product with potential to drive the growth of our oncology franchise in the near and medium term and extending into 2018;” and (v) “[Erbitux] is a first-in-class novel blockbuster drug for treating cancer” Id. at 557.

Plaintiffs sued after the FDA declined to approve Erbitux. The court granted defendants’ motion to dismiss, holding that these statements were not material. Id. at 558. Biovail’s statements here were much less optimistic and more obviously immaterial on their face than the statements that were rejected as insufficient to state a Section 10(b) claim in Bristol-Myers.

Plaintiff’s related “omission” theory—namely, that these statements are nevertheless actionable, because Defendants did not disclose that the BVF-033 NDA was at greater risk of non-approval (or delayed approval) in light of the FDA’s stated preference for single-dose studies in ANDAs for generic versions of Wellbutrin—is equally unavailing. The fact that Biovail used a multiple-dose study in a full-blown *New Drug Application* for BVF-033—a non-

generic, different drug—was simply not material information that Biovail had to disclose in light of the total mix of information available to investors, including the disclosed risk of “the difficulty of predicting U.S. Food and Drug Administration . . . approvals.” (See, e.g., Giuffra Decl., Ex. 4, at 11 (May 10, 2007 press release).) Indeed, Plaintiff’s own allegations demonstrate that the allegedly omitted information was immaterial, because it acknowledges that the FDA ultimately approved BVF-033 without requiring submission of a single-dose study. And, as the Court observed above in connection with its discussion of scienter, there was absolutely no information from the FDA that would have led a reasonable applicant to assume that an NDA (as opposed to an ANDA) supported with multiple-dose study data would experience a delay in final approval.

Furthermore, the PSLRA provides a safe harbor shielding a defendant from liability for forward-looking statements, even if those statements later prove to be incorrect. See generally 15 U.S.C. § 78u-5. Under the safe harbor, a forward-looking statement cannot provide the basis for liability where it “is identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement” 15 U.S.C. § 78u-5(c)(1)(A)(i). Here, the PSLRA safe harbor immunizes all of the statements challenged in the Amended Complaint.²

The first two of the three challenged statements were made during analyst conference calls. The third appeared in Biovail’s May 23, 2007 Annual Report, filed with the SEC on Form

² Another separate prong of the PSLRA safe harbor provides that there is no liability for a forward-looking statement if the plaintiff fails to establish that the statement was made “with actual knowledge by [the speaker] that the statement was false or misleading.” 15 U.S.C. § 78u-5(c)(1)(B). Given the Amended Complaint’s complete absence of any well-pled, non-conclusory allegations of scienter, this prong of the safe harbor applies here as well.

20-F/A. Each of the three forward-looking statements was identified as such and was accompanied by an appropriate risk disclosure. For example, at the beginning of the May 10, 2007 analyst conference call, a speaker recited the following PSLRA safe harbor statement:

On behalf of the speakers who follow, investors are cautioned that the presentations and responses to questions may contain forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, and which comprise forward-looking information within the meaning of the Safe Harbor Provisions of Canadian Provincial Securities laws.

Forward-looking statements involve risk and uncertainties and undue reliance should not be placed on such statements. Certain material factors or assumptions are implied in making forward-looking statements, and actual results may differ materially from those expressed or implied in such statements. Forward-looking statements include but are not limited to our goals, targets, strategies, intentions, plans, beliefs, estimates, expectations, outlook, guidance, and other statements which contain language, such as guidance, belief, anticipate, expect, intend, plan, will, may, and other similar expressions.

For additional information . . . about the material factors that may cause actual results to vary from those expressed or implied in such statements, please consult the Company's earnings press release dated May 10, 2007.

(See Giuffra Decl., Ex. 3, at 1 (May 10, 2007 Analyst Conference Call) (emphasis added).)³

The May 10, 2007 Biovail press release referenced during the analyst call in the quote above expressly identified the risk of FDA non-approval, stating:

Although Biovail believes that the expectations reflected in such forward-looking statements are reasonable, such statements involve risks and uncertainties, and undue reliance should not be placed on such statements. . . . Important factors that could cause actual results to differ materially from these expectations include, among other things: a decrease in sales of Wellbutrin XL®, *the difficulty of predicting U.S. Food and Drug Administration, Canadian Therapeutic Products Directorate and European regulatory approvals*, acceptance and demand for new

³ Because the Amended Complaint quotes and relies upon statements made during the two analyst calls and in Biovail's SEC Form 20-F/A (see Am. Compl. ¶¶ 53, 56, 60), the Court may properly consider the full transcripts of those calls and the complete referenced SEC filings in connection with the Rule 12(b)(6) motion without converting it to one for summary judgment. See Ingrassia, 262 F. Supp. 2d at 119-20.

pharmaceutical products . . . the regulatory environment . . . and other risks detailed from time to time in the Company's filings with the [SEC]

(See Giuffra Decl., Ex. 4, at 11 (May 10, 2007 press release) (emphasis added).) Substantially similar disclosures were made during the other analyst conference call referenced in the Amended Complaint (on March 15, 2007), including a reference to a press release issued on the day of the call with a virtually identical risk disclosure. (See Giuffra Decl., Ex. 5, at 1 (March 15, 2007 Analyst Conference Call); Giuffra Decl., Ex. 6, at 12-13 (March 15, 2007 press release).) And substantially similar PSLRA safe harbor disclosures and cautionary language were also included in Biovail's May 23, 2007 SEC Form 20-F/A. (See Giuffra Decl., Ex. 7.)

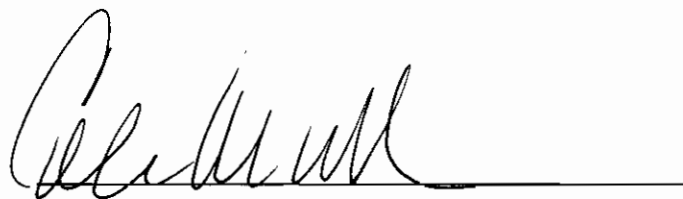
These detailed disclaimers and risk disclosures indisputably satisfy the PSLRA safe harbor, and immunize from liability all of the alleged misrepresentations cited in the Amended Complaint. See In re Sierra Wireless, Inc. Sec. Litig., 482 F. Supp. 2d 365, 381-82 (S.D.N.Y. 2007) ("Because each forward-looking . . . statement cited by plaintiffs as false or misleading was accompanied by meaningful cautionary language, the statements are considered immaterial under the PSLRA safe harbor.").

CONCLUSION

For the foregoing reasons, the Court grants Defendants' motion (Docket No. 12) and dismisses the Amended Complaint in its entirety. Because plaintiff has already amended its complaint once, and because the flaws in pleading are incurable on the facts of this case, dismissal is with prejudice.

This constitutes the decision and order of the Court.

Dated: May 8, 2009

A handwritten signature in black ink, appearing to read "Robert M. Wall", is written over a solid horizontal line.

U.S.D.J.

BY ECF TO ALL COUNSEL