IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

NORTH MIAMI BEACH GENERAL EMPLOYEES RETIREMENT FUND, *et al.*,	)	**No. 10 C 6514**
Plaintiffs,	)	**Judge John J. Tharp**
v.	)	
ROBERT L. PARKINSON, *et al.*,	)	
Defendants,	)	
-and-	)	
BAXTER INTERNATIONAL, INC.,	)	
Nominal Defendant.	)	

MEMORANDUM OPINION AND ORDER

This is a suit brought on behalf of Baxter International Inc. by a shareholder against certain officers and directors who allegedly violated duties they owed to the company. Shareholders may assert claims on a corporation's behalf only when the board of directors—which is normally responsible for decisions to bring lawsuits—has wrongfully refused the shareholders' demand that they pursue litigation, or when such a demand would be futile because the board is incapable of impartially evaluating whether to pursue the legal claims at issue. Lead Plaintiff Westmoreland County Employee Retirement System ("Westmoreland") did not ask Baxter to pursue the claims it advances in this case, asserting instead that it would have been futile to do so. Baxter and the Individual Defendants (who are directors and/or officers of Baxter) maintain that demand on the board was not excused and that the Plaintiff therefore lacks standing to go forward

with this law suit. The Court agrees with the Defendants that Plaintiff has not met its burden to show that demand would be futile and, accordingly, grants the Defendants' motions to dismiss.[1]

BACKGROUND

Westmoreland alleges that, between January 2008 and the filing of this lawsuit in October 2010, the Individual Defendants breached duties they owed to Baxter in four respects. First and foremost, Westmoreland alleges that the Individual Defendants failed to remediate long-standing problems with Baxter's Colleague Infusion Pumps, which the FDA ultimately banned from the market in 2010.[2] Westmoreland also maintains that that the Defendants failed to ensure the safe manufacture of the drug heparin, resulting in recalls and patient deaths. The Amended Consolidated Complaint ("Complaint") also alleges that the Defendants made various misrepresentations concerning Baxter's profits and revenues and that certain defendants engaged in insider trading. Based on these alleged breaches, the Complaint sets forth a total of seven claims for breach of fiduciary duty, waste of corporate assets, gross negligence, unjust enrichment, insider trading, and aiding and abetting a conspiracy. The facts alleged to support these claims, which for the purposes of this motion only are taken as true, are summarized as follows.

1. Failure to Remediate Problems With the Colleague Infusion Pumps

Baxter began selling Colleague Pumps, which deliver intravenous fluids such as medication or nutrients to patients, in the mid-1990s. The FDA began scrutinizing the

[1] The Individual Defendants also move to dismiss the Complaint pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim. Because the Court finds that the demand requirement is not excused (and that Westmoreland therefore lacks standing to assert claims on behalf of Baxter), the Court does not address the 12(b)(6) argument.

[2] Westmoreland devotes most of its brief to this issue, although it is not the first issue listed in the Complaint's recitation of Baxter's alleged failures. Cmplt. ¶ 3.

Colleague Pumps in 1999. Between 1999 and 2005, the FDA issued a series of warning letters to Baxter detailing its consistent failure to bring the Colleague Pumps into compliance with applicable standards, but Baxter nevertheless failed to successfully address the problems with the devices. Thereafter, the FDA filed a complaint seeking the forfeiture of all Baxter-owned Colleague Pumps. In 2006, Baxter entered into a Consent Decree of Condemnation and Permanent Injunction ("Consent Decree") which required Baxter to stop selling Colleague Pumps in the U.S. market and to submit and implement a corrective action plan to bring existing Colleague Pumps being used by doctors and hospitals into compliance with federal law. The Consent Decree also gave the FDA the option of ordering a recall of all Colleague Pumps if Baxter violated the Consent Decree or federal standards.

The events leading to entry of the Consent Decree, however, are not at issue in this law suit. The claims asserted here are based on conduct beginning in 2008, relating to Baxter's "failure to comply with the Consent Decree." Cmplt. ¶ 3(b). The Complaint alleges that Baxter's efforts to comply with the Consent Decree were "minimal" and "deeply flawed," *id.* ¶ 94, but includes virtually no allegations as to what would have constituted a more-than-minimal effort to comply with the Consent Decree or what should have been done to correct the flaws in Baxter's remediation program. Instead, the Complaint describes the hundreds of millions of dollars of charges and costs that Baxter incurred in connection with its efforts to remediate the Colleague Pumps, the sixty-plus meetings of the board of directors (or committees thereof) to discuss the remediation program, a substantial recall of the pumps that Baxter made on its own initiative, and its

development and submission to the FDA of a proposed correction schedule in 2010.[3] Cmplt. ¶¶ 60-61, 94.

Despite Baxter's efforts, in May 2010 the FDA ordered Baxter to recall and destroy all of its Colleague Pumps because Baxter had "failed to adequately correct, within a reasonable timeframe, the deficiencies in the Colleague infusion pumps still in use." *Id.* ¶ 111. Baxter's stock price fell by more than 5% after the recall announcement, and Westmoreland claims the recall cost Baxter $588 million. *Id.* ¶ 112; Dkt. 104 at 3. In announcing the recall, the FDA acknowledged that Baxter had been working to correct the problems with the pumps since 1999, and that "Baxter has made numerous changes to the Colleague pumps but these changes have not corrected the product defect." Cmplt. ¶ 111. But the FDA determined that Baxter's proposed correction schedule, which projected a completion date in 2012, was unacceptable and ordered the recall of all of the Colleague Pumps that were still in use.

2. Heparin Contamination

Heparin is a prescription drug used as a blood thinner to reduce the chance of blood clots forming in patients. The active pharmaceutical ingredient ("API") in heparin is an enzyme extracted from pig intestines. In 2008, Baxter supplied approximately half of the heparin sold in the United States. Baxter obtained component ingredients for heparin from a supplier, Scientific Protein Laboratories LLP ("SPL"), which had a manufacturing plant in Changzhou, China. Westmoreland alleges upon information and belief that the Changzhou facility "obtained the API for the heparin from entirely

[3] The Plaintiff also attached as exhibits to its opposition brief two declarations from former FDA employees indicating that Baxter took repeated actions to attempt to solve the Colleague Pump issues, but that its actions were insufficient to remediate the problems successfully. Dkt. 104-1, ¶¶ 10-14.

unregulated and often unclean multiple, small, family-owned workshops that failed to process the crude heparin effectively, which resulted in a dangerous product that contained animal cartilage and contaminated the API." Cmplt. ¶ 69.

Westmoreland alleges that Baxter never made a single inspection or visit to the Changzhou manufacturing plant, and never took any effective action to verify the purity of the API. *Id.* ¶ 72. The Complaint asserts that, despite the fact that no Baxter employees had ever visited the Changzhou manufacturing plant, Baxter represented and warranted that it "places significant emphasis on providing quality products," that it "works closely with its suppliers" in an effort to manage risk associated with raw materials, that "great care is taken in assuring the safety of these raw materials," that it "regularly reviews its quality systems," and that it "performs assessments of its suppliers and raw materials." *Id.* ¶ 70. Westmoreland alleges that these statements were false and that the Individual Defendants knew them to be false. *Id.* ¶ 71. The Court takes judicial notice, however, of the fact that Baxter received FDA approval to use API from the Changzhou plant in its heparin products. Dkt. 98-2 at 3.[4]

[4] The Complaint does not refer to the FDA's approval of the Changzhou facility, but the defendants argue, correctly, that it is a matter of public record of which the Court may take judicial notice even on a motion to dismiss. *Ennenga v. Starns*, 677 F.3d 766, 773 (7th Cir. 2012). Judicial notice is appropriate where facts are (1) not subject to reasonable dispute and (2) either generally known within the territorial jurisdiction or capable of accurate and ready determination through sources whose accuracy cannot be questioned. *Id.* at 773-74. It is not subject to reasonable dispute that the Deputy Commissioner for Operations of the FDA testified to Congress that "Baxter received FDA approval to use the API manufacturer, Changzhou SPL in Changzhou, China." Dkt. 98-2 at 3. And this fact is capable of ready determination in accurate sources. The testimony is available on the FDA website at http://www.fda.gov/NewsEvents/Testimony/ucm115242.htm and also on the website of the U.S. Government Printing Office at http://www.gpo.gov/fdsys/pkg/CHRG-110shrg79104315/html/CHRG-110shrg79104315.htm (websites last visited Sep. 18, 2012).

In 2007, Baxter became aware of severe allergic reactions, including death, experienced by patients using its heparin. Cmplt. ¶ 74. In early 2008, Baxter and the FDA announced recalls of heparin, and the FDA announced that the drug had been contaminated.[5] *Id.* ¶¶ 75-77. Westmoreland alleges that Baxter's stock price fell by approximately 15% when the public became aware of the full extent of the heparin contamination and its implications for Baxter. *Id.* ¶ 80.

3. Misrepresentations

Westmoreland also alleges that the Individual Defendants misrepresented or failed to disclose several pieces of material information to shareholders. For example, it claims that the Individual Defendants did not disclose that Baxter benefitted from a supply constraint allowing it to charge high prices for plasma-based products because one of its competitors was experiencing manufacturing disruptions and seeking a merger with another competitor.[6] *Id.* ¶ 84. Rather than disclosing that this was only a short term advantage, the Individual Defendants stated that Baxter's gross margin was sustainable and could be expanded even further, indicating that plasma product prices would remain high. *Id.* ¶¶ 96, 99, 103, 105. The FTC eventually disapproved the competitors' merger,

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Furthermore, "transcripts of Congressional hearing testimony . . . are public records, which courts . . . have found to be subject to judicial notice." *In re Moody's Corp. Sec. Litig.*, 599 F. Supp. 2d 493, 504 (S.D.N.Y. 2009); *see also Johnson & Johnson v. American Nat. Red Cross*, 528 F. Supp. 2d 462, 464 n. 1 (S.D.N.Y. 2008); *In re Healthsouth Corp. Sec. Litig.*, No. CV-98-J-2634-S, 2000 WL 34211319, at *2 (N.D. Ala. Dec. 13, 2000).

[5] The FDA acknowledged, after the recall, that its approval of the Changzhou plant had been issued erroneously. Dkt. 98-2 at 3.

[6] The Complaint includes allegations of other claimed misrepresentations by the defendants, but because the Complaint does not include allegations of resulting damages, those allegations are not detailed here.

which caused Baxter's competitor to return to full production, adversely affecting Baxter's ability to maintain high prices. *Id.* ¶¶ 85-88.

The Individual Defendants also failed, it is alleged, to account for the impact of healthcare reform legislation in their initial financial guidance for 2010, forcing Baxter to revise its revenue estimates downward after healthcare legislation was enacted. The healthcare bill was signed into law on March 23, 2010, and on April 22, 2010, Baxter issued a press release reducing its expected annual revenue growth from 5-7% to 1-3%, and reducing its earnings estimates. *Id.* ¶ 108. The press release specifically stated that the "revised financial guidance primarily reflects the impact of the recent healthcare reform legislation in the U.S. and [Baxter's] outlook for continued plasma market pressures." *Id.* Baxter's stock price declined over 13% on the day the press release was issued. *Id.* ¶ 109.

4. Insider Trading

Finally, Westmoreland also accuses several of the Individual Defendants (Defendants Boomer, Martin, Shapazian, Stallkamp, Riedel, McGillivray, and White, hereinafter the "Trading Defendants") of selling Baxter stock at times when they knew—because of material non-public information that they gained in the course of their board meetings and/or employment—that the stock was artificially inflated. Westmoreland alleges the number of shares that each Trading Defendant sold, the dates of the sales, and the amount of proceeds received. But it does not allege what percentage of their shareholdings each Trading Defendant sold, provides no information about their trading history or basis to discern whether the trades described were aberrational, and fails to

associate the trades with any particular facts in a manner that would make the timing of the sales were suspicious.

LEGAL STANDARD

The Defendants move to dismiss the Complaint in its entirety pursuant to Federal Rule of Civil Procedure 23.1 and Delaware Chancery Rule 23.1. The Delaware rule is essentially identical to the federal rule and, in any event, federal procedural rules govern in diversity suits. *Starrels v. First Nat. Bank of Chicago*, 870 F.2d 1168, 1170 (7th Cir. 1989) (applying federal procedural requirements to substantive claim under Delaware Rule 23.1); *see also Hale v. China Online, Inc.*, No. 08 C 5548, 2009 WL 2601357, *3 (N.D. Ill. Aug. 21, 2009) (same).

Fed. R. Civ. P. 23.1(b)(3) requires that a plaintiff bringing a shareholder derivative action state with particularity the following:

> (A) any effort by the plaintiff to obtain the desired action from the directors or comparable authority and, if necessary, from the shareholders or members; and
>
> (B) the reasons for not obtaining the action or not making the effort.

Fed. R. Civ. P. 23.1(b)(3).

"In contrast to a motion to dismiss pursuant to Rule 12(b)(6), a Rule 23.1 motion to dismiss for failure to make a demand is not intended to test the legal sufficiency of the plaintiffs' substantive claim. 'Rather, its purpose is to determine who is entitled, as between the corporation and its shareholders, to assert the plaintiff's underlying substantive claim on the corporation's behalf.'" *In re Veeco Instruments, Inc. Sec. Litig.*, 434 F. Supp. 2d 267, 273 (S.D.N.Y. 2006) (quoting *Levine v. Smith*, No. 8833, 1989 WL 150784, *5 (Del. Ch. Nov. 27, 1989), *aff'd* 591 A.2d 194 (Del. 1991), *overruled on other*

grounds by Brehm v. Eisner, 746 A.2d 244 (Del. 2000)); *Gordon v. Goodyear*, No. 12 C 369, 2012 WL 2885695, *5 (N.D. Ill. July 13, 2012).

The law of the state of incorporation governs whether a demand may be excused when a shareholder files a derivative suit on behalf of a corporation. *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 98-99 (1991); *see also CDX Liquidating Trust v. Venrock Assocs.*, 640 F.3d 209, 212 (7th Cir. 2011) ("Illinois choice of law principles, which govern this case because it was filed in Illinois, make[] the law applicable to a suit against a director for breach of fiduciary duty that of the state of incorporation."). Baxter is incorporated in Delaware and, accordingly, it is Delaware law that governs whether the plaintiffs may bring the claims asserted in this suit on Baxter's behalf.

Under Delaware law, "directors of a corporation and not its shareholders manage the business and affairs of the corporation," and accordingly, the directors are responsible for deciding whether to engage in litigation. *Levine v. Smith*, 591 A.2d 194, 200 (Del. 1991), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000). Given the directors' central role, Delaware law requires a pre-suit demand on the corporation's board unless such a demand would be futile. *Rales v. Blasband*, 634 A.2d 927, 932 (Del. 1993) ("Because directors are empowered to manage, or direct the management of, the business affairs of the corporation, . . . the right of a stockholder to prosecute a derivative suit is limited to situations where the stockholder has demanded that the directors pursue the corporate claim and they have wrongfully refused to do so or where demand is excused because the directors are incapable of making an impartial decision regarding such litigation."); *Louisiana Mun. Police Emp. Ret. Sys. v. Pyott*, 46 A.3d 313, 328 (Del. Ch. 2012) (same). The demand requirement "exists to preserve the primacy of board

decisionmaking regarding legal claims belonging to the corporation." *In re American Int'l Grp., Inc.*, 965 A.2d 763, 808 (Del. Ch. 2009) (citing *Aronson v. Lewis*, 473 A.2d 805, 811-12 (Del. 1984), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000)).

The Supreme Court of Delaware—in *Aronson*, 473 A.2d 805, and *Rales*, 634 A.2d 927—has articulated two tests for determining the futility of a demand on directors. Where "a decision of the board of directors is being challenged," the *Aronson* test applies. *In re Abbott Labs. Derivative Shareholder Litig.*, 325 F.3d 795, 804 (7th Cir. 2003). Under *Aronson*, a plaintiff can plead demand futility by creating a reasonable doubt that: (1) a majority of the directors are disinterested and independent; or (2) the challenged transaction was otherwise the product of a valid exercise of business judgment. 473 A.2d at 814.

But where a board "did not make a business decision"—*i.e.*, when the plaintiff alleges an unconsidered failure of the board to act or a failure in its oversight duties—the business judgment rule has no application, *id.* at 813, and thus a different test—the *Rales* test—applies. 634 A.2d at 933-34. Under *Rales*, "a court must determine whether or not the particularized factual allegations of a derivative stockholder complaint create a reasonable doubt that, as of the time the complaint is filed, the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand." 634 A.2d at 934. "If the derivative plaintiff satisfies this burden, then demand will be excused as futile." *Id.*

Aronson is the more favorable of the two tests to shareholders, if only to the extent that it provides them with a quiver holding two arrows while *Rales* offers only one.

Even so, the parties agree that the *Rales* test applies to Westmoreland's claims related to heparin, the alleged misrepresentations, and insider trading. Dkt. 104 at 17. They disagree, however, about which test applies to assess demand futility with respect to the allegations concerning the Colleague Pump remediation program. Characterizing the allegations relating to the Defendants' remediation efforts as "conscious inaction"—*i.e.*, the result of affirmative decisions by the board, Westmoreland maintains that the *Aronson* test applies. Defendants, for their part, assert that what the Complaint alleges with respect to the Colleague Pump remediation is not an affirmative act (or series of acts) by the board but a failure to monitor/oversee—*i.e.,* inaction—that is the province of the *Rales* test.

In *Abbott Labs,* the Seventh Circuit resolved a similar dispute about the application of the *Aronson* and *Rales* tests in the context of evaluating a board's failure to take the necessary action to prevent regulatory action by the FDA. Abbott Labs' shareholders claimed that the company's directors "knew of [a] continuing pattern of noncompliance with FDA regulations and knew that the continued failure to comply with FDA regulations would result in severe penalties and yet ignored repeated red flags raised by the FDA . . . and chose not to bring a prompt halt to the improper conduct causing the noncompliance." 325 F.3d at 802. The district court applied *Rales* because it determined that "the plaintiffs were alleging an omission rather than a conscious decision of the board," and it dismissed the suit because the plaintiffs could not show that the board was not independent or disinterested. *Id.* at 805. The Seventh Circuit reversed, holding that allegations that the board knew "of long-term violations which had not been corrected" but chose not to address them in a timely manner, *id.* at 806, distinguished the

case from a failure to monitor case like *In re Caremark Int'l Inc. Derivative Litigation*, 698 A.2d 959 (Del. Ch. 1996), where the directors "were blamelessly unaware of the conduct leading to the corporate liability," and were not "conscientiously permitt[ing] a known violation of law by the corporation to occur." 698 A.2d at 969, 972.

In this regard, the Court finds *Abbott Labs* controlling. With respect to the Colleague Pump, the Complaint does not allege a situation akin to that of *Rales* or *Caremark*, where the board's failure to take action can be characterized as "unconsidered." *Abbott Labs* holds that where directors "'knowingly,' in an 'intentional breach and/or reckless disregard' of their fiduciary duties, 'chose' not to address the FDA problems in a timely manner," the *Aronson* test applies. *Id.* at 806. That is precisely the nature of the allegations relating to Baxter's failure to remediate the problems with the Colleague Pumps. The Complaint alleges that "[e]ach director of Baxter knowingly participated in, approved, and permitted . . . violations of state and federal law." Cmplt. ¶ 59(a)-(b). In particular, it alleges that the defendants knew that the Colleague Pumps violated FDA requirements, but they nonetheless failed to correct the deficiencies. *Id.* ¶ 59(d), (f). To be sure, Plaintiff's brief spells out the "considered inaction" thesis more clearly than does the Complaint (which muddies the water with allegations, *e.g.*, at ¶ 4, of the Defendants' "complete failure . . . to maintain adequate oversight and internal controls"), but as the non-moving party, Plaintiff is entitled to reasonable inferences that can be drawn from its allegations. The inference Westmoreland urges—that the Company's inability to solve the problems with the Colleague Pumps was the product of knowing choices by the Defendants rather than blameless inaction—is reasonably discernible in the allegations of the Complaint.

The Individual Defendants argue that *Abbott Labs* is no longer good law because it is inconsistent with subsequent decisions of the Delaware Supreme Court holding that the *Rales* test applies to cases involving allegations of the board's violations of its oversight responsibilities. They cite specifically *Stone v. Ritter*, 911 A.2d 362 (Del. 2006) and *Wood v. Baum*, 953 A.2d 136 (Del. 2008) for the proposition that the *Rales* test applies to "conscious inaction" by a board, but neither case can carry that weight. *Stone* did not address the question of which test to use to assess demand futility; the parties in that case agreed that "the directors neither 'knew [n]or should have known that violations of law were occurring,'" so the *Rales* test applied. 911 A.2d at 364. *Wood*, which does nothing more than state the *Aronson* test applies when the directors have made a conscious business decision in breach of their fiduciary duties, while the *Rales* test applies to alleged violations of the board's oversight duties, sheds no light on the substantive difference between these situations. 953 A.2d at 140.

In *Stone*, moreover, the court addressed the question of the directors' oversight duties only in the context of its evaluation of whether there was reasonable doubt as to the directors' independence in light of their potential liability on the claims alleged (an issue that was not raised in *Abbott Labs*). In that context, the *Stone* court endorsed the Delaware Chancery Court's prior holding in *Caremark* that directors are liable for breach of the duty of loyalty on a failure to monitor theory when they (1) utterly fail to implement any reporting or information system or controls, or (2) consciously fail to use the system or controls that they previously implemented. But neither of these scenarios describes the allegations concerning the Colleague Pump. Plaintiffs do not allege that the Individual Defendants are liable because they punted on their obligations to implement,

or use, a system of controls and reporting that would ensure that they had the requisite information about the pump remediation efforts; they allege that despite having the information they needed, they made poor decisions that resulted in the company's failure to do what was necessary, quantitatively and/or qualitatively, to solve the problem. *See* Complaint ¶ 94 ("Baxter made . . . minimal, and deeply flawed attempts to comply with the Consent Decree."). In short, the theory of Westmoreland's allegations about the Colleague Pump remediation program is not that the board was unaware of the problem because it failed to monitor the program but that the board's actions were ineffective despite monitoring the problem very closely.

Defendants assert that there are no Delaware cases holding that demand futility should be measured by the *Aronson* test rather than *Rales* in the context of "conscious inaction" by the board. But they ignore the fact that *Aronson* itself noted that "a conscious decision to refrain from acting may nonetheless be a valid exercise of business judgment and enjoy the protections of the rule." 473 A.2d at 813. The Seventh Circuit applied this rationale in *Abbott Labs*, reasonably concluding that, viewed in the light most favorable to the shareholders, the Abbott board's failure to take any action to resolve Abbott's FDA problems constituted an affirmative decision by the board that was subject to the business judgment rule (as incorporated into the *Aronson* demand futility standard). That holding is perfectly consistent with Delaware law—neither *Stone* nor *Wood* purports to overturn *Aronson* in anyway, much less on this point—and even if this Court believed otherwise, the Delaware Supreme Court would have to speak to this issue much more

clearly before this Court would have license to interpret the applicability of the *Aronson* test differently than has the Seventh Circuit.[7]

Labels aside, the choice between the *Aronson* and *Rales* tests turns on whether the conduct described in the complaint plausibly describes one or more affirmative decisions—whether decisions to act, or not to act—of the directors and officers. Defendants argue that the Complaint lacks specific allegations that the board decided anything, but that criticism goes (as will be seen) to the evaluation of whether the particularized allegations of the complaint plausibly show that demand was futile under the *Aronson* test rather than to whether the test itself applies. Drawing all reasonable inferences in its favor, Westmoreland adequately alleges that the board knew of Baxter's obligations under the Consent Decree, was informed as to Baxter's progress with respect to remediating the Colleague Pumps, and knew of the dangers of failing to develop a solution. Cmplt. ¶¶ 60-62. The board's evaluation and oversight of Baxter's remediation program required it to determine whether or not affirmative intervention or other action was necessary at any given point; that determination can therefore reasonably be characterized as a "conscious business decision"—or more accurately, series of decisions—by the board. Accordingly, the *Aronson* test applies to the allegations regarding the failure to solve the problems afflicting Baxter's Colleague Pump.

[7] Insofar as other courts have similarly concluded that the business judgment rule does not apply in cases of "conscious inaction," the Court finds them unpersuasive for the same reason. *See, e.g.*, *Fagin v. Gilmartin*, 432 F.3d 276, 282 (3d Cir. 2005) (declining to follow *Abbott Labs*); *In re Bidz.com, Inc.*, 773 F. Supp. 2d 844, 852 (C.D. Cal. 2011) (same); *In re Intel Corp.*, 621 F. Supp. 2d 165, 173 (D. Del. 2009) (same).

DISCUSSION

I. Westmoreland Fails to Plead Demand Futility With Regard to the Colleague Pumps.

A. Westmoreland Has Not Created a Reasonable Doubt that the Defendants Face a Substantial Likelihood of Personal Liability.

Under the first prong of the *Aronson* test, demand is futile if a plaintiff alleges with particularity facts sufficient to create a reasonable doubt that a majority of the board is disinterested or independent. 473 A.2d at 814. Westmoreland does not attempt to allege that the board lacked independence, but argues only that the directors are not disinterested. A disinterested director "can neither appear on both sides of a transaction nor expect to derive any personal benefit from [the challenged transaction] in the sense of self-dealing, as opposed to a benefit which devolves upon the corporation or all stockholders generally." *Id.* at 812. Westmoreland claims that the Director Defendants are not disinterested because they face a "substantial likelihood of personal liability" in this lawsuit. *Wood*, 953 A.2d at 141 n. 11 (quoting *Aronson*, 473 A.2d at 815). "The mere threat of personal liability . . . is insufficient to challenge either the independence or disinterested of directors." *Id.* But in the "rare case . . . where defendants' actions [are] so egregious that a substantial likelihood of director liability exists," there is a reasonable doubt about the board's disinterest. *Seminaris v. Landa*, 662 A.2d 1350, 1354 (Del. Ch. 1995).

The Individual Defendants note that Baxter's Amended and Restated Certificate of Incorporation contains a provision exculpating directors from liability for a breach of the duty of care, but the provision does not prevent liability for conduct that is not in good faith or for a breach of the duty of loyalty. Dkt. 98-7 at 8; 8 Del. C. § 102(b)(7); *Stone*, 911 A.2d at 367. Therefore, to show that the directors face a "substantial

likelihood of personal liability" (and correspondingly that a demand on the board is excused pursuant to Rule 23.1), Westmoreland must allege with particularity facts raising a reasonable doubt that the directors complied with their duties of good faith and loyalty. Failure to act in good faith is not an independent fiduciary duty, but rather "is a subsidiary element, i.e., a condition, of the fundamental duty of loyalty." *Stone*, 911 A.2d at 370 (internal quotes omitted). "A director cannot act loyally towards the corporation unless she acts in the good faith belief that her actions are in the corporation's best interest." *Id*.

"[A]n action that is . . . the result of a conscious disregard of a known duty breaches the duty of loyalty because it is not undertaken in good faith." *In re Textron, Inc.*, 811 F. Supp. 2d 564, 575 (D.R.I. 2011). Westmoreland alleges that the board consciously disregarded a known duty because it "allowed remediation of the Colleague Infusion Pump to languish." Cmplt. ¶ 59(e). But while allegations of this ilk suffice to show that the Plaintiff's theory is premised on board action, not a failure to monitor, such that the *Aronson* test applies, they do not rise to the level of the particularized allegations required by Rule 23.1 to establish that the Director Defendants, by not doing more, were acting in bad faith.

Indeed, the Complaint fails to include facts showing that there was anything more the board could have done with respect to the Colleague Pumps. Westmoreland finds fault with the pace of Baxter's remediation efforts, but fails to allege specific facts showing that the board knew that it had a duty to speed up the remediation. The directors may reasonably be charged with understanding that the FDA's patience was not infinite, but the Complaint provides no basis to infer that they should have known, after years of

working with the FDA on the problems associated with the pumps, that the timetable Baxter submitted in 2010 would be so intolerable that the agency would simply pull the plug on the remediation effort and recall all of the remaining pumps. Nor does Westmoreland allege that the board could have accelerated the remediation process, even had it been able to predict when the FDA's patience would be exhausted. For that matter, for all we know complete remediation may not even have been technologically possible. The Complaint does not say that it was (much less include allegations that would make that claim plausible). And even if technically feasible, the Complaint does not allege that complete remediation would have been less costly than the recall ordered by the FDA.

The allegations of the Complaint reveal that Baxter tried to correct the problems with the Colleague Pump but failed to do so to the FDA's satisfaction. That Baxter failed to solve the problems, however, does not permit an inference that board ignored the problem or that its efforts were not in good faith. "With the benefit of hindsight, the plaintiffs' complaint seeks to equate a bad outcome with bad faith." *Stone*, 911 A.2d at 373. On the facts alleged, that is not a reasonable inference to draw. Westmoreland has therefore failed to meet its heavy burden of creating a reasonable doubt that the board is disinterested in the lawsuit on the grounds that a majority of directors faced a "substantial likelihood of personal liability." The Court cannot, therefore, find that a pre-lawsuit demand on the board is excused under the first prong of *Aronson*.

B. Westmoreland Has Not Rebutted the Presumption of the Business Judgment Rule.

For similar reasons, Westmoreland has not rebutted the presumption that the business judgment rule protects the directors' actions. "The business judgment rule is a presumption that in making a business decision, 'the directors of a corporation acted on

an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the company.'" *Abbott Labs*, 325 F.3d at 807 (quoting *Aronson*, 473 A.2d at 812). To establish liability despite the protections of the business judgment rule, a plaintiff must show that the directors' actions were at least grossly negligent. *Aronson*, 473 A.2d at 812-13 & n. 6 (confirming that simple negligence is insufficient to establish liability and equating gross negligence to intentional, reckless and bad faith conduct). As the *Caremark* court explained, this requires an assessment not of the content of the decision alone but only in connection with consideration of whether the decision was the product of a good faith process: "[T]he business judgment rule is process oriented and informed by a deep respect for all *good faith* board decisions." 698 A.2d at 967-68. *See also Abbott Labs*, 325 F.3d at 808 (the second prong of the *Aronson* test requires consideration of both substantive and procedural due care).[8]

Westmoreland maintains that the Seventh Circuit's holding in *Abbott Labs* is "controlling" on the question of whether, after years of failing to meet the FDA's standards, the business judgment rule shields the Defendants. The Seventh Circuit held that the rule did not protect the defendants in *Abbott Labs*, but while the allegations in both cases permit the inference that the defendants made affirmative decisions about how to deal with the FDA problems their companies confronted, only the *Abbott Labs* complaint contained particularized allegations sufficient to raise a reasonable doubt about whether those decisions were made in good faith. That complaint, which included

[8] The parties' debate over whether to apply the *Aronson* or *Rales* test to the Colleague Pump claims appears, in this case, anyway, to be largely academic. Here, both prongs of the *Aronson* test effectively turn on whether the Complaint alleges with sufficient particularity that the Defendants acted in bad faith, effectively making both prongs of the *Aronson* test, rather than just the first, the functional equivalent of the *Rales* test.

express allegations that the defendants "chose not address the FDA problems in a timely manner," described an intentional, sustained, and systemic failure by the board to take any action. 325 F.3d at 806, 809. Little wonder, then, that the court concluded that there was reason to doubt that the board's decision was the product of a valid exercise of business judgment.

The allegations in this case are markedly different. If the Complaint and the affidavits attached to Westmoreland's opposition brief show anything, it is that Baxter's board *acted*, devoting substantial resources and attention over a prolonged period of time to Baxter's efforts to remediate the Colleague Pump problems. Cmplt. ¶¶ 60-61, 94. The allegations of the sixty-plus board meetings the defendants attended, for example, are the antithesis of the intentional "sustained and systematic failure of the board to exercise oversight" that prompted the Seventh Circuit to conclude that the *Abbott Labs* defendants had not acted in good faith. 325 F.3d at 809. Westmoreland alleges not that Baxter did nothing, but that it did not do enough, and that what it did it did not do well. Westmoreland describes Baxter's efforts as "minimal" and "deeply flawed," Cmplt. ¶ 94, but these cursory labels do not change the fact that the allegations relating to the substantial attention and resources that the Baxter defendants devoted to the company's remediation program stand in stark contrast to the allegations at issue in *Abbott Labs*, where "neither FDA censures nor public notice motivated the directors to take *any action* concerning the problems over a six-year period." 325 F.3d at 809 (emphasis added). *Abbott Labs* is readily distinguishable on this basis.

Again, that Baxter's remediation efforts were "deeply flawed" says nothing about whether they were in good faith. As *Caremark* colorfully explains, "whether a judge or

jury considering the matter after the fact, believes a decision substantively wrong, or degrees of wrong extending through 'stupid' to 'egregious' or 'irrational', provides no ground for director liability, so long as the court determines that the process employed was either rational or employed in a *good faith* effort to advance corporate interests." 698 A.2d at 967 (emphasis in original). Unquestionably, the remediation program the Individual Defendants oversaw was unsuccessful. As discussed above in connection with the first prong of the Aronson test, that may be because the problems were unsolvable,[9] or it may be because the Defendants, and others acting under their authority, simply made poor decisions. The Complaint does not tell us what the Defendants could or should have done differently, and therefore provides no basis to believe that they were acting in bad faith (or that their decisions were substantively flawed).

Westmoreland has therefore failed to establish reasonable doubt that the Individual Defendants acted within the scope of discretion afforded by the business judgment rule. The development and manufacture of complex medical devices and pharmaceuticals is risky business.[10] Executives in that industry do not forfeit the

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[9] Unlike *Abbott Labs*, where the company's FDA problems stemmed from its failure to enact proper quality assurance procedures and manufacturing practices, 325 F.3d at 799-800, which are inherently correctable, in this case the FDA problem was with the design of the Colleague Pumps and there is no specific allegation about what, if anything, the Defendants could have done to spur a solution to that problem.

[10] The development of a new medical product within the FDA's jurisdiction is much more likely to fail than to succeed. The FDA has found that "a new compound entering Phase 1 testing, often representing the culmination of upwards of a decade of preclinical screening and evaluation, is estimated to have only an 8 percent chance of reaching market." Food and Drug Administration, Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products (March 2004). And, as Baxter disclosed in its 2010 10-k, it operates in a field where there is pervasive regulation and where the risk of regulatory action is omnipresent. *See, e.g.*, Baxter 10-K at 6 and 40, Feb. 23, 2010 (available at http://investor.baxter.com/phoenix.zhtml?c=86121&p=irol-SECText&TEXT=aHR0cDovL2lyLmludC53ZXN0bGF3YnVzaW5lc3MuY29tL2RvY3

protections of the business judgment rule simply because their initiatives fail—even if they fail spectacularly. Absent some reason to believe that Baxter's directors approved decisions to pour millions of dollars into an effort to remediate a product that they had no reason to believe would ever meet the FDA's acceptance criteria (and why would independent directors do so? the Complaint provides no plausible explanation), there is no basis to strip the directors of the protections of the business judgment rule.

Westmoreland's complaint therefore fails to establish demand futility with respect to its Colleague Pump claims. By failing to make a pre-suit demand on the board, Westmoreland failed to comply with Rule 23.1 and therefore lacks standing to pursue claims based on the failure of the Colleague Pump remediation program.

II. Westmoreland Failed to Plead Demand Futility With Regard To Its Other Claims.

The *Rales* demand futility test applies to Westmoreland's other claims. This test is essentially the same as the first prong of the *Aronson* demand futility test: demand is futile if a plaintiff alleges with particularity sufficient facts to raise a reasonable doubt that a majority of the board is disinterested or independent. *See, e.g., In re Textron, Inc.*, 811 F. Supp. 2d at 576 (the *Rales* test "recapitulates the first prong of *Aronson*"); *In re MIPS Tech., Inc.*, 542 F. Supp. 2d 968, 975 (N.D. Cal. 2008) ("the *Rales* test and the first prong of *Aronson* . . . are the same"). Westmoreland alleges that the board is not disinterested with regard to its alleged oversight failures related to the heparin contamination, misrepresentations, and alleged insider trading. Because the Baxter certificate of incorporation contains an exculpatory provision for directors, "the necessary

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conditions predicate for director oversight liability [are]: (a) the directors utterly failed to implement any reporting or information system or controls; *or* (b) having implemented such a system or controls, consciously failed to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring their attention." *Stone*, 911 A.2d at 370. "In either case, imposition of liability requires a showing that the directors knew that they were not discharging their fiduciary obligations." *Id.* Westmoreland cannot make the required showing with respect to any of the alleged oversight failures described in the Complaint.

A. Heparin Contamination

Westmoreland argues that the board utterly failed to implement any reporting or information system or controls over the production of heparin. Dkt. 104 at 28. This claim is based on Baxter's alleged failure to inspect the facility in Changzhou, China, which supplied the API for Baxter's heparin, but Westmoreland omits any reference to the public record evidence that the FDA had (1) approved Baxter's procurement of the API from that facility and (2) advised Baxter that it had inspected the plant. The defendants cited that evidence in their opening brief, Dkt. 98-2 at 3, and Westmoreland does not counter this evidence or allege that it is mistaken (indeed, its brief makes no reference to it at all). In the absence of any explanation as to why it was unreasonable for the board to rely on inspection and approval of the Changzhou facility by the government's regulator (the same regulator whose approval Baxter had so much difficulty obtaining for the Colleague Pumps), Westmoreland's claim that "Defendants face a substantial likelihood of liability for producing heparin without any controls" collapses, thereby eliminating the only basis Westmoreland offers for the specter of director liability arising from the heparin contamination. In light of the FDA's approval

of that facility, the allegations of the Complaint provide no basis at all to infer that the board *knew* it was not discharging its fiduciary obligations with respect to the manufacture of heparin. Accordingly, there is no reasonable doubt as to the directors' ability to evaluate a shareholder demand pertaining to the heparin contamination and Westmoreland therefore lacks standing to pursue claims on Baxter's behalf arising from that episode.

B. Misrepresentations

Westmoreland presents no argument whatsoever in its brief as to why the board was substantially likely to incur personal liability for Baxter's alleged misrepresentations. And Westmoreland's own allegations in the Complaint show that the board did not "utterly fail" to institute controls regarding financial reporting, nor did it consciously fail to monitor or oversee financial reporting. The Complaint acknowledges, for example, that the board created an Audit Committee which was "primarily concerned with the integrity of Baxter's financial statements" and which met eleven times in 2009 alone. Cmplt. ¶ 45. These allegations are fatally inconsistent with Westmoreland's demand futility claim relating to alleged financial reporting misrepresentations.

In addition, a number of the topics Baxter allegedly "concealed" from investors were not topics on which it had any duty of disclosure. For example, Westmoreland complains that Baxter failed to disclose the material facts of a proposed merger between two of Baxter's competitors and misstated revenue guidance for 2010. Baxter had no duty to disclose the proposed merger because it was not firm-specific, however; "securities laws do not require issuers to disclose the state of the world." *See Asher v. Baxter Int'l Inc.*, 377 F.3d 727, 729 (7th Cir. 2004); *City of Lakeland Emp. Pension Plan*

v. Baxter Int'l, No. 10 C 6016, 2012 WL 607578, *3 (N.D. Ill. Jan. 23, 2012).[11] And though Baxter reduced its 2010 revenue targets based on enactment of healthcare legislation, it had expressly noted when it previously announced its 2010 guidance that its projections did "not reflect any impact of potential US healthcare legislation reform." Dkt. 98-4 at 6. Absent a duty of disclosure, the board members do not face any prospect of oversight liability arising from an alleged failure to insure that the company made such disclosures.

Finally, there is a disconnect between Westmoreland's misrepresentation claims and its assertion that a demand on the board would be futile. Few (if any) of the misrepresentations Westmoreland alleges are statements by the board as a whole (or that can be attributed to the board as a whole); rather, they are statements attributable to the company or to a small number of individual defendants. Defendants Parkinson, Davis and Riedel, for example, are alleged to have made misstatements about Baxter's ability to sustain its margins in the BioScience business (of which its plasma business was an important part) during an investor conference in 2009. Cmplt. ¶ 96. But the Complaint provides no basis to infer that any of the other directors bear responsibility for these statements and the law does not impute responsibility to them. There is no "group pleading doctrine" in the Seventh Circuit; plaintiffs must create a strong inference of scienter with respect to each individual defendant they seek to hold liable for an alleged

[11] In the shareholder class action pending against Baxter based on the same facts, Judge Coleman dismissed the portion of the claim alleging that Baxter failed to disclose information regarding its competitors' potential merger. *Lakeland*, 2012 WL 607578 at *3. A failure to satisfy the less demanding pleading standard of a motion pursuant to Rule 12(b)(6) means, *a fortiori*, that the pleading falls short of the requirements under Rule 23.1. *See, e.g., Levine*, 591 A.2d at 207 ("Plaintiffs' pleading burden under Rule 23.1 is also more onerous than that required to withstand a Rule 12(b)(6) motion to dismiss.").

misstatement in a securities fraud case. *Pugh v. Tribune Co.*, 521 F.3d 686, 693 (7th Cir. 2008). Even if, as Westmoreland claims, Baxter or some individuals representing Baxter made material misstatements, the Complaint provides no basis to infer that each director (or even a majority of the directors) would face liability as a result of those statements.[12] As a result, Westmoreland fails to create a reasonable doubt that a majority of the board members would not be able to evaluate impartially a demand predicated on the alleged misrepresentations.

All of these shortcomings may explain Westmoreland's failure to devote any argument in its brief to the support of its assertion that demand on the board would be futile with respect to the alleged misrepresentations set forth in the Complaint. As the brief offers no such argument, and the Court can discern no basis for one, the Court concludes that Westmoreland lacks standing to advance claims on behalf of Baxter arising from those alleged misrepresentations.

C. Insider Trading

Westmoreland's claim that a majority of the board was not disinterested with respect to its insider trading claims is flawed in several respects. As a threshold problem, Westmoreland alleges that only four out of the thirteen directors engaged in any insider trading. Cmplt. ¶ 3(e). Even if those four directors were interested parties, a majority of the directors remained disinterested. *See, e.g., In re First Bancorp Derivative Litig.*, 465 F. Supp. 2d 112, 121 (D.P.R. 2006) ("Because a majority of the directors are not alleged to have engaged in insider trading, the court finds that plaintiffs' insider trading

[12] Indeed, only two of the defendants in this case (Parkinson and Davis) are named as defendants in the securities fraud class action that pertains to many of the same alleged misrepresentations.

allegations do not raise a reasonable doubt that the Board is incapable of being impartial in considering a demand to challenge the insider-trading transactions.").

Westmoreland's allegations also fail, in at least two different ways, to satisfy the Rule 23.1 requirement that they be plead with specificity. First, as the Individual Defendants point out in their brief, the Complaint lacks specific allegations about the negative information that the Trading Defendants allegedly sought to unlawfully use to their advantage. Dkt. 97 at 25-26. Westmoreland alleges only that the defendants executed trades on the basis of "material non-public information including negative developments with respect to Baxter's pump platforms." Cmplt. ¶¶ 25, 32-34. But Westmoreland never alleges with particularity what those "negative developments" were. Westmoreland does not allege that the defendants sold their stock after Baxter learned that the FDA would require a recall of the Colleague Pumps but before that information became public. In fact, all of the stock sales Westmoreland notes took place either well before Baxter proposed corrections to the FDA on April 8, 2010, at which time Baxter did not know the FDA would order a recall, or well after Baxter and the FDA publicly announced the recall on May 3, 2010. *Id.* Without specific allegations that the defendants had and used material nonpublic information, Baxter's claim fails.

Second, the Complaint alleges only the amounts of stock that each defendant sold and the timing of the sales; there are no specific allegations showing impropriety. "[B]ecause executives sell stock all the time, stock sales must generally be unusual or suspicious to constitute circumstantial evidence of scienter." *Pugh*, 521 F.3d at 695; *see also Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 759 (7th Cir. 2007) (dismissing plaintiff's insider trading argument as "neither compelling nor cogent" in the absence of

facts indicating that executives were in possession of material, non-public information at the time of the stock sale). Westmoreland fails to allege any facts that would allow an assessment of whether the trading was unusual or suspicious, and instead merely set forth number of shares sold by each Trading Defendant on each particular date.

In short, the Complaint provides no basis to infer that the sales constituted "insider trading" rather than trading in the normal course by directors who received a substantial portion of their compensation in the form of stock and stock options. Nor does it provide a basis to infer that the board as a whole would not be able to assess impartially a demand arising from that trading activity and, accordingly, Westmoreland lacks standing to assert claims on Baxter's behalf based on that activity.

*** * ***

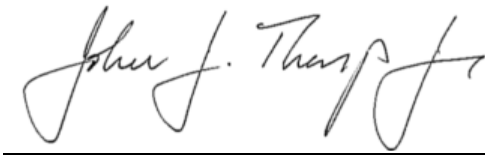
The Complaint fails to allege with adequate particularity facts showing that a pre-suit demand on the board would have been futile; indeed, the facts alleged in the Complaint show that there is no basis for reasonable doubt as to the ability of Baxter's board to review impartially a shareholder demand concerning the issues raised in the Complaint. Pre-suit demand was therefore required. Westmoreland made no demand and therefore lacks standing to bring this suit. Accordingly, the Court grants the motions of the Individual Defendants and Baxter to dismiss the Amended Consolidated Shareholder Derivative Complaint.

The dismissal is without prejudice as to shareholder standing to assert the substantive causes of action; Westmoreland's lack of standing derives from its failure to

make a demand on the board, which can be cured.[13] The dismissal is with prejudice, however, on the issue of demand futility with respect to the substantive claims set forth in the Complaint. Even though the Defendants requested dismissal with prejudice in their motions, Westmoreland's response does not request leave to further amend, essentially and rightly conceding the point. This is a consolidated complaint, built on (at least) four prior complaints that were filed by various plaintiffs in this District alone, and has already been amended once. Before filing the Complaint, Westmoreland appropriately availed itself of its right to access Baxter's corporate records via 8 Del. C. § 220(b) in order to bolster its allegations of demand futility. *See* Cmplt. ¶ 60. It has even submitted witness affidavits with its response to the motion (Resp. Exs. A & B), which the Court has considered in reaching its ruling. In addition, to the extent that Westmoreland's brief spells out its "conscious inaction" theory more clearly than does the Complaint, the Court has allowed the brief to supplement the allegations of the Complaint, interpreting those allegations in light of Westmoreland's argument; this dismissal is not the result of a rejection of information set forth in a brief but not in the Complaint. Westmoreland, then, has had ample opportunity to put its best foot forward and there is little basis to believe that it can further supplement its allegations of demand futility to satisfy the requirements of *Aronson* and *Rales*. In any event, and as noted above, it is largely the allegations that Westmoreland has made, more than the absence of allegations, that demonstrate that it cannot establish that demand would be futile. Accordingly, the Court

[13] If Westmoreland opts to make a demand on the board, and the board takes over the claims, or authorizes Westmoreland to pursue them, this Order will have no preclusive effect. Nor, if the board chooses not to initiate litigation, will this ruling have any preclusive effect with regard to any challenge Westmoreland may wish to make with respect to that decision.

dismisses the demand futility claim with prejudice. This case is dismissed and the dismissal constitutes a final and appealable order.



Date: September 19, 2012

John J. Tharp, Jr.
United States District Judge