FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

SPENCER ABRAMS Individually and on Behalf of All Others Similarly Situated, et al., Plaintiffs, v. MIMEDX GROUP, INC., et al., Defendants.	CIVIL ACTION FILE NO. 1:13-CV-3074-TWT

OPINION AND ORDER

This is a securities fraud class action. The Plaintiffs allege that MiMedx Group, Inc., a developer of therapeutic biomaterials, falsely stated that its injectable products qualified for an FDA exemption from drug regulation, and that the Defendants failed to disclose an FDA investigation of the products. The Defendants argue that they properly disclosed the risks associated with marketing the injectable products without FDA approval, and that the Plaintiffs did not incur economic losses from any alleged misrepresentations.

I. Background

MiMedx Group, Inc., develops and markets biomaterials and bioimplants to help the healing process. Two of its injectable products, AmnioFix and EpiFix, are at

issue in this case. These products seek to hasten the healing process and reduce the development of scar tissue.[1] The Plaintiffs contend that MiMedx misled its shareholders by stating that AmnioFix and EpiFix would be qualified as "human cells, tissues, and cellular and tissue-based products" under FDA regulations.[2] These products, also called "361 HCT/Ps," are exempt from FDA regulation of drugs, devices, or biological products. To obtain 361 HCT/P status, the cell or tissue-based product can only be "minimally manipulated." Tissue products are more than "minimally manipulated," according to FDA regulations and guidelines, when the tissue's original characteristics have been altered during processing.[3] MiMedx allegedly did not inform investors that AmnioFix and EpiFix could not meet the "minimal manipulation" criterion for exemption under Section 361 although MiMedx pulverizes or grinds the amniotic tissues and cells in making the products.[4] Additionally, MiMedx did not disclose that the FDA performed an on-site inspection in 2012 to scrutinize whether the injectable products were indeed 361 HCT/Ps.[5]

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1 MiMedx 2011 Annual Report, Defs.' Mot. to Dismiss, Ex. C.

2 See 21 C.F.R. § 1271.1(a).

3 Am. Compl. ¶¶ 36-42.

4 Am. Compl. ¶¶ 61-70.

5 Id.

On September 3, 2013, the FDA sent MiMedx an "Untitled Letter," stating that AmnioFix and EpiFix did not meet the requirements for Section 361 exemption.[6] "Untitled Letters" notify the regulated company that current violations exist but are not significant enough to warrant a more severe "Warning Letter."[7] When MiMedx publicized the letter, its stock fell 36%, from $6.06 per share to $3.85 per share.[8] In December 2013, MiMedx announced that it would seek FDA approval for its injectable products as if they were regulated biologics, not 361 HCT/Ps.[9] At close on December 4, 2013, when MiMedx made this announcement, its stock price had rebounded to $6.76 per share.[10]

The Plaintiffs filed suit on September 13, 2013, and their amended complaint brings claims against MiMedx and its executives under §§ 10(b) and 20(a) of the Securities Exchange Act of 1934, as well as under Rule 10b-5. The individual defendants are Parker H. Petit, the Chairman, CEO, and President of MiMedx,

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6 Am. Compl. ¶ 71.

7 See U.S. Food & Drug Admin., "Untitled Letters (CBER)", http://www.fda.gov/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/complianceactivities/enforcement/untitledletters/default.htm (last visited Feb. 25, 2014).

8 Am. Compl. ¶¶ 72-74.

9 See Defs.' Br. in Supp. of Defs.' Mot. to Dismiss, Ex. G.

10 See id. Exs. G, H.

Michael J. Senken, the CFO, and William C. Taylor, the COO. The Plaintiffs seek to represent a class of all purchasers of MiMedx common stock from March 29, 2012 through September 4, 2013. The Defendants, collectively, have moved to dismiss the amended complaint.

II. Legal Standard

A complaint should be dismissed if, even accepting all well-pleaded factual allegations as true, it fails to state a claim upon which relief can be granted.[11] Complaints that allege fraud under federal securities law must satisfy the heightened pleading requirements of both Rule 9(b) and the Private Securities Litigation Reform Act of 1995. "A complaint satisfies Rule 9(b) if it sets forth precisely what statements or omissions were made in what documents or oral representations, who made the statements, the time and place of the statements, the content of the statements and manner in which they misled the plaintiff, and what benefit the defendant gained as a consequence of the fraud."[12]

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[11] Fed. R. Civ. P. 12(b)(6); Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009).

[12] In re Theragenics Corp. Securities Litigation, 105 F. Supp. 2d 1342, 1348 (N.D. Ga. 2000) (citing Brooks v. Blue Cross and Blue Shield of Fla., Inc., 116 F.3d 1364, 1371 (11th Cir. 1997)).

III. Discussion

MiMedx argues that the Plaintiffs have not stated a claim under the Private Securities Litigation Reform Act's (the "PSLRA") enhanced pleading standards. To state a claim, a securities fraud plaintiff must plead six elements: "(1) a material misrepresentation or omission; (2) made with scienter; (3) a connection with the purchase or sale of a security; (4) reliance on the misstatement or omission; (5) economic loss; and (6) a causal connection between the material misrepresentation or omission and the loss."[13] According to MiMedx, the amended complaint fails to identify a culpable misrepresentation or omission of material fact, the amended complaint fails to plead economic loss and loss causation, and the amended complaint fails to properly allege a strong inference of scienter. Additionally, because the Plaintiffs' securities fraud claims fail, their claims under Section 20(a) must be dismissed as well.

A. Does the Amended Complaint Identify a Material Misrepresentation or Omission?

The PSLRA requires that a "securities fraud class action complaint specify each statement alleged to have been misleading [and] the reason or reasons why the

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[13] Mizzaro v. Home Depot, Inc., 544 F.3d 1230, 1236-37 (11th Cir. 2008).

statement is misleading."[14] According to MiMedx, the two misrepresentations identified in the amended complaint – that MiMedx misrepresented the feasibility of its AmnioFix and EpiFix products as being capable of obtaining Section 361 exemption and that MiMedx failed to disclose the FDA's 2012 site inspection – were not misleading.

MiMedx's characterizations of the Plaintiffs' allegations do not capture the extent of the misrepresentation described in the amended complaint. According to the Plaintiffs, MiMedx and its officers could never have reasonably believed that AmnioFix and EpiFix would be classified as 361 HCT/Ps. Rather than being "minimally manipulated," as Section 361 requires, the AmnioFix and EpiFix products are produced by grinding up and processing amniotic tissue taken from human placenta.[15] And FDA regulations provide that when the salient characteristics of the tissue are altered, the tissue is no longer "minimally manipulated."[16]

Several allegations in the Plaintiffs' complaint support their contention that MiMedx misrepresented the feasibility of AmnioFix and EpiFix's Section 361 eligibility. The Plaintiffs allege that, despite holding AmnioFix and EpiFix out as

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[14] Id. at 1238 (quoting 15 U.S.C. § 78u-4(b)(1)(B)).

[15] Am. Compl. ¶ 2.

[16] See Am. Compl. ¶¶ 38-42.

minimally manipulated under Section 361, MiMedx never sought an initial or formal determination from the FDA's Tissue Reference Group that the products qualified as 361 HCT/Ps.[17] Additionally, in 2006, the Tissue Reference Group released a public recommendation stating that, in general, products made from amniotic membrane – AmnioFix and EpiFix are made from amniotic tissue – are not minimally manipulated and therefore not 361 HCT/Ps.[18] The Plaintiffs contend that MiMedx sought to skirt FDA regulations to avoid the significant costs and time involved in obtaining a license from the FDA.[19]

The Plaintiffs also allege that MiMedx tried to hide the fact that it was seeking to skirt the regulatory process. In 2012, the FDA performed a site inspection of MiMedx's Surgical Biologics unit to scrutinize AmnioFix. The result of the inspection was an establishment inspection report stating that the purpose of the inspection was to gather information for the FDA's Center for Biologics Evaluation and Research ("CBER"), which determines whether a product is ultimately fit for the 361 HCT/P exemption.[20] Although the report, which was sent to Defendant Taylor, ended with a

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17 Am. Compl. ¶¶ 41-43.

18 Am. Compl. ¶ 44.

19 Am. Compl. ¶ 45.

20 See Am. Compl. ¶¶ 46-54.

"no action indicated" notice, the Plaintiffs allege that such notices only relate to quality control issues, not issues pertaining to Section 361 eligibility itself.[21] Despite the report, MiMedx continued to report in its SEC filings that it believed AmnioFix was Section 361 eligible.[22] MiMedx did not disclose the establishment inspection report in its SEC filings following the inspection, and in general MiMedx only published boilerplate disclaimers that the FDA may not agree with MiMedx's classifications.[23]

These allegations are sufficient to conclude at this stage of the litigation that the Defendants' representations were misleading. In FindWhat Investor Group v. FindWhat.com, the Eleventh Circuit held that a company's statements assuring investors of the feasibility of its computer monitoring system were misleading in the face of contrary information that the company possessed.[24] The statements in the SEC filings led investors to believe that the defendant produced an advanced monitoring system capable of detecting fraudulent revenue-generating practices. However, according to the plaintiffs' allegations, that system contained substantial defects and

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21 Am. Compl. ¶¶ 76-77.

22 Am. Compl. ¶ 70.

23 See Am. Compl. ¶¶ 61-68.

24 See 658 F.3d 1282, 1298-99 (11th Cir. 2011).

could not function as touted. The court held that the company's "failure to disclose these defects rendered their statements materially misleading, which was not cured by any general cautionary or risk-disclosing language."[25]

Here, too, MiMedx's failure to disclose clear hurdles, or even barriers, in achieving Section 361 exemption was misleading to investors. After the FDA visited the site and issued the establishment inspection report, MiMedx knew that AmnioFix was coming under increased scrutiny, especially given the fact that modified amniotic fluid had been specifically classified as *not* "minimally manipulated" in 2006. Likewise, MiMedx stated that the FDA may not agree with MiMedx's classification and that the FDA regulatory process was "evolving." But MiMedx never formally or informally filed for Section 361 status. And stating that the process was "evolving" suggested to investors that MiMedx had in fact begun formal discussions with the FDA. Considering these statements and actions, MiMedx may have misled investors when it continued touting AmnioFix and EpiFix as exempt under Section 361 just as the company in FindWhat misled investors by failing to disclose defects in the computer system it was touting. Accordingly, the Court concludes that the amended complaint does identify misleading statements.

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[25] Id. at 1299.

B. Does the Amended Complaint Properly Allege Loss Causation and Economic Loss?

The Plaintiffs must allege facts demonstrating that the Defendants' misrepresentations caused the losses for which the Plaintiffs seek to recover.[26] MiMedx argues that the Plaintiffs cannot show loss causation because they have not alleged any post-disclosure sale and because the stock price bounced back to pre-disclosure levels within a few months. MiMedx relies on this Court's decision in In re Immucor, Inc. Securities Litigation[27] to support its arguments.

However, Immucor does not stand for the propositions that MiMedx claims. First, in Immucor, this Court did *not* hold that plaintiffs in a securities fraud action must allege a post-disclosure sale. Indeed, the Court specifically stated that it did not require the plaintiffs to allege a post-disclosure sale in a subsequent order denying a motion for reconsideration.[28]

Further, although this Court held in Immucor that an almost immediate rebound in a stock price could preclude plaintiffs from alleging economic loss, that holding does not preclude the plaintiffs from alleging economic loss here by alleging that the

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[26] See 15 U.S.C. § 78u-4(b)(4).

[27] No. 1:09-cv-2351, 2011 WL 2619092 (N.D. Ga. June 30, 2011).

[28] See In re Immucor, Inc. Sec. Litig., No. 1:09-cv-2351, 2011 WL 3844221, at *2 (N.D. Ga. Aug. 29, 2011).

Plaintiffs paid inflated prices for their stock. In addition, MiMedx's stock price did not "rebound" to the pre-disclosure price until almost three months after the disclosure.[29] The PSLRA itself includes a "bounce-back" provision that specifically addresses how damages should be measured when the stock price returns to its pre-disclosure prices.[30] The provision provides that damages shall not exceed the difference between the price the plaintiff paid for the stock and "the mean trading price of that security during the 90-day period beginning on the date" of disclosure.[31] Thus, the calculation of damages under the PSLRA allows defendants to mitigate damages when share prices have recovered, but it does not preclude investors from recovering altogether when the share prices rebound.

The Second Circuit thoroughly explored the requirements for establishing economic loss in a securities fraud action where the price rebounded following a disclosure in Acticon AG v. China North East Petroleum Holdings, Ltd.[32] The court reversed the district court's determination that the plaintiffs could not show any economic loss because they could have sold their shares for a profit after the

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29 See Defs.' Mot. to Dismiss, Ex. H.

30 See 15 U.S.C. § 78u-4(e)(1).

31 Id.

32 692 F.3d 34 (2d. Cir. 2012).

disclosure of negative information, even if the disclosure initially caused the price to fall. The court stated it was "improper to offset gains that the plaintiff recovers after the fraud becomes known against losses caused by the revelation of the fraud if the stock recovers for completely unrelated reasons."[33] Because the court could not know at the motion to dismiss stage whether the price rebound reflected a market reaction to the disclosure, the court concluded that the recovery of the stock price did not negate economic losses.[34]

Here, although MiMedx's stock price returned to pre-disclosure levels by the end of November 2013, the Court cannot conclude that the Plaintiffs suffered no economic loss from the alleged misrepresentations and omissions. According to MiMedx, its AmnioFix and EpiFix products only account for 15 percent of the company's business, which suggests that other factors could account for the price rebound. In any event, based on Acticon, the Court will not hold that the Plaintiffs cannot establish economic loss as a matter of law. The allegations in the amended complaint that MiMedx shares dropped in value following the release of the September 3, 2013, letter from the FDA are sufficient to establish loss causation and

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[33] Id. at 41.

[34] Id.

economic loss, and the Defendants' motion to dismiss will not be granted on those grounds.

C. Does the Amended Complaint Properly Allege Scienter?

A securities fraud plaintiff must allege facts, with particularity, that give rise to an inference that the defendant acted with scienter, which is either the intent to defraud or severe recklessness in allowing fraudulent activity.[35] MiMedx argues that the Plaintiffs only conclusorily allege that the Defendants acted with the requisite intent and that the allegations do not even support a finding of severe recklessness on the part of the Defendants. However, the Court concludes that the Plaintiffs have alleged particular facts supporting an inference of scienter.

The Plaintiffs' allegations support an inference that the Defendants had no reasonable basis to consistently represent to investors that AmnioFix and EpiFix were eligible for Section 361 exemption. First, the Plaintiffs allege that MiMedx never sought an initial or formal determination from the FDA concerning the exemptions.[36] Next, the Defendants knew that the FDA was scrutinizing their products for Section 361 status following the 2012 inspection.[37] The establishment inspection report issued

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[35] 15 U.S.C. § 78u-4(b)(2); Edward J. Goodman Life Income Trust v. Jabil Cir., Inc., 594 F.3d 783, 790 (11th Cir. 2010).

[36] Am. Compl. ¶ 43.

[37] See Am. Compl. ¶¶ 54, 60.

following the inspection specifically stated that the FDA was sending information to the CBER to continue reviewing MiMedx's contentions that the products were 361 HCT/Ps.[38] The "no action indicated" conclusion of the report should not have convinced the Defendants that the FDA would not continue scrutinizing Section 361 status because the "no action indicated" segment only addresses health and sanitation concerns.[39] Finally, Defendant Taylor, after receiving the establishment inspection report, and in the month before September 3, 2013, sold a significant amount of MiMedx shares.[40]

To support a strong inference of scienter, the Plaintiffs must show that a reasonable person *would* be more likely to infer that the Defendants acted with scienter than to infer otherwise.[41] In Mizzaro, the court concluded that the inference of scienter was not stronger than any opposing inference because the alleged fraud could have been carried out without the knowledge of senior management, because the amount of the fraud was speculative, and because there were no suspicious stock

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38 Am. Compl. ¶ 76.

39 Am. Compl. ¶ 76.

40 Pls.' Resp. in Opp'n to Defs.' Mot. to Dismiss, Ex. B.

41 Mizzaro, 544 F.3d at 1239.

sales.[42] Here, by contrast, the alleged fraud – misrepresenting the feasibility of AmnioFix and EpiFix as 361 HCT/Ps – could only have been carried out by senior management. According to the complaint, management never sought to have the products actually classified as 361 HCT/Ps, and management was aware that the FDA was scrutinizing the products. Further, the allegations show that MiMedx was pulverizing and grinding amniotic tissue to make AmnioFix and EpiFix, and the FDA had stated that products that destroy original characteristics or are made from amniotic fluid are generally not 361 HCT/Ps. Likewise, the extent of the fraud is connected solely to the development, promotion, and sales of AmnioFix and EpiFix and no other MiMedx product, unlike the sprawling fraud alleged in Mizzaro that spanned hundreds of stores and countless products. Further, the allegations in the complaint support an inference that the individual defendants knew or should have known that the FDA would never approve AmnioFix and EpiFix for Section 361 exemption. As noted, the products appear to fall squarely into a category the FDA had previously announced would not be exempt from regulation. Finally, Defendant Taylor sold a substantial amount of MiMedx shares after the FDA sent the establishment inspection report, suggesting that Taylor knew that the true status of AmnioFix and EpiFix had been hidden from the market until then. Accepting the allegations as true, the Court

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[42] See id. at 1251-54.

concludes that a reasonable person would conclude that the Defendants more likely than not acted with scienter. Because the amended complaint states a claim for relief under the PSLRA, the Plaintiffs' claims, including their claims for liability under Section 20(a), should not be dismissed.

IV. Conclusion

For the reasons set forth above, the Defendants' Motion to Dismiss for Failure to State a Claim [Doc. 41] is DENIED. The Plaintiff Tim Kelly's Motion for Oral Argument [Doc. 46] is also DENIED.

SO ORDERED, this 13 day of August, 2014.

/s/Thomas W. Thrash
THOMAS W. THRASH, JR.
United States District Judge