IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

LOUISIANA MUNICIPAL POLICE EMPLOYEES' RETIREMENT SYSTEM, Plaintiff, v. DAVID PYOTT, HERBERT W. BOYER, LOUIS J. LAVIGNE, GAVIN S. HERBERT, STEPHEN J. RYAN, LEONARD D. SCHAEFFER, MICHAEL R. GALLAGHER, ROBERT ALEXANDER INGRAM, TREVOR M. JONES, DAWN E. HUDSON, RUSSELL T. RAY, and DEBORAH DUNSIRE, Defendants, and ALLERGAN, INC., Nominal Defendant.	)	C.A. No. 5795-VCL

NOMINAL DEFENDANT ALLERGAN, INC.'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS THE COMPLAINT

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

PRELIMINARY STATEMENT[1]

On September 3, 2010, just *two days* after Allergan announced that it had settled off-label marketing claims with the FDA, Plaintiff raced to file this derivative action without fully analyzing the facts or making a demand on Allergan's Board. As addressed in Allergan's opening brief, demand should not be excused. Even after amendment, the Complaint neglects to plead a single fact against *any* of Allergan's twelve sitting directors—let alone a majority of the Board—that creates a reasonable doubt that any members of the Board have a conflict that would render him or her unable to exercise independent business judgment in responding to a demand. Under both *Aronson* and *Rales*, the Complaint should therefore be dismissed.

In its opposition brief, Plaintiff argues that demand would be futile for two reasons. **First**, according to Plaintiff, "demand is excused because the Individual Defendants' scheme was *ultra vires* and, as such could not constitute a valid exercise of business judgment." (PAB 20.) More specifically, Plaintiff contends that, under the second prong of *Aronson*, its allegations "raise a reasonable doubt that the business judgment rule protects the Board's decision to approve illegal Strategic Plans." (*Id.*) Yet, nowhere in in its Complaint does Plaintiff specify the Board's involvement in any "scheme" or how any of Allergan's Strategic Plans were "illegal." At most, Plaintiff suggests that "many" of Allergan's Strategic Plans forecast sales for off-label *uses of* BOTOX®. It is settled law, however, that doctors are free to prescribe drugs for off-label uses and drug companies are equally free to make sales for off-label uses. While federal law proscribes *marketing* for off-label uses, the Complaint never alleges that any Allergan director engaged in prohibited activities. Plaintiff simply concludes, without factual support, that there was an illicit "scheme" directed by unspecified members of the Board at unspecified times in

[1] Defined terms herein are used as defined in Allergan's opening brief in support of its motion to dismiss, which is cited in the form of "AOB __." (D.I. 18.) Citations to the Individual Defendant's opening brief in support of its motion to dismiss are in the form "IOB __." (D.I.19.) Citations to Plaintiff's answering brief in opposition to Defendants' motions to dismiss are in the form "PAB __ ." (D.I. 27.)

unspecified ways, which was approved in unspecified versions of Allergan's strategic plan in unspecified provisions by unspecified Board members on unspecified occasions. This hardly meets the heightened pleading requirements of Court of Chancery Rule 23.1.

Yet, interestingly, Plaintiff maintains in its brief that its Complaint is "replete with concrete facts showing that the Defendants knew and approved the illegal marketing scheme." (PAB 4.) At pages 21-22 of its brief, Plaintiff purports to list seventeen actions taken by "the Board" in support of such a scheme. In fact, examination of the paragraphs of the Complaint cited in support of each reveals that "Allergan"—and not the Board—is alleged to have taken these actions, most of which, if assumed true, appear to have been taken by low-level employees and not by a director of a global health care company. These include, for example, providing injectors for seminars and training sessions, providing free vials of BOTOX® to sales representatives and field personnel, or hiring low level managers. (*See* bullets 6-9 at PAB 21.) On occasion, the Complaint states in a conclusory fashion that "the Board knew" of such activities, but nowhere does the Complaint state which directors knew, how they knew, when they knew, what they knew, or what they did in response to such "knowledge." This Court has consistently rejected such conclusory pleadings and should do the same here. Although Plaintiff relies on two other government investigation and settlement cases for a different result, the plaintiffs in those cases pled specific facts establishing that the directors were aware of known violations and in their pleadings provided evidence of board inaction in the face of direct knowledge. In sharp contrast, the Complaint here contains no particularized facts showing either wrongful director action (under the *Aronson* test) or director knowledge coupled with inaction (under the *Rales* test). Accordingly, the Complaint should be dismissed.

In its **second** argument, Plaintiff contends that "demand should be excused because the Individual Defendants face a substantial likelihood of personal liability." (PAB 29.) Yet, neither

the Complaint nor the criminal information from which it is drawn contains a single fact showing that Allergan's Board members personally engaged in wrongdoing, approved of any off-label marketing activities, or learned of illegal marketing of BOTOX® and looked the other way.

In recognition of the shortcomings of its Complaint, Plaintiff improperly appends to and references in its opposition brief (i) the government's sentencing memorandum, and (ii) Allergan's guilty plea and plea agreement. Again, neither of these documents references any misconduct or knowledge of misconduct by any Allergan director. Nor, after its detailed investigation, did the Government see fit to take action against any of Allergan's board members personally.

Plaintiff argues that the Board knew that Allergan was engaged in off-label marketing of BOTOX® because Allergan received three unrelated FDA letters over the course of the last decade. (Am. Compl. ¶ 94.) None of these letters refers to the alleged off-label marketing and, thus, provide no basis for the Court to infer that these letters somehow alerted the Board to supposed off-label marketing of BOTOX®. Nor does the Complaint allege which Board members received notice of the FDA letters, whether and how the letters reached the Board, and what, if anything, the Board did in response. Even more nonsensical is Plaintiff's suggestion that the Court should infer knowledge of off-label marketing activities from the bare fact that "at least nine of the Individual Defendants . . . are doctors themselves and/or have experience in the medical field." (PAB 30.) Such medical experience hardly proves knowledge of misconduct. Nor has Allergan itself admitted knowledge in its plea. Allergan pled guilty to a single, strict liability misdemeanor "misbranding" charge, which includes no knowledge or *mens rea* component.

Finally, Plaintiff's own pleading refutes its repeated contention that Allergan's Board did nothing to curtail illegal conduct. The Complaint itself details the compliance systems and

controls that Allergan's Board put in place, (Am. Compl. ¶¶ 75, 115-116), and alleges no specific red flags that should have alerted the Board to off-label marketing of BOTOX®. In short, Plaintiff has not succeeded in alleging demand futility, and the Complaint should be dismissed.

STATEMENT OF FACTS

Allergan restates its recitation of the facts as set forth in its opening brief in support of its motion to dismiss. (AOB 5-9.) Plaintiff's opposition brief introduces new materials that are not properly before the Court and should be disregarded, including the references to the Sentencing Memorandum, (*see, e.g.*, PAB nn.4, 6-15, 23), and to "facts" quoted from various websites such as the Center for Responsive Politics. (*See, e.g.*, PAB 14-15, 17 n.16, 27 n.21.)

Plaintiff makes no motion to have these documents recognized and has no basis through which it could introduce these documents on a motion to dismiss. The exceptions to the general prohibition against considering documents outside of the pleadings at the motion to dismiss stage are limited to two situations, "when the document is integral to a plaintiff's claim and incorporated into the complaint" and "when the document is not being relied upon to prove the truth of its contents." *Vanderbilt Income & Growth Assocs., L.L.C. v. Arvida/JMB Mgrs., Inc.*, 691 A.2d 609, 613 (Del. 1996). Neither of these exceptions is present. Plaintiff itself recognizes the impropriety of using the Sentencing Memorandum in its opposition brief. (*See* PAB 2 n.4 ("To the extent Plaintiff refers to the Sentencing Memorandum and Allergan Plea, we have done so in footnotes rather than in the text of this opposition to the motions.").) Outside documents cited in the Plaintiff's opposition brief should be disregarded in assessing Defendants' motions to dismiss. Demand futility is assessed solely based on the allegations in the complaint. *See, e.g.*, *Rattner v. Bidzos*, 2003 WL 22284323, at *7 (Del. Ch. Oct. 7, 2003) ("In considering whether a

derivative plaintiff has satisfied Court of Chancery Rule 23.1, [courts are] confined to reviewing the well-pled allegations of the complaint.")

Even if the outside documents had been incorporated in the Complaint, Plaintiff still could not successfully plead demand futility. Reference to these documents demonstrates how deficient Plaintiff's allegations are and likely will continue to be. For example, the Sentencing Memorandum cited by Plaintiff contains no attributions of liability to directors. In contrast, the court in *Pfizer* commented on how the complaint there was "seemingly corroborated in material respects by the Government's own charges that led to the 2009 settlement" and cited to a government sentencing memorandum that had noted that the marketing scheme was implemented "with knowledge and approval of senior management." *In re Pfizer Inc. S'holder Deriv. Litig.*, 2010 WL 2747447, at *2, 4 (S.D.N.Y. July 13, 2010). Plaintiff's inability to allege any specific facts about director participation or knowledge despite relying on the publicly available sources scrutinizing the very conduct at issue highlights the problems with the Complaint. The Complaint pleads no facts that support finding demand futility and should be dismissed.

ARGUMENT

I. THE COMPLAINT MUST BE DISMISSED FOR FAILURE TO MAKE A PRE-SUIT DEMAND

The Complaint is deficient for its failure to make allegations about the participation or knowledge of the Board in the actions that led to the Company's multiple settlements. Plaintiff's strategy is clear from its opposition brief: it hopes to impute all of Allergan's actions in the off-label marketing of BOTOX® to the Board. However, Delaware law is clear that bad outcomes do not equal bad faith and, furthermore, specific allegations about director conduct are required to establish demand futility. The rationale behind this is simple—directors have no duty to ferret out wrongdoing they had no reason to know existed and are not responsible for ensuring all employees comply with the law. If demand could be excused simply because wrongdoing occurred, there effectively would be no demand requirement, and companies would always have to cede control of the company's litigation to plaintiffs, rather than their company's duly elected board members. Although Plaintiff recounts in its opposition brief all of the prosecutorial allegations it is able to collect about Allergan's conduct that led to the strict liability criminal misdemeanor charge, it is unable to rescue its Complaint's deficiencies with respect to specific allegations about the directors.

Lacking any such specific allegations about director action or director knowledge and inaction, the Complaint fails the test for demand futility, under *Aronson* and *Rales*. *See White v. Panic*, 783 A.2d 543, 550-51 (Del. 2001) ("Where . . . a stockholder plaintiff initiates a derivative action without making a pre-suit demand on the board, Rule 23.1 requires that the complaint allege with particularity the reasons for the plaintiff's failure to demand action from the board."); *Brehm v. Eisner*, 746 A.2d 244, 254 (Del. 2000) ("A prolix complaint larded with conclusory language, like the Complaint here, does not comply with these fundamental pleading

mandates."). As discussed in Allergan's opening brief, the gravamen of the Complaint is that the Board failed to take action to stop particular practices as they relate to BOTOX®, (AOB 10-13), and is thus most appropriately analyzed under the test set forth in *Rales*. (AOB 12-23; *see also infra* Section I.B).

Recognizing that demand is rarely excused for claims of board inaction, Plaintiff attempts to sidestep the *Rales* analysis altogether by arguing that its theory of the case is based on director action. Where the claim is of affirmative board action, the two-pronged *Aronson* test determines whether demand is excused. *Wood v. Baum*, 953 A.2d 136, 140 (Del. 2008) (holding that *Aronson* applies where a plaintiff alleges particularized facts that the directors made a "conscious business decision in breach of their fiduciary duties"); *accord In re Citigroup Inc. S'holder Deriv. Litig.*, 964 A.2d 106, 120, 136 (Del. Ch. 2009). Contrary to Plaintiff's suggestions, Allergan analyzed Plaintiff's allegations under both *Aronson* and *Rales*. (AOB 10-31.) And regardless of whether Plaintiff's allegations are cast as arising from affirmative board action or inaction, Plaintiff has not and cannot establish demand futility because it did not plead any non-conclusory particularized allegations as required by Rule 23.1.[2] Accordingly the Complaint should be dismissed for failure to meet either the *Aronson* or *Rales* tests for demand futility.

[2] Plaintiff understates (or misunderstands) the legal standards for demand futility. (*See* PAB 19-20.) The test is not, as Plaintiff suggests, whether "the plaintiff has alleged facts sufficient to create a reasonable doubt concerning the disinterestedness and independence of a majority of the Board, which is determined from the consideration of all the facts taken together." (PAB 19 (citing *Harris v. Carter*, 582 A.2d 222, 229 (Del. Ch. 1990) and *In re Cendant Corp. Deriv. Action Litig.*, 189 F.R.D. 117, 128 (D.N.J. 1999).) The applicable analysis here depends on the particularized factual allegations and whether Plaintiff's claims are based on the board's failure to act (*Rales*) or board action or approval of a transaction (*Aronson*). (*See* AOB 10-12.) Even considering the totality of the circumstances approach that Plaintiff advocates, it "does not permit the Plaintiff to rely only on general allegations and avoid a director-by-director analysis." *Coca-Cola Enters., Inc. Deriv. Litig.*, 478 F. Supp. 2d 1369, 1378 (N.D. Ga. 2007) (applying Delaware law and granting motion to dismiss on demand futility grounds where plaintiff failed to plead particularized allegations). Nor can Plaintiff rely on "aggregating a number of factors, none of which excuses demand, [to] somehow excuse demand." *In re Pfizer Inc. Deriv. Sec. Litig.*, 503 F. Supp. 2d 680, 686 (S.D.N.Y. 2007) (applying Delaware law and granting motion to dismiss on demand futility grounds).

A. Plaintiff's Claims Of Director Action Fail To Establish Demand Futility Under *Aronson*

The two-pronged *Aronson* test for demand futility "requires that the plaintiff allege particularized facts creating a reason to doubt that (1) the directors are disinterested and independent or that (2) the challenged transaction was otherwise the product of a valid exercise of business judgment." *Wood*, 953 A.2d at 140 (quotations and internal punctuation marks omitted). To satisfy either prong of the *Aronson* test, Plaintiff's allegations of demand futility must also comply with Rule 23.1's "stringent requirements of factual particularity." *Brehm*, 746 A.2d at 254.

1. Plaintiff Fails To Plead Particularized Facts Showing A Majority Of The Board Is Interested Or Lacks Independence

Nothing in the Complaint creates a reason to doubt the disinterest or independence of a single Allergan director, let alone a majority of the Allergan Board. Plaintiff has effectively waived argument on the first prong of *Aronson* by failing to provide any analysis on this issue in its opposition brief. (*Compare* AOB 13-17, 24-25 (analyzing why Plaintiff has failed to plead any particularized facts showing that a majority of the directors are interested or lack independence) *with* PAB 20 (beginning its argument with an analysis of its allegations under the second prong of *Aronson*).) *See Emerald Partners v. Berlin*, 2003 WL 21003437, at *43 (Del. Ch. Apr. 28, 2003) ("It is settled Delaware law that a party waives an argument by not including it in its brief."), *aff'd*, 840 A.2d 641 (Del. 2003); *King v. VeriFone Holding, Inc.*, 994 A.2d 354, 360 n.21 (Del. Ch. 2010) ("A party's failure to raise an argument in its answering brief constitutes a waiver of that argument."); *Emerald Partners v. Berlin*, 726 A.2d 1215, 1224 (Del.

1999) ("Issues not briefed are deemed waived."). Thus, any argument regarding director interest and lack of independence should be considered waived.[3]

2. Plaintiff Fails To Plead Particularized Facts Sufficient To Create A Reasonable Doubt As To Whether The Board Exercised Valid Business Judgment

Plaintiff has failed to plead particularized facts that satisfy the second prong of *Aronson* by creating "(1) a reason to doubt that the action was taken honestly and in good faith or (2) a reason to doubt that the board was adequately informed in making the decision." *In re Dow Chem. Co. Deriv. Litig.*, 2010 WL 66769, at *9 (Del. Ch. Jan. 11, 2010) (quotations omitted). "Plaintiff faces a substantial burden, as the second prong of the *Aronson* test is directed to extreme cases in which despite the appearance of independence and disinterest[,] a decision is so extreme or curious as to itself raise a legitimate ground to justify further inquiry and judicial review." *Greenwald v. Batterson*, 1999 WL 596276, at *7 (Del. Ch. July 26, 1999) (quotations omitted). Plaintiff appears to address this argument under its first point heading—"Demand is Excused Because the Individual Defendants' Scheme Was *Ultra Vires* and, As Such, Could Not Constitute a Valid Exercise of Business Judgment." (PAB 20-29.) Plaintiff has not come close to meeting its burden under the second prong of *Aronson*.

a. Plaintiff Has Pled No Particularized Facts That Create A Reason To Doubt That Affirmative Actions Were Taken Honestly And In Good Faith

Because the Court's inquiry under the second prong of *Aronson* is "predicated upon concepts of gross negligence," *Aronson v. Lewis*, 473 A.2d 805, 812 (Del. 1984), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000), Plaintiff must show how "defendants completely and utterly failed to even attempt to meet their duties" sufficient to

[3] To the extent Plaintiff's independence argument falls under its second point heading titled "Demand Is Excused Because The Individual Defendants Face A Substantial Likelihood of Personal Liability," (*see* PAB 29-32), Plaintiff has not come forth with the necessary factual allegations to excuse demand. Such deficiencies will be discussed below under the *Rales* analysis. (*See infra* Section I.B.1.)

establish bad faith on behalf of the Board members. *Dow Chem.*, 2010 WL 66769, at *10 (quotations omitted). Although Plaintiff says that the Complaint is "replete with concrete facts showing that Defendants knew and approved the illegal marketing scheme that led to the [government settlement]" (PAB 4), Plaintiff utterly fails to plead any such facts in the Complaint. There are no allegations that permit any analysis of the "substance of the transaction and the process by which the board approved it." *Carauna v. Saligman*, 1990 WL 212304, at *4 (Del. Ch. Dec. 21, 1990). Nor are there facts that evidence the particular wrongs of each director. Plaintiff's allegations in this respect are conspicuously missing. *See, e.g.*, *Guttman v. Huang*, 823 A.2d 492, 503 (Del. Ch. 2003) ("Entirely absent from the complaint are well-pled, particularized allegations of fact detailing the precise roles that these directors played at the company, the information that would have come to their attention in those roles, and any indication as to why they would have perceived the [problems].") (citation omitted); *Wood*, 953 A.2d at 143 ("This case is but another replay of other similar cases where the plaintiff failed to allege with particularity any facts from which it could be inferred that particular directors knew or should have been on notice of alleged . . . improprieties, and any facts suggesting that the board knowingly allowed or participated in a violation of law."); *King v. Baldino*, 648 F. Supp. 2d 609, 623 (D. Del. 2009) ("A significant problem with plaintiff's complaint is the failure to identify which individual director defendants breached his or her fiduciary duties, and when those duties were breached.")

Notwithstanding the Complaint's lack of particularized allegations pertaining to Board action, Plaintiff argues in its opposition brief that "[d]efendants consciously caused and allowed Allergan to engage in an illegal off-label marketing scheme for BOTOX® as the centerpiece of the Company's Strategic Plans for nearly a decade" and that "every member of the Allergan Board was directly involved in, and approved, the illegal off-label marketing scheme for

BOTOX®." (PAB 20-21 (emphasis omitted).) This conclusory argument is not supported by a single fact pled in the Complaint. First, Plaintiff provides no actual instances of Board or director action through particularized facts showing the Board's actual review and approval of off-label marketing of BOTOX®. Plaintiff provides no facts regarding when any such approval occurred, which directors approved it, how it was implemented, the Board's involvement in any purported implementation, or how the Board failed to remain informed or adequately inquire into the off-label marketing activities. (*See* AOB 26.) Absent any such particularized facts, Plaintiff cannot meet its burden of establishing demand futility. Second, Plaintiff misstates the overarching regulatory scheme under which the Government's investigation falls (1) by failing to acknowledge that off-label sales are legal and, absent other facts, cannot be used to impute knowledge of illegal marketing and (2) by failing to acknowledge the nature of the strict-liability offense to which Allergan pled guilty.

Plaintiff's allegations regarding the Board's "scheme" are wholly conclusory. Plaintiff's assertions that the Individual Defendants were aware of a "scheme" regarding BOTOX® and that this "scheme" is *ultra vires* represents legal slight-of-hand. (*See* PAB 21-22 (citing Am. Compl. ¶¶ 35, 38, 39, 40-48, 50-56, 58-77).) First, it is an improper argument because "a plaintiff cannot use [its] briefing to rewrite [its] complaint." *Morgan v. Cash*, 2010 WL 2803746, at *8 n.64 (Del. Ch. July 16, 2010); *accord McGowan v. Ferro*, 2002 WL 77712, at *4 n.27 (Del. Ch. Jan. 11, 2002) ("Arguments contained in a brief, however, cannot cure a defect caused [by] the failure to allege critical facts in the complaint."). Nothing in the Complaint alleges that this "scheme" is *ultra vires*. Plaintiff's framing of the issue assumes that Allergan's Strategic Plans were illegal, yet the Complaint neglects to point to or quote anything from those plans or specify in any way how they were improper, let alone "illegal." Likewise, while Plaintiff states in its brief that "every member of the board was directly involved in, and

approved, the illegal off-label marketing scheme for BOTOX®," (PAB 21 (emphasis omitted)), there is not a single factual allegation in the Complaint tying any director to such approval or implementation.

Plaintiff seeks to remedy its pleading deficiencies by attributing to the Board actions that were pled in its Complaint to have been taken by others. Most of the actions in Plaintiff's laundry list of purported affirmative "Board" actions were in fact plead as actions by "Allergan" in the Complaint, including that Allergan:

- ***Received*** detailed Customer Surveys showing that over two-thirds of BOTOX® sales;
- ***Directed*** the "CD/HA Initiative" through which Allergan exploited its on-label CD indication to grow off-label pain and headache sales;
- ***Promoted*** the use of off-label seminars and presentations, at which physicians, at which physicians where instructed on various off-label uses;
- ***Provided*** Allergan-paid injectors for seminars and other off-label injection training sessions and workshops;
- ***Provided*** free vials of BOTOX® to its sales representatives;
- ***Facilitated*** the hiring of Provider Reimbursement Account Managers;

(PAB 21-22 (emphasis added).) (*Compare* PAB 21-22 (emphasis added, attributing actions to Board) *with* Am. Compl. ¶ 35, (Allergan used Customer Surveys), ¶ 40 (the Company developed the "CD/HA Initiative"), ¶ 44 (Allergan held off-label seminars and presentations), ¶ 46 (Company had Allergan-paid injectors and other off-label injection training sessions and workshops), ¶ 47 (Allergan provided sales representatives and field personnel with free vials of BOTOX®), ¶ 48 (Allergan employed Provider Reimbursement Account Managers).) Plaintiff's attempt, through its briefing, to attribute corporate action to directors not only fails to satisfy the requirements of Rule 23.1 with respect to complaints, but misapprehends the role of the directors

in a company of Allergan's size, which typically does not include involvement with the day-to-day aspets of the company's business.

Of the forty allegations purporting wrongful acts by the Board now cited by Plaintiff, only four[4] even mention the Board, directly or indirectly. *See* Am. Compl. ¶ 38 (alleging that Allergan and its Board executed a strategic plan to promote and sell BOTOX®, not based on any fact but because a federal prosecutor said the Company made it a top corporate priority to maximize sales of non-FDA off-label uses); ¶ 55 (alleging that Allergan and the Board knew that the WE MOVE guidelines were exceptionally high because of animal studies the Company conducted in the 1990s); ¶ 60 (alleging that some non-specific "false statements" "were known to the Board" because they were either current or former executives of the Company or because of their practical experience); ¶ 63 (alleging that, according to a *qui tam* complaint, that "Defendants knew that the results of the Company's Phase II trials did not support BOTOX® as prophylactic therapy for various forms of headache" because of a statement made in 2007 by an Allergan Regional Scientific Specialist Manager).

None of these four allegations, however, alleges any actual action taken, either by the Board or any individual on the Board. At best, and like the rest of the Complaint, these hearsay-based allegations merely paraphrase government advocacy. More importantly, these allegations are wholly conclusory and therefore should be rejected. *Beam ex. rel. Martha Stewart Living Omnimedia, Inc. v. Stewart*, 845 A.2d 1040, 1048 (Del. 2004) ("Conclusory allegations are not considered as expressly pleaded facts or factual inferences.") (quotations and internal punctuation marks omitted); *Guttman*, 823 A.2d at 493-94 (rejecting demand futility allegations

[4] The allegations in paragraphs 72-77 of the Complaint make conclusory allegations regarding the Board's disclosure obligations. As discussed in Allergan's opening brief, (AOB 22-23), and further below in Section I.B.3, these allegations are insufficient to show a substantial likelihood of liability on a disclosure violation.

lacking particularized facts and observing that "[w]hen the case most cries out for the pleading of real facts . . . the complaint is at its most cursory, substituting conclusory allegations for concrete assertions of fact"); *Desimone v. Barrows*, 924 A.2d 908, 927 (Del. Ch. 2007) (requiring "non-conclusory factual allegations" and refusing to "accept cursory contentions of wrongdoing as a substitute for the pleading of particularized facts").

Without any particularized non-conclusory allegations of Board action, the Complaint fails the second prong of *Aronson*. "Demand futility under the second *Aronson* prong arises only in an extreme case of directorial failure. The situation must be one of the rare cases in which a transaction may be so egregious on its face that board approval cannot meet the test of business judgment, and a substantial likelihood of director liability exists." *Norfolk Cnty. Ret. Sys. v. Jos. A. Bank Clothiers, Inc.*, 2009 WL 353746, at *7 n.50 (Del. Ch. Feb. 12, 2009) (quotations and internal punctuation marks omitted), *aff'd mem.*, 977 A.2d 899 (Del. 2009). Plaintiff's failure to plead any facts showing that the action at issue is "so egregious on its face" is fatal to its *Aronson* argument.

Plaintiff misunderstands the regulatory scheme and plea. To fit its argument within *Aronson*, Plaintiff has reiterated its conclusory argument that the Individual Defendants (a) formulated and approved the Strategic Plans during the period from 1997 through at least 2008, which in some unexplained way illegally promoted off-label uses of BOTOX®, (b) directed alleged improper actions taken to support that initiative, and (c) concealed their unidentified actions by issuing false and misleading proxy statements. (PAB 22.) Nothing in the Complaint, however, supports these assertions.

Plaintiff's argument regarding off label use is just as conclusory as its allegations. (*See* PAB 22-24.) To clear up the record, it must be pointed out that Plaintiff misstates the regulatory scheme for off-label use, as well as how plea agreements operate in the criminal justice system.

Plaintiff appears to argue any off-label use is per se illegal. In reality, off-legal use is permissible. In fact, "'[o]ff-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize.'" *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 n.5 (2001) (quoting Beck & Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 72 (1998)); *see also* IOB 5-8 (providing a succinct background of off-label uses for FDA approved drugs); Individual Defendants' Reply Brief 2-3 (providing additional background). Dissemination of medical and scientific information regarding off-label use also is not illegal. *See King*, 648 F. Supp. at 612 (explaining that while "there are strict regulations regarding promotions for off-label use," the Food and Drug Administration Modernization Act of 1997 authorizes a manufacturer to communicate information regarding an unapproved use to inform practitioners of risks associated with the drug, so long as it does not promote the unapproved use); *see also Guidance for Industry: "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms* at 2 (Jan. 2004), *available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm070068.pdf (summarizing the FDA distinction between FDA-approved labeling and promotional labeling). Allergan pled guilty to a single misdemeanor "misbranding" charge, which is a strict liability offense, covering the period of 2000 through 2005. (Am. Compl. ¶ 98.) Misbranding and promotion for off-label use are two distinct things.

Plaintiff's attempt to use a case about a withdrawal of a guilty plea, (*see* PAB 24 n.19 (quoting *United States v. Sgarlat*, 705 F. Supp. 2d 347 (D.N.J. 2010)), to somehow suggest that a guilty plea for a strict liability crime imputes knowledge sufficient to prove culpability for another crime is both disingenuous and illogical. The resulting guilty plea for misdemeanor

misbranding has no bearing on the Board's intent or knowledge and cannot be used to show knowledge or awareness of what Plaintiff terms "widespread" "off-label marketing practices." (*See* AOB 15; IOB 9.) Despite what Plaintiff attempts to infer from the guilty plea, (*see* PAB 24 n.19), Allergan did not admit to any offense with a scienter element. FDCA violations, like those at issue in the plea agreement, are "strict liability" offenses that do not turn on awareness of wrongdoing or consciousness of fraud. *United States v. Dotterweich*, 320 U.S. 277, 281 (1943) (holding that FDCA violations are strict-liability offenses that do not turn on awareness of or intent to commit wrongdoing). Plaintiff's allegations are also contrary to the express terms of the Settlement Agreement, where Allergan disclaimed any and all wrongdoing related to allegations about government reimbursements. (*See* AOB Aff. Ex. C at 5.) The Settlement Agreement contained no findings that any of the board members personally engaged in any wrongdoing. (*See id.* ("Neither this Agreement, its execution, nor the performance of any payment, nor the fact of any settlement, is intended to be, or shall be construed as an admission of liability or wrongdoing, or other expression reflecting on the merits of the dispute by Allergan.").) Plaintiff's attempt not only to suggest wrongdoing by the corporation but further to suggest wrongdoing by directors from such a plea relies on a deliberate misunderstanding of the regulatory regime and the terms of the plea, and cannot be the basis for a successful demand futility argument.

Plaintiff's argument using these conclusory allegations and its misunderstanding of the regulatory scheme should be rejected. Throughout its *Aronson* argument, Plaintiff attempts to equate misbranding with off-label promotion. (*See* PAB 22-24.) Based on this erroneous premise, and because of the guilty plea, Plaintiff argues that the Board must have violated the law *per se*, and therefore the business judgment rule does not apply. (*See id.* (arguing that the "scheme" is *ultra vires*).) Plaintiff is incorrect. First, as discussed above,

Plaintiff has pled no particularized facts concerning board action regarding this purported "scheme." Second, a strict liability offense, by its nature, does not have a *mens rea* element to it. Plaintiff's attempt to use the guilty plea to somehow impute knowledge to the Board rests solely on its assumption that the Board ***must*** have been involved if wrongdoing occurred. This premise is wrong as a matter of law. *See Stone ex rel. AmSouth Bancorp. v. Ritter*, 911 A.2d 362, 373 (Del. 2006) (holding in case where corporation incurred $50 million government fine that "[w]ith the benefit of hindsight, the plaintiffs' complaint seeks to equate a bad outcome with bad faith. The lacuna in the plaintiffs' argument is a failure to recognize that the directors' good faith exercise of oversight responsibility may not invariably prevent employees from violating criminal laws, or from causing the corporation to incur significant financial liability, or both."); *King*, 648 F. Supp. 2d at 625-26 (holding complaint that partially premised demand futility allegations on mere fact of government investigations that eventually resulted in a settlement agreement and guilty plea improperly "[sought] to equate a bad outcome with bad faith").[5]

Plaintiff's failure to allege any particularized facts concerning board action also renders its reliance on cases involving specific board action, such as options backdating or issuance of shares, unpersuasive. (*See* PAB 22-24 (citing *Ryan v. Gifford*, 918 A.2d 341 (Del. Ch. 2007) (options backdating), *In re Nuveen Fund Litig.*, 1996 WL 328001 (N.D. Ill. June 11, 1996) (rights offering)), *Reimel v. MacFarlane*, 9 F. Supp. 2d 1062 (D. Minn. 1998) (shareholders rights plan); *Desimone v. Barrows*, 924 A.2d 908 (Del. Ch. 2007 (options backdating); *Metro*

[5] Additional cases only reinforce this point. *See Graham v. Allis-Chalmers Mfg. Co.*, 188 A.2d 125, 131 (Del. 1963) ("[I]ndividual director defendants are not liable as a matter of law merely because, unknown to them, some employees of [the corporation] violated the anti-trust laws thus subjecting the corporation to loss."); *In re Caremark Inc. Int'l Deriv. Litig.*, 698 A.2d 959, 971-72 (Del. Ch. 1996) ("If the directors did not know the specifics of the activities that lead to the indictments, they cannot be faulted. The liability that eventuated in this instance was huge. But the fact that it resulted from a violation of criminal law alone does not create a breach of fiduciary duty by directors."); *Lewis v. Fites*, 1993 WL 47842 (Del. Ch. Feb. 19, 1993) (holding that entry of an SEC Consent Order that established violations of federal securities laws does not render directors interested when "[t]he Consent Order does not contain any admission of wrongdoing and it does not include any findings concerning [the] directors").

Commc'n Corp. BVI v. Advanced Mobilecomm Techs. Inc., 854 A.2d 121 (Del. Ch. 2004) (finding allegations of board's knowledge of bribery sufficient to state a common law fraud claim); *Cal. Pub. Emps. Ret. Sys. v. Coulter*, 2002 WL 31888343 (Del. Ch. Dec. 18, 2002) (options "repricing"); *Sanders v. Wang*, 1999 WL 1044880 (Del. Ch. Nov. 8, 1999) (issuing stock).)[6] Simply asserting that the business judgment rule does not apply to illegal activity and citing cases generally supporting that point cannot withstand legal scrutiny when the Complaint contains no allegations, particularized or otherwise, that the Board took any action that led to the ultimate action (the settlement) from which Plaintiff now seeks relief. Plaintiff's attempts to conjure a claim out of this conclusory argument should reveal what Plaintiff is trying to do: equate a bad outcome with bad faith. As previously explained, the latent premise to Plaintiff's argument—that because wrongdoing occurred, the Board must have failed in its duties—has been explicitly foreclosed by *Caremark* and its progeny. *See, e.g.*, *In re Caremark*, 698 A.2d at 969 ("[N]either corporate boards nor senior officers can be charged with wrongdoing simply for assuming the integrity of employees and the honesty of their dealings on the company's behalf."); AOB 27-30. It should not be accepted here.

In further support of its *Aronson* argument, Plaintiff also attempts to align its case with *In re Pfizer Inc. Shareholder Derivative Litigation*, 2010 WL 2747447 (S.D.N.Y. July 13, 2010), and *In re Abbott Laboratories Derivative Shareholders Litigation*, 325 F.3d 795 (7th Cir. 2003). Neither case applies to the facts at hand. Both will be addressed in the section where these cases truly belong, under a *Rales* analysis. (*See infra* Section I.B.)

Because Plaintiff has not alleged any particularized facts concerning any board action, there is no basis for the Court to conclude that the directors acted in any way sufficient to create

[6] Curiously, in the *Reimel* case cited by Plaintiff, the District Court of Minnesota found futility was not "plain from the circumstances," and required the plaintiff in that case to make a demand upon the board. *Reimel v. MacFarlane*, 9 F. Supp. 2d 1062, 1067 (D. Minn. 1998).

a reason to doubt that the action was taken honestly and in good faith, much less in a manner that is contrary to any rational business purpose. The allegations of the Complaint do not and cannot satisfy the second prong of *Aronson*.

b. Plaintiff Has Pled No Particularized Facts That Create A Reason To Doubt That The Board Was Adequately Informed In Making Affirmative Decisions

Plaintiff failed to address Allergan's argument that Plaintiff has alleged no particularized facts that the directors breached the duty of procedural due care or were inadequately informed. (AOB 27-30.)[7] Its failure to brief this issue results in waiver of its argument for this aspect of the *Aronson* analysis. *See Emerald Partners*, 2003 WL 21003437, at *43; *VeriFone Holding, Inc.*, 994 A.2d at 360 n.21; *Emerald Partners*, 726 A.2d at 1224.

3. Plaintiff Has Waived its "Commission of Waste" Claim Under Rule 23.1

Plaintiff has also ignored Allergan's argument that Plaintiff's perfunctory "commission of waste" claim fails to meet Rule 23.1's requirements and should be dismissed. (AOB 30-31.) "To excuse demand on grounds of corporate waste, plaintiffs must allege particularized facts that the consideration received by the corporation was so inadequate that no person of ordinary sound business judgment would deem it worth that which the corporation has paid." *Ash v. McCall*, 2000 WL 1370341, at *6 (Del. Ch. Sept. 15, 2000) (quotations and citation omitted) (dismissing waste claims for failure to plead demand futility). Although Plaintiff addresses waste in the 12(b)(6) context, (*see* PAB 44-45), it has not provided any analysis under Rule 23.1 and has therefore waived this argument. *See Emerald Partners*, 2003 WL 21003437, at *43; *VeriFone*

[7] Plaintiff, however, appears to concede Allergan's argument that there are no particularized allegations regarding how the individual directors' previous experiences have any relevance to Allergan's involvement with the Government's BOTOX® investigation or how they would have put them on a "heightened alert" to the issues for which they eventually settled. (*Compare* AOB 30 *with* PAB 30 n.24.)

Holding, Inc., 994 A.2d at 360 n.21; *Emerald Partners*, 726 A.2d at 1224. Plaintiff's "waste" claim should be dismissed.

For these and for the reasons discussed in the opening brief (AOB 24-31), Plaintiff cannot satisfy either prong of *Aronson*. The Complaint should be dismissed for failure to comply with Rule 23.1.

B. Plaintiff's Claims of Director Inaction Fail To Establish Demand Futility Under *Rales*

Given that Plaintiff alleges roughly a decade of wrongs, without providing any particularized facts demonstrating affirmative board action, the Complaint raises *Caremark* claims. Under *Rales*, demand is excused in the context of *Caremark* allegations where a plaintiff comes forth with particularized facts to establish that (1) a majority of the board is interested or lacks independence or (2) the directors face a substantial likelihood of liability. *Rales v. Blasband*, 634 A.2d 927, 934 (Del. 1993); *see also Guttman*, 823 A.2d at 501. Demand futility in this instance should be analyzed under this framework.

Notably, Plaintiff makes no attempt to establish that demand is excused under *Rales*. (PAB 29-32, 39-43.) Instead, Plaintiff concentrates its efforts on avoiding and ignoring a *Rales* analysis. Application of *Rales* clearly shows that Plaintiff has not pled allegations sufficient to prove demand futility.

That this action should be analyzed under *Rales* is essentially conceded by Plaintiff in its attempt to equate this case to *In re Pfizer Inc. Shareholder Derivative Litigation*, 2010 WL 2747447 (S.D.N.Y. July 13, 2010). (PAB 25-28.) Despite Plaintiff's assertion that *Pfizer* applies the *Aronson* test, the Southern District of New York actually applied *Rales* to find demand futility where the named directors "intentionally approved or deliberately disregarded Pfizer's alleged promotion of off-label drugs and its payment of alleged illegal kickbacks to

health care professionals." *Id.* at *1. In finding the *Rales* standard met, *id.* at *8, the *Pfizer* court found that "the allegations of the Complaint evidence misconduct of such pervasiveness and magnitude, undertaken in the face of the board's own express formal undertakings to directly monitor and prevent such misconduct, that the inference of deliberate disregard by each and every member of the board is entirely reasonable." *Id.* at *7.

As Plaintiff acknowledges, (PAB 27 n.21), *Pfizer* is readily distinguishable from the instant case. In *Pfizer*, the court confronted particularized demand futility allegations describing facts about how the company at issue had been subject to four government settlements—one of which involved an off-label "marketing scheme, implemented 'with knowledge and approval of senior management,'" 2010 WL 2747447, at *2, another of which uncovered the corporation's "own records show[ing] that [illegal] activities generated an estimated $664 million" in revenue, *id.* at *3—and three corporate integrity agreements, "express formal undertakings to directly monitor and prevent such misconduct" like off-label marketing and that "imposed affirmative obligations on Pfizer's board that went ***well beyond*** the basic fiduciary duties required by Delaware law." *Id.* at *7 (emphasis added). Allergan has not been subject to any previous settlements or CIAs. *Cf. id.* at *1-2. Nor did the investigation and settlement here arise from continued actions taken after the time when a CIA was in effect. *Cf. id.* at *3. There are no pleadings that the Allergan Board made "repeated promises [in multiple CIAs] to closely monitor and prevent" misconduct such as off-label marketing. *Cf. id.* at *7.[8] Completely contrary to *Pfizer*, the instant allegations of demand futility targeting Allergan's Board are based

[8] The *Pfizer* court, in excusing demand, also expressly relied on the "sheer size" of the record-breaking fines (a criminal fine of $1.195 billion, criminal forfeitures of $105 million, and a $1 billion civil settlement—"'the largest civil fraud settlement in history against a pharmaceutical company.'" *Id.* at *3. The fines here more substantially resemble the $425 million settlement agreement addressed in *King*, 648 F. Supp. 2d at 614, a case the court in *Pfizer* claimed was "dwarf[ed] by several orders of magnitude" by the allegations before it. *Pfizer*, 2010 WL 2747447, at *7 n.7. The allegations here are also "dwarfed by several orders of magnitude" by those in *Pfizer*.

on a government settlement made public forty-eight hours before this case was filed. With no particularized allegations of wrongdoing by the Allergan Board, no history of repeated acknowledgement of wrongdoing followed by noncompliance, and only Plaintiff's conclusory allegations and argument. This case is easily distinguished by the facts of *Pfizer*.

Similarly, Plaintiff's reliance on *In re Abbott Laboratories Derivative Shareholder Litigation*, 325 F.3d 795 (7th Cir. 2001), which found that *Aronson* applies to allegations of "conscious inaction" by directors when a corporate governance structure exists and *Rales* only applies where directors are "blamelessly unaware" of the conduct in question, is also erroneous. (PAB 26-27.)[9] *Abbott Labs* was rejected by the U.S. District Court for the District of Delaware in *In re Intel Corp. Derivative Litigation*, 621 F. Supp. 2d 165, 173 (D. Del. 2009).

In *Intel*, the District Court stated that the holding of *Abbott Labs* has been rejected by the Third Circuit because the Seventh Circuit's "interpretation of Illinois law was not a faithful application of Delaware law." *Intel*, 621 F. Supp. 2d at 173 (citing *Fagin v. Gilmartin*, 432 F.3d 276, 282 (3d Cir. 2005)). Instead, the court in *Intel* applied *Rales* and concluded that the plaintiff's allegations failed to adequately plead demand futility.

The plaintiff in *Intel* also alleged that the Intel directors had breached their *Caremark* duties by failing to prevent the company from committing anti-competitive practices to monopolize the microprocessor market. 621 F. Supp. 2d at 169. With respect to demand futility,

[9] Furthermore, on the facts, *Abbott Labs* is clearly distinguishable such that it would not govern this case, even if it had been a faithful application of Delaware law. In *Abbott Labs*, the Seventh Circuit considered demand futility allegations in light of alleged wrongdoing by an Illinois corporation perpetuated despite years of public knowledge, including a half-decade old *Wall Street Journal* article and an outside analyst report criticizing the corporation for dragging its feet with respect to (1) the wrongdoing, (2) multiple FDA warning letters (a) directly concerning the conduct at issue and (b) directly sent to certain defendant board members, and (3) a years-old "Voluntary Compliance Plan" created by the corporation and the FDA that had been "closed down [by the FDA] . . . due to continued violations" by the company long before the derivative litigation. 325 F.3d at 799-800, 806, 808. Such circumstances are far afield from the instant charges lobbed at the Board forty-eight hours after announcement of a settlement agreement that cast no aspersions on Allergan board members, and are premised on FDA Warning Letters that addressed unrelated conduct or were mostly sent to non-board members.

the plaintiff alleged that the Intel directors could not properly exercise their independent and disinterested business judgment in responding to a demand because they faced a substantial likelihood of liability for ignoring red flags, specifically, ongoing investigations of the company's anti-competitive business practices. *Id.* at 174. The plaintiffs failed, however, to allege what the Intel directors actually knew about the red flags or how they responded to them. In addition, the red flags were not so severe that the defendants faced a substantial likelihood of liability for allegedly ignoring them. *Id.* at 174-75. The District Court also noted that *Abbott Labs* was distinguishable in this regard because it included a more compelling collection of red flags:

> [I]n *In re Abbott*, the FDA conducted thirteen inspections of the company to determine whether it was in compliance with FDA regulations, sent four formal warning letters to the company (three of which were sent directly to the chairman of the board), implemented a "Voluntary Compliance Plan" to remedy compliance problems, filed a complaint for an injunction, ordered the company to destroy non-compliant product inventory, and met at least 10 times with company representatives, including the chairman of the board. *In re Abbott*, 325 F.3d at 799-802. These events, which were widely reported and caused one analyst to question why the company continued to "drag[ ] [its] feet fixing the FDA problems," ultimately culminated in "the largest civil fine ever imposed by the FDA" and total losses to the company of approximately $250 million. *Id.* at 808-09. Although the Court has not reached any conclusions as to whether these types of facts would establish demand futility under Delaware law, in the Court's view, the alleged wrongdoing by Intel in this case does not rise to the *Abbott* level of wrongdoing. In addition, unlike *In re Abbott*, there is no indication that government agencies have specifically reached out to individual board members to apprise them of problems within the company. Accordingly, *In re Abbott* is not particularly useful in deciding the question of whether demand is futile in this case.

Id. at 176-77. The facts alleged in this Complaint are closer to *Intel* than *Abbott Labs*. As in *Intel*, Plaintiff has utterly failed to plead any allegations that would impute knowledge of off-label marketing of BOTOX® to the Board.

At best, the Complaint alleges that the Board should have been on notice because Allergan had received three letters from the FDA over the course of the last decade, not one of

which related to the off-label marketing practices challenged here. The Complaint fails to specify whether the Board saw those letters, and if so when, how and what, if any, response it had. The Court cannot reasonably infer knowledge of off-label marketing of BOTOX® from such conclusory and irrelevant allegations.

As the Delaware District Court found in *King v. Baldino*, the *Rales* test should be applied where the plaintiff's complaint fails to identify which of the individual directors breached his or her fiduciary duties and when those duties were breached. 648 F.Supp. 2d at 623. Much like the case at hand, the complaint in *King v. Baldino* alleged that "defendants intentionally breached and/or recklessly and/or with gross negligence disregarded their fiduciary duties, choosing to implement a marketing scheme that completely ignored FDA mandates" and provided "no facts supporting the conclusory statement that the defendants chose to implement the new marketing scheme." *Id.* (emphasis omitted). Thus, despite Plaintiff's efforts to avoid it, a *Rales* analysis is necessary.

1. Plaintiff Fails To Plead Particularized Facts That Create A Reasonable Doubt That The Board Could Have Properly Exercised Its Independent And Disinterested Business Judgment

Plaintiff's *Rales* argument appears to fall under its second point heading titled "Demand Is Excused Because The Individual Defendants Face A Substantial Likelihood of Personal Liability." (*See* PAB 29-32.) Plaintiff has not come forth with the necessary factual allegations to excuse demand. First, the Board cannot be interested or lack independence simply because the Individual Directors served on the Board during the time in question. (*See* PAB 29-30.) Such allegations are insufficient as a matter of law. (*See* AOB 14-17; *see also* AOB 24-25.)

Second, Plaintiff asserts that the Individual Defendants were "acutely aware of the problems posed by off-label marketing and promotion, and of violating FDA rules and regulations through the Strategic Plans that made off-label promotion of BOTOX® a primary

corporate priority." (PAB 30.) Plaintiff, however, does not allege any particularized facts that support its assertion except that the directors should have known of the problems "by virtue of fact that they are doctors themselves and/or have experience in the medical field." (*Id.*) This is simply an improper attempt at using the directors' personal experience to impute knowledge, interest, or a lack of independence. *See Citigroup*, 964 A.2d at 129-30 (rejecting plaintiff's conclusory argument that "involvement with the Enron related scandals should have in any way put the director defendants on a heightened alert to problems in the subprime mortgage market" and finding that plaintiff's "utterly failed to show how Citigroup's involvement with the financial scandals at Enron has any relevance to Citigroup's investments in subprime securities"); (*see also* AOB 30.)

Third, Plaintiff concludes that "[n]ot only did the Individual Defendants' conduct subject the Company to substantial criminal and civil sanctions, but it violated Allergan's own Ethics Code, which requires that all employees 'comply with all applicable laws and regulations,' and it was further in contravention of the nature of the Board's performance of their duties under the Charters of the Board's various committees." (PAB 30.) Plaintiff does not explain what specific conduct these unspecified Individual Defendants engaged in; nor does Plaintiff explain how this conclusory allegation makes a majority of the Board interested or lack independence. Moreover, director knowledge cannot be imputed through board members' positions on committees. Mere participation on a board committee overseeing the purported wrongdoing does not establish an inability to evaluate demand. *See, e.g.*, *Wood,* 953 A.2d at 142 (rejecting director liability by virtue of audit committee membership); *Rattner*, 2003 WL 22284323, at *13 (Del. Ch. Oct. 7, 2003) (same); *see also Desimone*, 924 A.2d at 942 (rejecting "contention that [directors] knew [of wrongdoing] simply because" of committee membership alone).

As previously discussed, the thrust of Plaintiff's argument is that the majority of the Board lacks independence and is interested because the Board members sat on the Board at the time the off-label marketing occurred and are therefore subject to liability for the underlying claims Plaintiff seeks to bring. Such allegations fail as a matter of law. *See In re Citigroup Inc. S'holders Litig.*, 2003 WL 21384599, at *1 (Del. Ch. June 5, 2003) (observing that "[t]his excuse is clearly insufficient" and dismissing complaint for failure to plead demand excusal); *see also* AOB 24-25.

The Complaint is bereft of facts to support Plaintiff's contention that the Board could not have fairly considered a stockholder demand under *Rales* (or for that matter the first prong of *Aronson*). (AOB 13-17; 24-25.) As such, the requisite *Rales* analysis centers on whether Plaintiff pled particularized facts showing that the directors face a substantial likelihood of liability. Plaintiff has not done so.

2. Plaintiff Fails To Plead Particularized Facts Showing That The Directors Face A Substantial Likelihood Of Liability

As noted in its opening brief, Allergan has adopted a section 102(b)(7) provision which exculpates directors from the breach of duty of care. *See* AOB 17-18. As a result, the directors can only be held personally liable for acts of disloyalty or bad faith. *Stone*, 911 A.2d at 367 (noting that a section 102(b)(7) provision "can exculpate directors from monetary liability for a breach of the duty of care, but not for conduct that is not in good faith or a breach of the duty of loyalty"). To establish that the directors are subject to a substantial likelihood of liability, Plaintiff must plead particularized facts showing bad faith. *See id.* at 362; *see also Dow Chem.*, 2010 WL 66769, at *12 (stating "demand will be excused . . . only in the rare case when a plaintiff is able to show director conduct that is 'so egregious on its face that board approval

cannot meet the test of business judgment, and a substantial likelihood of director liability therefore exists.'") (quoting *Citigroup*, 964 A.2d at 121).

To prevail on a failure of oversight claim, Plaintiff must demonstrate "a sustained or systematic failure of the board to exercise oversight—such as an utter failure to attempt to assure a reasonable information and reporting system exists . . . ." *Caremark*, 698 A.2d at 971. This requires Plaintiff to show that the defendants acted with scienter. *Citigroup*, 964 A.2d at 125 (stating "when a plaintiff seeks to show that demand is excused because directors face a substantial likelihood of liability where directors are exculpated from liability except for claims based on fraudulent, illegal or bad faith conduct, a plaintiff must also plead particularized facts that demonstrate that the directors acted with scienter, i.e., that they had actual or constructive knowledge' that their conduct was legally improper") (internal quotations and citations omitted).

Despite its allegations, Plaintiff makes no attempt to establish that demand is excused under the *Rales* test, which governs demand futility for board inaction. (PAB 29-32, 39-43.) Instead, Plaintiff insists that the directors face a substantial likelihood of liability for purported board action. Namely, Plaintiff argues that the directors face substantial likelihood of liability because they "engage[d] in illicit activities" and "violated various FDCA provisions and federal laws." (PAB 30, 32.) While these allegations are inappropriately analyzed under *Rales*, it appears that Plaintiff's argument is centered on the premise that the directors acted in bad faith and that its allegations pass *Rales* scrutiny for that reason. (PAB 42.)

To support its allegations, Plaintiff makes sweeping accusations without providing any particularized facts to support them. Specifically, Plaintiff alleges that the directors "directed [an] illegal scheme, are responsible for allowing Allergan to engage in it, and failed to curtail that conduct." (PAB 29.) Plaintiff also alleges that the directors are responsible for the following laundry list of wrongs:

> (1) failing to implement any reporting or information system or controls, or
> (2) assuming such a system or controls exists, consciously failing to monitor or oversee the Company's operations, what type of board could faithfully fulfill their oversight duties by:
>
> > (a) allowing their company to engage in an illegal off-label marketing scheme involving its most important product for nearly a decade;
> > (b) making this illegal scheme a top corporate priority of the company's strategic plans;
> > (c) engraining the illegal off-label marketing scheme into nearly every aspect of Allergan's corporate culture, including hiring, training, the provision of programs and seminars, the development of business units that targeted physicians in order to advance the scheme, surreptitiously funding company-controlled organizations and websites to advance the illegal marketing scheme, distributing promotional videos, and implementing an extensive lobbying program to further develop the scheme;
> > (d) causing the company to make a variety of false public statements, both with regard to the efficacy of its primary product for off-label uses and with regard to their disregard of their responsibilities under the company's ethics code and applicable committee charters; and
> > (f) allowing the company to provide illegal kickbacks to physicians to further the scheme, in violation of the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), and other federal laws.

(PAB 41.)

As discussed in detail in Allergan's opening brief, these are naked allegations unsupported by any particularized facts. (*See* AOB 18-22.) Plaintiff does not and cannot identify any facts that support its conclusory allegations listed above. Absent from Plaintiff's opposition brief and its Complaint is the discussion of what specific compliance systems were in place at Allergan and what systems, if any, were deficient. Nor is there any detail of what the directors ignored.

In certain instances, Plaintiff's accusations even contradict its own Complaint. For example, Plaintiff identifies no fact that demonstrates the board failed to implement any reporting and information system or control. To the contrary, the Complaint explicitly recognized the existence of the Audit and Finance Committee and its role to "assist the Board in its oversight of the Company's compliance with legal and regulatory requirements." (Am.

Compl. ¶ 75.) Plaintiff also acknowledges the existence of a Code that required all employees "comply with all applicable laws and regulations" and systems for reviewing, updating and enforcing the Code and for providing comprehensive reports to the Board regarding compliance related matters affecting Allergan and compliance oversight. (PAB 30 and n.25.)

As discussed above, the only allegation that Plaintiff specifically identifies is the directors' approval of Allergan's 1997 to 2001 Strategic Plan, which Plaintiff seems to fault as the root of all of Allergan's misconduct, without so much as specifying what part of what plan it finds offensive. (PAB 29.) Plaintiff attempts to equate the Court's unequivocal statement regarding backdating stock options in *Ryan v. Gifford*, 918 A.2d 341, 355 (Del. Ch. 2007) ("*Maxim*") with the conduct at issue in the Government's investigation and subsequent plea agreement. (PAB 31-32.) In particular, Plaintiff argues that "[d]efendants' participation in the illegal conduct at issue here is even more egregious . . . than that alleged in *Maxim*" because it violated various FDCA provisions and federal laws." (PAB 32.) Contrary to Plaintiff's allegations and argument, the approval of strategic plans do not come close to the type of misconduct alleged in *Maxim* that gave rise in that case to a substantial likelihood of liability. The allegations in *Maxim* were "unusual" and backdating options qualified as one of those "rare cases" in which *Rales* was met, in part because of the allegations that three of the six board members "approved backdated options, and another board member accepted them." 918 A.2d at 354-56. The plaintiff in *Maxim* also pointed to "specific grants, specific language in option plans, specific public disclosures, and supporting empirical analysis to allege knowing and purposeful violations of shareholder plans and intentionally fraudulent public disclosures" by half of the directors. *Id.* at 355. In sharp contrast, Plaintiff here completely fails to allege which directors did what, when, where and how with respect to anything. Its allegations of board misconduct are completely conclusory. Additionally, unlike the backdating of options, the

wrongs Plaintiff alleges have not been held by this Court to give rise to a substantial likelihood of liability.

3. Plaintiff Has Waived Any Argument That The Directors Face A Substantial Likelihood Of Liability For Violating Duties Of Disclosure Through Material Omissions

Plaintiff has also not addressed Allergan's argument that Plaintiff failed to identify any actual disclosure that was misleading or any statement that was rendered misleading as a result of an omission of material fact and, therefore, this aspect of Plaintiff's fiduciary duty claim also fails to meet Rule 23.1's requirements and should be dismissed. (AOB 22-23.) Because of the section 102(b)(7) provision operative in the Company's governing documents, in order to show a substantial likelihood of liability on a disclosure violation, Plaintiff must plead particularized facts that suggest "a majority of the defendants knowingly engaged in fraudulent or illegal conduct or breached in bad faith the covenant of good faith and fair dealing." *Wood*, 953 A.2d at 141 (quotations omitted). In a footnote, Plaintiff argues that its disclosure claims are "part of its derivative claim for breach of the Individual Defendants' fiduciary duty of loyalty to the Company" and state a viable claim under Rule 12(b)(6), (PAB 38 n.29), but otherwise does not address the Rule 23.1 analysis. Because Plaintiff failed to address this argument in its opposition brief, it has waived this argument. *See Emerald Partners*, 2003 WL 21003437, at *43; *VeriFone Holding, Inc.*, 994 A.2d at 360 n.21; *Emerald Partners*, 726 A.2d at 1224.

In short, Plaintiff fails to make any allegations that could support a substantial likelihood of personal liability for any Allergan director. For this reason, the entire Complaint must be dismissed under *Rales* for failure to make a pre-suit demand upon the Board.

CONCLUSION

For the foregoing reasons and for the reasons discussed in its Opening Brief, Nominal Defendant Allergan, Inc. respectfully requests that the Court grant its motion to dismiss the Complaint.

FISH & RICHARDSON P.C.

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