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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON DERIVATIVE LITIGATION	CIVIL NO. 3:10-CV-02033 (FLW) (DEA) **JOHNSON & JOHNSON'S REPLY BRIEF IN FURTHER SUPPORT OF ITS MOTION TO DISMISS OR, IN THE ALTERNATIVE, MOTION TO STAY** ORAL ARGUMENT REQUESTED

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INTRODUCTION

Plaintiffs seek to bring shareholder derivative litigation on behalf of Johnson & Johnson ("J&J" or the "Company") without first complying with New Jersey's shareholder demand requirement. New Jersey only permits plaintiffs to proceed if their Complaint demonstrates through particularized facts that demand would have been futile. Plaintiffs have not made the required showing that J&J's Board acted in bad faith or knowingly violated the law. Thus, they may not proceed.

Plaintiffs' arguments to the contrary in their opposition ("Opposition" or "Opp.") to J&J's motion to dismiss and supporting brief ("Motion" or "Mtn.") rest on faulty premises, flawed reasoning, and rhetoric that goes far beyond the Complaint's actual factual allegations. The Opposition falls flat in the following key respects. First, its core premise is faulty because plaintiffs confuse conclusory allegations of illegal conduct with the demonstrated existence of illegal conduct. The Opposition repeatedly attempts to portray J&J as a rogue company operating outside the law, but the Complaint's allegations of illegality are nothing more than conclusory. The fact that investigations are ongoing or that settlements are reached does not establish that misconduct occurred, let alone that the Board knew about ongoing misconduct and failed to stop it. Neither the underlying facts nor the factual allegations in the Complaint support plaintiffs' hyperbolic assertions of illegality. Second, the Opposition is flawed with respect to both the facts and the

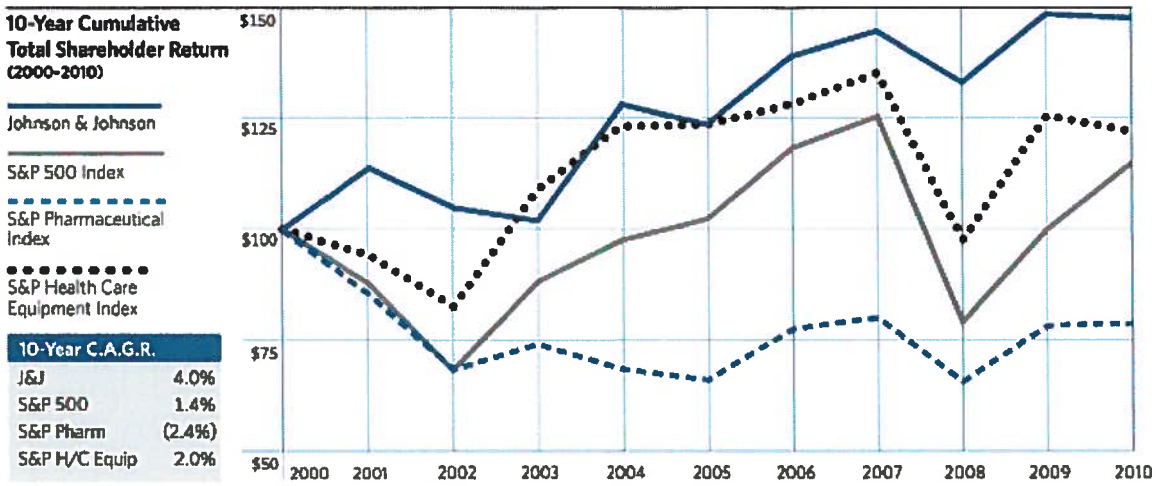
law. Plaintiffs attempt to clear New Jersey's demand futility hurdle by conflating distinct issues at various J&J subsidiaries, distorting alleged red flags, and double-counting issues. For example, one of plaintiffs' repeated mantras is that there were 90 red flags to warn the Board that J&J was awash in supposed illegal conduct. But, when plaintiffs' actual allegations are examined and the law regarding red flags is applied to them, none of them pass muster as a red flag that was ignored by the Board. Third, plaintiffs' inflammatory rhetoric is not supported by the required particularized facts. The actual facts alleged in the Complaint do not remotely support the overwrought rhetoric of the Opposition.

Indeed, plaintiffs' characterizations of J&J and the purported failings of its Board bear no relationship to reality. Plaintiffs make conclusory attacks on J&J's performance, which by any objective measure has been impressive over the period about which plaintiffs complain. The following table sets forth J&J's performance over the past decade:

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Total Sales (in millions)	29,172	32,317	36,298	41,862	47,348	50,514	53,324	61,095	63,747	61,897	61,587
Net Earnings (in millions)	4,764	5,405	6,277	6,848	8,180	10,060	11,053	10,576	12,949	12,266	13,334
Cash Dividend Per Share	0.620	0.700	0.795	0.925	1.095	1.275	1.455	1.620	1.795	1.930	2.110

(2010 Form 10-K, at 74.)

Over this same time period, J&J's cumulative shareholder returns have outperformed the S&P Health Care Equipment Index, the S&P Pharmaceutical Index, and the S&P 500 Index, as set forth in the following graph:



	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Johnson & Johnson	$100.00	114.01	105.03	102.81	128.68	124.36	139.83	144.88	133.63	148.70	147.83
S&P 500 Index	$100.00	88.11	68.64	88.33	97.94	102.75	118.97	125.51	79.07	100.00	115.07
S&P Pharmaceutical Index	$100.00	85.46	68.33	74.33	68.81	66.49	77.04	80.62	65.95	78.22	78.83
S&P Health Care Equipment Index	$100.00	94.93	82.93	109.50	123.32	123.38	128.47	135.06	97.73	125.86	122.45

(*Id.* at 75.)

This actual record of performance under the oversight of J&J's distinguished Board cannot be ignored. At the same time, J&J—as with any business—has confronted issues. With more than 250 subsidiaries, roughly 114,000 employees, operations in virtually every country, and 139 manufacturing facilities worldwide—all under the close regulation of the healthcare industry—J&J has, and will always have, to address issues. But J&J's Board has not shirked from addressing them, much less egregiously failed to act in the face of red flags.

Plaintiffs wholly fail to meet the legal standard for moving forward with this action. Their sweeping generalizations are no substitute for the careful and rigorous analysis that New Jersey courts apply to demand futility allegations. When the Complaint is analyzed under the applicable legal standard, plaintiffs' allegations do not demonstrate a substantial likelihood of liability on the part of any J&J director, let alone a majority of them. Demand was not futile here.

ARGUMENT

I. THE COMPLAINT SHOULD BE DISMISSED BECAUSE PLAINTIFFS FAILED TO DEMONSTRATE DEMAND FUTILITY.

A. Plaintiffs Were Required To Plead Particularized Facts Establishing Board Knowledge Of Continuing Misconduct And A Deliberate Failure To Take Corrective Actions.

The Opposition makes three significant errors in discussing the legal standards for evaluating whether the Complaint establishes demand futility: (1) it misstates the applicable pleading standards; (2) it incorrectly claims that the exculpatory clause in J&J's Certificate of Incorporation should not be considered; and (3) it wrongly claims that *Aronson v. Lewis*, 473 A.2d 805 (Del. 1984), rather than *Rales v. Blasband*, 634 A.2d 927 (Del. 1993), applies here.

Plaintiffs' first error is misstating their pleading burden. They assert that *all* of the Complaint's allegations must be taken as true. (Opp. 25–26.) This is not accurate. As the *In re Cendant Corp. Derivative Action Litigation* decision cited by plaintiffs explained:

> While a court will accept well-pleaded allegations as true for the purposes of the motion, it will not accept unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations.

189 F.R.D. 117, 127 (D.N.J. 1999). Moreover, because this is a derivative suit governed by Federal Rule of Civil Procedure 23.1, the facts must be pleaded with particularity, a heightened standard akin to that for pleading fraud. *See In re Merck & Co., Inc. Sec., Deriv., & ERISA Litig.*, 493 F.3d 393, 403 (3d Cir. 2007); *Brehm v. Eisner*, 746 A.2d 244, 254 (Del. 2000). Allegations that lack particularity are *not* to be taken as true. *Kanter v. Barella*, 489 F.3d 170, 177 (3d Cir. 2007) ("[A] court need not credit either 'bald assertions' or 'legal conclusions' in a complaint when deciding a motion to dismiss."); *In re Prudential Ins. Co. Deriv. Litig.*, 282 N.J. Super. 256, 276 (Ch. Div. 1995) ("Conclusory allegations of fact or law unsupported by allegations of specific facts are insufficient.").

Plaintiffs' second error is asserting that J&J's exculpatory charter provision should not be considered on a motion to dismiss. (Opp. 43.) Numerous New Jersey cases have recognized that exculpatory clauses are to be considered at the motion to dismiss stage because there can be no substantial likelihood of liability—and thus no interestedness—regarding claims for which, as a matter of law, the directors cannot be liable. *E.g.*, *In re Merck & Co., Inc. Deriv. & ERISA Litig.*, 2006 WL 1228595, at *14 (D.N.J. May 5, 2006), *remanded on other*

grounds, 493 F.3d 393 (3d Cir. 2007); *Kanter v. Barella*, 388 F. Supp. 2d 474, 479 n.9 (D.N.J. 2005).[1] The exculpatory provision squarely applies here and requires that plaintiffs plead a non-exculpated claim to establish a substantial likelihood of liability. (Mtn. 20–21.) Thus, plaintiffs must demonstrate through particularized allegations that the Board acted egregiously or in bad faith. *Merck*, 2006 WL 1228595, at *14–15.

Plaintiffs' third error is arguing that *Aronson*, rather than *Rales*, applies here because the alleged misconduct is supposedly the intentional result of affirmative action by the Board. (Opp. 26–27.) This argument is refuted by plaintiffs' own framing of their claims as concerning *failures to act*: they allege that certain of J&J's subsidiaries engaged in various sets of misconduct, and that J&J's Board "knowing[ly] fail[ed]" to halt the misconduct, thereby "refus[ing] to engage in good faith oversight." (*Id.* 1–3.) Such claims are evaluated under *Rales*. *E.g.*, *In re SFBC Int'l, Inc. Sec. & Deriv. Litig.*, 495 F. Supp. 2d 477, 483 (D.N.J. 2007)

[1] The cases plaintiffs cite are inapposite. *Emerald Partners v. Berlin* did not involve a motion to dismiss for failure to make a demand, 726 A.2d 1215, 1218 (Del. 1999), and the Delaware Supreme Court has subsequently expressly held on several occasions that defendants can assert exculpatory provisions at the motion to dismiss stage. *Malpiede v. Townson*, 780 A.2d 1075, 1094–96 (Del. 2001); *Wood v. Baum*, 953 A.2d 136, 141 (Del. 2008). *In re Tower Air, Inc.*, 416 F.3d 229, 231 (3d Cir. 2005), was not a derivative suit and was rejected on this point by the Third Circuit's subsequent decision in *Merck*, in which the court stated that "courts routinely examine exculpatory agreements in demand futility motions to dismiss," 493 F.3d at 402–04 & n.5.

(cited in Opp. 29–30). Moreover, plaintiffs' rhetoric that there were "conscious decision[s] to allow illegal conduct" (Opp. 26–27) is entirely conclusory—they identify no specific Board decisions, let alone which directors allegedly participated in those decisions or when they were made. Under New Jersey law, plaintiffs must plead particularized facts of board action to trigger *Aronson*. *Prudential*, 282 N.J. Super. at 283 (holding that, "absent particularized pleading of underlying facts, . . . unspecific allegations" of board "participation" in and "approval" of wrongdoing do not plead affirmative action); *see also Fagin v. Gilmartin*, 432 F.3d 276, 282–83 (3d Cir. 2005).

Regardless, the distinction between *Rales* and *Aronson* does not make a difference here. *See, e.g.*, *Merck*, 2006 WL 1228595, at *8 ("[T]he analysis under *Rales* . . . embodies the concerns relevant to both the first and second prongs of *Aronson*."). As plaintiffs concede, to establish demand futility under *Rales*, they must establish Board knowledge of ongoing illegal conduct and an egregious failure to respond with good faith corrective action. (*See* Opp. 28.) *See also SFBC*, 495 F. Supp. 2d at 484; *Prudential*, 282 N.J. Super. at 277 (noting the importance of pleading directors' "actual knowledge of the alleged wrongdoings at the time they were committed"). Both of these elements are also necessary conditions under *Aronson*. Plaintiffs have not made the requisite showing under either test.

B. The Complaint Does Not Properly Plead The Board's Knowledge Of Ongoing Misconduct Or Its Failure To Respond In Good Faith For Any Set Of Misconduct.

J&J's Motion explained in detail how the Complaint fails to meet its pleading burden with respect to the Board's knowledge and actions. (Mtn. 22–48.) The Opposition does nothing to rescue the Complaint. Indeed, the Opposition moves further afield from what New Jersey law requires by (1) conflating the alleged misconduct and alleged red flags over a period of years as if they are all interrelated, and (2) presenting the alleged red flags in a misleading way that is not supported by the factual allegations of the Complaint.

1. The alleged misconduct and red flags cannot be lumped together.

The Opposition's demand futility analysis jumbles together all of the Complaint's allegations of wrongdoing and red flags as if they are interrelated. (*See* Opp. 28–29, 32–37; *see also id.* 1–25.) But each of the seven[2] sets of alleged misconduct presents a distinct claim covering a distinct time period and J&J subsidiary. To be a red flag for particular misconduct, an event must constitute "cause for suspicion" that misconduct is afoot. *Stone v. Ritter*, 911 A.2d 362, 368

[2] Plaintiffs seek to hold the defendants liable for: off-label marketing of Risperdal; off-label marketing of Topamax; off-label marketing of Natrecor; off-label marketing of biliary stents; Omnicare kickbacks; DePuy kickbacks; and the 2009-2010 McNeil recalls. This list does not include the 2010 Acuvue recalls or DePuy hip replacement recalls because those events occurred after this suit was initiated and are therefore irrelevant to demand futility. (*See* Mtn. 17 n.3.)

(Del. 2006). Such cause is apparent where the event concerns the misconduct at issue. But where it does not, plaintiffs must demonstrate why the event—*e.g.*, a 2005 subpoena regarding the promotion of Risperdal—should have alerted the Board to some other, unrelated set of alleged misconduct—*e.g.*, the 2009 and 2010 McNeil manufacturing problems. But plaintiffs do not even attempt to explain the relationships between the sets of alleged misconduct and red flags that they lump together, despite the lack of any logical connection between them.

Plaintiffs' approach is to spin a tale of allegedly unbounded misconduct by J&J and its Board. But that tale bears absolutely no relationship to reality (or to the particularized allegations of the Complaint). Plaintiffs' Complaint alleges misconduct at *3 percent*—8 of 250—of J&J's operating companies. The alleged misconduct involved just two of the hundreds of medical devices sold by J&J subsidiaries, and just three of J&J's many pharmaceutical drugs. (*See* 2005 Form 10-K, at 1–2.) Similarly, the manufacturing issues at Fort Washington and Las Piedras in 2009 and 2010 involve just two of the Company's 139 worldwide manufacturing facilities. (*See* 2010 Form 10-K, at 4.) It is unreasonable to suggest, as plaintiffs do, that these discrete issues should have led the Board to conclude that there were systemic problems affecting every aspect of J&J's operations, particularly given the separation of alleged misconduct over differing time periods at different subsidiaries.

2. The Opposition's discussion of red flags is misleading.

The Opposition's tale of alleged wrongdoing and red flags is also deeply flawed on its own terms, and these flaws further demonstrate that plaintiffs have not shown that the Board knew about any ongoing misconduct yet failed to act regarding that particular misconduct. The Opposition's argument with respect to the alleged red flags is unreliable and misleading in the following ways:

- **Claiming that there were more than 90 red flags.** (*E.g.*, Opp. 2.) Setting aside the merits of plaintiffs' claim that *any* of these events qualify as red flags, the number 90 is inflated for rhetorical purposes. Plaintiffs appear to reach this total by simply adding up the number of bullet-pointed statements in Paragraphs 280–85 of the Complaint. But 35 of those bullet points come from 2010 alone, because plaintiffs essentially repeat (and double count) the allegations of Paragraph 283 in Paragraph 285. Paragraphs 280–285 in fact list fewer than 70 unique events that occurred before this suit was filed. And that number includes many repetitive events, primarily subpoenas and lawsuits, regarding the same subjects. For example, plaintiffs list nine subpoenas and six lawsuits as separate alleged red flags for the same alleged off-label marketing of Risperdal. (Cmplt. ¶¶ 280–85.) The same is true with respect to plaintiffs' other alleged "red flags."[3] Moreover, at least 21 of the purported red flags concern issues or products, such as the drugs Ultram or Procrit, regarding which there is no misconduct alleged in the Complaint.

- **Using dates that conflict with the Complaint's allegations.** For example, the Opposition (1) discusses sales of Topamax through 2008 (Opp. 14), even though the alleged misconduct ended in 2003 (*infra* at 13); (2) discusses sales of Risperdal through 2007 (Opp. 13) despite the end of alleged off-label marketing in 2002 (*infra* at 13); and (3)

[3] None of these events actually qualify as red flags because, for each issue, the first supposed red flag occurred *after* the last particularized allegation of misconduct. (*Infra* at 13.)

references Scios's November 2007 write-down of Natrecor's book value (Opp. 15) even though the alleged Natrecor misconduct ended in 2005 (*infra* at 13).

- **Repeatedly relying on conclusory allegations.** For example, the Opposition asserts that the Board was aware of data regarding the off-label marketing of Risperdal (Opp. 6, 13), Topamax (*id.* 14), and Natrecor (*id.* 15). But the Complaint contains no well-pleaded allegation that the Board had such knowledge, instead resting solely on the bald assertion that information regarding off-label use was "followed . . . at the Board level." (Cmplt. ¶ 167.) This is not a particularized pleading of fact. Moreover, the existence of off-label *sales* in no way suggests that the Board approved or condoned off-label *marketing*. Indeed, plaintiffs make no response to the fact that off-label use of drugs is entirely proper, commonplace, and accepted. The fact that doctors have prescribed a drug for off-label use does not in any way establish off-label promotion. (*See* Mtn. 8–9.)

- **Making conclusory assertions that are demonstrably false.** For example, plaintiffs repeatedly falsely argue that McNeil's recent manufacturing problems resulted in serious public health and safety threats. (*E.g.*, Opp. 4, 23.) In fact, the FDA has publicly stated that McNeil's products did not pose any such threat. (*See, e.g.*, FDA Guidance, at #5–10 (available at http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/guidances/ucm192869.htm) (Las Piedras TBA product recalls); FDA May 1, 2010, Press Release (available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm210441.htm) (Fort Washington recalls).) Plaintiffs also falsely state that DePuy pled guilty in 2007 to violating federal law. (Opp. 16.) In fact, DePuy entered into a deferred prosecution agreement and did not admit wrongdoing or plead guilty. (Mtn. 40–41.)

- **Materially misrepresenting the Complaint's allegations.** The Opposition repeatedly misstates what is actually pleaded. As just one example, on page three of the Opposition, plaintiffs assert that "*in 2008, J&J's Board learned* that OTC drugs manufactured at J&J's Fort Washington, Pennsylvania facility and its Las Piedras, Puerto Rico facility were contaminated with a pesticide that caused widespread gastrointestinal distress in consumers" and cite to Paragraph 106 of the

Complaint (emphasis added). What Paragraph 106 actually alleges is that *in January 2010, the FDA issued a warning letter to Mr. Weldon* regarding the Las Piedras facility (¶ 105) and in that letter noted that J&J had received "uncharacteristic odor" complaints beginning in 2008, "some of which caused adverse events, such as gastrointestinal distress" (¶ 106). The Opposition twists the Complaint's allegation of a letter sent to Mr. Weldon in January 2010 into the clearly false assertion that the Board knew something in 2008.

- **Conflating knowledge of allegations of misconduct with knowledge of proof of misconduct.** Many of plaintiffs' alleged red flags involve Board knowledge of government investigations. However, knowledge that an investigation is ongoing does not imply either (1) that misconduct occurred or (2) Board knowledge that misconduct occurred. In fact, J&J has denied any illegal conduct regarding Risperdal, Natrecor, biliary stents, the alleged Omnicare kickbacks, and the McNeil recalls, and did not admit to any wrongdoing regarding the alleged DePuy kickbacks. While judicial and regulatory proceedings are still ongoing for many of these issues, J&J has obtained dismissal of a number of allegations in a number of jurisdictions.

3. The actual allegations of the Complaint do not support a finding of demand futility.

Not only does plaintiffs' Opposition grossly distort what is pleaded, analysis of the Complaint itself shows that plaintiffs have not established a substantial likelihood of liability on the part of any J&J Board member for any alleged misconduct. The following chart summarizes the Complaint's allegations (including from any incorporated qui tam or government complaint) regarding when each set of alleged misconduct occurred and the first alleged source of Board knowledge. It demonstrates that the Board did not receive any alleged red flags for most of the alleged misconduct until after the conduct had already ended.

Alleged Misconduct	**Dates Occurred** (cites to Cmplt.)	**First Alleged Red Flag** (cites to Cmplt.)
Off-label marketing of Risperdal by Janssen	1997–2002 (¶¶ 177–79, 181)	January 2004 subpoena (¶ 280.)
Off-label marketing of Topamax by Ortho-McNeil	2001–2003 (¶¶ 196, 200, 207)	December 2003 subpoena (¶ 280)
Off-label marketing of Natrecor by Scios	2003–July 2005 (¶¶ 213, 235–37)	July 2005 subpoena (¶ 281)
Off-label marketing of biliary stents by Cordis	1996–2007 (¶ 242)	June 2008 subpoena (¶ 282)
Omnicare kickbacks	1999–2004 (¶ 270)	September 2005 subpoena (¶ 281)
DePuy kickbacks	2002–2006 (¶ 275)	March 2005 subpoena (¶ 281)
McNeil recalls	2009–2010 (¶¶ 103–05, 113)	The initial recalls (¶¶ 282–83)

The first red flag occurs after, or coincident with, the end of the alleged misconduct for each of the Risperdal,[4] Topamax,[5] Natrecor, biliary stent, and

[4] The Complaint's only bases for alleging misconduct after 2002 are the April 2004 Warning Letter and the Louisiana Risperdal case. (Cmplt. ¶¶ 181, 183.) Neither suffices, for several reasons. First, neither relates to off-label marketing. The April 2004 Warning Letter concerned a "Dear Healthcare Provider" letter dated November 10, 2003, which allegedly did not sufficiently summarize a warning that recently had been added to Risperdal's label. (*See* April 19, 2004, Warning Letter, attached as Ex. 4 to Mtn. Certification of Donald Robinson.) This letter is not a particularized fact suggesting that Janssen was engaged in off-label marketing of Risperdal after 2002. The Louisiana case also concerned the November 10, 2003, letter, and thus also cannot provide a basis for properly alleging off-label marketing after 2002. (*See, e.g.*, Plaintiffs' Motion in Limine, at 1, attached as Ex. 7 to Mtn. Robinson Cert.) Second, the misconduct alleged in the Louisiana case ended in July 2004 when the November 2003 letter ceased to be disseminated, so the Louisiana case does not suggest that the Board egregiously failed to halt misconduct over an extended period of time. (*See id.*) (Plaintiffs contest the Court's authority to consider information from public court filings (Opp. 14 n.5.),

Omnicare allegations. The Board could not have egregiously failed to act with respect to alleged misconduct that had ceased before the first red flag was received.

As for the DePuy allegations, although plaintiffs allege that the misconduct at DePuy continued for a short period after the first red flag was received, the DePuy allegations do not establish a likelihood of Board liability because the Complaint contains *no* particularized allegations of wrongdoing. The Complaint's five paragraphs regarding DePuy merely note that the two-page federal criminal complaint alleged, on a notice-pleading standard, that misconduct had occurred at *DePuy*. (Cmplt. ¶¶ 273–77.) In settling the DePuy matter, DePuy denied any wrongdoing, and J&J was not a party to the settlement. (*See* Mtn. 40–41.) None of this suggests any involvement by the J&J Board in wrongdoing or any egregious behavior in failing to stop the alleged misconduct. *See also Markewich v. Collins*

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but given plaintiffs' citation of the Louisiana complaint and jury verdict (Cmplt. ¶¶ 183, 285), they had fair notice of the suit's details and those details were incorporated into the Complaint. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).) Third, there is no pleading at all, let alone particularized fact pleading, that the Board had any involvement with the November 10, 2003, letter distributed by Janssen, much less any reason to believe that that letter would subsequently be revised.

[5]The September 2004 Warning Letter concerning Topamax does not constitute a particularized fact suggesting that off-label marketing of Topamax continued beyond 2003. Like the April 2004 Risperdal Warning Letter, this letter concerns the omission from promotional materials of risk information contained in the Topamax label. (*See* September 15, 2004, Warning Letter, attached as Ex. 5 to Mtn. Robinson Cert.)

("*Medtronic*"), 622 F. Supp. 2d 802, 812 (D. Minn. 2009) (misconduct cannot be inferred from settlements, which are often "routine business decisions").

Nor is there a significant likelihood of Board liability for the McNeil recalls. The Complaint does not allege that the Board knew of the manufacturing problems that caused the 2009 and 2010 McNeil recalls until those recalls were undertaken.[6] Moreover, there is no doubt that extensive good faith actions have been taken to fix problems at McNeil. (*See* Mtn. 24–28.) The Opposition tries to ignore these actions, instead focusing on the recent consent decree between the FDA and McNeil. (*E.g.*, Opp. 20.[7]) The decree is irrelevant to the issue of demand futility because it occurred after this suit was filed. Moreover, there is nothing in the consent decree that suggests that McNeil's remediation efforts were not taken in good faith, or that there were issues at McNeil beyond the specific plants identified

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[6] Plaintiffs erroneously suggest that two items should have generally alerted the Board to manufacturing problems. First, they point to a Warning Letter from 2004 with respect to manufacturing issues at the medical devices subsidiary Cordis. (Opp. 4.) But the Warning Letter only pertained to Cordis, and the FDA subsequently notified Cordis in 2007 that these problems were completely resolved. (*See* June 13, 2007, FDA close-out letter, attached as Ex. 1 to Reply Certification of Donald Robinson.) Second, plaintiffs conclusorily assert that J&J had more recalls than other pharmaceutical companies from 2004–2007. (Opp. 19.) But even for the few of these recalls that involved McNeil and aside from methodological problems with their calculations, plaintiffs provide no reason to believe that any were the result of misconduct rather than regular and natural occurrences in the highly regulated healthcare industry.

[7] The "Defendants" referenced at Opposition page 20 are McNeil-PPC, Inc. and two of its officers. Neither J&J nor any Board member was a party.

in the decree. Although the FDA's complaint alleges that remediation did not progress as quickly as the FDA desired, this does not indicate bad faith, and is not a particularized pleading of any egregious failure by the J&J Board. Indeed, the decree notably lacks *any* monetary penalty against McNeil, much less J&J, which would seem incompatible with an FDA belief that there had been *any* bad faith conduct. *Compare Abbott Labs*, 325 F.3d at 798 ($100 million penalty).

Because review of the Complaint's actual factual allegations shows that the Complaint does not plead a substantial risk of liability as to any Board member, the Complaint does not establish demand futility for any of the claims plaintiffs seek to assert on behalf of J&J.

C. This Case Is Not Like *Abbott Labs*, *Pfizer*, Or *SFBC*.

Plaintiffs attempt to support their demand futility argument by contending that this case is analogous to *In re Abbott Laboratories Derivative Shareholders Litigation*, 325 F.3d 795 (7th Cir. 2003), *In re Pfizer, Inc. Shareholder Derivative Litigation*, 722 F. Supp. 2d 453 (S.D.N.Y. 2010), and *In re SFBC International, Inc. Securities & Derivative Litigation*, 495 F. Supp. 2d 477 (D.N.J. 2007), and unlike the cases cited in J&J's Motion. (Opp. 29–34, 38–43.) Plaintiffs essentially argue that *Abbott Labs*, *Pfizer*, and *SFBC* are on-point because—they contend—the Complaint alleges similar wrongdoing and red flags. (*Id.* 32–34.) Plaintiffs are wrong. This case is nothing like *Abbott Labs*, *Pfizer*, or *SFBC*.

Abbott Labs involved serious manufacturing deficiencies that continued for six years at the same two facilities. 325 F.3d at 799–800. During that period, the two facilities were inspected by the FDA thirteen times, and each inspection resulted in a Form 483 deficiency report; the FDA sent four Warning Letters concerning the same deficiencies, two at the beginning of the period and two towards the end; two years into the period, the company and the FDA entered into a "Voluntary Compliance Plan" to fix the facilities' problems, which was unsuccessful and ended after three years; and the FDA met with the chairman of the board. *Id.* at 799–800, 806–08. Thus, red flags, all of which concerned the same ongoing misconduct, occurred at the beginning, middle, and end of the period, and the problems were not addressed. Based upon this unique set of facts, and the lengthy temporal relationship between particularized misconduct and board knowledge of that specific misconduct, demand was excused. *Id.* at 807–09.[8]

Pfizer involved a similar extended coexistence of misconduct and red flags. Over the course of a decade, various subsidiaries and Pfizer itself allegedly engaged in the off-label promotion of thirteen different drugs, including seven of its nine most profitable drugs. 722 F. Supp. 2d at 455–57. While the alleged

[8] In addition to being factually inapposite, the Third Circuit has recognized that the demand futility standard applied in *Abbott Labs* is not consistent with New Jersey law. *Fagin*, 432 F.3d at 282–83.

misconduct at issue was ongoing, various Pfizer subsidiaries settled other, separate charges of off-label promotion for three more drugs, and as part of those earlier settlements the Pfizer board agreed to multiple corporate integrity agreements. *Id.* Under each of those agreements, the Pfizer board expressly undertook heightened responsibility for ferreting out and preventing further off-label marketing. *Id.* Because the corporate integrity agreements required that compliance information be reported directly to Pfizer's board, the plaintiffs were able to plead particularized facts demonstrating that the Pfizer board was "bombarded" for years by a "large number of reports" of ongoing off-label marketing. *Id.* at 460–62.

SFBC involved highly improper clinical trials procedures at SFBC's facilities, including the corporate headquarters, over the course of three years. 495 F. Supp. 2d at 480–81, 485. During that time, the FDA issued seven Form 483 inspection reports, finding the same deficiencies each time, and the corporate headquarters was cited more than 80 times for building code violations that ultimately caused it to be demolished. *Id.* Moreover, SFBC had contracted with "independent" review boards that were not independent, and had hired both an unqualified CEO and an unqualified Chief Legal Officer. *Id.* Judge Chesler found that, given the pervasive presence of extremely serious misconduct in every aspect of this small company's operations—from its core operations to executive hiring to basic maintenance to financial transactions and accounting—it was

"inconceivable" that the board was unaware of ongoing misconduct, and thus the particularized factual allegations excused demand. *Id.* at 486–87.

These three cases are far from what has been pleaded here.[9] As discussed above, for most, if not all, of the sets of alleged misconduct, J&J's Board did not receive *any* red flags until after that alleged misconduct *had already ended*. (*Supra* at 13.) And any overlap that might have existed was brief, as opposed to the multi-year periods involved in each of *Abbott Labs*, *Pfizer*, and *SFBC*.[10]

Plaintiffs' attempt to distinguish the cases cited by defendants in the Motion (Opp. 38–43) is unavailing. Plaintiffs' allegations involve only a small number of J&J's subsidiaries, products, and manufacturing facilities, and they attempt to conflate issues arising at different subsidiaries at different points in time. More

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[9] Plaintiffs cite in passing a few additional cases, but none has any relevance here. Plaintiffs cite *Tower Air*, but not only did that case not apply Fed. R. Civ. P. 23.1 and not analyze demand futility, it applied a notice-pleading standard to claims by the bankruptcy trustee against the officers and directors who had ignored aircraft safety problems and bankrupted the company. 416 F.3d at 239. *See also Merck*, 493 F.3d at 403 (distinguishing *Tower Air* from a prescription-drug-related derivative suit). Plaintiffs' other citations are also easily distinguished. *See In re Veeco Instr., Inc. Sec. Litig.*, 434 F. Supp. 2d 267, 277–78 (S.D.N.Y. 2006) (10-K acknowledged that internal controls were deficient, yet board made no remediation efforts); *In re AIG, Inc.*, 965 A.2d 763, 777 (Del. Ch. 2009) (applying notice-pleading standard to claims against officers because special committee endorsed claims); *McCall v. Scott*, 239 F.3d 808, 819–23 (6th Cir. 2001), *revised in part*, 250 F.3d 997 (board had specific knowledge about accounting irregularities that were tell-tale signs of fraud).

[10] In fact, far from pleading inaction, the Complaint demonstrates that when problems were brought to the attention of J&J's Board, good faith efforts to remedy them were swiftly made, as was the case for the McNeil recalls.

fundamentally, the cases cited by defendants highlight the requirements that for demand to be excused as futile there must be particularized allegations that (1) the Board received warnings of ongoing—not past—misconduct, and (2) the Board egregiously failed to address them. *See Merck*, 2006 WL 1228595, at *14–15.

The cases cited in the Motion establish the following three principles, each of which squarely applies to this case.

First, the existence of off-label *sales* does not establish any wrongdoing whatsoever, and even the existence of improper off-label *marketing* does not establish board knowledge of wrongdoing. In *King v. Baldino*, the plaintiff alleged significant off-label sales and off-label promotion activities over a period of years for several of Cephalon's drugs.[11] 648 F. Supp. 2d 609, 623 (D. Del. 2009). Both the district court and the Third Circuit found that these facts were insufficient to establish board knowledge of wrongdoing because the complaint failed to properly

[11] For example, in 2000 and 2001, the company allegedly implemented off-label marketing strategies; one drug's sales jumped 92 percent in the first six months of 2002; an intra-company audit in 2003 found multiple violations of FDA mandates over several years; data showed that doctors were prescribing the drugs off-label; and when the company curtailed off-label marketing of one drug in 2005 under FDA pressure, its sales dropped 23 percent. 648 F. Supp. 2d at 623. Plaintiffs' attempt to distinguish *King* because the complaint in that case was shorter than the Complaint here is unavailing. (Opp. 38–39.) The district court in *King* carefully analyzed the complaint in that case, including the allegations in the *Wall Street Journal* articles that were incorporated into the complaint. *See* 648 F. Supp. 2d at 611–14 & n. 4. The Complaint in this case, while prolix, is equally devoid of any well-pled facts regarding J&J's Board.

plead "any *specific connection* between any of those practices and the *board*," 2010 WL 5078008, at *3 (3d Cir. Dec. 14, 2010) (first emphasis added); 648 F. Supp. 2d at 623–26, and the district court specifically noted that off-label sales of drugs "frequently exceed that for FDA-approved use," 648 F. Supp. 2d at 612.

Second, the existence of government investigations does not establish board knowledge of misconduct. Just as in *In re Intel Corp. Derivative Litigation*, plaintiffs here "catalog the ongoing investigations into [J&J]'s alleged wrongdoing, and then assert that the thickness of the catalog demonstrates that [J&J]'s conduct was so egregious and widespread that the [d]irectors certainly must now face at least a 'substantial likelihood' of personal liability for having ignored the 'red flags.'" 621 F. Supp. 2d 165, 175 (D. Del. 2009). But ongoing investigations and even settlements that do not admit wrongdoing do not establish that misconduct in fact occurred, let alone establish that there is a substantial likelihood of board liability because the board knew about the misconduct. *See id.* at 174–76.

Third, bad faith and disloyalty are pleaded only where the board fails to act in response to wrongdoing. However, cooperating with a governmental investigation is a good faith response. In *King*, the district court found that the existence of government investigations, a settlement, and a guilty plea to a federal misdemeanor did not give rise to a substantial likelihood of liability because the

board did not ignore these events: Cephalon cooperated with the investigations. 648 F. Supp. 2d at 625–26; *see also Intel*, 621 F. Supp. 2d at 174–76. The same is true here: for each investigation that plaintiffs claim is a red flag, J&J has cooperated. (*See, e.g.*, Form 10-Q filed Aug. 10, 2005, at 27–28.) The Board did not ignore government investigations at all, let alone egregiously.

* * *

In sum, plaintiffs—who are willing to engage in outrageous distortions of the Company's record and their own pleading—ask this Court to allow them to bring this lawsuit on the Company's behalf without having made the requisite demand on the Board. But they have pleaded no particularized facts showing that the Board could not fairly consider a demand. Plaintiffs make no claim that any of J&J's distinguished independent directors received improper benefits or are not independent. They have pleaded no reason to believe that these directors acted improperly, much less that they had knowledge of illegal conduct and egregiously failed to do anything about it. Plaintiffs' demand futility arguments fall far short of New Jersey's requirements for all of the reasons discussed above. Plaintiffs' Complaint should be dismissed for failure to make a demand.

II. IN THE ALTERNATIVE, THIS ACTION SHOULD BE STAYED PENDING THE SPECIAL COMMITTEE'S INVESTIGATION.

Unlike plaintiffs, other shareholders made written demands that the Board investigate the same matters alleged in this suit. When it received those shareholder demand letters, the Board did what New Jersey law contemplates. It established a Special Committee to investigate the allegations of the demand letters and the plaintiffs' claims here. For all of the reasons discussed above, the derivative litigation should be dismissed at this time. However, at a minimum, the Court should stay this action pending the Special Committee's investigation.

Plaintiffs object to a stay for three reasons. First, they claim that the Special Committee's advisory mandate means it should not be respected. (Opp. 45.) This is plainly wrong. The rationales for a stay apply regardless of the Committee's mandate, and none of plaintiffs' cases hold, or even suggest, differently.

Second, plaintiffs argue that three of the Committee members are interested and lack independence. (Opp. 46–47.) But this argument is both wrong and premature. Most importantly, the Opposition's attacks on three of the four Special Committee members are wholly without substance. As discussed above, there is no substantial likelihood of liability for the members of the Special Committee. The Special Committee's engagement of independent counsel Lowenstein Sandler, P.C. is also significant. *See In re PSE&G S'holder Litig.*, 173 N.J. 258, 278–82

(2002) (engagement of independent counsel who performed detailed, thorough, and good faith investigation supported dismissal).

Finally, the Compensation & Benefits Committee's recent actions regarding Defendants Weldon and Deyo do not compromise the Special Committee's investigation. (Opp. 47–48.) As set forth in the 2011 Proxy, the Compensation Committee is charged with oversight of the Board's duties, *inter alia*, with respect to compensation of the Company's executive officers. (2011 Proxy Statement at 16.) That Committee has retained an independent compensation consultant to assist it with its duties. (*Id.* at 23.) The Committee reported thoroughly on its evaluation of the performance of the Company and its senior executives. (*Id.* at 21–45.) The Committee found that, although the Company's earnings per share had met objectives and the Company's total shareholder return had met or exceeded peer indices over both the past three and five year periods (*see id.* at 21, 27), the Company's overall performance in 2010 was mixed and the Committee specifically highlighted the product recalls at McNeil as a disappointment. (*Id.* at 22, 38–39.) Mr. Weldon's annual performance bonus was cut by 45 percent. (*Id.* at 39.) Mr. Deyo's performance in 2010 was assessed with equal care. (*Id.* at 40–41.) Nothing in this careful work reflects any prejudging of the merits of the matters that are currently under the Special Committee's review.

The Special Committee clearly should be allowed to complete its investigation.

CONCLUSION

For all of the foregoing reasons, nominal defendant J&J respectfully requests that the Court dismiss the Consolidated Amended Complaint, or, in the alternative, stay this action pending the completion of the Special Committee's investigation.

Respectfully submitted,

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