

assert claims of failure to monitor co-fiduciaries and knowing participation in co-fiduciaries' breaches. (ECF #29, ¶¶194-200; 205-13)²

Throughout the class period, the Plan offers participants a choice of 20 different investment funds, including the Invacare Company Stock Fund. After six months of service, Plan participants are eligible for employer matching contributions and Invacare may make discretionary quarterly contributions to the Plan and discretionary profit sharing contributions to the Plan on behalf of eligible participants. While the SAC alleges that Invacare stock was the exclusive form of matching contributions during the class period, Defendants note that Plan documents provide that any matching contributions shall be in the form of cash. Moreover, employer matching and quarterly and profit-sharing contributions are invested in accordance with the participant's voluntary contribution elections. Thus, Participants have complete control over how to direct their own voluntary contributions to the Plan, as well as the employer matching, quarterly, and profit-sharing contributions.

Invacare is a global manufacturer and distributor of long term and home medical equipment. (ECF #29 ¶ 2) Invacare is headquartered in Elyria, Ohio and operates manufacturing facilities in the United States in Elyria, Ohio (the "Talylor Street Facility") and Sanford, Florida (the "Sanford Facility"). (Id. at ¶2) Invacare is regulated by the U.S. Food and Drug

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Plaintiff's SAC mirrors many of the factual allegations contained in the amended complaint in *Gov't of Guam Ret. Fund v. Invacare Corp.*, a securities class action alleging that defendants made numerous false statements and misrepresentations regarding Invacare's compliance with the Food, Drug and Cosmetic Act ("FDCA") and current Good Manufacturing Practices ("cGMP"). Judge Boyko denied Defendants' Motion to Dismiss the Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b). *Gov't of Guam Ret. Fund v. Invacare Corp.*, No. 1:13CV1165(CAB), 2014 WL 4064256 (N.D. Ohio Aug.18, 2014).

Administration (“FDA”) because its products are considered “medical devices” under the Federal Food, Drug and Cosmetics Act (“FDCA”). (Id. at ¶3) The SAC explains that such regulation includes compliance with certain labeling and record keeping, product design, and manufacturing controls. (Id.)

Plaintiff alleges that Invacare has a long history of noncompliance with FDA safety and manufacturing regulations, evidenced by its receipt of twelve Forms 483 and five Warning Letters dating back to 1996. (Id. at ¶4) More pertinent to the time frame at issue here, Plaintiff asserts that on August 18, 2010, the Company received a Form 483 which detailed serious deficiencies noted by the FDA in connection with its two-week investigation of Invacare’s Sanford Facility. Invacare sent the FDA a response letter on September 8, 2010, attempting to address the FDA’s concerns. (Id. at ¶¶ 6-7). On December 15, 2010, the FDA sent a Warning Letter to Invacare concerning the August 2010 inspection of the Sanford Facility. The Warning Letter identified a litany of current Good Manufacturing Practices (“cGMP”) violations and “recurring” consumer complaints concerning the safety of Invacare’s beds, including incidents of fatality caused by entrapment and fire. The Warning Letter allegedly chastised Invacare for failing to take preventive action, document and evaluate serious complaints, and complete risk assessments to ensure safety of its products. The Letter also noted that Invacare’s September 8th letter was “not adequate” and that failure by Invacare to promptly address and correct these issues could result in regulatory action. (Id. at ¶8)

On December 17, 2010, Invacare received two additional Forms 483 detailing compliance concerns at its Headquarters and the Taylor Street Facility. Plaintiff alleges that Invacare did not disclose the Warning Letter or the Forms 483 to Plan Participants when they

were received.

However, on January 4, 2011, the FDA released the Warning Letter to the public. Plaintiff alleges that the disclosure caused Invacare stock to drop over 4 percent from \$30.67 per share on January 3, 2011 to close at \$29.29 per share on January 4, 2011, representing a market capitalization loss of about \$40 million. (Id. at ¶9). That same day, Invacare announced that it had assembled a team to address the FDA's concerns. Further, Invacare notes that by January 12, 2011, Invacare stock was trading back up a \$30.41 and closed at \$30.09. Invacare also addressed the Warning Letter in its February 3, 2011 8-K where it also disclosed its fourth quarter and year end financial results. The Company explained that "[t]he letter does not call into question the safety or efficacy of Invacare products, and production has not been impacted." Invacare did note that the Company "does have areas to improve." Invacare made similar disclosures during the earnings call it held that same day. (Id. ¶99). Plaintiff views these statements as nothing more than dissembling attempts to diffuse the grave import of the Warning Letter and further notes that the statement is misleading because it "directly contradicts the Warning Letter's disclosure regarding the fire and entrapment related deaths caused by Invacare products." (Id. at ¶¶10, 94).

In its 2010 Form 10-K, filed on February 25, 2011, Invacare discussed the Warning Letter, stating that it was taking these issues seriously and noted possible consequences for failure to comply with FDA requirements, including a statement that "[a]n unfavorable resolution or outcome of an FDA inspection or investigation could materially and adversely affect the company's business, financial condition, and results of operations." (2010 10-K at I-23) For the first time on February 25, 2011, Invacare disclosed the possibility of a consent

decree—“[t]he company’s failure to comply with the regulatory requirements of the FDA . . . may subject the company to . . . sanctions includ[ing] . . . consent decrees.” (Id.)

Invacare continued to reference its regulatory compliance concerns in its SEC filings throughout 2011. In the April 28, 2011 8-K, the Company noted that it was providing updates to the FDA regarding improvements it is making and adding resources to its regulatory affairs and corporate compliance department and provided similar updates in subsequent SEC filings and press releases as the year progressed. (SAC ¶¶ 109-10, 113-14, 116)

On August 8, 2011, the same day that Invacare filed its Form 10-Q with the SEC for the second quarter of 2011 which reiterated the Company’s earlier statements about its regulatory issues and progress, Invacare received two additional Forms 483 from the FDA setting forth more violations at its Headquarters and the Taylor Street Facility. Many of the violations cited by the FDA were problems noted by the FDA in past notices. (Id. at ¶¶11, 113-115)

Invacare did not disclose the receipt of the additional Forms 483 until November 8, 2011 when it filed another Form 10-Q. In that disclosure Invacare reiterated that it was “actively making systemic improvements in its reporting processes and enhancing its documentation and tools for capturing, investigating and assessing product complaints and quality data,” but also warned that if the FDA determined that Invacare “has not adequately addressed the inspectional observations or has not remained in compliance with the quality systems regulations,” it could pursue enforcement actions including “issuing a corporate warning letter, seeking a consent decree, bringing an action for injunction or seizing or detaining the Company’s products.” (SAC ¶¶122-123; 11/8/11 10-Q at 21).

One month later, on December 8, 2011, Invacare announced that the FDA had requested

it “negotiate and agree to a consent decree of injunction relating to its previously disclosed inspectional observations at the Company’s corporate facility and its wheelchair manufacturing facility in Elyria, Ohio,” (*i.e.*, Headquarters and Taylor Street). Invacare reported that the proposed consent decree “would require suspension of certain operations at the facilities until they are determined by the FDA to be in compliance.” (SAC ¶¶13, 125-26; 12/8/11 8-K at 5). Invacare’s share price dropped nearly 29 percent from the closing price of \$20.58 per share on December 7, 2011 to \$14.70 per share at the close of the market on December 8, 2011. (SAC ¶127).

The FDA and Invacare negotiated the terms of the final consent decree throughout 2012. On December 20, 2012 the United States filed the FDA complaint against Invacare, Gerald B. Blouch, CEO and Ronald J. Clines, Director, Product Risk and Quality Engineering seeking a permanent injunction against the Company. (SAC ¶65) On that same day Invacare announced that it and the FDA had reached an agreement on the terms of the consent decree. (SAC ¶ 138; 12/20/12 8-K at 2) The decree requires that Invacare successfully complete a three-part, third party expert audit of its quality system regulations followed by an FDA inspection. First, after third-party inspection of the qualification and validation procedures at the Taylor Street manufacturing facility and FDA review and acceptance of the report, Invacare would be permitted to resume manufacturing certain components at Taylor Street. Second, a third-party inspector would review Invacare’s design control systems at its Headquarters and Taylor Street Facility; upon FDA acceptance, Invacare would be allowed to resume wheelchair and power bed design activities at both facilities. Third, the third-party expert would perform a “comprehensive review of the Company’s compliance with the FDA’s quality system regulations” at

Headquarters and Taylor Street, “followed by an FDA inspection.” If found to be in compliance, Invacare would then be allowed to resume full operations at its Headquarters and Taylor Street.

(12/20/12 8-K at 6, 4)

The consent decree has had a significant impact on Invacare’s business in that Invacare “suspended most new product development over the past year because the majority of our engineering team was redeployed to focus on remediation.” SAC ¶13, 125; 2/8/13 8-K at 1) Invacare was able to complete two of the three part audit process to the satisfaction of the FDA. However, as of the filing of the SAC, the final third party audit had not been completed. (5/13/13 8-K at 5; 7/16/13 8-K at 5; 2/6/14 8-K at 6)

STANDARD OF REVIEW

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) allows a defendant to test the legal sufficiency of a complaint without being subject to discovery. See *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 566 (6th Cir. 2003). In evaluating a motion to dismiss, the court must construe the complaint in the light most favorable to the plaintiff, accept its factual allegations as true, and draw reasonable inferences in favor of the plaintiff. See *Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007). However, "the tenet that a court must accept a complaint's allegations as true is inapplicable to threadbare recitations of a cause of action's elements, supported by mere conclusory statements." *Ashcroft v. Iqbal*, 129 S.Ct. 1937,1940 (2009). See also *Gregory v. Shelby County*, 220 F.3d 433, 446 (6th Cir. 2000) (court will not accept conclusions of law or unwarranted inferences cast in the form of factual allegations.)

In order to survive a motion to dismiss, a complaint must provide the grounds of the entitlement to relief, which requires more than labels and conclusions, and a formulaic recitation

of the elements of a cause of action. See *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). That is, "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* (internal citation omitted). Accordingly, the claims set forth in a complaint must be plausible, rather than conceivable. See *Twombly*, 550 U.S. at 570.

On a motion brought under Rule 12(b)(6), the court's inquiry is limited to the content of the complaint, although matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint may also be taken into account. See *Bassett v. Nat'l Collegiate Athletic Ass'n*, 528 F.3d 426, 430 (6th Cir. 2008); *Amini v. Oberlin College*, 259 F.3d 493, 502 (6th Cir. 2001). Public records include any materials subject to judicial notice, including securities filings made with the SEC and publicly available stock prices. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S.Ct. 2499, 2509 (2007); *Bovee v. Coopers & Lybrand C.P.A.*, 272 F.3d 356, 360-61 (6th Cir. 2001).

DISCUSSION

In their Motion to Dismiss, Defendants argue that under the pleading standards established in *Fifth Third Bancorp v. Dudenhoeffer*, 134 S. Ct. 2459 (2014), Count I of the SAC fails to state a *Twombly*-viable claim that fiduciaries of Invacare's Retirement Savings Plan breached their fiduciary duties of prudence and loyalty by allowing participants to invest their individual Plan accounts in publicly-traded Invacare stock. Moreover, Defendants argue that the Court may dismiss Count I for the additional or alternative reason that Plaintiff fails to adequately plead loss causation under the loss causation standard of *Dura Pharmaceuticals, Inc. v. Broudo*, 554 U.S. 336 (2005). Finally, Defendants assert that Plaintiff's monitoring and co-

fiduciary breach claims (Counts II and III) are wholly derivative of her defective prudence and loyalty claims in Count I. Thus, if the Court dismisses Count I, the derivative monitoring and co-fiduciary breach claims fail as well. The Court will address these arguments in order.

Defendants' first contend that Plaintiff fails to state a claim for breach of fiduciary duties of prudence and loyalty under the pleading standards set forth by the Supreme Court in *Dudenhoeffer*. In *Dudenhoeffer*, the Court determined that the same standard of prudence applies to all ERISA fiduciaries, including ESOP fiduciaries, except that an ESOP fiduciary is under no duty to diversify the ESOP's holdings. *Dudenhoeffer*, 135 S. Ct. at 2467. A district court's inquiry into whether a complaint states a claim that an ESOP fiduciary has acted imprudently depends on the circumstances prevailing at the time of the fiduciary acts. That is, a court must determine if Plaintiff's claim is based on publicly available information that the market was over or undervaluing the stock or whether Plaintiff's claim is based on inside, non-public information. 135 S.Ct. at 2471-72.

With respect to claims based upon publicly available information, the Court stated that as a general rule, "where a stock is publicly traded, allegations that a fiduciary should have recognized from publicly available information alone that the market was over or undervaluing the stock are implausible as a general rule, at least in the absence of special circumstances." 135 S. Ct. at 2471. In her opposition to Defendants' motion for summary judgment, Plaintiff clarifies that her claim is based on a fiduciary "who holds material, non-public, negative, company-specific facts and allows plan participants to continue to invest in company securities then-known to be an imprudent investment." (ECF #33 at 4)

To state a claim for breach of the duty of prudence on the basis of inside information, "a

plaintiff must plausibly allege an alternative action that the defendant could have taken that would have been consistent with the securities laws and that a prudent fiduciary in the same circumstances would not have viewed as more likely to harm the fund than to help it.” 135 S.Ct. at 2472. The Court set forth three points to inform a lower court’s analysis under this standard.

First, the duty of prudence under ERISA does not require a fiduciary to break the law. Thus, an ESOP fiduciary is not required to perform an action, such as divesting a fund’s holdings of the employer’s stock on the basis of inside information, that would violate the securities laws.

Second, where, as here, a complaint faults fiduciaries for failing to decide, on the basis of inside information, to refrain from making additional stock purchases (or permit participants to make additional stock purchases) or for failing to disclose the inside information to the public so that the stock would no longer be overvalued, the court “should consider the extent to which an ERISA-based obligation either to refrain on the basis of inside information from making a planned trade or to disclose inside information to the public could conflict with the complex insider trading and corporate disclosure requirements imposed by the federal securities laws or with the objectives of those laws.” 135 S.Ct. at 2473.

Third, the court should consider “whether the complaint has plausibly alleged that a prudent fiduciary in the defendant’s position could not have concluded that stopping purchases—which the market might take as a sign that insider fiduciaries viewed the employer’s stock as a bad investment—or publicly disclosing negative information would do more harm than good to the fund by causing a drop in the stock price and a concomitant drop in the value of the stock already held by the fund.” 135 S.Ct. at 2473.

In response to *Dudenhoeffer*, Plaintiff amended her complaint to “excise her

misrepresentation claim and her breach of fiduciary claims against defendants predicated on their failure to sell Company stock while in possession of material non-public information” while retaining her breach of fiduciary duty claim based upon Defendants continuing to allow further investment in Company stock at a time that they knew from inside information that such investment was imprudent. (ECF #33 at 4). Defendants argue that while *Dudenhoeffer* explicitly bars such obvious securities law violations such as selling off company stock based on inside information, it also requires the Court to “‘consider the extent to which an ERISA-based obligation’ to ‘refrain’ from buying stock [based on inside information] may ‘conflict with the complex insider trading and corporate disclosure requirements imposed by federal securities laws or with the objectives of those laws.’”(ECF #34 at 2) Thus, Defendants contend that halting investments in company stock based upon inside information undermines if not the letter, than certainly the objectives of the securities laws. Specifically, those objectives include leveling the playing field for all investors which would be undermined by freezing company stock purchases to protect plan participants giving them an advantage over the rest of the market who would not be similarly protected.

Moreover, *Dudenhoeffer* requires this Court to consider “whether the complaint has plausibly alleged that a prudent fiduciary in the defendant’s position **could not have concluded** that stopping purchases—which the market might take as a sign that insider fiduciaries viewed the employer’s stock as a bad investment. . . would do more harm than good to the fund by causing a drop in the stock price and a concomitant drop in the value of the stock already held by the fund.” 135 S. Ct. at 2473. (Emphasis added)

Plaintiff notes that the Ninth Circuit recently addressed these issues, applying

Dudenhoeffer to hold that removing company stock as an investment option because of negative, nonpublic information is consistent with a fiduciary's duties under ERISA and the federal securities laws because the act of not purchasing or selling shares does not implicate the federal securities laws, and whatever signal is sent to the market from such cessation is highly unlikely to do more harm than good to the plan. *Harris v. Amgen*, 770 F.3d 865, 878-79 (9th Cir. 2014). In *Amgen*, the court acknowledged that removing Amgen Common Stock Fund as an investment option would have sent a negative signal to investors and that such a signal may have caused a drop in the share price but that several factors would have mitigated that effect. First, the efficient market theory suggests that the ultimate decline in price would have been no more than the amount by which the price was artificially inflated and secondly, once the Fund was removed as an investment option, plan participants would have been protected from making additional purchases of the Fund while the price of Amgen shares was artificially inflated. Finally, the court opined that "if defendants had acted to remove the Fund as an investment option when Amgen's share price began to be artificially inflated—that is, when some of the defendants began to violate their obligations under the securities laws—that action may well have caused those defendants to comply with those obligations." 770 F.3d at 878.

In this case, the SAC alleges facts, which if true, show that Defendants knew that Invacare was not complying with FDA safety and compliance standards applicable to the Company's most important products; that Invacare was not sufficiently addressing its FDA compliance issues, and may have been hindering enforcement of the FDA regulations; that these continued deficiencies would likely result in harsh penalties to the Company, including cessation of production, all which would materially impact the financial performance of the Company and

harm all shareholders, including Plan participants who held shares of Invacare. These allegations also show that a prudent fiduciary armed with this inside information, would have known that Invacare stock was artificially inflated during the time that the market was unaware of the true nature and extent of the Company's FDA compliance problems and that a significant fall was inevitable. Accordingly, a prudent fiduciary in Defendants' position could have concluded that stopping Plan participants from further investment in Company stock before the fall occurred would not have caused the Plan more harm than good. The SAC alleges that the Defendants should have made this decision at the beginning of the class period on July 22, 2010. While Defendants argue that the stock was trading at \$23 on that day and the Company had reported strong financial results for the second quarter of 2010, the SAC alleges that the stock price was artificially inflated and that the Company's reports were misleading.

The Court recognizes that "closing the stock fund" is a fairly extreme action with significant consequences. However, as recognized by the Ninth Circuit in *Amgen, Dudenhoeffer* does not foreclose such an action if the complaint has plausibly alleged that a prudent fiduciary in defendant's position could have concluded that such an action would not cause more harm than good. In this case, Plaintiff has met her pleading burden, sufficiently supporting her claim that Defendants breached their duties of prudence and loyalty with respect to their management of the Plan's investment in Invacare stock.³

Defendants' also argue Count I should be dismissed because Plaintiff failed to allege loss

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Since Plaintiff has clarified that Count I is based only on inside information unknown to the public, this claim should be limited to the time period between July 22, 2010, the beginning of the class period and December 8, 2011, the announcement of the FDA consent decree.

causation under *Dura Pharmaceuticals*. The Sixth Circuit has now confirmed that the *Dura Pharmaceuticals* loss causation requirement applied in securities fraud cases also applies to ERISA artificial inflation claims in the Rule 12(b)(6) context. *Metyk v. KeyCorp*, 560 Fed. Appx. 540, 542-44 (6th Cir. 2014). In *Dura*, the Supreme Court noted that stock prices drop for many reasons other than alleged misrepresentations and permitting plaintiffs to state a claim without pleading that the alleged inflation proximately caused an economic loss would improperly transform these actions “into a partial downside insurance policy.” 544 U.S. 343, 347–48. Thus, to state a artificial inflation claim, a plaintiff must allege that she bought stock at a price inflated by misrepresentations, but that the market later learn the truth, causing “the share price [to] f[a]ll significantly.” 544 U.S. at 346-47. In *Metyk*, Plaintiffs artificial inflation claim was dismissed because Plaintiffs did not identify a single instance in which the truth regarding some alleged prior misrepresentation was ever revealed to the market, or in which KeyCorp's stock price dropped significantly as a result. Rather, Plaintiffs admitted that the alleged misrepresentations were known to the market before the class period began and the only disclosures that Plaintiffs can point to that were followed by a drop in KeyCorp’s stock price were announcements of new adverse developments, not corrections of earlier false statements. *Metyk v. KeyCorp.*, No. 1:10 CV 2112, 2013 WL 33112 at *4 (N.D. Ohio Jan. 29, 2013)

Here Plaintiff notes that she has alleged how each representation concerning the Company’s FDA compliance issues were misleading due to the absence of various facts known to the Defendants at the time such representations were made. She also describes how the SAC details how upper management were acutely aware of every detail of the Company’s FDA compliance issues and how it would purposefully obstruct proper FDA inspections. The SAC

also alleges that none of the serious compliance issues and evasive tactics were disclosed to the public at the time the Company was making misleading statements such as “[the Company] does have areas to improve,” that discussions with the FDA were a “work in progress,” and that “Invacare also disclosed the possibility [not the known great likelihood] of a consent decree [in February 2011].” Plaintiff specifically alleges that the revelation of the misleading nature of these statements caused the decline in the price of Invacare stock. The SAC identifies three stock price drops that occurred in reaction to revelations of the truth by Invacare: 4.5% upon the January 4, 2011 release of the Warning Letter; 4.3% upon the October 27, 2011 disclosure of system-wide improvements to quality and regulatory segments of the Company in response to FDA investigations; and 29% upon the December 8, 2011 press release revelation of the FDA Consent Decree of injunction. Judge Boyko found that the amended complaint in *Gov’t of Guam Ret. Fund* met the *Dura* pleading standard for loss causation by identifying the same three discrete Invacare price drops asserted here. *Gov’t of Guam Ret. Fund*, 2014 WL 4064256 at *8.

Defendants counter that FDA Forms 483 or Warning Letters received prior to the class period at issue here are irrelevant and bear no plausible relation to any claim that Invacare stock was artificially inflated on July 22, 2010. Further, Defendants maintain that the only alleged misrepresentations in this case were known to the market either before the class period began or by January-February 2011 and that the only disclosures followed by a drop in Invacare’s stock price were announcements of new adverse developments, not corrections of earlier false statements. Plaintiff contends that Defendants’ argument that the truth had already been disclosed to the public by its “nebulous puffery and outright misstatements concerning the facts then-known to them should not be taken seriously.” (ECF #33 at 16.)

After careful review of the SAC , and taking the factual allegations as true, the Court finds that Plaintiff has sufficiently alleged loss causation under *Dura Pharmaceuticals*. As such, Defendants' motion to dismiss Count I is denied.

Defendants move to dismiss Counts II and II on the theory that they are derivative of Count I. However, as the Court has determined that the SAC states a claim in Count I for breach of the fiduciary duties of loyalty and prudence with respect to Defendants' management of the Plan's investment in Invacare stock, Defendants' motion to dismiss Counts II and II must also be denied.

Conclusion

For the reasons set forth herein, Defendants' Motion to Dismiss the SAC pursuant to Rule 12(b)(6) (ECF #31) is denied. A status conference is set in this matter for September 11, 2015 at 10:00 a.m. IT IS SO ORDERED.

/s/Donald C. Nugent
DONALD C. NUGENT
UNITED STATES DISTRICT JUDGE

DATED: August 28, 2015