IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE VIROPHARMA INCORPORATED SECURITIES LITIGATION	:	CIVIL ACTION
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	:	NO. 12-2714
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MEMORANDUM

Jones, II, J. **May 15, 2014**

I. Introduction

The instant motion relates to the consolidated class action in which lead Plaintiff Carpenters' Local 27 Defined Benefit Fund asserts that Defendants ViroPharma Incorporated ("ViroPharma"), Vincent J. Milano, Charles A. Rowland, Thomas F. Doyle, and John P. Wolf violated Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78j(b) ("Section 10(b)"); Rule 10b–5 promulgated thereunder, 17 C.F.R. § 240.10b–5 ("Rule 10b–5"); and Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a) ("Section 20(a)"). Plaintiff filed this litigation on behalf of all persons who purchased ViroPharma securities between December 14, 2011 and April 9, 2012 (the "Class Period").

Having considered the motion, the pleadings, and the oral arguments made in open court on June 10, 2013, for the reasons set forth below, Defendant's Motion is denied.

II. Factual Background

ViroPharma Incorporated ("ViroPharma) is a publicly traded biotechnology company that maintains a principal place of business in Exton, Pennsylvania. ViroPharma markets and sells a number of products, one of which is the antibiotic Vancocin, which treats the

gastrointestinal infection, *Clostridium difficile* associated diarrhea ("CDAD"). Vancocin was a lucrative property for ViroPharma, and comprised a substantial portion of ViroPharma's revenues from 2005-2011.

The Complaint alleges that the patent for Vancocin expired in 1996. The FDA's requirement that a generic version of Vancocin be tested on humans, however, created a barrier for generics to enter the market. In 2006 the FDA changed its position regarding the proof necessary to establish bioequivalence, allowing for laboratory testing instead of testing on human subjects. The Complaint alleges that this change substantially lowered any barriers to entry and threatened ViroPharma's hold on the Vancocin Market. As a challenge to the FDA's decision, ViroPharma filed a Citizen's Petition[1] with the FDA, which was amended twenty times between 2006 and 2011. A generic drug could not be introduced while the Citizen's Petition was pending.

In 2008, Congress passed the QI Program Supplemental Funding Act of 2008 (the "QI Act"), which permits the FDA to grant an additional three years of marketing exclusivity for "Old Antibiotics"—such as Vancocin—under the Hatch-Waxman Act[2] if a company can demonstrate that the "Old Antibiotic" can be administered for a new "condition of use."[3]

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[1] A Citizen's Petition is a means by which a party can "petition to the FDA to issue, amend or revoke an agency regulation or take other administrative action ." *Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135, 137 (3d Cir. 1987)

> A citizen petition must describe the FDA action requested, include a statement of the factual and legal grounds on which the petitioner relies, and certify that the petition includes 'all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.' 21 C.F.R. § 10.30(a).

In re Wellbutrin XL Antitrust Litig., CIV.A. 08-2431, 2012 WL 1657734 (E.D. Pa. May 11, 2012)

[2] "The Hatch–Waxman Act provides a streamlined regulatory pathway for generic pharmaceutical companies to seek approval of their drugs, while giving branded pharmaceutical companies an opportunity to sue to defeat approval of the generic drugs." *In re OxyContin Antitrust Litig.*, 04 MD. 1603

In an effort to stave off the arrival of generics from other companies and to gain three years of statutory exclusivity under the QI Act,[4] and to market Vancocin for a new "condition of use," ViroPharma licensed a study conducted by Genzyme Corporation ("Genzyme Study"), to support a supplemental New Drug Application ("sNDA") that ViroPharma would file with the FDA.

The Genzyme Study compared tolamer—a Genzyme experimental drug used to treat CDAD—with Vancocin. Though the Genzyme study was ultimately a failure, in that Genzyme could not gain approval for tolamer, ViroPharma sought to use this data. Based on analysis of the licensed data in the Genzyme study, ViroPharma submitted an sNDA to the FDA on April 23, 2010, even though ViroPharma "knew, based on FDA policy statements, that the FDA would not accept such an analysis as evidence of effectiveness for any use." In February 2011, the FDA rejected the sNDA, which ViroPharma then amended and resubmitted in June 2011.[5]

SHS, 2014 WL 128013 * 3 (S.D.N.Y. Jan. 14, 2014). "Hatch–Waxman created an abbreviated approval process for generic non-antibiotic drugs, while retaining incentives for pioneer drugs, such as marketing exclusivity and patent protections." *ViroPharma, Inc. v. Hamburg*, 898 F. Supp.2d 1 (D.D.C. Apr. 23, 2012) (quoting *Allergan, Inc. v. Crawford*, 398 F. Supp.2d 13, 16–17 (D.D.C.2005)).

[3] The QI Act amended the Federal Food, Drug, and Cosmetic Act to make Old Antibiotics, like Vancocin, eligible for an additional three year exclusivity period for changes approved in a supplemental New Drug Application ("sNDA") if the sNDA contains reports of new clinical investigations . . . essential to the approval of the [sNDA] and conducted or sponsored by the [applicant]." 21 U.S.C. § 355(j)(5)(F)(iv). However, exclusivity under the QI Act "shall not apply to any condition of use for which the [old antibiotic] was approved before [October 8, 2008,] the date of the enactment of [the QI Act]." 21 U.S.C. §355(v)(3)(B).

[4] ViroPharma's application for exclusivity was the first one brought under the new QI Act and the issue of what constituted a new "condition of use" was a matter of first impression before the FDA.

[5] Plaintiff alleges that on at least four occasions prior to the start of the Class Period, the FDA informed ViroPharma that the Genzyme Study was not adequate and well-controlled as to Vancocin. Plaintiff alleges that because Defendants' exclusivity claim was based on the Genzyme study—which ViroPharma knew was inadequate—ViroPharma would not be able to achieve extended exclusivity for Vancocin. Plaintiff points to:

> 1) a letter from the FDA to ViroPharma dated February 18, 2011, which stated that, based on ViroPharma's sNDA of April 23, 2010, the Genzyme study was "problematic" for a number of issues related to the trials;

On December 14, 2011, the FDA approved the sNDA for Vancocin's new label.[6] Plaintiff alleges that despite approving the label change, "the FDA was clearly stating that ViroPharma's new label did not support a new active ingredient, a new indication, a new dosing regime, or a new route of administration." Plaintiff alleges that the FDA was warning ViroPharma that the labelling change would not be sufficient for a grant of the additional three year exclusivity. Nevertheless, on that same day, ViroPharma issued a press release announcing the approved label change and also that "[a]s a result of today's sNDA approval, ViroPharma believes Vancocin meets the requirements for, and thus has, three years of [marketing] exclusivity, and that generic vancomycin capsules will not be approved during this period."

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2) a letter from J. Christopher Davi, MS, Senior Regulatory Project Manager at the Division of Anti-Infective Products ("DAIP") dated May 20, 2011, in anticipation of a May 24, 2011 teleconference between ViroPharma and DAIP, which indicated that the Genzyme Study was not an "adequate and well-controlled" study;

3) A May 24, 2011 teleconference between ViroPharma and FDA representatives; and

4) A December 8, 2011 "labeling teleconference" between the FDA and ViroPharma, the sum and substance of which was memorialized in an April 9, 2012 letter internal FDA memo.

[6] In the December 14, 2011 letter, the FDA stated:

> This "Prior Approval" efficacy supplemental new drug application provides for updates to the prescribing information for VANCOCIN with clinically relevant new safety and efficacy information . . . We have completed our review of this supplemental application as amended. It is approved effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

The letter goes on to state:

> Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosage regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.
>
> Because none of these criteria apply to your application, you are exempt from this requirement.

Plaintiff alleges that "market accepted Defendants' statements [regarding the prospect of exclusivity] and believed that the additional three years of marketing exclusivity for Vancocin was a *fait accompli*." In turn, ViroPharma stock jumped 17.85% on the day of the announcement. Notwithstanding warning signs from prior communications with the FDA, on December 22, 2011 ViroPharma nevertheless supplemented their Citizen's Petition to the FDA and asserted that the new label provided several new "conditions of use" and this qualified for the additional three years of marketing exclusivity.

During the Class Period, and before the FDA ultimately made a decision on ViroPharma's Citizen's Petition, Plaintiff alleges that ViroPharma continued to make materially false and misleading statements to the public, and omit crucial information from public statements and documents regarding the FDA's indication that Vancocin would not be approved for a "new condition of use."[7]

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[7] In addition to the aforementioned December 14, 2011 Press Release, which Plaintiff alleges omitted material information regarding prior communications with the FDA and included false and misleading statements, Plaintiff identifies six additional instances of materially false and misleading statements:

> 1) A Form 8-K filed by ViroPharma with the SEC dated January 4, 2012, which attached ViroPharma's December 22, 2011 Citizen's Petition Supplement, which Plaintiff alleges contain false and misleading statements regarding the label changes—describing them as a "new indication and dosing regimen," despite contrary indications in the FDA's December 14, 2011 letter and in prior communications.;
>
> 2) A Form 8-K filed by ViroPharma with the SEC dated January 5, 2012 attaching a press release that projected future earnings and stated:
>
> > We believe that 2012 will not only be yet another year of strong growth…, as a result of our sNDA approval, we believe Vancocin (vancomycin hydrochloride, USP) Capsules meets the requirements for, and thus has, three years of exclusivity and that generic vancomycin capsules will not be approved during this period… These investments in our clinical pipeline are designed to ultimately bring us closer to delivering solutions for patients as well as provide additional future growth for our shareholders;
>
> 3) Statements at a January 11, 2012 presentation at the J.P. Morgan Global Healthcare Conference, in which Defendant stated that [ViroPharma] "created an exclusivity proposition" based on the label change;

On April 9, 2012, the FDA formally denied ViroPharma's Citizen's Petition, stating that:

> Notably, ViroPharma's position that [the Genzyme] studies were essential to the approval of a new indication and new dosing regimen are inconsistent with the contents of the sNDA that contained those studies, and the letter detailing the approval of the sNDA. As indicated in the approval letter, the Agency determined that the supplement supported "updates to the prescribing information" and "conversion of the current label into the [PLR] format." In addition, had you intended to seek approval for a new indication or a new dosing regimen (or a new active ingredient, new dosage form, or new route of administration), you would have been required by statute to have conducted an assessment of the safety and effectiveness of the product for the claimed indication in the pediatric patients under the Pediatric Research Equity Act (PREA). You did not submit any such assessments in your sNDA or otherwise reference PREA's requirements by seeking a deferral or waiver of this requirement. Moreover, your approval letter to which you did not object, confirmed that PREA was not triggered by your sNDA. This confirms that you, like the Agency, did not believe your labeling changes constituted a new indication, new dosing regimen, or other PREA-triggered change.

Upon the news of the formal denial of exclusivity, and the FDA's simultaneous approval of three generic versions of Vancocin produced by competitors, ViroPharma shares declined 21%.

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4) A February 28, 2012 Form 8-K filed with the SEC attaching a Press Release that touted as a highlight "the approval of our Vancocin sNDA leading to modernized labeling and, we believe, three years of exclusivity";

5) A February 28, 2012 earnings call that included allegedly false and misleading statements and omitted key information when an analyst inquired about FDA feedback;

6) A February 28, 2012 Form 10-K filed with the SEC that stated "As a result of the sNDA approval, we believe Vancocin meets the requirements for three years of exclusivity, and that generic vancomycin capsules will not be approved during this period. Under FDA's regulations, labeling changes based on new clinical investigations that are essential to approval of the sNDA and to which the applicant has exclusive rights may be entitled to three years of exclusivity.

III. Legal Standard

a. Motion to Dismiss under 12b(6)

In deciding a motion to dismiss pursuant to Rule 12(b)(6), courts must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (internal quotation marks omitted). After the Supreme Court's decision in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007), "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678 (citing *Twombly*, 550 U.S. at 556). This standard, which applies to all civil cases, "asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 678; *accord Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) ("[A]ll civil complaints must contain more than an unadorned, the-defendant-unlawfully-harmed-me accusation.") (internal quotation marks omitted). "In analyzing a motion to dismiss under the PSLRA, this Court must examine the complaint in its entirety, as well as documents incorporated into the complaint by reference or matters of which a court may take judicial notice. *In re NutriSystem, Inc. Sec. Litig.*, 653 F. Supp. 2d 563, 566 fn.2 (E.D. Pa. 2009) (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 127 S.Ct. 2499, 2509, 168 L.Ed.2d 179 (2007); *Winer Family Trust v. Queen*, 503 F.3d 319, 327 (3d Cir.2007)).

b. Heightened Pleading for Section 10b and Rule 10b5

Section 10(b) of the Exchange Act makes it unlawful for any person, through the use of "any means of interstate commerce, the mails, or any national securities exchange, to employ . . . any manipulative or deceptive device or contrivance in contravention of rules" promulgated by the Securities and Exchange Commission (SEC). 15 U.S.C. § 78j.

Section 10(b) is enforced by Rule 10b-5, one such rule promulgated by the SEC, and prohibits, in connection with the purchase or sale of securities, the making of "any untrue statement of a material fact" or the omission of "a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b–5 (1951).

Here, Plaintiff alleges omissions of material fact. To state a claim for omissions under Section 10(b) of the Exchange Act and Rule 10b–5, a plaintiff must allege: (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. *Dura Pharm., Inc. v. Broudo,* 544 U.S. 336, 341–42 (2005).

Plaintiffs bringing claims for securities fraud under Section 10(b) and Rule 10-b5 must satisfy the heightened pleading standards of both Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act of 1995 (the "PSLRA").[8] The heightened pleading

[8] The Third Circuit discussed the interplay of the standards of Rules 12(b)(6) and 9(b) with the PSLRA:

> '[U]nless plaintiffs in securities fraud actions allege facts supporting their contentions of fraud with the requisite particularity mandated by Rule 9(b) and the Reform Act [PSLRA], they may not benefit from inferences flowing from vague or unspecific allegations—inferences that may arguably have been justified under a traditional Rule 12(b)(6) analysis.' .... In other words, pursuant to this 'modified' Rule 12(b)(6) analysis, 'catch-all' or 'blanket' assertions that do not comply with the particularity requirements are disregarded.

California Pub. Employees' Ret. Sys. v. Chubb Corp., 394 F.3d 126, 144, 145 (3d Cir. 2004).

standard of Rule 9(b), which requires that "'[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity,' . . . has been rigorously applied in securities fraud cases." *California Pub. Employees' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 144 (3d Cir. 2004) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1417 (3d Cir. 1997)). "At a minimum, to meet the stringent requirements imposed by Rule 9(b), plaintiffs in a securities fraud case must support their allegations 'with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue.'" *Clark v. Comcast Corp.*, 582 F. Supp. 2d 692, 703 (E.D. Pa. 2008) (citations omitted). The heightened pleading standard of the PSLRA "'imposes another layer of factual particularity to allegations of securities fraud'" above and beyond that which is required by Rule 9(b) *Id.* (citing *In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002).[9] The PSLRA requires that " the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u–4(b)(1).

[9] Congress enacted the PLSRA "to address problems plaguing securities class action litigation." Stephen J. Choi & Robert B. Thompson, *Securities Litigation and Its Lawyers: Changes During the First Decade After the PSLRA*, 106 COLUM. L. REV. 1489 (2006). "[T]he PSLRA is intended to 'curb frivolous lawyer-driven litigation, while preserving the [plaintiffs'] ability to recover on meritorious claims.'" *Wiest v. Lynch*, 710 F.3d 121, 144 (3d Cir. 2013) (citing *Winer Family Trust*, 503 F.3d at 326).

> The purpose of the Act was to restrict abuses in securities class-action litigation, including: (1) the practice of filing lawsuits against issuers of securities in response to any significant change in stock price, regardless of defendants' culpability; (2) the targeting of "deep pocket" defendants; (3) the abuse of the discovery process to coerce settlement; and (4) manipulation of clients by class action attorneys.

In re Advanta Corp. Sec. Litig., 180 F.3d 525, 531 (3d Cir. 1999).

The PSLRA additionally mandates that a plaintiff allege that defendants acted with scienter for each alleged misstatements or omissions.[10] A plaintiff must "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). The Third Circuit has described the analysis of the existence of a "strong inference of scienter" as a "totality-of-the-circumstances test" that relies on a court's "practical judgment about whether, accepting the whole factual picture painted by the Complaint, it is at least as likely as not that defendants acted with scienter." *Institutional Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 269 (3d Cir. 2009) (citations omitted).

c. Section 20(a)

Section 20(a) of the Exchange Act provides that:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t.

Section 20(a) is a derivative cause of action, predicated upon § 10(b) liability by a "controlled person," such that a "plaintiff cannot maintain a claim under § 20(a) without meeting the pleading requirements for a primary violation of the Act." *In re Aetna, Inc. Sec. Litig.*, CIV.A. 07-4451, 2009 WL 1619636 *28 (E.D. Pa. June 9, 2009) *aff'd in part*, 617 F.3d 272 (3d Cir. 2010) (citations omitted). "If no controlled person is liable, no controlling person liability

[10] As described by the Third Circuit,

> The PSLRA replaced [Rule] 9(b) as the applicable pleading standard in private securities class actions. Nonetheless, 'Rule 9(b)'s particularity requirement is comparable to and effectively subsumed by the requirements of [15 U.S.C. § 78u–4(b)(l) of] the PSLRA.' The PSLRA's requirement for pleading scienter, on the other hand, marks a sharp break with Rule 9(b).

Rahman v. Kid Brands, Inc., 736 F.3d 237, 242 fn. 3 (3d Cir. 2013) (internal citations omitted)

exists." *Belmont v. MB Inv. Partners, Inc.*, CIV.A. 09-4951, 2010 WL 2348703 *9 (E.D. Pa. June 10, 2010) *aff'd*, 708 F.3d 470 (3d Cir. 2013) (citations omitted). "[A] plaintiff can survive a motion to dismiss a controlling person claim upon a showing of a primary violation of the federal securities laws by a controlled person and control of the primary violator by the defendant." *Id.* at *10.[11]

IV. Discussion

1. Section 10b

To state a securities fraud claim under Rule 10b–5, "a plaintiff must show that (1) the defendant made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading; (2) the defendant acted with scienter; and (3) the plaintiff's reliance on the defendant's misstatement caused him or her injury." *Marion v. TDI, Inc.*, 591 F.3d 137, 152 (3d Cir.2010) (internal quotation marks omitted). These pleading requirements are heightened by the PSLRA, which imposes the additional requirements that: 1) "the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u–4(b)(1); and 2) "the complaint shall, with respect to each act or omission alleged to violate this title, 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).

[11] A split has emerged in this District regarding the pleading requirements for a Section 20(a) claim, particularly with regard to whether "culpable participation" must be plead. *See Belmont v. MB Inv. Partners, Inc.*, 708 F.3d 470, 485 fn. 20 (3d Cir. 2013) (describing split).

A. Material Misrepresentations and Omissions

The PSLRA requires that plaintiffs "specify each allegedly misleading statement, the reason or reasons why the statement is misleading, and, if an allegation is made on information and belief, all facts supporting that belief with particularity." *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 259 (3d Cir. 2009) (citing 15 U.S.C. §78u-4(b)(1)). Plaintiff alleges that Defendants made at least eight material misrepresentations and omissions in press releases, SEC filings, conference calls, public statements, and letters:

- **Defendants stated their belief that Vancocin's label met the requirements for QI Act Exclusivity.** [12] ¶¶ 95, 110, 113, 118, 125, 128, 132. The statements were false and misleading because Defendants omitted that the FDA told them the studies upon which Defendants based their new label did not and could not meet the QI Act standards for exclusivity. ¶¶ 75-90, 96 (b)-(e), 111 (c)-(e), 114 (b)-(e), 119 (b), (c), (e), 126, 133.

- **Defendants stated that under FDA regulations, labeling changes based on new clinical investigations may be entitled to three years of exclusivity.** [13] ¶ 95, 118, 132. The statement was false and misleading because Defendants omitted that, as applied to "Old Antibiotics," FDA regulations stated that the changes had to reflect a new condition of use to qualify for exclusivity, required "adequate and well-controlled studies" in order to support a new condition of use, and the FDA had already told Defendants that the Genzyme Study was not "adequate and well controlled." ¶ 99, 120, 133

- **Defendants stated that the label contained "new indications" and a new dosing regimen, and "numerous new conditions of use"** [14] ¶ 110, Appendix A. The statements were false and misleading because they omitted that the FDA communicated to Defendants in the sNDA Approval Letter and other private communications that the label did not support a new indication or new dosing regimen and that the Genzyme Study could not support a new condition of use. ¶¶ 87, 111 (a)-(e).

[12] Corresponding paragraphs refer to statements in Defendants': December 14, 2011 Press Release and Form 8-K, January 4, 2012 8-K, January 5, 2012 8-k, January 11, 2012 J.P. Morgan Global Healthcare Conference, February 28, 2012 Form 8-K, February 28, 2012 Earnings Call, and February 28, 2012 Form 10-K.

[13] Corresponding paragraphs refer to statements in Defendants': December 14, 2011 Press Release and Form 8-K, January 11, 2012 J.P. Morgan Global Healthcare Conference, and February 28, 2012 Form 10-K.

[14] Corresponding paragraphs refer to statements in Defendants' January 4, 2012 8-K.

- **Defendants stated that the new indication "was one of the new changes to the Vancocin labeling approved in the recent sNDA"** [15] ¶ 110. The statements were false and misleading because the Approval Letter, received by Defendants, did not "approve" a new indication by approving the sNDA. ¶¶ 87, 111 (a)-(e).

- **Defendants stated that the new labeling information "derives from new controlled clinical data."** [16]¶ 110. The statements were false and misleading because Defendants omitted that the FDA told them that the Genzyme Study upon which the new label was based was not an adequate and well-controlled clinical trial as to Vancocin. ¶¶ 75-90.

- **Defendants stated that the label contained efficacy data for the BI/NAP1 strain of the disease.** [17] ¶ 95. This statement was false and misleading because new efficacy for Vancocin against CDAD caused by the B1/NAP1 strain could only be shown through an adequate and well-controlled trial, and Defendants had been told that the Genzyme Study did not meet this standard. ¶ 98.
- **Defendants stated that based on the changes to the label, the Company expected to reap record sales on their exclusivity-protected Vancocin.** [18] ¶¶ 113, 118, 125. The statements were false and misleading because the FDA told Defendants that the studies upon which Defendants based their new label did not and could not meet the QI Act standards for exclusivity. Therefore, there was no basis to make bullish projections for Vancocin. ¶¶ 115, 122, 126.

(Pl's Opp. to MTD at 14).

As is required under Rule 10b-5, in paragraphs 75- 133 of the Complaint, Plaintiff has set forth those specific statements and omissions they allege were misleading. Plaintiff identified who made each statement or omission, when the statement was made, and the reasons each was misleading. Of course to be actionable, these misrepresentations or omissions of fact must be material, which is addressed in Section C, below.

[15] Corresponding paragraphs refer to statements in Defendants' January 4, 2012 8-K.

[16] Corresponding paragraphs refer to statements in Defendants' January 4, 2012 8-K.

[17] Corresponding paragraphs refer to statements in Defendants' December 14, 2011 Press Release and Form 8-K.

[18] Corresponding paragraphs refer to statements in Defendants': January 4, 2012 8-K, January 11, 2012 J.P Morgan Global Healthcare Conference, and February 28, 2012 Form 8-K.

B. Safe Harbor

Defendants argue that the alleged misrepresentations and omissions are not actionable because they constitute forward-looking[19] statements protected by the PSLRA's safe harbor provision. *See* 15 U.S.C. § 78u–5(c)(1). The safe harbor applies to forward-looking statements if: "(1) the issuer identifies which statements are forward-looking; (2) the issuer makes a meaningful, cautionary statement identifying important factors which could cause the results to differ from the forward-looking statements; and (3) the plaintiff is unable to prove the forward-looking statement was made with actual knowledge of its falsity." *Bldg. Trades United Pension Trust Fund v. Kenexa Corp.*, CIV.A. 09-2642, 2010 WL 3749459 (E.D. Pa. Sept. 27, 2010).

Defendants argue that "statements regarding the likelihood and timing of FDA approval for a drug and the reasons for management's beliefs that such approval will occur fall under the statutory definition of 'forward-looking.'" Defendants further contend that "[t]he statements at issue in this case are precisely the type of forward-looking statements that the PSLRA's safe harbor is designed to protect from lawsuits such as this where a plaintiff seeks to apply 20-20 hindsight when future results disappoint."[20]

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[19] The term "forward-looking statement" means:

> (A) a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items; (B) a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer; (C) a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission; (D) any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C); (E) any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer; or (F) a statement containing a projection or estimate of such other items as may be specified by rule or regulation of the Commission.

5 U.S.C. § 78u–5(i)(1)

[20] Defendants' coloring of this case as "fraud-by-hindsight" is well-taken, but is not something that the Court is tasked with tackling at this stage, given the inferences owed to the Plaintiff. While Plaintiff's

At the gravamen of Plaintiff's Complaint are ViroPharma's public statements of confidence in the prospect of achieving an additional three years of exclusivity for Vancocin, made while its Citizen's Petition was pending before the FDA. Though Defendant's statements regarding Vancocin's chance of receiving an additional three years of exclusivity concerned a future FDA decision, Plaintiff alleges that all of these statements were "false and misleading" because they omitted the fact that the FDA repeatedly informed ViroPharma that the Genzyme study upon which the sNDA and Citizen's Petition were based, was not "adequate and well-controlled" as to Vancocin. Assuming what Plaintiff alleges is true, those public statements directly contradict information Viropharma had privately received from the FDA regarding the Administration's view on the inadequacies of the Genzyme Study.

Courts in this District have held that omissions of existing facts or circumstances are not forward-looking, and thus do not qualify for safe harbor protection. *In re Cell Pathways Inc. Sec. Litig.*, No. 99-725, 2000 WL 805221, at*10-11 June 20, 2000) ("[A]llegations based upon omissions of existing facts or circumstances do not constitute forward looking statements protected by the safe harbor of the Securities Act.") (citing *In re MobileMedia Sec. Litig.*, 28 F. Supp. 2d 901, 930 (D.N.J. 1998). Taking Plaintiff's allegations as true, Defendants' identified statements were not forward looking, despite being accompanied by "meaningful cautionary language," because the risks being warned of had already come to pass at the time the statements were made. *See e.g. Marsden v. Select Med. Corp.*, No. CIV. A. 04-4020, 2006 WL 891445, at *7 (E.D. Pa. Apr. 6, 2006) *vacated in part on other grounds*, 2007 WL 518556 (E.D. Pa. Feb. 12,

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Complaint crafts a narrative that is sufficient to survive a Motion to Dismiss, viewed another way—perhaps the way Defendants present—another telling is certainly believable: ViroPharma had exclusivity for a drug, sought to extend that exclusivity under a relatively new statute, thought it had done enough to secure the exclusivity, but was ultimately denied by the FDA. The FDA's denial of a Citizen's Petition will invariably affect a stock price in a negative way, regardless of whether a company sees it coming or not. The Complaint, drafted in the way that it is, however, entitles Plaintiff to discovery to flesh out the truth of the narrative.

2007) (determining safe harbor was inapplicable to statements challenged on basis they omitted "'present facts'-facts known at the time the statement was made."); *In re Majesco Sec. Litig.,* No. CIV. A 05CV-3557 PGS, 2006 WL 2846281, at *4 (D.N.J. Sept. 29, 2006); *Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp*., No. 00-4285 2002 WL 33934282, at *11 (D.N.J. June 26, 2002). Accordingly, any cautionary language could not cure the fact that, at the time the statements were made, the sNDA was already lacking a necessary condition precedent to exclusivity. [21]

C. Materiality

There is no bright-line rule for determining materiality. *Matrixx Initiatives, Inc. v. Siracusano*, ___ U.S. ___ ,131 S. Ct. 1309 (2011). A misrepresentation or omission "is material if there is a substantial likelihood that a reasonable shareholder would consider it important in deciding how to [act]." *TSC Industries, Inc. v. Northway, Inc.,* 426 U.S. 438, 449,(1976). "Materiality is a mixed question of law and fact, and the delicate assessments of the inference a reasonable shareholder would draw from a given set of facts are peculiarly for the trier of fact." *EP Medsystems, Inc. v. Echocath, Inc.,* 235 F.3d 865, 875 (3d Cir.2000) (citation omitted) "[T]o fulfill the materiality requirement 'there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available.'" *Basic v. Levinson,* 485 U.S. 224, 231–32 (1988).

[21] Even if some of the alleged statements were forward-looking, or included proper cautionary language, Plaintiff has alleged certain misstatements and omissions that are clearly actionable and fall outside of the safe-harbor. Indeed, certain alleged statements contained no cautionary language, such as those in the Citizen's Petition Supplement and those at the J.P. Morgan Global Health Conference on January 11, 2012. *See, e.g., In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 536 n.8 (E.D. Pa. 2010). Certain statements about the potential for exclusivity could be deemed as puffery, or permissibly predicative, but other statements and omissions were false at the time they were made, because the condition precedent to exclusivity had already manifest.

Plaintiff alleges that once the Defendants began speaking about "exclusivity," they had the duty to disclose information relating to their communications with the FDA. Defendants are correct in their argument that, as part of an ongoing dialogue with the FDA, they are not obligated to disclose *all* conversations or questions from FDA staffers. *See In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995). Nevertheless, Plaintiff has adequately alleged that the FDA's ***conclusions*** regarding deficiencies in the Genzyme Study, which bore directly on the exclusivity issue, were essential to any discussion of exclusivity, and thus Defendants had a corresponding duty to reveal that information. *See In re Merck & Co., Inc. Sec., Derivative & ERISA Litig.*, MDL 1658 SRC, 2012 WL 3779309 (D.N.J. Aug. 29, 2012) (noting that when a company "put[s] an issue in play," it acquires a duty to disclose information relating to that topic).[22]

This Court cannot find as a matter of law that a reasonable investor would not have found the information regarding ViroPharma's ongoing communications with the FDA−specifically those regarding whether the Genzyme Study was "adequate and well controlled" as to Vancocin−significant in making investment decisions. *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449, 96 S. Ct. 2126, 2132, 48 L. Ed. 2d 757 (1976).

V. Scienter

Scienter, "a mental state embracing intent to deceive, manipulate, or defraud" is necessary to state a claim under Rule 10b-5 and the PSLRA. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007). Defendants argue that Plaintiff's Complaint "does not plead sufficient

[22] Defendants' argument regarding the novelty of the FDA's interpretation of the QI Act only serves to underscore Plaintiff's materiality argument. If the FDA had not yet interpreted the statute, then the investing public would certainly view any information regarding the FDA's communications with respect to the Genzyme Study and the prospects of exclusivity as a significant part of the "total mix" of information.

facts to give rise to a strong inference of scienter, as is required by the PSLRA." 15 U.S.C. § 78u–4(b)(2). A court's analysis of the complaint requires that it consider:

> plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff. The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the smoking-gun genre, or even the most plausible of competing inferences.... Yet the inference of scienter must be more than merely reasonable or permissible—it must be cogent and compelling, thus strong in light of other explanations. 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 would draw from the facts alleged.

Tellabs, 551 U.S. at 324 (quotation marks, citation, and footnote omitted).

Scienter may also be established if a Plaintiff "set[s] forth facts that constitute circumstantial evidence of either reckless or conscious behavior." *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 534 (3d Cir. 1999). "While allegations relating to motive and opportunity may not independently support a finding of scienter, such considerations may amplify an inference of scienter as part of the holistic information available to the court." *Frater v. Hemispherx Biopharma, Inc.*, 2:12-CV-07152-WY, 2014 WL 272027 (E.D. Pa. Jan. 24, 2014) (citation omitted).

At its heart, the Complaint alleges that Defendants had access to information showing that they knew that Vancocin would not achieve an additional three years of exclusivity based on the inadequacy of the Genzyme Study. This information, as Plaintiff alleges, directly contradicts public statements that Defendants made about the prospect of achieving an additional term of exclusivity. *See In re Cambrex Corp. Sec. Litig.*, No. 03-CV-4896(WJM), 2005 WL 2840336, at *11 (D.N.J. Oct. 27, 2005). Plaintiff also alleges that the Approval Letter regarding the label change underscores this fact. Plaintiff alleges that the FDA made it known to Defendants on five occasions that the Genzyme study was inadequate.

What's more, assuming what Plaintiff alleges as true regarding confidential witnesses (several of whom were high-ranking individuals within ViroPharma), the witnesses stated the Defendants were actively involved in the sNDA application and were in contact with the FDA. When dealing with Confidential Witnesses, Courts should assess the "'detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia.'" *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 244 (3d Cir. 2013) (citing *Avaya*, 564 F.3d at 261). The Confidential witnesses were at meetings with top ViroPharma executives during which the significance of pediatric testing was discussed, were intimately familiar with the purpose of the Genzyme study, and were involved in the details of the bid for extended exclusivity.

Furthermore, the fact that sales of Vancocin comprised ViroPharma's "core business," also supports the inference that Defendants either knew or should have been aware of the issues concerning the drug's approval. *See, e.g.*, *Avaya*, 564 F.3d at 271. It is undisputed that, during the class period, sales of Vancocin accounted for more than 50% of ViroPharma's revenue and profit margins. This ties directly to Plaintiff's theory of Defendants motive—that Defendants knew that exclusivity was not forthcoming, so they sought to mislead investors and delay the ultimate denial of exclusivity. The strong inference of scienter is supported by Plaintiff's several confidential witnesses, and the allegations supported by documentation in the Complaint.

The strong inference of scienter is also supported by allegations of stock sales by Defendants Doyle and Rowland, given their unusual scope and timing. *Avaya*, 564 F.3d at 279. The Complaint alleges that Defendants Doyle and Rowland sold their personal shares of ViroPharma stock, netting an $8 million dollar profit, just weeks before the FDA issued their

denial of exclusivity. During the year before the Class Period, Doyle and Rowland only sold roughly $400,000 in stock. These sales support an inference of scienter. *Id.* Although Defendants Milano and Wolf are not alleged to have engaged in insider trading, the insider sales of the other Defendants still support the strong inference arising from the conduct of Defendants Doyle and Rowland. *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 277 (3d Cir. 2006). (finding that where two of six defendants sold stock for $7 million in proceeds, strong inference of scienter was supported).[23]

Plaintiff has alleged facts establishing both motive and opportunity. *Advanta*, 180 F.3d at 534-35. Accepting Plaintiff's allegations as true, and taking in to account competing inferences, the inference that Defendants have acted with scienter is "*at least as likely* as any plausible opposing inference," *Tellabs*, 551 U.S. at 328. Thus, Plaintiff's complaint gives rise to a strong inference of scienter that is "cogent and compelling," thus satisfying the heightened requirements of the PSLRA. *See Tellabs*,551 U.S. at 323.

VI. Section 20(a)

"Section 20(a) of the Exchange Act imposes joint and several liability upon one who controls a violator of Section 10(b)." *Suprema*, 438 F.3d at 284 (citing 15 U.S.C. § 78t(a)). Defendants argue that Plaintiff's Section 20(a) claim for control person liability must be dismissed because Plaintiff has failed to state an actionable Section 10(b) claim. *See Avaya*, 564

[23] Defendants argue that the sales of insider trading are incongruent with the fact that ViroPharma engaged in a massive stock repurchase of 1.6 million shares during the class period. There are many inferences that a Court could draw from a stock repurchase. This Court is not persuaded that the existence of the stock repurchase plan wholly negates the strong inference of scienter, in light of other factors such as the conscious misbehavior and recklessness that Plaintiff has adequately pleaded. As such, this Court finds that the repurchasing plan weighs neither in favor of nor against an inference of scienter.

F.3d at 252. Because this Court finds that Plaintiff indeed does state a claim under Rule 10b–5, Plaintiff's Section 20(a) claim survives.

VII. Conclusion

For the aforementioned reasons, the Motion to Dismiss of Defendants is denied. An appropriate order follows.