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June 9, 2008

Via Hand Delivery

The Honorable William T. Hart
United States District Court,
Northern District of Illinois
219 South Dearborn Street
Room 2246
Chicago, Illinois 60604

Re: ***Fojas v. Ackerman, et al.*, No. 08 CV 00423**

Dear Judge Hart:

In further support of Defendants' Motion to Dismiss For Failure to Adequately Plead Demand Futility (Docket No. 17), enclosed is a recent decision by Northern District of Illinois Judge Virginia M. Kendall. The May 30, 2008 Memorandum Opinion and Order grants a motion to dismiss a shareholder derivative action for failure to adequately plead demand futility.

Very truly yours,

Jonathan E. Hinkemeyer

Enclosure (1)

cc: Attached Service List

CERTIFICATE OF SERVICE

I, Jonathan E. Hinkemeyer, an attorney, hereby certify that on June 9, 2008, I caused the forgoing **Letter dated June 9, 2008 to The Honorable William T. Hart** to be served **via fax** to the following counsel of record:

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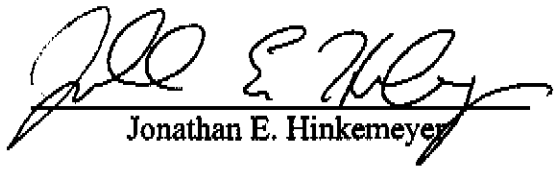

Jonathan E. Hinkemeyer

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

LEONARD BRONSTEIN, on behalf of himself and derivatively on behalf of Abbott Laboratories, Plaintiff, v. ROXANNE S. AUSTIN, WILLIAM M. DALEY, W. JAMES FARRELL, H. LAURENCE FULLER, RICHARD A. GONZALEZ, THE RT. HON. LORD OWEN CH, BOONE POWELL, JR., W. ANN REYNOLDS, PH.D., ROY S. ROBERTS, SAMUEL C. SCOTT, III, WILLIAM D. SMITHBURG, GLENN F. TILTON and MILES D. WHITE, Defendants, and ABBOTT LABORATORIES, Nominal Defendant.	)	No. 07 C 3984 Judge Virginia M. Kendall

MEMORANDUM OPINION AND ORDER

Plaintiff Leonard Bronstein ("Bronstein") brings this shareholder derivative action on behalf of nominal defendant, Abbott Laboratories ("Abbott" or the "Company"), against the individual defendant directors of Abbott ("Board" or "Directors," and together with Abbott, "Defendants") to remedy alleged breaches of their fiduciary duties. Plaintiff asserts that the breaches arise from Directors' knowing failure, over a period of time, to exercise their oversight responsibility over Abbott's Diagnostic Division to assure compliance with the Quality Service Regulations ("QSRs") of the Food and Drug Administration ("FDA"). Defendants moved to dismiss for failure to

adequately plead demand futility. This Court grants Defendants' Motion to Dismiss and dismisses Bronstein's Complaint without prejudice.

STATEMENT OF FACTS

I. The Parties

Bronstein is a current shareholder of Abbott stock. Compl. ¶ 4. Miles D. White ("White'), Roanne S. Austin ("Austin"), William M. Daley ("Daley"), W. James Farrell ("Farrell"), H. Laurance Fuller ("Fuller"), David Owen ("Owen"), Boone Powell, Jr. ("Powell"), W. Anne Reynolds ("Reynolds"), Roy S. Roberts, Ph.D. ("Roberts"), Samuel L. Scott ("Scott"), William D. Smithburg ("Smithburg"), and Glenn F. Tilton ("Tilton") are Directors of Abbott. Compl. ¶¶ 17. As Directors, Bronstein alleges that the Defendants owed Abbott's stockholders fiduciary duties such as candor, fidelity, trust and loyalty, and were required to use their ability to oversee and control Abbott's operations and business in a fair, just, and equitable manner. Compl. ¶ 18. Defendants were further obligated to act in the best interest of Abbott and its stockholders. Compl. ¶ 18. Defendants were required to exercise reasonable and prudent supervision over management and the Company itself. Compt. ¶¶ 19-20. This included overseeing Abbott's compliance with FDA regulations. *Id.*

II. The FDA Regulatory Scheme

Because Abbott is in the business of manufacturing and selling healthcare products, it is subject to FDA regulation. The FDA has issued QSRs that define Current Good Manufacturing Practices ("CGMPs"), *see* 21 C.F.R. § 820.1-820.250 (2007), and periodically inspects facilities to assure compliance. Following these inspections, the FDA may provide the company with a Form 483 detailing QSR non-compliance and asking the company to formulate a remedial plan. *See*

Fujisawa Pharm. Co. V. Kapoor, 16 F. Supp. 2d 941, 943 (N.D. Ill. 1998). Subsequently, the FDA may choose to take no further action or to issue a "warning letter" detailing QSR violations and demanding they be remedied promptly. *Id.*

III. Prior Non-Compliance

At the end of 1999, the FDA brought a suit against Abbott for QSR violations at its Illinois facilities. (Compl. Ex. C.) The suit resulted in a $100 million fine and led to a subsequent shareholder's derivative suit. *See In Re Abbott Lab. S'holder Derivative Litig.*, 325 F.3d 795 (7th Cir. 2003). As part of the settlement of the latter suit, Abbott agreed to make changes in its corporate governance structure, amending the Charter of the Public Policy Committee of the Board of Directors ("Public Policy Charter') to specifically address the Board's oversight responsibility with respect to FDA compliance. (Compl. Ex. A.) The resulting Public Policy Committee today reviews and evaluates Abbott's regulatory compliance through investigation and reporting from management. *Id.* The Public Policy Committee has been functioning as intended. (Compl. ¶ 35); (Defs.' Mem. Supp. Mot. Dismiss 4.)

IV. Abbott and General Electric

On January 18, 2007, Abbott issued a press release announcing the sale of its Diagnostics Division to General Electric ("GE") for $8.13 billion. (Compl. ¶ 23.) The press release stated that the deal was subject to customary closing conditions, including regulatory approval. *Id.* Bronstein alleges that Defendants knew of the serious long-standing FDA regulatory problems that were plaguing the Irving, Texas facility of the Diagnostic Division's operation at the time that Abbott entered into the contract with GE. Compl. ¶ 24.

IV. March 13 Warning Letter

On March 13, 2007, the FDA sent Abbott a warning letter (the "March 13 Letter") about QSR non-compliance at its Irving, Texas facility. (Compl. Ex. B.) The letter stated the FDA had conducted an investigation there in late 2006 and had found several QSR violations. *Id.* Some were repeat violations, incomplete corrections stemming from observed violations as far back as 2003. (Compl Ex. B at 2.) The letter further stated that the FDA had issued Forms 483 in response to the violations and that Abbott had responded. *Id.* It detailed ongoing communications between the FDA and Abbott, acknowledging Abbott's commitment to improve product quality and compliance through a comprehensive corrective action plan. *Id.* Despite this commitment, the letter expressed dissatisfaction with the pace of the progress and demanded Abbott comply in a timely manner. *Id.* The letter also provided for further follow-up inspections to assure compliance. *Id.* Finally, the letter warned Abbott that failure to bring the facility into compliance could result in FDA regulatory action including seizure, injunction, and/or civil penalties and could affect awards of contracts and pre-market approval application for certain devices. Compl. ¶ 25. Defendants did not publicly disclose the Warning Letter or the adverse impact it would have on the sale of Abbott's core Diagnostic Division to GE. *Id.* Bronstein claims that Defendants knew of the serious nature of the potential consequences because in December 1999, Abbott paid $100 million in civil penalties to the United States for failure to bring its Diagnostic Division into FDA compliance. Compl. ¶ 25.

V. The General Electric Deal

Bronstein alleges that Defendants' repeated failure to act reasonably to address the deficiencies recited by the FDA in its Form 483 and Warning Letter, put "at serious risk" Abbott's sale of it core diagnostic business to GE. Compl. ¶ 26. On July 11, 2007, Abbott issued a statement

that the parties had terminated the sale because they were unable to agree on final terms and conditions. (Compl. ¶ 27.) Although it is customary to pay a termination fee in such situations, GE paid no such fee to Abbott. (Compl. ¶ 28.) Following the breakdown of the sale, securities analysts' reaction focused upon Abbott's regulatory problems with the FDA in its diagnostic business and particularly on the Warning Letter as a principal reason why GE was able to walk away from the $8.13 billion deal without paying the customary break-up fee. Compl. ¶ 28. Though they owed Abbott's stockholders duties of loyalty, honestly, diligence, and fairness, Bronstein alleges that the Defendants knowingly, or with gross recklessness, breached their fiduciary duties by orchestrating, devising, carrying out, participating in and/or failing to prevent, terminate, or timely correct the deficiencies outlined in the Warning Letter. Compl. ¶ 29. As a result, Abbott "will not be able to close on the sale of its core diagnostic business to GE." Compl. ¶ 31.

On July 13, 2007, Plaintiff filed this shareholder's derivative action. Defendants move to dismiss Bronstein's Complaint based upon his failure to make demand under Federal Rule of Civil Procedure ("FRCP") 23.1.

DISCUSSION

It is a fundamental principle of corporate law that directors, rather than shareholders, are free to manage the business and affairs of the corporation. Del. Code Ann. Tit. 8, § 141(a) (2006).[1] Shareholders are not powerless, however, to challenge this directorial freedom. *Aronson v. Lewis*, 473 A.2d 805, 811 (Del. 1984), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del.

[1] The parties agree that Delaware law applies to this dispute because Illinois law follows Delaware law with respect to the test for demand futility and accordingly, "Delaware law controls" on the issue. In *re Abbott Labs. Derivative Shareholders Litig.*, 325 F.3d 795, 804 (7th Cir. 2003).

2000). The derivative suit is a powerful defense against directorial action that is harmful to the corporation. *Id.* Because a derivative suit, by its very nature, infringes on directorial freedom, however, the law limits the shareholders' right to bring suit to situations where "either the stockholder has demanded the directors pursue a corporate claim and the directors have wrongfully refused to do so, or where demand is excused because the directors are incapable of making an impartial decision regarding whether to institute such litigation." *Stone v. Ritter*, 911 A.2d 362, 366-67 (Del. 2006) (citing *Aronson*, 473 A.2d at 811).

As such, FRCP 23.1 requires that the complaint in a derivative action "allege with particularity the efforts, if any, made by the plaintiff to obtain the action the plaintiff desires from the directors [or] the reasons for the plaintiff's failure to obtain the action or for not making the effort." Fed. R. Civ. P. 23.1 (Subsequent cases refer to this element of pleading). In addition, the Supreme Court has clearly stated that the substantive law of the state of incorporation governs whether failure to make demand is excused. *Kamen v. Kemper Fin. Serv., Inc.*, 500 U.S. 90, 108-09 (1991). As a result, Abbott is an Illinois corporation, and Illinois law governs the issue. *Abbott*, 325 F.3d at 803. Illinois law follows Delaware law regarding demand futility requirements. *Id.*

In *Aronson v. Lewis*, the Delaware Supreme Court set forth a two-prong test for demand futility pleading requirements in cases concerning the validity of a certain business transaction. *Aronson*, 473 A.2d at 814. In that case, the plaintiff filed a derivative suit challenging the Board's decisions to associated with certain transactions, including loans, between the company and one of its directors. *Id.* at 808-09. In *Rales v. Blasband*, however, the Delaware Supreme Court recognized that liability could also stem from a board's inaction. *Rales v. Blasband*, 634 A.2d 937, 934 (Del. 1993). The Court developed a second test for those situations. *Id.* As a result, depending on the

nature of the allegations giving rise to the derivative suit, one of the two tests applies. In either test, demand is excused "where the facts are alleged with particularity which create a reasonable doubt that the directors' actions were entitled to the protections of the business judgment rule." *Aronson*, 473 A.2d at 808. The business judgment rule is a presumption that "the directors of a corporation acted on an informed basis, in good faith, or (sic) in the honest belief that the action taken was in the best interests of the company." *Aronson*, 473 A.2d at 812. In other words, it is a presumption that the directors did not breach their fiduciary duties in making the decision. In addition, "where a majority of the directors are independent or outside directors receiving no income other than usual directors' fees, the presumption of good faith is heightened."[2] *Parnes v. Bally Entm't Corp.*, 2001 Del. Ch. LEXIS 34, at *31 (Del. Ch. 2001); *see Moran v. Household Int'l, Inc.*, 490 A.2d 1059, 1074-75 (Del. Ch. 1985); citing *Warshaw v. Calhoun*, 221 A.2d 487 (Del. 1966)).

Delaware courts use the *Aronson* test when the subject of the derivative suit is a challenged transaction of the board of directors. Courts must determine whether "accepting the well-pleaded facts as true, the alleged particularized facts raise a reasonable doubt that either: (1) the directors are disinterested or independent; or (2) the challenged transaction was the product of a valid exercise of the directors' business judgment." *Aronson*, 473 A.2d at 814. Although Bronstein argues that the second prong of the *Aronson* test applies to his allegations, the Complaint does not challenge the validity of a particular business transaction; but rather, challenges the Directors' decision not to respond to the FDA's Warning Letter.

Bronstein pleads that the Directors -- despite knowing the potential ramification of their

[2] Only two of Abbott's directors, Mr. White and Mr. Gonzalez, hold management positions and are therefore considered inside directors.

failure to act-- failed to act reasonably to address deficiencies recited by the FDA in the FDA Forms 483 and the Warning Letter. Compl. ¶ 26. In other words, though they knew the potential ramification of non-compliance, the Directors sat by idly while the FDA called into question the ADD's practices.

Under *Rales*, to excuse the demand element, the Court must determine whether the complaint creates 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." *Rales*, 634 A.2d at 934. To make this determination, *Rales* requires a court to analyze whether particularized facts are alleged that either: 1) the underlying conduct being challenged renders any of the directors 'interested' and, if so, whether other directors were compromised in their ability to act independently of the interested directors; or 2) at least half of the directors face a sufficiently substantial threat of personal liability as to the conduct alleged in the complaint to compromise their ability to act impartially on a demand." *Desimone v. Barrow*, 924 A.2d 908, 928 (Del. Ch. 2007). The mere threat of liability is not enough, the threat must be substantial. *Rales*, 634 A.2d at 936.

Bronstein has not alleged facts in his Complaint that the underlying conduct renders any of the directors interested nor has he alleged particularized facts showing that a least half of the directors face a sufficiently substantial threat of personal liability.[3]

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[3] Indeed, under the terms of the exculpatory charter provision in Abbott's Restated Articles of Incorporation, Abbott's directors are exempt from a liability for a breach of the duty of care rendering Bronstein's ability to succeed on this theory questionable. Under the terms of the exculpatory provision in Abbott's Restated Articles of Incorporation, however, Abbott's directors are relieved of any liability for a breach of the duty of care. (Defs.' Mem 3.) Delaware law allows for this type of provision. Del. Code Ann. tit. 8 § 102(b)(7) (2006). It limits, however, the relief from liability to breaches of the duty of care that are negligent. *Stone*, 911 A.2d at 367. No relief exists for breaches that are reckless or intentional. *Id.*

Moreover, Bronstein's allegations do not fit squarely within the *Rales* test because a *Rales* claim is predicated on the board's ignorance of liability-creating activities. *See In Re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959, 971 (Del. Ch.1996). Here, Bronstein alleges that the Directors "knowingly, in an intentional breach and/or reckless disregarding of their fiduciary duties, chose not to exercise their oversight responsibility and failed to address the state of regulatory noncompliance at the Diagnostic Division in a timely and effective manner." Hence, Bronstein challenges the Directors' conscious decision not to act in the face of the Warning Letter. In fact, Bronstein argues that the *Rales* test does not apply for that reason in light of the Seventh Circuit's decision in *In re Abbott Laboratories Derivative Shareholders Litigation*, 325 F.3d 795 (7th Cir. 2003). Specifically, Bronstein denies the applicability of the *Rales* test because he pleads that there were specific corporate governance procedures that the Board put in place, namely, the Public Policy Committee Charter, to ensure that the Directors would receive all of the information from management concerning FDA regulatory compliance issues so that they were able to timely and effectively exercise their oversight responsibility. Plt. Resp., p. 9.

Bronstein alleges facts that are best analyzed when viewed in light of the Supreme Court of Delaware's analysis in *In re Walt Disney Co. Deriv. Litig* and *Stone v. Ritter*. *See In re Walt Disney*, 906 A.2d 27 (Del. 2006); *see also Stone v. Ritter*, 911 A.2d 362, 269 (Del. 2006). In *Stone*, the Court elucidated the standard set forth in *In re Caremark Int'l Inc. Deriv. Litig.* which detailed the conditions predicate for director oversight liability; namely:

> (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. In either case, imposition of liability requires a showing that the directors knew that they were not discharging their fiduciary obligations. Where directors fail to act in the face of a known duty to act,

> thereby demonstrating a conscious disregard for their responsibilities, they breach their duty of loyalty by failing to discharge that fiduciary obligation in good faith.

Stone v. Ritter, 911 A.2d 362, 369 (Del. 2006); *citing Guttman v. Huang*, 823 A.2d 492, 506 (Del. Ch. 2003); *see also In re Caremark*, 698 A.2d 959, 971 (Del. Ch. 1996) . Here, Bronstein alleges that a reporting and/or information system was in place, but that the Directors consciously disregarded their fiduciary duties by choosing not to exercise their oversight responsibility and failing to address the state of regulatory noncompliance at the Diagnostic Division in a timely and effective manner. *See Walt Disney*, 906 A.2d 27; (A failure to act in good faith may be shown, for instance, where the fiduciary intentionally fails to act in the face of a known duty to act, demonstrating a conscious disregard for his duties.) Yet, Bronstein's Complaint falls short of pleading particularized facts establishing bad faith on the part of the Directors having received one letter from the FDA which acknowledged their continuing efforts to resolve the problem. In fact, some of Bronstein's allegations run contrary to the theory set forth in *Stone* as he pleaded that the Directors actually had a Public Policy Committee in place to review and evaluate Abbott's FDA compliance, and there were not factual allegations that, having implemented this monitoring system, any of the defendants consciously failed to utilize it or that they failed to ensure that management responded to the FDA following receipt of the March 13 letter.

More important, Bronstein failed to plead particularized facts showing that the breaches he alleged caused any injury to Abbott. *See In re Caremark*, 698 A.2d at 971 (listing proximate causation of losses as an element of a failure to oversee claim). Instead, Bronstein's Complaint is wholly speculative. For example, the March 13 Letter does not make a final determination that Abbott failed to bring the facility into compliance nor does it impose regulatory action against it. Instead, it acknowledged Abbott's commitment to improve product quality and compliance through

a comprehensive corrective action plan and provided for further follow-up inspections to assure compliance. In fact, Bronstein does not allege that the March 13 Letter caused the GE Deal to collapse, but rather, Bronstein alleges that Defendants' repeated failure to act reasonably to address the deficiencies recited by the FDA in its Form 483 and Warning Letter, put "at serious risk" Abbott's sale of it core diagnostic business to GE. Compl. ¶ 26. Instead, Bronstein cites the opinions of analysts speculating on the cause of the breakup of the deal. Indeed, Bronstein's allegations speculate that Abbott "will not be able to close on the sale of its core diagnostic business to GE." Compl. ¶ 31. Such conclusory allegations and predictions fall short of pleading causation with particularity.

Accordingly, Bronstein's Complaint, as pleaded, does not fit within any theory of liability under demand futility, is devoid of particularized facts, and is speculative with regard to causation.

CONCLUSION

For the reasons set forth above, the Complaint cannot survive a Motion to Dismiss for failure to adequately plead demand futility. Since this is Bronstein's first attempt to meet the heightened demands of pleading demand futility, the Court will allow Bronstein leave to amend his Complaint to determine whether the facts allow for a claim against the Board directly and whether, in light of the March 13 Warning Letter, any theory of causation is viable under the circumstances. Wherefore, Defendants' Motion to Dismiss is granted and Bronstein's Complaint is dismissed without prejudice.

So ordered.

Virginia M. Kendall, United States District Judge
Northern District of Illinois

Date: May 30, 2008