UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE IMPAX LABORATORIES, INC. SHAREHOLDER DERIVATIVE LITIGATION

Case No. 14-cv-04266-HSG

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

Re: Dkt. No. 42

Plaintiffs Randall K. Wickey and International Union of Operating Engineers Local 478 Pension Fund bring this shareholder derivative action against nominal Defendant Impax Laboratories, Inc. ("Impax") and individual Defendants Larry Hsu, G. Frederick Wilkinson, Arthur M. Koch, Bryan M. Reasons, Robert L. Burr, Leslie Z. Benet, Allen Chao, Nigel T. Fleming, Mary K. Pendergast, Michael J. Nestor, Michael Markbreiter, and Peter R. Terreri. Pending before the Court is Defendants' motion to dismiss Plaintiffs' verified consolidated shareholder derivative complaint. For the reasons articulated below, the Court GRANTS the motion with leave to amend.

I. BACKGROUND

Plaintiffs filed a consolidated complaint on February 20, 2015. Dkt. No. 37 ("Complt."). The following allegations are taken as true for purposes of this motion to dismiss.

Defendant Impax "is a technology-based specialty pharmaceutical company engaged in the development and manufacture of both proprietary and generic prescription drugs." *Id.* ¶ 18. Defendants Hsu, Wilkinson, Benet, Burr, Chao, Fleming, Markbreiter, Pendergast, and Terreri are current and former directors of Impax. *Id.* ¶¶ 19-27.

In August 2009, April 2010, and January 2011, Impax received Form 483s from the FDA. *Id.* ¶¶ 46-47, 49. Form 483s are issued by FDA inspectors who observe "conditions that may

constitute violations of the law or of cGMP regulations." *Id.* ¶ 40. The 2009-2011 Form 483s identified the following issues:

- **August 2009**: (1) "Quality System"; (2) "Facilities & Equipment"; (3) "Laboratory Systems"; and (4) "Production Systems." *Id.* ¶ 46.

- **April 2010**: (1) "Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established"; (2) "Written procedures are not established for the cleaning and maintenance of equipment"; (3) "Procedures for the cleaning and maintenance of equipment are deficient regarding the protection of clean equipment from contamination prior to use"; (4) "Written procedures for cleaning and maintenance fail to include description in sufficient detail of methods, equipment, and materials used"; (5) "The sensitivity and specificity of test methods have not been established"; (6) "There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has already been distributed"; and (7) "The master production and control records are deficient in that they do not include complete manufacturing, control, and procedures." *Id.* ¶ 47.

- **January 2011**: (1) "There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has already been distributed," designated as a "Repeat Observation" from the April 2010 Form 483; (2) "Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product"; (3) "Equipment and utensils are not maintained at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product"; (4) "Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance"; and (5) "Written procedures are not established and followed for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected." *Id.* ¶ 49.

In May 2011, the FDA sent a Warning Letter to Impax, noting that the company's response to the January 2011 Form 483 "lack[ed] sufficient corrective actions," and that "'[f]ailure to promptly correct these violations may result in legal action without further notice including, without limitation, seizure and injunction,' the loss of contracts with federal agencies, and the FDA's withholding approval of pending drug applications." *Id.* ¶¶ 52, 54. The FDA issues Warning Letters when "the Agency considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), its implementing regulations and other federal statutes." *Id.* ¶ 43. Warning Letters are issued only

"for violations of regulatory significance, *i.e.*, those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected." *Id.*

Following the May 2011 Warning Letter, Impax received three additional Form 483s in March 2012, February 2013, and August 2014. Those Form 483s identified the following issues:

- **March 2012**: (1) "Drug products failing to meet established standards and specifications are not rejected"; (2) "Investigations of a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product"; (3) "Written procedures for sampling and testing plans are not followed for each drug product"; (4) "Written production and process control procedures are not followed in the execution of production and process control functions"; (5) "Written records are not made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications." *Id.* ¶ 66.

- **February 2013**: (1) "The accuracy, sensitivity, specificity, and reproducibility of test methods have not been established," designated as a "Repeat Observation" from previous investigations; (2) "Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product," designated as a "Repeat Observation" from previous investigations; (3) "Procedures describing the warehousing of drug products are not followed," designated as a "Repeat Observation" from previous investigations; (4) "There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed"; (5) "Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel"; (6) "Written procedures for cleaning and maintenance fail to include description in sufficient detail of methods, equipment and materials used, description in sufficient detail of the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance, and parameters relevant to the operation"; (7) "Batch production and control records do not include complete information relating to the production and control of each batch"; (8) "Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals"; (9) "Drug products are not stored under appropriate conditions of humidity so that their identity, strength, quality, and purity are not affected"; (10) "An annual report did not include a full description of the manufacturing and control changes not requiring a supplemental application, listed by date in the order in which they were implemented"; (11) "Written procedures are not followed for evaluations done at least annually and including provisions for a review of complaints, recalls, returned or salvaged drug products, and investigations conducted for each drug product"; and (12) "Employees engaged in the manufacture and processing of a drug product lack the training and experience

required to perform their assigned functions." *Id.* ¶ 70.

- **August 2014**: (1) "The accuracy, sensitivity, specificity, and reproducibility of test methods have not been established and documented," designated as a "Repeat Observation" from previous investigations; (2) "Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel," designated as a "Repeat Observation" from previous investigations; (3) "There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed"; (4) "Written procedures for cleaning and maintenance fail to include description in sufficient detail of methods, equipment and materials used and instructions for protection of clean equipment from contamination prior to use"; (5) "The responsibilities and procedures applicable to the quality control unit are not fully followed"; (6) "Buildings used in the manufacturing and holding of a drug product are not maintained in a good state of repair"; and (7) "Changes to written procedures are not drafted, reviewed and approved by the appropriate organizational unit." *Id.* ¶ 90.

Plaintiffs also allege that the FDA issued a Form 483 in July 2014, containing ten observations, after an inspection of Impax's Taiwan Facility. *Id.* ¶ 86.

"Despite the numerous Form[] 483[s] and the May 2011 Warning Letter, the defendant members of the Board and Impax's senior management, who knew of the underlying recurring legal and regulatory violations, disregarded their obligations and the consequences of continued violations and allowed those violations to fester." *Id.* ¶ 5. Plaintiffs allege that the Defendants' failure to remedy the FDA compliance issues "gave rise to federal securities class actions against the Company," resulted in the delay of FDA approval "of the Company's key drug, Rytary," and led to the loss of important commercial opportunities. *Id.* ¶¶ 8, 10.

Plaintiffs allege a single cause of action for breach of fiduciary duties, based on 1) the Individual Defendants' failure "to comply with legal and regulatory obligations, including [the failure] to take adequate, necessary corrective action in response to the Form[] 483[s] and the May 2011 Warning Letter," and 2) the Individual Defendants' "knowing[] dissemination to the public [of] materially false and misleading statements concerning the quality control matters at the Hayward Facility and Taiwan Facility from October 2012 through May 2014." *Id.* ¶¶ 139-40.

A. Demand Futility Allegations

Plaintiffs concede that they did not make a demand on the Impax Board before filing suit, but allege that "pre-suit demand was excused as a matter of law." *Id.* ¶ 120. In support, Plaintiffs

allege that a majority of the nine directors at the time the action was initiated "(a) would have been 'interested' in (and therefore conflicted from and unable to fairly consider) a demand because they face a substantial likelihood of liability for their role in Impax's recurring, significant violations; and/or (b) engaged in conduct that is not a legitimate exercise of business judgment and, therefore, does not have the protections of the business judgment rule, in turn exposing them to a substantial risk of personal liability in the event they pursued the claims alleged herein." *Id.* ¶ 121.

Plaintiffs allege that at least seven directors—Hsu, Benet, Burr, Fleming, Markbreiter, Chao, and Terreri—were "aware of, and improperly refused to take corrective action to address, the endemic, recurring problems that the FDA identified in the Form[] 483[s] and the May 2011 Warning Letter," such that they face a substantial likelihood of liability. *Id.* ¶ 128. Plaintiffs allege that these directors had knowledge of the "red flags" alleged in the complaint because (1) they signed Impax's SEC filings acknowledging receipt of the FDA Form 483s and Warning Letter, (2) the alleged "violations" had a "material impact" on Impax's business of which the directors were "surely aware," and (3) Defendants Benet, Chao, Terreri, and Pendergast were members of the Compliance Committee charged with overseeing the company's FDA regulatory compliance. *Id.* ¶¶ 122-24, 131-32. The directors' alleged failure to "protect the Company from continued and further legal and regulatory violations" culminated in the FDA's delayed approval of the drug Rytary, loss of a partnership contract with GlaxoSmithKline, and "numerous significant risks that pose material harm to the Company's earnings and operations." *Id.* ¶ 130.

Plaintiffs further allege that all of the directors face a substantial likelihood of liability because they each "knowingly disseminated to Impax shareholders materially false and misleading statements concerning the quality control matters at the Hayward Facility and Taiwan Facility from October 2012 through May 2014." *Id.* ¶ 134.

Finally, Plaintiffs allege that the Impax Board "affirmatively adopted, implemented, and condoned a business strategy based on deliberate non-compliance with legal and regulatory requirements aimed at ensuring that unsafe, adulterated drugs do not harm consumers and the public." *Id.* ¶ 135. Because "such conduct can in no way be considered a valid exercise of business judgment," it is not protected by the business judgment rule and subjects the director

defendants to a substantial likelihood of liability. *Id.*

II. DISCUSSION

A. Futility Of Demand

1. Legal Standard

"The derivative form of action permits an individual shareholder to bring suit to enforce a corporate cause of action against officers, directors, and third parties." *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 95 (1991) (internal quotation marks and emphasis omitted). The purpose of such an action is "to place in the hands of the individual shareholder a means to protect the interests of the corporation from the misfeasance and malfeasance of faithless directors and managers." *Id.* However, a "shareholder seeking to vindicate the interests of a corporation through a derivative suit must first demand action from the corporation's directors or plead with particularity the reasons why such demand would have been futile." *In re Silicon Graphics Inc. Secs. Litig.*, 183 F.3d 970, 989 (9th Cir. 1999). This demand requirement is intended to effectuate "the basic principle of corporate governance that the decisions of a corporation—including the decision to initiate litigation—should be made by the board of directors or the majority of shareholders." *Kamen*, 500 U.S. at 101.

Federal Rule of Civil Procedure 23.1 articulates the pleading standard for assessing allegations of demand futility, but "[t]he substantive law which determines whether demand is, in fact, futile is provided by the state of incorporation of the entity on whose behalf the plaintiff is seeking relief." *Scalisi v. Fund Asset Mgmt., L.P.*, 380 F.3d 133, 138 (2d Cir. 2004). Because Impax is a Delaware corporation, Delaware law regarding demand futility applies here.

Under Delaware law, "the entire question of demand futility is inextricably bound to issues of business judgment and the standards of that doctrine's applicability." *Aronson v. Lewis*, 473 A.2d 805, 812 (Del. 1984). In the context of demand futility, "directors are entitled to a *presumption* that they were faithful to their fiduciary duties," and "the burden is upon the plaintiff in a derivative action to overcome that presumption." *Beam ex rel. Martha Stewart Living Omnimedia, Inc. v. Stewart*, 845 A.2d 1040, 1048-49 (Del. 2004) (emphasis in original).

"[D]emand is excused if Plaintiffs' particularized allegations create a reasonable doubt as

to whether a majority of the board of directors faces a substantial likelihood of personal liability for breaching the duty of loyalty." *Rosenbloom v. Pyott*, 765 F.3d 1137, 1150 (9th Cir. 2014). Where "directors are contractually or otherwise exculpated from liability for certain conduct, then a serious threat of liability may only be found to exist if the plaintiff pleads a non-exculpated claim against the directors based on particularized facts." *Wood v. Baum*, 953 A.2d 136, 141 (Del. 2008) (emphasis omitted). Because the Impax directors are exculpated from liability for all claims except those based on fraudulent, illegal, or bad faith conduct, *see* Impax Bylaws, Article IX, Section 61, Plaintiffs must "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." *Id.* (internal quotation marks omitted).[1] A plaintiff may plead a bad faith claim by alleging particularized facts that show that a company's Board failed "to act in the face of a known duty to act, thereby demonstrating a conscious disregard for their responsibilities." *Stone ex rel. AmSouth Bancorporation v. Ritter*, 911 A.2d 362, 370 (Del. 2006).

Plaintiffs did not make a pre-suit demand. Complt. ¶ 120. Therefore, Plaintiffs must adequately plead demand futility in order to proceed with this litigation.

2. Plaintiffs Fail To Plead Particularized Facts That Demonstrate That Demand Would Be Futile

Plaintiffs do not allege that the majority of the Board was not independent, and Defendants assert that "[a]ll but two of the nine Director Defendants at the time the Complaint was filed were outside directors with no connection to Impax beyond their roles as directors." Dkt. No. 42 ("Mot.") at 11. Therefore, to adequately plead demand futility, Plaintiffs must allege sufficient facts to show that a majority of the directors were interested.

Plaintiffs focus their interestedness argument on Defendants Burr, Chao, Hsu, Markbreiter,

[1]Plaintiffs assert that their "claims cannot be dismissed at the pleading stage based on the 'exculpatory provision' of Impax's charter because such an argument is considered an affirmative defense, which is not suitable at the pleading stage." Dkt. No. 45 ("Opp.") at 25. But Defendants do not seek to dismiss the complaint pursuant to Rule 12(b)(6) based on the exculpatory provision. Rather, Defendants argue that the presence of the exculpatory provision sets the demand futility pleading standard. This is a well-settled principle. *See In re Polycom, Inc. Derivative Litig.*, No. 13-cv-03880-SC, 2015 WL 164198, at *3 (N.D. Cal. Jan. 13, 2015) ("This type of so-called exculpatory clause . . . is appropriately considered at the pleading stage in assessing demand futility.") (citing *In re Citigroup S'holder Derivative Litig.*, 964 A.2d 106, 133 (Del. Ch. 2009)).

and Terreri ("Director Defendants"). Plaintiffs assert three primary arguments in support of their position that the Director Defendants face a substantial likelihood of personal liability. First, Plaintiffs argue that the Director Defendants knew of Impax's numerous compliance violations and did not respond appropriately, thereby failing to act in the face of a known duty to act. Second, Plaintiffs argue that the Director Defendants knowingly disseminated false statements. Finally, Plaintiffs argue that the Director Defendants "affirmatively adopted, implemented, and condoned a business strategy based on deliberate non-compliance with legal and regulatory requirements." Complt. ¶ 135.

i. Failure to act in the face of a known duty to act

"A plaintiff . . . can plead that the board consciously failed to act after learning about evidence of illegality—the proverbial 'red flag.'" *South v. Baker*, 62 A.3d 1, 15 (Del. 2012). The conscious failure to act after learning about such illegality may subject directors to a substantial likelihood of personal liability. *Rosenbloom*, 765 F.3d at 1150.

a. Known duty to act

Plaintiffs allege that the various Form 483s and the single May 2011 Warning Letter received by Impax from the FDA over the 2009-2014 time period constituted "red flags." *See* Complt. ¶ 106. Plaintiffs argue that the Director Defendants had knowledge of the alleged red flags because (1) as members of the Audit and Compliance Committees, they were repeatedly informed of the FDA compliance violations, met regularly during the relevant time period, and were charged with oversight of Impax's compliance risks; and (2) they signed SEC filings describing the FDA compliance violations. The Court agrees that these allegations reasonably imply that the Director Defendants were aware of the Form 483s and May 2011 Warning Letter.

However, the Court questions whether the Director Defendants had a known duty to act in response to the majority of the alleged "red flags"—namely, the Form 483s. The Delaware Supreme Court describes "the proverbial 'red flag'" as "evidence of illegality." *South*, 62 A.3d at 15. The Ninth Circuit similarly suggests that "knowledge of violations of law" would act as a red flag. *Rosenbloom*, 765 F.3d at 1151 ("If a majority of the Board had actual or constructive knowledge of violations of law at [the company], and did nothing, it violated its duty of loyalty

and faces a substantial likelihood of liability."). But here, Plaintiffs' complaint acknowledges that the Form 483s at issue simply informed Impax of "conditions that *may* constitute violations of the law or of cGMP regulations." *Id.* ¶ 40 (emphasis added). Moreover, it could be persuasively argued that the extremely granular and technical compliance issues identified by the FDA in the Form 483s did not impose a known duty on the Director Defendants to take concrete action in response to each observation.[2] In the cases cited by Plaintiffs in which courts held that demand futility was established, the "red flags" at issue were much more conclusive in nature. *See Rosenbloom*, 765 F.3d at 1146-47, 1153 (observing that "the Board was alerted to unlawful conduct" by four successive FDA warning letters received by the company over a five-year time period, which letters "constituted a red flag, waved nearly every year for five straight years, that Allergan was breaking federal law in its promotion of Botox"); *In re Pfizer Inc. S'holder Derivative Litig.*, 722 F. Supp. 2d 453, 455-56 (S.D.N.Y. 2010) (observing that the Board "was acutely aware of the need to prevent . . . illegal practices" because of three prior multimillion-dollar criminal and civil settlements with the government over a five year period); *In re Abbott Labs. Derivative S'holders Litig.*, 325 F.3d 795, 799, 808 (7th Cir. 2003) (acknowledging the company's receipt of Form 483s but focusing its analysis on the company's receipt of "four formal certified Warning Letters" from the FDA over a six-year period as evidence of "continuing violations of federal regulations" to which the Board should have acted in response).[3]

While a company should certainly be expected to take Form 483s seriously, the Court doubts that Form 483s, on their own, would constitute "red flags" sufficient to impose a known duty to act on the Director Defendants. But the May 2011 Warning Letter, which identified actual

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[2] Indeed, the Directors who were members of the Compliance Committee were responsible only for high-level compliance actions such as "oversee[ing] the Company's compliance policies and practices in areas of FDA regulatory compliance and responsibility and when appropriate report[ing] and mak[ing] recommendations to the Board with respect to such policies and practices." *Id.* ¶ 116.

[3] Plaintiffs also rely on *In re Veeco Instruments, Inc. Secs. Litig.*, 434 F. Supp. 2d 267 (S.D.N.Y. 2006). However, *In re Veeco* is not persuasive here because it addressed unlawful conduct—namely, adequacy of internal accounting controls and violation of federal export control laws—that is different in kind than the cGMP compliance violations at issue here. *Id.* at 277-78. As a result, the nature of the "red flags" in *Veeco*—as well as the duty of a Board of Directors to respond to those red flags—makes that case very different from this one.

violations of law, does reasonably create a known duty to act on the part of the Director Defendants and therefore likely qualifies as a "red flag." *See* Complt. ¶ 43 (noting that Warning Letters are issued when the FDA "considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), its implementing regulations and other federal statutes," and are issued only "for violations of regulatory significance, *i.e.*, those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected").

Thus, the Court assumes for purposes of this analysis that the Form 483s and the May 2011 Warning Letter, in combination, imposed some duty to act on the Director Defendants.

b. Failure to act

Even assuming the existence of a known duty to act, however, Plaintiffs have not sufficiently alleged a failure to act. Plaintiffs allege that the Director Defendants "were required to act upon [the alleged red flags] to protect the Company from continued and further legal and regulatory violations," and that they "did not do so, and instead allowed rampant violations to continue." *Id.* ¶ 130. However, other allegations in the complaint suggest that the Director Defendants ultimately *did* take some action in response to the May 2011 Warning Letter:

- In May 2013, the Impax Board created a Compliance Committee, the members of which have the responsibilities to "assist the Board in its oversight of FDA regulatory compliance and responsibility" and "oversee the Company's compliance policies and practices in areas of FDA regulatory compliance and responsibility and when appropriate report and make recommendations to the Board with respect to such policies and practices." *Id.* ¶¶ 93, 116.
- Of the 33 FDA observations described in the Form 483s prior to August 2014, only two resurfaced as "Repeat Observations" in the August 2014 Form 483. *Id.* ¶ 89.
- The FDA refused to approve Impax's drug Rytary in early 2013 due to compliance concerns, but ultimately approved the drug for manufacture a little over a year later. *Id.* ¶¶ 77, 82.

Moreover, Plaintiffs do not allege that the FDA ever instituted an enforcement action against Impax. Given that the FDA issues Warning Letters only "for violations of regulatory significance, *i.e.*, those that *may actually lead to an enforcement action if the documented*

violations are not promptly and adequately corrected," *id.* ¶ 43, the lack of an enforcement action implies that the violations were in fact eventually corrected—or, at the very least, that the FDA was satisfied with the actions taken by Impax to correct the noticed violations.

"Simply put, when it comes to 'red flags,' Plaintiff[s'] approach is little more than to catalog the ongoing investigations into [Impax's] alleged wrongdoing, and then assert that the thickness of the catalog demonstrates that [Impax's] conduct was so egregious and widespread that the Directors certainly must now face at least a 'substantial likelihood' of personal liability for having ignored the 'red flags.'" *In re Intel Corp. Derivative Litig.*, 621 F. Supp. 2d 165, 175 (D. Del. 2009). These allegations are not enough to support Plaintiffs' conclusory allegation that the Defendant Directors did nothing, particularly when Plaintiffs' allegations suggest that Impax actually *did* take remedial action in response to the May 2011 Warning Letter.

Again, the cases cited by Plaintiffs address circumstances far more extreme than those presented here. Plaintiffs rely heavily on *Rosenbloom*, but in that case, the plaintiffs alleged "that the Board of Directors was involved in and aware of [the alleged wrongdoing]. Specifically, they allege[d] that the Board either adopted plans premised on illegal conduct or made a conscious decision not to take action even when faced with 'red flags' of wrongdoing." 765 F.3d at 1144; *see id.* at 1142 (noting that the company "aggressively promoted" off-label uses of one of the company's largest products "[a]t the direction of the [Board]"), 1155 (noting that the Board kept a business plan premised on unlawful off-label marketing in place even after a number of FDA warnings made its illegality clear). Here, there are no particularized allegations that the Impax Board affirmatively adopted plans to perpetuate any illegal conduct or made a conscious decision not to take any action in response to the 2011 Warning Letter. Furthermore, Plaintiffs' allegations imply that the Impax Board took some remedial action in response to the alleged "red flags"; that those remedial actions allegedly did not immediately fix all of the compliance problems identified by the FDA is not sufficient to cast reasonable doubt on the presumption that the Director Defendants are entitled to the protections of the business judgment rule.

Plaintiffs also rely on *Pfizer*, but that case, like *Rosenbloom*, involved more specific and conclusive allegations of actual wrongdoing and the Board's involvement in such wrongdoing

than are alleged here. In *Pfizer*, the Department of Justice imposed $2.3 billion in fines and penalties as a result of illegal off-label marketing of various drugs. 722 F. Supp. at 454. The *Pfizer* plaintiffs alleged "a rather blatant pattern of misconduct by Pfizer, undertaken with the knowledge, approval, or, at the very least, conscious disregard, of Pfizer's board and senior management." *Id.* at 457. The board's alleged actions included "retaliat[ion] against employees who reported internally that Pfizer's marketing practices were illegal." *Id.* at 456. The Court ultimately held 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 462. Here, as described above, Plaintiffs rely on hindsight inferences instead of alleging specific actions or inactions that demonstrate similar levels of wrongdoing on the part of the Director Defendants.

Finally, Plaintiffs cite to *In re Abbott*, a case in which, following six years of federal violations, the defendant entered into a consent decree with the FDA requiring it to pay the largest civil fine ever imposed by the FDA, withdraw 125 types of medical diagnostic tests from the market, and destroy certain inventory. 325 F.3d at 798, 809. As the court observed,

> Given the extensive paper trail . . . concerning the violations and the inferred awareness of the problems, the facts support a reasonable assumption that there was a "sustained and systematic failure of the board to exercise oversight," in this case intentional in that the directors knew of the violations of law, took no steps in an effort to prevent or remedy the situation, and that failure to take any action for such an inordinate amount of time resulted in substantial corporate losses, establishing a lack of good faith. We find that six years of noncompliance, inspections, 483s, Warning Letters, and notice in the press, all of which then resulted in the largest civil fine ever imposed by the FDA and the destruction and suspension of products which accounted for approximately $250 million in corporate assets, indicate that the directors' decision to not act was not made in good faith and was contrary to the best interests of the company.

Id. at 809. While an inference of affirmative misconduct or inaction on the part of the Board is reasonable on the basis of the facts in *Abbott*, the facts in this case simply "do[] not rise to the *Abbott* level of wrongdoing." *Intel*, 621 F. Supp. 2d at 177.

Finally, Plaintiffs urge the Court to excuse demand because Impax's loss of "its key

commercial partner GSK, lost commercial opportunities, lost sales," and exposure to "significant risk of FDA actions with increasing severity" create a reasonable doubt that the Director Defendants acted in good faith. Opp. at 20. This argument reinforces Plaintiffs' reliance on hindsight: they "seek[] to equate a bad outcome with bad faith." *Stone*, 911 A.2d at 373 ("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 [causing harm to the corporation]."); *see also In re Citigroup Inc. S'holder Derivative Litig.*, 964 A.2d 106, 124 (Del. Ch. 2009) ("When one looks past the lofty allegations of duties of oversight and red flags used to dress up these claims, what is left appears to be plaintiff shareholders attempting to hold the director defendants personally liable for making (or allowing to be made) business decisions that, in hindsight, turned out poorly for the Company.").

The Court finds that Plaintiffs have failed to allege particularized facts, rather than inferences supported only by hindsight, that establish a reasonable doubt that the Director Defendants "could have properly exercised [their] independent and disinterested business judgment in responding to a demand." *Wood*, 953 A.2d at 140. As such, Plaintiffs have not carried their burden to overcome the presumption under Delaware law that the Director Defendants were "faithful to their fiduciary duties." *Beam*, 845 A.2d at 1048.

ii. Knowing dissemination of false statements

Although Plaintiffs have specifically alleged those statements they contend to be false, and the reasons why they are allegedly false, Plaintiffs have not alleged particularized facts demonstrating how each Director Defendant—aside from Defendant Hsu—was involved in the preparation and/or dissemination of those statements. As such, Plaintiffs' allegations do not demonstrate a substantial likelihood that the Director Defendants would be subject to personal liability on the basis of those statements. *See In re Citigroup Inc.*, 964 A.2d at 134 ("[T]he Complaint does not contain specific factual allegations that reasonably suggest sufficient board involvement in the preparation of the disclosures that would allow me to reasonably conclude that the director defendants face a substantial likelihood of personal liability. . . . Instead of providing factual allegations regarding the knowledge or bad faith of the individual director defendants, the

Complaint makes broad group allegations about the director defendants or the members of the [risk management] Committee."). For example, Plaintiffs do not allege that the Director Defendants condoned any allegedly false statements made at investor conferences or on conference calls, or that they knew about any alleged misrepresentations or omissions merely as a result of signing financial reports. *See Talley v. Mann*, No. 11-cv-05003-GAF, 2012 WL 946990, at *12 (C.D. Cal. Feb. 14, 2012) ("Indeed, the purported misstatements were all made in the context of investor conferences and conference calls, and Plaintiff has not alleged that any of these misstatements was subject to pre-approval or any other form of authorization by the Board."); *Kococinski v. Collins*, 935 F. Supp. 2d 909, 920 (D. Minn. 2013) ("[T]he existence of false and misleading financial statements, by itself, is insufficient to establish a substantial likelihood of liability for a non-exculpated claim on the part of outside directors."); *Polycom*, 2015 WL 164198, at *6 ("Plaintiffs have not made any specific allegations about the Director Defendants' state of mind at all, which is necessary to determine whether any allegedly misleading statements were made with knowledge or bad faith.").

iii. Affirmative adoption of deliberate non-compliance strategy

Plaintiffs do not plead any particularized factual allegations that support their conclusory allegation that "[t]he Board affirmatively adopted, implemented, and condoned a business strategy based on deliberate non-compliance with legal and regulatory requirements aimed at ensuring that unsafe, unadulterated drugs do not harm consumers and the public." Complt. ¶ 135. Accordingly, the Court finds that Plaintiffs' allegations do not create a reasonable doubt as to whether the Director Defendants face a substantial likelihood of personal liability on the basis of any business strategy affirmatively adopted by the Impax Board.

B. Failure to State a Claim

Because Plaintiffs' complaint must be dismissed on demand futility grounds, the Court does not consider Defendants' Rule 12(b)(6) arguments.

III. CONCLUSION

For the foregoing reasons, the Court GRANTS Defendants' motion to dismiss WITH LEAVE TO AMEND. Plaintiffs may amend their complaint if they are able to plead

particularized allegations, on a director-by-director basis, that demonstrate that demand was futile. The Court cautions Plaintiffs that it will consider only factual, rather than conclusory, allegations when assessing the viability of any amended complaint. Plaintiffs shall file their amended complaint within 21 days of the date of this Order.

IT IS SO ORDERED.

Dated: September 3, 2015

HAYWOOD S. GILLIAM, JR.
United States District Judge

United States District Court
Northern District of California