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 MARCH 28, 2003

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,

* The panel issued an opinion on June 6, 2002. *In re Abbott Lab. Derivative S'holder Litig.*, 293 F.3d 378 (7th Cir. 2002). An order vacating the panel opinion was issued on August 2, 2002. *In re Abbott Lab. Derivative S'holder Litig.*, 299 F.3d 898 (7th Cir. 2002).

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. § 820, and the requirements of the "Current Good Manufacturing Practice" ("CGMP"), as defined in 21 C.F.R. § 820.1. These regulations expressly assign corporate management the responsibility to assure compliance with the CGMP. 21 C.F.R. § 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[1] 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[2] 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

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[1] "In vitro" is defined as "within glass; observable in a test tube; in an artificial environment." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 915 (29th ed. 2000).

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

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, detailing 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[3] and current CEO. 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 30 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, a news service providing national and international financial information. 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

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[3] White replaced Burnham as chairman of the board of directors in April 1999.

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 at that time.

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 one 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 extensive corporate losses which arose from the continuing FDA violations.

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. At the time the suit was filed, all of the directors except for

four had served on the board throughout the six-year period.[4]

In their claim for breach of fiduciary duty, plaintiffs maintain that the directors were 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 alluding to the regulatory problems, 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

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[4] White and Parkinson were long-time Abbott employees. The remaining eleven directors were: J. Laurance Fuller, serving since 1988; David A. Jones, serving since 1982; Jeffrey M. Leiden, serving since April 1999; the Right Hon. Lord Owen CH, serving since 1996; Boone Powell, Jr., serving since 1985; Addison Barry Rand, serving since 1992; W. Ann Reynolds, serving since 1980; Roy S. Roberts, serving since 1998; William D. Smithburg, serving since 1990; John R. Walter, serving since 1990; and William L. Weiss, serving since 1998.

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 state that the directors were aware of the problems as several directors were also members of the Audit Committee, which "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, due in part to the fact that a majority of the board who would have reviewed the demand were the same directors who had been board members during the six-year period in ques-

tion. 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 filed an amended complaint, which the district court again dismissed. Plaintiffs now appeal.

II. ANALYSIS

A. Standard of Review

The Seventh Circuit has held that a uniform federal-law approach applies to procedural questions which concern the allocation of responsibility between the trial court and appellate court. *See Mayer v. Gary Partners & Co.*, 29 F.3d 330, 335 (7th Cir. 1994). State law does not govern the relation between the trial court and the appellate court in a diversity litigation. *Id.* Therefore, while the district court was required to apply state substantive law, appellate review is governed by federal law, which is deferential except on questions of law. *See Gasperini v. Center for the Humanities, Inc.*, 518 U.S. 415, 437 (1996); *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). Appellate review of the

legal precepts used by the district court and the court's interpretation of those precedents is plenary. *Salve Regina College v. Russell*, 499 U.S. 225, 239 (1991) ("courts of appeals review the state-law determinations of district courts *de novo*"); *Donovan v. Robbins*, 752 F.2d 1170, 1178 (7th Cir. 1985).

Given the district court's dismissal of the case on defendants' motion, any inferences reasonably drawn from the factual allegations of the complaint must be viewed in the light most favorable to the plaintiffs. *In re Healthcare Compare Corp. Sec. Litig.*, 75 F.3d 276, 279 (7th Cir. 1996).

B. Demand Futility

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), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244, 253 (Del. 2000) (overruling abuse of discretion standard of review on Rule 23.1 motion to dismiss derivative suit). *See Spillyards v. Abboud*, 662 N.E.2d 1358, 1366 (Ill. App. Ct. 1996). Both parties correctly agree that Delaware law controls.

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. As a prerequisite to a derivative action, Illinois law requires that a demand be made unless the demand is excused because the request would be futile. 805 ILL. COMP. STAT. 5/7.80(b) (1999) (also referred to as § 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 "almost 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.

After carefully reviewing the plaintiffs' complaint, we conclude that the district court erred in determining the interpretation and application of state law.

1. Rales test

The district court, in interpreting Delaware state law, applied the test for demand futility under *Rales v. Blasband*, 634 A.2d 927 (Del. 1993). In *Rales*, the Delaware Supreme Court was asked to determine whether the plaintiffs had alleged facts sufficient to show that demand on a board of directors was excused, accepting the well-pleaded factual allegations of the derivative complaint as true when based on a motion of dismissal. *Id.* at 931. Plaintiffs pleaded that review was based upon the two-part *Aronson* test. *Id.* at 932. The court noted that its analysis was not limited to the *Aronson* test but required a determination as to whether demand was excused "under the 'substantive law of the State of Delaware.'" *Id.*

The *Rales* court found that the "essential predicate" for applying the *Aronson* test was that "a decision of the board of directors is being challenged in the derivative suit." *Rales*, 634 A.2d at 933 (citing *Pogostin v. Rice*, 480 A.2d 619, 624 (Del. 1984)). The court in *Rales* stated that "where the board that would be considering the demand did not make a business decision which is being challenged in the derivative suit," there are three scenarios in which the *Aronson* test would not apply:

> (1) where a business decision was made by the board of a company, but a majority of the directors making

> the decision have been replaced; (2) where the subject of the derivative suit is not a business decision of the board; and (3) where [ ] the decision being challenged was made by the board of a different corporation.

Id. at 934. Given the facts in the present case that a majority of the directors during the six years in question remained at the time the demand was made and that the board of a different corporation was not involved, the district court determined that plaintiffs were alleging an omission rather that a conscious decision of the board. *In re Abbott*, 141 F.Supp.2d 946, 948 (N.D. Ill. 2001) (citing *Rales*, 634 A.2d at 934). However, in arriving at this conclusion, we find the district court failed to fully scrutinize Delaware case law and the necessary circumstances for application of the *Rales* test.

The plaintiffs in *In re Caremark Int'l Inc. Derivative Litigation*, 698 A.2d 959, 967 (Del. Ch. 1996), charged the board of directors with a breach of their duty of attention or care in connection with the on-going operation of corporate business. Where there is no conflict of interest or no facts suggesting suspect motivation, it is difficult to charge directors with responsibility for corporate losses for an alleged breach of care. *Id.* In determining the directors' alleged breach of the duty of care, the court noted that liability may arise from two possible situations—liability for decisions made by the directors or liability for the directors' failure to monitor the actions of the corporation.

> Director liability for a breach of the duty to exercise appropriate attention may, in theory, arise in two distinct contexts. First, such liability may be said to follow *from a board decision* that results in a loss because that decision was ill advised or "negligent." Second, liability to the corporation for a loss may be said to arise from an *unconsidered failure of the*

> *board to act* in circumstances in which due attention would, arguably, have prevented the loss.

Id. at 967 (citation omitted) (emphasis in original). The first setting for liability is subject to review under the business judgment rule, assuming the decision "was the product of a process that was either deliberately considered in good faith or was otherwise rational." *Id.* (citing *Aronson*, 473 A.2d at 812).

The *Caremark* court labels the second approach as "unconsidered" failure to act, *id.* at 968, the same characterization the district court gave in describing the board's inaction in *Abbott*. 141 F.Supp.2d at 948, 951 ("plaintiffs allege an omission, rather than a conscious board decision") (discussing defendants' inaction). In analyzing a case of unconsidered failure to take action by the directors, the court in *Caremark* followed the reasoning in *Graham v. Allis-Chalmers Mfg. Co.*, 188 A.2d 125 (Del. 1963), which addressed the issue of director liability for corporate losses suffered as a result of anti-trust violations. *In re Caremark*, 698 A.2d at 969. "There was no claim in [*Graham*] that the directors knew about the behavior of . . . employees of the corporation that had resulted in the liability." *Id.*

In re Caremark is a case where the corporation was comprised of 7,000 employees with ninety branch operations, having had a decentralized management structure, and, as a result of government investigations, had begun making attempts to centralize management oversight of the company's business practices. *Id.* at 962. The court compared the defendants in *In re Caremark* to the defendants in *Graham*, stating that the claim asserted in both cases was only that the directors "ought to have known" of the violations, and that the directors had no duty "to ferret out wrongdoing which [the directors] have no reason to suspect exists," particularly where "there were *no grounds for suspicion* . . . and the directors

were *blamelessly unaware* of the conduct leading to the corporate liability." *In re Caremark*, 698 A.2d at 969 (quoting *Graham*, 188 A.2d at 130) (emphasis added). The court noted that the true intent of a review where there is no "considered" board action is based more upon corporate governance—whether there is a corporate information gathering and reporting system in existence. *See id.* at 969-70.

As the court in *Caremark* explained, review of directors liability was "predicated upon ignorance of liability creating activities," 698 A.2d at 971, where there were no facts to indicate the directors "conscientiously permitted a known violation of law by the corporation to occur." *Id.* at 972. Plaintiffs in *Abbott* allege facts that the directors were aware of known violations, providing evidence that there was direct knowledge through the Warning Letters and as members of the Audit Committee. Under proper corporate governance procedures—the existence of which is not contested by either party in *Abbott*—information of the violations would have been shared at the board meetings. In addition, plaintiffs have alleged that, as fiduciaries, the directors all signed the annual SEC forms which specifically addressed government regulations of Abbott's products. The *Abbott* case is clearly distinguished from the "unconsidered" inaction in *In re Caremark*.

Plaintiffs allege that the 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. Although *Brehm v. Eisner*, 746 A.2d 244 (Del. 2000), dealt with a shareholder derivative action which was limited to breach of the duty of care, we agree with the court's analysis as to the proper application of the *Rales* test.

> 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. The facts in *Abbott* do not support the conclusion that the directors were "blamelessly unaware of the conduct leading to the corporate liability." *In re Caremark*, 698 A.2d at 969 (quoting *Graham*, 188 A.2d at 130).

The district court noted, correctly, that the plaintiffs did not allege that Abbott's reporting system was inadequate. In *Abbott*, the first two Warning Letters were copied to Burnham, chairman of the board. After the Voluntary Compliance Plan was initiated in 1995, the FDA sent a letter in 1998 closing down the plan due to continued violations. The final Warning Letter was sent to White, at the time a member of the board. The directors who were members of the Audit Committee were aware of the violations. The SEC disclosure forms acknowledging noncompliance with the QSR imputes knowledge to the directors. And as early as 1995, the FDA's problems with Abbott were public knowledge. All of these alleged facts imply knowledge of long-term violations which had not been corrected. In *Abbott*, reasonable inferences determined from all of the facts taken together are exactly the opposite of *Caremark*; members of the board in *Abbott* were aware of the problems. Where there is a corporate governance structure in place, we must then assume the corporate governance procedures were followed and that the board knew of the problems and decided no action was required. Therefore, we cannot agree that the *Rales* test is applicable in this particular factual situation.

2. 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 reasonable 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 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 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. 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 sufficient 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. Although plaintiffs have raised the allegation that perhaps one of the reasons behind the board's refusal to act was to conceal the extent of Abbott's problems while a buyout of Alza was pending, there are no specific allegations indicating that individual directors were influenced by outside sources or considerations in making decisions, or that Burnham or White dominated or controlled the board. *See id.* at 815.

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

The business judgment rule is a presumption that in making a business decision, "the directors of a corpora-

tion 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." *Aronson*, 473 A.2d at 812 (citations omitted). To determine whether the complaint raises a reasonable doubt that the directors exercised proper business judgment, the second prong of the *Aronson* test "requires us to look at both the substantive due care (substance of the transaction) as well as the procedural due care (an informed decision) used by the directors." *Starrells*, 870 F.2d at 1171 (citing *Grobow v. Perot*, 539 A.2d 180, 189 (Del. 1988), *overruled on other grounds by Brehm*, 746 A.2d at 253).

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).

Delaware law imposes three primary fiduciary duties on the directors of corporations; the duty of care, the duty of loyalty, and the duty of good faith. *Emerald Partners v. Berlin*, 787 A.2d 85, 90 (Del. 2001) (citing *Malone v. Brincat*, 722 A.2d 5, 10 (Del. 1998)). The shareholders of the corporation "are entitled to rely upon their board of directors to discharge each of their three primary fiduciary duties at all times." *Id.*

The chairman of the board received copies of the two Warning Letters in 1994 and another in early 1999. Although the district court described the language in the Warning Letters as "boilerplate" and stated that the

plaintiffs "ascribe much greater importance to the warning letters than they probably deserve," *In re Abbott*, 141 F.Supp.2d at 949, 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 was charged with assessing any risks involved in regulatory compliance. In addition, the directors had a fiduciary duty under the SEC to comply with "comprehensive government regulations" and signed SEC forms attesting to knowledge and responsibility for government regulation compliance, noting that "[the] Company is involved in various claims and legal proceedings" regarding these regulations, as stated in the 1996 10-K.

The FDA met at least ten times with Abbott representatives, including White and other senior officers, concerning the continuing violations. 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.

Delaware law 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*, 698 A.2d at 967 (citation omitted) (emphasis in original). 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. In *Caremark*, there was a claim of fraud with no evidence to indicate

that the Caremark directors knew of the violations of law and the directors' liability was "predicated upon ignorance" of liability-creating activities which resulted in unconsidered failure to act. *See id.* Given the extensive paper trail in *Abbott* concerning the violations and the inferred awareness of the problems, the facts support a reasonable assumption that there was a "sustained and systematic failure of the board to exercise oversight," in this case intentional in that the directors knew 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 substantial corporate losses, establishing a lack of good faith. We find that six years of noncompliance, inspections, 483s, Warning Letters, and notice in the press, all of which then resulted in 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, indicate that the directors' decision to not act was not made in good faith and was contrary to the best interests of the company. *See Aronson*, 473 A.2d at 812.

We also note that in *McCall v. Scott*, 239 F.3d 808 (6th Cir. 2001), *amended on denial of rehearing by McCall v. Scott*, 250 F.3d 997 (6th Cir. 2001), although the court's decision was based upon allegations of the directors' "unconsidered inaction," *id.* at 817, the Sixth Circuit held that the directors' sustained failure to act against a corporation's systematic health care fraud occurring from at least 1994 to 1996 alleged sufficient facts "to present a substantial likelihood of liability." *Id.* at 814, 819. 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, and

an investigation by the NEW YORK TIMES into the company's billing practices, based on the board's inaction prior to 1997. *Id.* at 819-20. While 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 *Abbott* 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 an approximate two-year period in *McCall*. *Id.* at 814.

With respect to demand futility based on the directors' conscious inaction, we find that the plaintiffs have sufficiently pleaded allegations, if true, of a breach of the duty of good faith to reasonably conclude that the directors' actions fell outside the protection of the business judgment rule. *Aronson*, 473 A.2d at 812. The totality of the complaint's allegations need only support a reasonable doubt of business judgment protection, not "a judicial finding that the directors' actions are not protected by the business judgment rule." *Grobow*, 539 A.2d at 186. Under the demand futility doctrine, demand should therefore have been excused. *Aronson*, 473 A.2d at 815; *see In re Baxter Int'l, Inc. S'holders Litig.*, 654 A.2d 1268, 1270-71 (Del. Ch. 1995).

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

The directors contend that they are not liable under Abbott's certificate of incorporation provision which exempts the directors from liability. The Articles of Amendment to Abbott's Articles of Incorporation dated April 29, 1994, include 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,[5] 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. § 5/2.10(b)(3). The provision was adopted pursuant to DEL. CODE ANN. tit. 8, § 102(b)(7),[6] which eliminates personal

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[5] 805 ILL. COMP. STAT. 5/8.65 details particular circumstances other than those specified in § 5/2.10(b)(3), and not pertinent to this case, when a corporate director may be held liable.

[6] The Delaware Code provides under Title 8, § 102(b)(7) that:

> (b) In addition to the matters required to be set forth in the certificate of incorporation by subsection (a) of this section, the certificate of incorporation may also contain any or all of the following matters:
>
> ***
>
> (7) A provision eliminating or limiting the personal liability of a director to the corporation or its stockholders for mone-

(continued...)

liability of the directors for damages for breaches of the duty of care.

Generally, when the validity of a waiver clause is not contested and where the plaintiffs allege only a breach of the duty of care, with no claims of "bad faith, intentional misconduct, knowing violation of law, or any other conduct for which the directors may be liable," the waiver provision may be considered and applied in deciding a motion to dismiss. *See In re Baxter*, 654 A.2d at 1270; *see also Zirn v. VLI Corp.*, 681 A.2d 1050, 1062 (Del. 1996) (holding that breach of care claim is barred with § 102(b)(7) waiver provision); *Malpiede v. Townson*, 780 A.2d 1075, 1094 (Del. 2001) (affirming dismissal of shareholder action under 12(b)(6) where the complaint alleged only duty of care violations and corporation's charter had waiver provision).

As noted, breaches other than duty of care may not exempt the directors from liability and would disable the directors from considering a demand fairly. *In re Baxter*, 654 A.2d at 1270; *Emerald Partners v. Berlin*, 726 A.2d 1215, 1223-24 (Del. 1999) (holding that § 102(b)(7) is an affirmative defense, that breach of loyalty claim falls outside of exculpatory waiver provision, and burden of demonstrating good faith rests with party seeking protection of the statute). Directors are not protected under a

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[6] (...continued)
tary damages for breach of fiduciary duty as a director, provided that such provision shall not eliminate or limit the liability of a director: (i) For any breach of the director's duty of loyalty to the corporation or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) under § 174 of this title; or (iv) for any transaction from which the director derived an improper personal benefit.

§ 102(b)(7) provision when a complaint alleges facts that infer a breach of loyalty or good faith. *See Emerald Partners*, 787 A.2d at 94. The complaint must plead these other claims of 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. Where the complaint sufficiently alleges a breach of fiduciary duties based on a failure of the directors to act in good faith, bad faith actions present a question of fact that cannot be determined at the pleading stage. *Desert Equities, Inc. v. Morgan Stanley Leverage Equity Fund*, 624 A.2d 1199, 1209-10 (Del. 1993). While plaintiffs' complaint did allege a breach of the duty of care with grossly negligent conduct on the part of the directors, it also, as previously discussed, alleged "omissions not in good faith" and "intentional misconduct" concerning "violations of law," which conduct falls outside of the exemption and cannot be determined at the pleading stage.

The Sixth Circuit followed Delaware law in *McCall* in finding that the directors' fiduciary duties include not only the duty of care but also the duties of loyalty and good faith, stating that although "duty of care claims alleging only grossly negligent conduct are precluded by § 102(b)(7) waiver provision, it appears that duty of care claims based on reckless or intentional misconduct are not." 250 F.3d at 1000; see also *Emerald Partners*, 787 F.3d at 90. The *McCall* court noted, "To the extent that recklessness involves a conscious disregard of a known risk, it could be argued that such an approach is not one taken in good faith and thus could not be liability exempted under the [ ] statute." *Id.* at 1000-01 (internal quotations and citation omitted). The court further stated, "Under Delaware law, the duty of good faith may be breached where a director consciously disregards his duties to the corporation, thereby causing its stockholders to suffer." *Id.*

at 1001 (citation omitted). Plaintiffs in *Abbott* accused the directors not only of gross negligence, but of intentional conduct in failing to address the federal violation problems, alleging "a conscious disregard of known risks, which conduct, if proven, cannot have been undertaken in good faith." *McCall*, 250 F.3d at 1001.

In *McCall*, where the duty of care claims arose from the board's unconscious 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 conscious disregard of known risks, which conduct, if proven, cannot have been undertaken in good faith. Thus, . . . plaintiffs' claims are not precluded by [the company]'s § 102(b)(7) waiver provision." 250 F.3d at 1001.

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.

A true Copy:

Teste:

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Clerk of the United States Court of Appeals for the Seventh Circuit