In the
United States Court of Appeals
For the Seventh Circuit

No. 01-1952

IN RE: ABBOTT LABORATORIES DERIVATIVE
SHAREHOLDERS LITIGATION

Appeal from the United States District Court
for the Northern District of Illinois, Eastern Division.
No. 99 C 7246--James B. Moran, Judge.

ARGUED October 23, 2001--DECIDED June 6, 2002

Before HARLINGTON WOOD, JR., CUDAHY, and KANNE, Circuit Judges.

HARLINGTON WOOD, JR., Circuit Judge. This shareholder derivative suit arises from a consent decree between Abbott Laboratories ("Abbott") and the Food and Drug Administration ("FDA"). The action was brought in federal court on behalf of Abbott shareholders against Abbott's board of directors alleging that the directors breached their fiduciary duties and are liable under Illinois law for harm resulting from a consent decree which required Abbott to pay a $100 million civil fine to the FDA, withdraw 125 types of medical diagnostic test kits from the United States market, destroy certain inventory, and make a number of corrective changes in its manufacturing procedures after six years of federal violations. The district court dismissed the original complaint for failure to plead demand futility with particularity under Fed. R. Civ. P. 23.1 and has now dismissed the amended complaint for the same reason. We reverse and remand for further proceedings.

I. BACKGROUND

Abbott, an Illinois corporation, is a diversified health care company that develops and markets pharmaceutical, diagnostic, nutritional, and hospital products. Abbott's Diagnostics Division ("ADD") manufactures hundreds of different kinds of diagnostic kits and devices, including tests which indicate the safety of donated blood, detect heart attacks, and identify cancerous tumors. These products are heavily regulated by the FDA and must be manufactured in accordance with the "Quality System

Regulations" ("QSR"), 21 C.F.R. sec. 820, and the requirements of the "Current Good Manufacturing Practice" ("CGMP"), as defined in 21 C.F.R. sec. 820.1. These regulations expressly assign corporate management the responsibility to assure compliance with CGMP. 21 C.F.R. sec. 820.20. The FDA periodically inspects manufacturing plants to ensure compliance.

During a six-year period from 1993 until 1999, the FDA conducted thirteen separate inspections of Abbott's Abbott Park and North Chicago facilities. The inspections, some lasting for two months or longer, were conducted under a program designed not only to ensure that data and information concerning the in vitro diagnostic products are scientifically valid and accurate, but to ensure that the human subjects are protected from undue hazard or risk during the course of the scientific investigations. After each inspection, the FDA first sends a Form 483 to the manufacturer which notes any deviations under the CGMP, then discusses the findings with the manufacturer's representative, and requests a plan for correcting the violations.

In addition to the Form 483s and the ensuing follow-up after each inspection, the FDA sent four formal certified Warning Letters to Abbott. The first was sent by the FDA's district director to David Thompson, president of ADD, on October 20, 1993, noting that an FDA on-site inspection at the North Chicago facility from April 7 through May 4, 1993 had found adulterated/1 in vitro diagnostic products not in conformance with the CGMP. The letter stated, "Failure to correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties." All of the Warning Letters and follow-up letters contained that statement. A second Warning Letter from the district director was sent on March 28, 1994 to Thompson and copied to Duane Burnham, chairman of the board of directors and Chief Executive Officer ("CEO") of Abbott. After an inspection at the Abbott Park facility, the FDA reiterated that certain in vitro diagnostic test kits had failed to comply

with the CGMP. A follow-up letter from the FDA's acting director to the manager of ADD, again copied to Burnham, was sent by overnight mail on October 11, 1994 which detailed the continuing deficiencies of certain diagnostic test kits. This letter also noted that the FDA had reviewed Abbott's responses to the 483s issued on June 10, 1994 and July 13, 1994, and requested "written documentation of any other specific steps you have taken or will be taking to correct these violations and to prevent the recurrence of similar violations in current and future studies."

On January 11, 1995, the Wall Street Journal published an article discussing the fact that the FDA had "uncovered a wide range of flaws in Abbott Laboratories' quality-assurance procedures used in assembling medical-diagnostic products, including kits to test for hepatitis and AIDS." The article also noted that Abbott stock had fallen fifty cents to $31.25 a share.

In July 1995, the FDA and Abbott entered into a comprehensive Voluntary Compliance Plan to work "together to achieve compliance in areas recognized by FDA and Abbott to be problematic" at the Abbott Park and North Chicago facilities. On February 26, 1998, the FDA district director sent the equivalent of a Warning Letter to Abbott, stating that although the FDA "recognize[d] Abbott Laboratories' efforts to meet all of the Compliance Plan commitments," after finding continued deviations from the regulations, the FDA was closing out the Compliance Plan.

On March 17, 1999, the FDA district director sent the fourth and final certified Warning Letter to Miles White, a member of Abbott's board of directors and current CEO./2 This letter discussed the findings of adulterated in vitro diagnostic kits and other problems after an inspection at the Abbott Park facility from September 8 to November 4, 1998. The letter stated that the FDA would be conducting a re-inspection to determine the adequacy of Abbott's compliance.

On April 13, 1999, White sold thirty percent of his Abbott stock, totaling 89,895 shares sold at $52.72 per share, receiving $4,739,264. On June 15, 1999,

the March 17 Warning Letter was reported in Bloomberg News. The article stated that Abbott was working with the FDA to resolve the problems and noted that Abbott shares had risen slightly to close at $43.25.

On September 28, 1999, Abbott issued a press release disclosing that it had been notified by the FDA of alleged noncompliance of the CGMP and QSR. The release stated that "[a]lthough Abbott believes that it is in substantial compliance with these regulations, the FDA disagrees," and noted that if the discussions were not successful, the FDA had advised the company that it would "file a complaint for injunctive relief which would include the cessation of manufacturing and sale for a period of time of a number of diagnostic products."

On September 29, 1999, Bloomberg News reported that shares of Abbott Laboratories "fell 6.3 percent [to $37.25] after U.S. regulators threatened to halt sales of some Abbott diagnostic products on concerns about quality controls," stating this was the latest setback "in a string of manufacturing problems for Abbott" dating from 1998 and that "the FDA has given them a swift kick to prod them into fixing things." The article noted that ADD represented approximately 22 percent, or $2.79 billion, of Abbott’s total sales in 1998, with an operating profit of $448 million, or 13 percent of the company’s total profit. Although the article quoted a stock analyst as having a "buy" rating on the stock, the analyst also stated that he did not understand "why [Abbott] seems to have dragged their feet fixing the problems. Wall Street punishes companies that have run-ins with the FDA."

On September 30, 1999, Abbott filed a disclosure form with the Securities and Exchange Commission ("SEC"), acknowledging it had received notification by the FDA of noncompliance with the QSR at two of its facilities. Abbott also reported they disagreed with the findings of noncompliance and would fight any legal suit. On November 2, 1999, the FDA filed a complaint for an injunction, detailing its problems with Abbott over the prior six-year period. On the same date, both parties signed a consent decree which prohibited Abbott

from the continued manufacture of certain in vitro diagnostic devices until independent experts and FDA inspectors deemed the two facilities in conformity with the CGMP and FDA regulations. The decree also stated that Abbott would pay a $100 million fine, the largest penalty ever imposed for a civil violation of FDA regulations.

In addition, under a proposed master compliance plan, Abbott was ordered to destroy under FDA supervision certain inventories of specific in vitro diagnostic kits and withdraw those kits from the U.S. market until compliance had been achieved. The suspension of these kits would result in a loss of approximately $250 million in annual revenue. In a press release following the consent decree, Abbott announced that it would take a $168 million charge against Abbott’s earnings in the third quarter of 1999 to cover the FDA fine and the loss from the unmarketable test kits.

Plaintiffs also maintain that these problems with the FDA caused the collapse of Abbott’s acquisition of Alza Corporation ("Alza"), a drug delivery company, in a planned acquisition valued at approximately $7.3 billion, which plaintiffs assert was in the best interest of Abbott. Alza shareholders were to exchange 1 share of Alza stock for 1.2 shares of Abbott stock. Plaintiffs allege that the directors had a motive to conceal Abbott’s quality problems because disclosure of the continuing pattern of violations over a six-year period would have possibly doomed the buyout or, at the very least, jeopardized the agreed-upon price. On December 11, 1999, Abbott announced it was abandoning the acquisition. On December 17, 1999, the Wall Street Journal reported, "Wall Street and industry officials widely viewed the transaction as being in jeopardy in recent weeks because the value to Alza shareholders had fallen" following a decline in the price of Abbott’s stock after the FDA filing and consent decree.

Shortly thereafter, several Abbott shareholders brought derivative actions which have been consolidated in this case. These plaintiffs seek to hold Abbott’s directors personally liable for the losses incurred as a result of the

consent decree. At the time the litigation was initiated, Abbott had thirteen directors. Two of those thirteen, Miles White, Abbott's chairman and CEO, and Robert Parkinson, president and Chief Operating Officer, were "inside directors" who are both corporate officers and full-time Abbott employees. The remaining eleven were "outside" or "independent" directors who received a monthly stipend for their services but were not Abbott employees.

In their claim for breach of fiduciary duty, plaintiffs maintain that the directors were or should have been aware of the six-year history of noncompliance problems with the FDA and that they had a duty to take necessary action to correct these problems in a division of Abbott which accounted for 20 percent of the company's annual revenues. They allege that the directors demonstrated gross negligence by ignoring the FDA problems for six years. Plaintiffs also maintain that the directors had a duty of due diligence by signing the SEC forms, which specifically address in part government regulations in the development, manufacture, sale, and distribution of products. These forms were signed by the directors every year during the six-year period in question. As the 1996 10-K illustrates, the directors signed off on statements such as, "[Abbott's products] are subject to comprehensive government regulation [which] substantially increases the time, difficulty, and costs incurred in obtaining and maintaining the approval to market newly developed and existing products," "[t]he FDA's . . . approach to regulations . . . will increase the cost of compliance with those regulations," "[t]he Company's facilities [including Abbott Park and North Shore] are deemed suitable," "[t]he Company is involved in various claims and legal proceedings . . . [and] management is of the opinion that their disposition should not have a material adverse effect on the Company's financial position, cash flows, or results of operations."

The plaintiffs allege that the directors met officially seven times in 1996, six times in 1997, eight times in 1998, and ten times in 1999. Plaintiffs maintain that the directors received relevant information concerning regulatory actions and that the Warning Letters, several of

which were sent to the chairman of the board, and Form 483s were "clearly information that was required to be brought to the attention of the Board members by the Chairman . . . who had a duty to [do so]." Plaintiffs also note that the Audit Committee, which included several members of the board, "is charged with communicating regularly with Abbott management" concerning management's assessment of business risks facing Abbott, and that one of the functions of the Audit Committee was to familiarize themselves with any risks involving the legal and regulatory framework which would affect Abbott's operations. Plaintiffs also stated that during the relevant time period, Abbott's proxy statements noted that the Audit Committee "met with Abbott's internal auditors to evaluate the effectiveness of their work in ensuring that Abbott's various departments, including its Regulatory Affairs Department [which was responsible for Abbott's compliance with FDA regulations], operated properly."

Plaintiffs, however, did not make any demand on Abbott's board of directors to institute an action against themselves for breach of their fiduciary duties, stating that such a demand would have been futile. Plaintiffs maintain that the facts as alleged in the complaint demonstrate that the directors

knew of the 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 in media reports and chose not to bring a prompt halt to the improper conduct causing the noncompliance, nor to reprimand those persons involved, nor to seek redress for Abbott for the serious damages it has sustained . . . .

The district court dismissed the complaint for failure to plead demand futility with particularity under Fed. R. Civ. P. 23.1, stating that the complaint did not plead facts to show Abbott's directors faced a substantial likelihood of liability for their actions. Plaintiffs appeal.

II. ANALYSIS

A. Standard of Review

Seventh Circuit precedent indicates that a district court's determination as to whether or not a demand upon the board of directors would have been futile, assuming no error of law has been made, is reviewed for abuse of discretion. See Starrels v. First Nat'l Bank of Chicago, 870 F.2d 1168, 1170 (7th Cir. 1989); Powell v. Gant, 556 N.E.2d 1241, 1245 (Ill. App. Ct. 1990) (holding that trial court's determination of whether demand is excused may only be reversed for "manifest abuse of discretion"). Because Abbott was incorporated under the laws of Illinois, Illinois law applies in determining whether a demand may be excused when shareholders file a derivative complaint on behalf of the company. See Kamen v. Kemper Fin. Servs., Inc., 500 U.S. 90, 98-99 (1991). Illinois case law follows Delaware law in establishing demand futility requirements and uses the test to determine demand futility set forth in Aronson v. Lewis, 473 A.2d 805 (Del. 1984). See Spillyards v. Abboud, 662 N.E.2d 1358, 1366 (Ill. App. Ct. 1996). Both parties agree Delaware law controls.

However, the Delaware Supreme Court recently stated that in a motion to dismiss a derivative suit for demand futility, "our review of decisions of the Court of Chancery applying Rule 23.1 is de novo and plenary." Brehm v. Eisner, 746 A.2d 244, 253 (Del. 2000) (en banc), overruling in part Aronson v. Lewis, 473 A.2d 805 (Del. 1984) (overruling abuse of discretion standard for demand futility in derivative action). The court in Brehm stated that its review was the same analysis applied by the trial court in making its decision and that decision is not a discretionary ruling such as an administrative agency's findings of fact or a credibility determination which would be accorded deference. Id. The court noted, "In a Rule 23.1 determination of pleading sufficiency, the Court of Chancery, like this Court, is merely reading the English language of a pleading and applying to that pleading statutes, case law and Rule 23.1 requirements. To that extent, our scope of review is analogous to that accorded a ruling under Rule 12(b)(6)." Id. at 254; see Conley v. Gibson, 355 U.S. 41, 45-46 (1957) (holding that because district

court’s grant of a motion to dismiss for failure to state a claim is a question of law, review is de novo); see also McCall v. Scott, 239 F.3d 808, 817 (6th Cir. 2001) ("we review de novo the question of whether plaintiffs alleged with sufficient particularity facts that create a reasonable doubt as to disinter estedness and independence of a majority of directors"). We agree with this reasoning and, because we are required to make a determination based on Aronson, will review de novo the dismissal of this derivative shareholder’s complaint based on failure to plead demand futility. And, as in a Rule 12(b)(6) motion to dismiss, any inferences drawn from the factual allegations of the complaint must be viewed in the light most favorable to the plaintiffs. Brehm, 746 A.2d at 255; In re Healthcare Compare Corp. Sec. Lit., 75 F.3d 276, 279 (7th Cir. 1996).

B. Demand Futility

In a derivative suit, an individual shareholder seeks to enforce a right that belongs to the corporation. See Kamen, 500 U.S. at 95. However, given "the basic principle of corporate governance that the decisions of a corporation--including the decision to initiate litigation--should be made by the board of directors or the majority of shareholders," most jurisdictions require a pre-suit demand be made of the corporation’s board of directors. Id. at 96. This allows the directors to exercise their business judgment and determine whether litigation is in the best interest of the corporation. Id.

Rule 23.1 requires the plaintiff "to allege with particularity the efforts, if any, made by the plaintiff to obtain the action the plaintiff desires from the directors . . . and the reasons for the plaintiff’s failure to obtain the action or for not making the effort." However, the requirement of a shareholder demand is more than a pleading requirement, it is a substantive right of the shareholder and the directors. See Kamen, 500 U.S. at 97. It is the law of the state of incorporation which controls these substantive rights and governs what excuses are adequate for failure to make demand. See id. at 98-99, 101; Boland v. Engle, 113 F.3d 706, 710 (7th Cir. 1997).

The "futility" exception establishes the circumstances in which the shareholder is allowed to circumvent the directors' authority to manage corporate affairs. See Kamen, 500 U.S. at 102. Whether a shareholder should be allowed to proceed without making demand "is based on the application of the State's futility doctrine . . . ." Id. at 104. Illinois law requires that a demand be made or excuses demand when the request would be futile as a prerequisite to a derivative action. 805 Ill. Comp. Stat. 5/7.80(b) (1999) (also referred to as sec. 7.80(b) of the Business Corporation Act of 1983); see also Schnitzer v. O'Connor, 653 N.E.2d 825, 829 (Ill. App. Ct. 1995) (stating that demand rule 7.80(b) is "al most identical" to Fed. R. Civ. P. 23.1). The shareholder must state with particularity why a demand would have been futile. Starrels, 870 F.2d at 1170 (citations omitted). However, it is not sufficient for the shareholder to simply state "in conclusory terms that he made no demand because it would have been futile." Id. (citation omitted). Although plaintiffs have a conclusory paragraph in their claim of demand futility, they have also incorporated all of the detailed factual allegations. A review for demand futility "is factual in nature," and the alleged facts are reviewed "to decide whether they raise a reasonable doubt . . . that the protections of the business judgment rule are available to the board." Aronson, 473 A.2d at 814-15. Our review is applied to the particularized facts, taking into consideration "the presumption of regularity of the Board's process." Brehm, 746 A.2d at 259.

1. Aronson test

To determine whether demand is futile under Illinois law, the Illinois courts have applied the standard set forth by the Delaware Supreme Court in Aronson, 473 A.2d at 808, holding that "demand can only be excused where facts are alleged with particularity which create a reason able doubt that the directors' action was entitled to the protections of the business judgment rule." See Spillyards, 662 N.E.2d at 1366; Powell, 556 N.E.2d at 1245; see also Starrels, 870 F.2d at 1170-71; Silver v. Allard, 16 F.Supp.2d 966, 969 (N.D. Ill. 1998). The Aronson test is applied in cases where there is a conscious decision by the board of

directors to act or refrain from acting. See 473 A.2d at 813. It is not applied "where directors have either abdicated their functions or . . . failed to act," although "a conscious decision to refrain from acting may nonetheless be a valid exercise of business judgment . . . ." Id.

The plaintiffs allege that the directors "knowingly" in an "intentional breach and/or reckless disregard" of their fiduciary duties "chose" not to correct the FDA problems in a timely manner, indicating a conscious decision not to act. As the court in Brehm stated,

This is a case about whether there should be personal liability of the directors of a [ ] corporation to the corporation for lack of due care in the decisionmaking process and for waste of corporate assets. This case is not about the failure of the directors to establish and carry out ideal corporate governance practices.

746 A.2d at 255-56. Given the facts of the instant case, where FDA notices were sent to the chairman of the board, where the directors had a duty under the SEC to comply with "comprehensive government regulations," where the ongoing violations lasted over an extended period of six years, and where information concerning the violations was made known to the general public beginning in 1995, we do not disagree with the plaintiffs' allegations that the facts indicate the directors purposefully took no action and will, therefore, apply the Aronson test./3

The court in Aronson stated that "the entire question of demand futility is inextricably bound to issues of business judgment and the standards of that doctrine's applicability," explaining that 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." 473 A.2d at 812. Plaintiffs have the burden of establishing facts to rebut this presumption. Id.

The two-pronged test in Aronson provides that demand futility is established if, accepting the well-pleaded facts as true,

the plaintiffs raise a reasonable doubt with alleged particularized facts 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. 473 A.2d at 814; Starrels, 870 F.2d at 1171.

a. First prong--disinterest or independence

A disinterested director "can neither appear on both sides of a transaction nor expect to derive any personal financial 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." Aronson, 473 A.2d at 812. Plaintiffs have not offered any specific facts to indicate that any of the directors had divided loyalties. There were no allegations of improper motives or conflicts of interest. Nor, with the exception of White's sale of stock prior to the FDA's legal action, have plaintiffs presented allegations that any of the other directors profited in any way by their actions, or lack thereof. See In re Gen. Instr. Corp. Sec. Litig., 23 F.Supp.2d 867, 874 (N.D. Ill. 1998) (using Aronson test in finding eight directors [out of thirteen] who sold their company stock at inflated price for over $500 million while concealing adverse financial information about company raised reasonable doubt as to directors' disinterest).

In addition, plaintiffs have not pleaded facts to raise reasonable doubt as to the directors' independence. Independence exists when "a director's decision is based on the corporate merits of the subject before the board rather than extraneous considerations or influences." Aronson, 473 A.2d at 816. There are no specific allegations as to how each individual director was influenced by outside sources or considerations in making decisions about the board's actions, or their failure to take action.

We find the plaintiffs have not pleaded specific allegations to create a reasonable doubt as to the majority of the directors' disinterestedness or independence.

b. Second prong--business judgment

Under Aronson, "the mere threat of personal liability for approving a questioned transaction, standing alone, is insufficient to challenge either the independence or disinterestedness of directors . . . ." 473 A.2d at 815. However, demand may be excused if "in rare cases a transaction may be so egregious on its face that board approval cannot meet the test of business judgment, [resulting in] a substantial likelihood of director liability," id., or if the directors exhibited "gross negligence" in breaching their duty of care. Brehm, 746 A.2d at 259 (citing Aronson, 473 A.2d at 812).

In order to invoke the protection of the business judgment rule, Aronson holds that "directors have a duty to inform themselves, prior to making a business decision, of all material information reasonably available to them." 473 A.2d at 812. Demand will be excused in a derivative suit only if the trial court and the appellate court, upon de novo review, "conclude that the particularized facts in the complaint create a reasonable doubt that the informational component of the directors' decisionmaking process, measured by concepts of gross negligence, included consideration of all material information reasonably available." Brehm, 746 A.2d at 259 (emphasis in original) (citing Aronson, 473 A.2d at 812).

We find that the facts alleged are sufficient to show that although corporate governance practices were in place, the directors were grossly negligent in failing to inform themselves of all reasonably available material information. See Brehm, 746 A.2d at 259. The chairman of the board received copies of the two Warning Letters in 1994 and another in early 1999, and even though the language in the Warning Letters is described as "boilerplate," continuing violations of federal regulations over a period of six years cannot be minimized. Several of the directors were members of the Audit Committee, which addressed any risks involved in regulatory compliance. In addition, given their responsibilities under the SEC filings, the directors knew of the ongoing violations and knew of the 1995 compliance plan and its subsequent

failure in 1998. The FDA met at least ten times with Abbott representatives, including White and other senior officers, concerning the continuing violations of the regulations. The Wall Street Journal published information about Abbott's FDA problems in 1995. By 1999, even a third-party analyst questioned why Abbott continued to "drag[] their feet fixing the [FDA] problems." Although Abbott sought to negate the effects of this news in its press release of 1999, the release itself substantiates the fact that the company, and, correspondingly, the board of directors, knew of the problems and were aware that the FDA had threatened to file an injunction against Abbott. All of the above was "material information reasonably available to [the directors]." Aronson, 473 A.2d at 815.

Delaware law also states that director liability may arise for the breach of the duty to exercise appropriate attention to potentially illegal corporate activities from "an unconsidered failure of the board to act in circumstances in which due attention would, arguably, have prevented the loss." In re Caremark Int'l, Inc. Derivative Litig., 698 A.2d 959, 967 (Del. Ch. 1996). The court held that "a sustained or systematic failure of the board to exercise oversight . . . will establish the lack of good faith that is a necessary condition to [director] liability." Id. at 971. Although the present case does not deal with a claim of fraud like that in In re Caremark, with the extensive paper trail concerning the violations and the implied awareness of the problems in the SEC filings, it is clear that the directors either knew or should have known of the violations of law, took no steps in an effort to prevent or remedy the situation, and that failure to take any action for such an inordinate amount of time resulted in the substantial losses incurred by the consent decree. See id.

Plaintiffs have alleged the directors ignored obvious problems concerning the continuing federal violations and that "the directors must have known of it." See In re Baxter Int'l, Inc. Shareholders Litig., 654 A.2d 1268, 1271 (Del. Ch. 1995). Plaintiffs have pleaded with particularity "what obvious danger signs were ignored" and that the directors failed to take any measures. Id. We find

that obvious danger signs, as particularized in six years of noncompliance, inspections, 483s, Warning Letters, notice in the press, the largest civil fine ever imposed by the FDA, and the destruction and suspension of products which accounted for approximately $250 million in corporate assets are sufficient facts to indicate that the directors failed to reasonably inform themselves and that their failure to act was not made in good faith and was contrary to the best interests of the company. See Aronson, 473 A.2d at 812, 818.

With respect to demand futility, plaintiffs have sufficiently pleaded allegations to reasonably conclude that the directors' actions fall outside the protection of the business judgment rule; allegations which demonstrate conduct "so egregious" that there is a substantial likelihood of director liability. Aronson, 473 A.2d at 815. Demand is therefore excused. Id.; see In re Baxter, 654 A.2d at 1270-71. We note that this holding applies only with respect to demand futility and reflects no opinion as to the truth of the allegations or the outcome of the claims on the merits.

c. Directors' exemption clause

Abbott's certificate of incorporation exempts the directors from liability. The Articles of Amendment to Abbott's Articles of Incorporation dated April 29, 1994, includes the following provision:

A director of the corporation shall not be personally liable to the corporation or its shareholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the corporation or its shareholders, (ii) for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (iii) under Section 8.65 of the Illinois Business Corporation Act,/4 or (iv) for any transaction from which the director derived an improper personal benefit . . . .

This language is identical to that of the Illinois Business Corporation Act. See 805 Ill. Comp. Stat. sec. 5/2.10(b)(3). When the certificate of incorporation

exempts directors from liability, the complaint must plead non-exempt conduct with sufficient particularity to permit the court to reasonably conclude the directors' conduct falls outside the exemption. See In re Baxter, 654 A.2d at 1270. As previously discussed, plaintiffs' complaint sufficiently alleges "omissions not in good faith" and "intentional misconduct" concerning "violations of law," which conduct falls outside of the exemption.

In McCall, where the duty of care claims arose from the board's failure to act, the Sixth Circuit held that with a certificate of incorporation which exempts the directors from personal liability (with language identical to the Abbott provision), a breach of the duty of care did not require intentional conduct on the part of the directors to overcome a waiver of liability pursuant to the certificate of incorporation. 239 F.3d at 818. The court held that it is possible that reckless acts, which are arguably acts not taken in good faith, may overcome the certificate's waiver. Id. The plaintiffs in McCall alleged that intentional or reckless disregard could be inferred from the directors' failure to act in the face of audit information, ongoing acquisition practices, allegations brought against the corporation in a qui tam action, a federal investigation, an investigation by the New York Times into the company's billing practices, and inaction by the board. Id. at 819-20.

The court in McCall held that the directors' failure to act against a corporation's systematic health care fraud from at least 1994 to 1996 alleged sufficient facts "to present a substantial likelihood of liability." Id. at 819. Although we recognize that there were many more specific allegations to support individual director liability in the McCall case, the court also noted that "the magnitude and duration of the alleged wrongdoing is relevant in determining whether the failure of the directors to act constitutes a lack of good faith." Id. at 823. The magnitude and duration of the FDA violations in the present case were so great that it occasioned the highest fine ever imposed by the FDA. We also take into consideration that evidently neither FDA

censures nor public notice motivated the directors to take any action concerning the problems over a six-year period, as opposed to the two-year period in McCall.

III. CONCLUSION

For the above-stated reasons, the order of the district court is REVERSED and the case is REMANDED for further proceedings consistent with this opinion. Circuit Rule 36 shall not apply on remand.

FOOTNOTES

/1 Under 12 U.S.C. sec. 351(h), a device is deemed "adulterated" if the product is not manufactured, processed, packed, or held in accordance with "current good manufacturing practices."

/2 White replaced Burnham as chairman of the board of directors in April 1999.

/3 A different analysis for demand futility is used in situations where the directors did not make a business decision which was challenged in the derivative suit. See Rales v. Blasband, 634 A.2d 927, 933-34 (Del. 1993). The court in Rales held that where there is "[t]he absence of board action," the plaintiffs need not demonstrate a reasonable probability of success on the merits, but must present "particularized factual allegations [which] create a reasonable doubt that, as of the time the complaint is filed, [a majority of] the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand." Id. at 934. In McCall, the shareholder plaintiffscharacterized the board’s failure to take action with respect to systematic fraud occurring in the corporation as a conscious decision, i.e., knowingly, intentionally. 249 F.3d at 813. But the Sixth Circuit held that where the plaintiffs’ "duty of care claims . . . arise out of allegations of nonfeasance by the Board (i.e., "intentional ignorance of," or "willful blindness to" the "red flags" that were signs of potentially fraudulent practices) and challenge the Board’s failure to take action or investigate under the circumstances," and which do not allege a conscious decision to refrain from acting, the Rales test must be applied. Id. at 816.

However, even if the Rales test had been applied in the instant case, the results would be the same, as detailed in the above-stated analysis concerning reasonable doubt as to the directors’ independent and disinterested status under the business judgment rule, given the fact

that at the time demand would have been made, it would have been to a majority of the same directors who were in control during the six-year period and when the consent decree was imposed. See id. at 819 (finding that factual allegations and reasonable inferences drawn in plaintiffs' favor sufficient to "create a reasonable doubt as to the disinterestedness and independence of a majority of the directors").

/4 805 Ill. Comp. Stat. sec. 5/8.65 details particular circumstances other than those specified in sec. 5/2.10(b)(3), and not pertinent to this case, when a corporate director may be held liable.