IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

BEN WILKIN, derivatively on behalf of OREXIGEN THERAPEUTICS, INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. 12412-VCMR
MICHAEL A. NARACHI, PRESTON S. KLASSEN, JOSEPH P. HAGAN, MARK D. BOOTH, HEATHER D. TURNER, ECKARD WEBER, BRIAN H. DOVEY, LOUIS C. BOCK, PATRICK J. MAHAFFY, PETER K. HONIG, LOTA S. ZOTH, DAVID J. ENDICOTT, AND WENDY L. DIXON,	)	
Defendants,	)	
and	)	
OREXIGEN THERAPEUTICS, INC., a Delaware corporation,	)	
Nominal Defendant.	)	

MEMORANDUM OPINION

Date Submitted: November 17, 2017
Date Decided: February 28, 2018

Blake A. Bennett, COOCH AND TAYLOR, P.A., Wilmington, Delaware; Brian J. Robbins, George C. Aguilar, and Jay N. Razzouk, ROBBINS ARROYO LLP, San Diego, California; Nicholas Koluncich III, THE LAW OFFICES OF NICHOLAS KOLUNCICH III, LLC, Albuquerque, New Mexico; *Attorneys for Plaintiff*.

William N. Lafferty, D. McKinley Measley, and Richard Li, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, Delaware; John C. Dwyer and Jessica Valenzuela Santamaria, COOLEY LLP, Palo Alto, California; Mary Kathryn Kelley, COOLEY LLP, San Diego, California; Jeffrey Lombard, COOLEY LLP, Seattle, Washington; *Attorneys for Defendants*.

MONTGOMERY-REEVES, Vice Chancellor

Pending before the Court is a motion to dismiss for failure to plead demand futility and failure to state a claim in a case involving a pharmaceutical company that was developing a drug to help in the battle against obesity. Early results of a clinical trial indicated that this drug may have unanticipated, but significant, positive effects on cardiovascular health. Excited by the prospect of following in the footsteps of the likes of Alexander Fleming, the board of directors sought regulatory approval of, and patent protection for, their drug. If further clinical trials confirmed the effects, the drug would be revolutionary and, presumably, worth a great deal of money.

As the company moved through the processes required for both regulatory approval and patent protection, two less-than-ideal events occurred. First, a greater number of people than originally contemplated became aware of the preliminary data. While this did not affect the market approval process, the dissemination of the data threatened the integrity of the ongoing trial and, in part, necessitated the commission of a new clinical trial to further test the safety of the drug. This new clinical trial came with a hefty price tag. Second, through the patent process, the preliminary data from the clinical trial eventually became public. The market originally reacted positively to the news, but later data revealed that the early results were an aberration. The drug was not a revolutionary treatment for heart disease, though it continued to prove safe for its intended weight-loss use. The company's

stock price declined in response to the news. Thereafter, stockholders filed this action, arguing that the board of directors made the wrong decisions along the way.

Plaintiff's case rests on the premise that "Delaware law does not charter law breakers."[1] Plaintiff alleges that the board was not free to make the decisions it did because doing so violated positive law. This case, however, is a prime example of the difference between a best practice and a legal obligation. Plaintiff sets forth an in-depth explanation of best practices in clinical drug trials. All the pages of filings Plaintiff submitted to the Court show that the directors' decisions ultimately led to a violation of these best practices, but Plaintiff fails to point to a single legal obligation the directors violated. The first clinical trial was compromised and a new trial required. This new trial cost the company money. The preliminary results were not confirmed, and the stock price dropped. But Plaintiff has not pled facts that give the Court reason to doubt that these outcomes stemmed from rational, good faith decisions of faithful, loyal directors.

These same directors, therefore, retain their ability to make managerial decisions for the company, including whether or not to bring suit on behalf of the company. Plaintiff has failed to plead that he made demand on the board and has failed to plead sufficient facts to show a majority of the board faces a substantial

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[1] *In re Massey Energy Co.*, 2011 WL 2176479, at *20 (Del. Ch. May 31, 2011).

likelihood of liability such that they cannot exercise their independent and disinterested business judgment when considering such a demand. Thus, the Motion to Dismiss pursuant to Court of Chancery Rule 23.1 is GRANTED.

I. BACKGROUND

All facts in this opinion are drawn from Plaintiff's Verified Amended Stockholder Derivative Complaint for Breach of Fiduciary Duty and Waste of Corporate Assets (the "Complaint") and the documents incorporated therein.[2] The Court has also taken judicial notice of a document submitted by Defendants as the doctrine of judicial notice so allows.[3]

A. Parties and Relevant Non-Parties

Plaintiff Ben Wilkin is a current stockholder of nominal defendant Orexigen Therapeutics, Inc. ("Orexigen").[4] He was a stockholder of Orexigen at the time of the wrongdoing complained of and has continuously been a stockholder since that

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2 *Wal-Mart Stores, Inc. v. AIG Life Ins. Co.*, 860 A.2d 312, 320 (Del. 2004); s*ee also In re Morton's Rest. Gp., Inc. S'holders Litig.*, 74 A.3d 656, 659 n.3 (Del. Ch. 2013).

3 The Court takes judicial notice of Exhibit L to Defendants' Opening Brief, which is a World Intellectual Property Organization Patent Application dated June 11, 2015. The Court relies on Ex. L only as support for the fact that the international patent was filed. *See Microstrategy, Inc. v. Acacia Research Corp.*, 2010 WL 5550455, at *4 (Del. Ch. Dec. 30, 2010). The Court does not rely on Exhibits E, N, O, or R. Along with Exhibit L, these were the only exhibits to which Plaintiff objected the Court taking judicial notice. Oral Arg. Tr. 55-57.

4 Compl. ¶ 8.

time.[5] Nominal defendant Orexigen is a Delaware corporation with a principal place of business in La Jolla, California.[6]

There are thirteen individual defendants. One defendant, Michael A. Narachi, served as both an officer and director of Orexigen.[7] He has been President, CEO, and a director since March 2009.[8]

At the time the Complaint was filed, four of the defendants had served only as officers of Orexigen (the "Officer Defendants"). Preston S. Klassen was Orexigen's Senior Vice President of Product Development from November 2009 to February 2015 and Executive Vice President of Product Development from February 2015 to May 27, 2016.[9] Joseph P. Hagan was Orexigen's Senior Vice President, Corporate Development, Strategy, Communications from May 2009 to June 2011; acting Chief Financial Officer from March 2011 to February 2015; Chief Business Officer from June 2011 to December 2015; and Chief Financial Officer from February 2015 to December 2015.[10] Defendant Hagan entered into a consulting

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5 *Id.*

6 *Id.* ¶ 9.

7 *Id.* ¶ 10.

8 *Id.*

9 *Id.* ¶ 11.

10 *Id.* ¶ 12.

agreement with the Company from December 12, 2015, to December 11, 2016.[11] Mark D. Booth was Orexigen's Chief Commercial Officer from August 2009 to September 2015, and entered into a consulting agreement with the Company from October 1, 2015, to April 7, 2016.[12] Heather D. Turner was Orexigen's Vice President, General Counsel, and Secretary from June 2007 to May 2010 and Senior Vice President, General Counsel, and Secretary from May 2010 to June 2015.[13] Defendant Turner entered into a consulting agreement with the Company from June 26, 2015, to March 31, 2016.[14]

At the time the Complaint was filed, eight of the defendants had served only as directors of Orexigen (these directors together with Narachi, the "Director Defendants"). Eckard Weber was a director of Orexigen from September 2002 to May 27, 2016, and served as chairman of the board from March 2004 to May 27, 2016.[15] Brian H. Dovey became a director of Orexigen in January 2004, and was an Orexigen director at the time the Complaint was filed.[16] Louis C. Bock became a

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11 *Id.*

12 *Id.* ¶ 13.

13 *Id.* ¶ 14.

14 *Id.*

15 *Id.* ¶ 15.

16 *Id.* ¶ 16.

director of Orexigen in April 2005, and was an Orexigen director at the time the Complaint was filed.[17] Patrick J. Mahaffy became a director of Orexigen in February 2009, and was an Orexigen director at the time the Complaint was filed.[18] Peter K. Honig became a director of Orexigen in February 2010, and was an Orexigen director at the time the Complaint was filed.[19] Lota S. Zoth became a director of Orexigen in April 2012, and was an Orexigen director at the time the Complaint was filed.[20] David J. Endicott became a director of Orexigen in November 2012, and was an Orexigen director at the time the Complaint was filed.[21] Wendy L. Dixon was an Orexigen director from April 2010 to January 2016.[22]

At the time the Complaint was filed, the board of directors of Orexigen consisted of Defendants Narachi, Bock, Dovey, Endicott, Honig, Mahaffy, and Zoth (the "Current Director Defendants"), and non-party Deborah A. Jorn.[23]

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17 *Id.* ¶ 17.

18 *Id.* ¶ 18.

19 *Id.* ¶ 19.

20 *Id.* ¶ 20.

21 *Id.* ¶ 21.

22 *Id.* ¶ 22.

23 *Id.* ¶ 150.

B. Facts

Orexigen is a biopharmaceutical company that developed the drug Contrave to help obese and overweight adults manage their weight.[24] Contrave is a combination of two pre-existing drugs, bupropion and naltrexone.[25] Orexigen sought market approval for Contrave from the U.S. Food and Drug Administration (the "FDA") on March 31, 2010 by submitting an official new drug application (the "Application").[26] In September 2010, Orexigen entered into an exclusive partnership with Takeda Pharmaceutical Company Limited ("Takeda") to develop and commercialize Contrave (the "Partnership Agreement").[27] Pursuant to this agreement, Takeda was responsible for covering certain costs associated with the development and commercialization of Contrave.[28]

On January 31, 2011, in response to the Application, the FDA issued a complete response letter (the "Response Letter") that explained that the FDA had concerns about the cardiovascular safety of Contrave.[29] Due to these concerns, the

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24 *Id.* ¶ 2.

25 *Id.*

26 *Id.* ¶ 38; Defs.' Opening Br. Ex. A Reference ID:3625465, at 2.

27 Compl. ¶ 38.

28 *Id.*

29 *Id.* ¶ 39.

FDA required that Orexigen "conduct a randomized, double-blind, placebo-controlled trial of sufficient size and duration to demonstrate that the risk of major adverse cardiovascular events in overweight and obese subjects treated with [Contrave] does not adversely affect the drug's benefit-risk profile" before the FDA would approve Contrave.[30] This type of clinical trial is referred to as a cardiovascular outcomes trial, or CVOT.[31]

1. The Light Study

On September 20, 2011, after negotiations with the FDA, Orexigen announced "that it had reached a tentative agreement with the FDA concerning the [CVOT] requirement and a corresponding approval pathway."[32] The FDA would grant expedited approval of Contrave if the data available a quarter of the way through the CVOT met a preset threshold for cardiovascular safety.[33] This approval would be subject to certain post-marketing requirements, such as the completion of the CVOT.[34]

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30 *Id.*

31 *See id.* ¶ 5.

32 *Id.* ¶ 43.

33 *Id.* ¶¶ 2, 3, 44.

34 *Id.* ¶ 44.

Orexigen and Takeda commissioned a CVOT called the Light Study or, simply, LIGHT (the "Light Study").[35] Under the Partnership Agreement, Takeda was responsible for half of the costs of the Light Study after the first $60 million.[36] An outside team known as the Executive Steering Committee (the "Steering Committee") led by Dr. Steven E. Nissen of the Cleveland Clinic conducted the Light Study.[37] Orexigen also engaged a separate independent team led by Dr. Thomas R. Fleming to review and analyze the interim data ("the Data Monitoring Committee").[38] The first subject enrolled in the Light Study on June 1, 2012.[39] The cut-off for the quarter way analysis was November 6, 2013.[40]

The Light Study measured major adverse cardiovascular events ("MACE"). "The Light Study randomized 8,910 obese patients with a primary endpoint of evaluating the impact of treatment on the combined incidence of myocardial infarction (heart attack), stroke and [cardiovascular] death in patients taking

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35 *Id.* ¶ 2.

36 *Id.* ¶ 38.

37 *Id.* ¶¶ 6, 49, 139.

38 *Id.* ¶¶ 4, 49.

39 Defs.' Opening Br. Ex. A Reference ID:3625465, at 3.

40 *Id.*

Contrave versus placebo."[41] "After a screening period, subjects enter[ed] a 2-week double-blind lead-in period . . . followed by a double-blind treatment period of approximately 4 years. . . . Regardless of whether subjects discontinue from treatment or study procedures, they are to be contacted to assess for the occurrence of MACE unless they revoke consent for all further follow up."[42]

In order for the FDA to consider granting expedited approval of Contrave, the results of the Light Study at the quarter way mark needed to rule out the risk that patients taking the drug experienced a doubling of cardiovascular risk.[43] The Data Monitoring Committee would conduct an analysis when one quarter of the total MACE were observed and adjudicated to determine whether the results ruled out a doubling of risk.[44]

2. Orexigen's first data action plan

The FDA, the Steering Committee, and the Data Monitoring Committee all had confidentiality concerns regarding the preplanned interim analysis because the Light Study was an ongoing, double-blind study. "Maintaining confidentiality of interim results from a trial is essential to maintain integrity and credibility of the

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41 Compl. ¶ 109 (quoting Orexigen's March 3, 2015 Form 8-K).

42 Defs.' Opening Br. Ex. A Reference ID:3625465, at 4.

43 *Id.*

44 *Id.*

ongoing trial."[45] If trial participants, or those conducting the trial, learned the interim results there could be adverse effects, "such as slowing recruitment, promoting dropouts or cross-ins, introducing bias with regard to outcome assessment or safety-related events, and amending the design of the trial itself based on interim knowledge."[46]

Due to these confidentiality concerns, Orexigen approved a data access plan on November 12, 2013 (the "First Plan").[47] The purpose of the First Plan was "to describe the strategy for maintaining confidentiality of unblinded interim data."[48] The First Plan described three levels of data access.[49] Table one in the First Plan described those three levels in more detail.[50] Full Access meant "access to unblinded, summarized, and individual subject study data."[51] Top Line meant "access to unblinded, summarized data provided in an abbreviated format, such as a verbal or written executive summary or a presentation prepared by someone with

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45 *Id.* at 6.

46 *Id.*

47 Compl. ¶ 69; Defs.' Opening Br. Ex. D, at 1.

48 Defs.' Opening Br. Ex. D, at 4.

49 *Id.*

50 *Id.* at 5.

51 *Id.*

Full Access."[52] Knowledge of Threshold meant that prior to the information going public the person would be informed as to whether or not the necessary threshold for expedited approval by the FDA had been met.[53]

Under the First Plan, Defendants Klassen, Taylor, Narachi, Hagen, Booth, and Turner all had Full Access to the unblinded data.[54] Defendants Klassen and Taylor had Full Access because they were "essential for the work necessary for preparing the Application resubmission, as well as meeting global regulatory needs."[55] Defendants Narachi, Hagen, Booth, and Turner had Full Access as "members of senior management with public disclosure and business development responsibilities."[56] Finally, the board of directors had "Top Line access to the unblinded data, with the exception of Dr. Peter K. Honing, who will have Full Access."[57] The First Plan further stated that after the Data Monitoring Committee performed the interim analysis, "[t]he Unblinded Team [made up of people with Full Access] will retain functional responsibility for unblinded activities, including

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52 *Id.*

53 *Id.*

54 *Id.* at 8.

55 *Id.* at 7-8.

56 *Id.* at 8.

57 *Id.*

responding to questions from regulatory agencies or providing information for partnering or financing activities."[58]

The following three members of Orexigen's senior management approved the First Plan: Heather Turner, Orexigen's Senior Vice President, General Counsel, and Secretary, Thomas Bicsak, Orexigen's Vice President of Regulatory Affairs, and Kristin Taylor, Oreixigen's Vice President/Head of Clinical Development.[59] There were no other approvals, signatures, or acknowledgments of any kind.

3. The first interim analysis

The Light Study reached the quarter way mark in November 2013. During the last week of November, the Data Monitoring Committee reviewed and analyzed the results from June 2012 to November 2013 (the "25% Results").[60] The 25% Results showed an unexpected outcome. Not only did Contrave meet the goal required by the FDA for expedited approval, but the 25% Results, "if accurate, would make Contrave one of the most effective cardiovascular drugs in history."[61]

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58 *Id.* at 10.

59 *Id.* at 14.

60 Compl. ¶¶ 4, 71.

61 *Id.* ¶ 119.

Based on the 25% Results, Orexigen resubmitted the Application to the FDA on December 10, 2013.[62]

4. Orexigen's second data action plan

The Data Monitoring Committee met on November 23, 2013, and raised and discussed two concerns. First, the First Plan allowed too many people access to the unblinded 25% Results. The Data Monitoring Committee agreed that the First Plan needed to be revised.[63] Second, too many subjects had left the Light Study. The Data Monitoring Committee recommended enrolling additional patients in the Light Study to ensure its viability.[64]

In response to the Data Monitoring Committee's confidentiality concerns, Orexigen approved a new data action plan on February 3, 2014 (the "Second Plan"). The Second Plan was substantially the same as the First Plan except that the category of Top Line access was eliminated. The Second Plan also included a new section entitled "Purpose of Unblinding and Levels of Data Access,"[65] which explained that an interim analysis would be conducted "to determine whether selected data should

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62 *Id.* ¶ 71.

63 Defs.' Opening Br. Ex. A Reference ID:3625465, at 6-7.

64 *Id.* at 8.

65 Defs.' Opening Br. Ex. F, at 4.

be released to Orexigen to enable a resubmission to the FDA."[66] This section also explained that "[u]nder circumstances that ensure confidentiality would be maintained, these interim data also could be used to support other global regulatory filings. As stated in the [Data Monitoring Committee] Charter, these interim data 'would then be released to the core group of individuals essential to the facilitation of [regulatory] resubmission.'"[67] The same individuals from Orexigen who approved the First Plan approved the Second Plan.[68] There were no additional signatures, approvals, or acknowledgments of any kind.

5. Unblinding the results to the board

On February 7, 2014, the Strategic Transaction Committee, comprised of Defendants Weber, Mahaffy, and Honig, held a meeting, also attended by Defendant Narachi, where they discussed "plans to unblind the full Board to the [25% Results]."[69] The Strategic Transaction Committee held another meeting on February 19, 2014, where Defendant Weber "reviewed with the [Strategic Transaction] Committee one theory to explain the [25% Results]."[70]

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66 *Id.*

67 *Id.*

68 *Id.* at 13.

69 Compl. ¶ 74 (quoting OREX-RA00001542).

70 *Id.* ¶ 75; Pl.'s Answering Br. Ex. P, at OREX-RA00001801.

On March 18, 2014, the board of directors held a meeting attended by Defendants Narachi, Dixon, Mahaffy, Honig, Zoth, and Dovey, where Defendant Narachi "reported to the Board the results of the Light Study interim analysis."[71]

6. The FDA raises confidentiality concerns

On April 11, 2014, the FDA requested Orexigen provide the FDA with a list of all individuals, excluding members of the Data Monitoring Committee, with access to or knowledge of the unblinded 25% Results.[72] Orexigen replied informally with a list of names on April 16, 2014.[73] On May 21, 2014, the FDA requested the date that each individual had Full Access and a copy of the exact information shared with him or her.[74] On May 23, Orexigen informally replied by email, and on May 30, Orexigen submitted a formal response to both the April 11 and May 21 requests.[75]

On June 4, 2014, the FDA and Orexigen had a meeting where the FDA sought to understand the full extent of the unblinding to assess the integrity of the remainder

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71 Compl. ¶ 75; Pl.'s Answering Br. Ex. Q, at OREX-RA00001789.

72 Compl. ¶ 76.

73 *Id.*

74 *Id.*

75 *Id.*

of the Light Study.[76] The FDA held a follow-up, internal meeting on June 5, 2014, to determine a path forward and set a new goal date of September 11, 2014 for its approval decision.[77] On August 24, 2014, the FDA informed Orexigen that the Light Study could not be used to fulfill post-marketing requirements after approval.[78] This decision would not affect the approval of Contrave based on the 25% Results.

7. The FDA approves Contrave

On September 10, 2014, the FDA approved Contrave and issued its Summary Review for Regulatory Action (the "Summary Review").[79] The FDA discussed its concerns about "data sharing after [the] interim analysis" in the Summary Review.[80] The FDA review team found that more than 100 individuals, including those with business interest in the trial, "had knowledge of the [25% Results] or access to unblinded interim data."[81] This caused the review team to have "serious concerns about the ability to maintain the integrity of the ongoing trial."[82] Thus, the review

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76 *Id.* ¶ 77.

77 *Id.* ¶ 80.

78 Defs.' Opening Br. Ex. A Reference ID: 3625465, at 6.

79 Compl. ¶ 83; Defs.' Opening Br. Ex. A Reference ID: 3625465.

80 Defs.' Opening Br. Ex. A Reference ID: 3625465, at 6.

81 *Id.* at 7.

82 *Id.*

team determined that the Light Study could not be used as a basis for the post-marketing requirement.[83] The FDA concluded that a new CVOT would be necessary to meet the post-marketing requirement that Contrave not increase the risk of MACE by 40% or more.[84]

The Summary Review noted two additional points, however. First, because all the activity that led to the confidentiality concerns happened *after* the interim analysis had been conducted "there was no debate among the review team . . . [that] the interim data can be used to rule out the agreed-upon pre-approval risk margin."[85] Second, "even if concerns did not arise because of the extent of the dissemination of interim data, the high percentage of treatment discontinuations calls into question the ability to interpret the final results should the LIGHT trial continue to completion . . . ."[86]

8. The domestic and international patent process

Orexigen sought patent protection for Contrave when the 25% Results were finalized and indicated a possibility that Contrave could be "one of the most effective

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83 *Id.*

84 *Id.* at 8.

85 *Id.* at 7.

86 *Id.* at 8.

cardiovascular drugs in history."[87] On July 2, 2014, Orexigen filed a confidential United States patent application with the United States Patent and Trademark Office (the "USPTO").[88] This application was for an invention titled "Compositions and Methods for Weight Loss in At Risk Patient Populations."[89] Orexigen also "submitted unexpected results which [show] that this combination as instantly claimed in fact provides cardiovascular protective effects which is persuasive."[90] On December 4, 2014, Orexigen also filed an international patent application with the World Intellectual Property Organization (the "WIPO").[91]

On January 5, 2015, Orexigen sent the USPTO a "Rescission of Previous Nonpublication Request," as required within forty-five days of filing a foreign or international filing like the WIPO patent application.[92] On January 16, 2015, the

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87 Compl. ¶ 119.

88 *Id.* ¶ 88; Defs.' Opening Br. Ex. K. Plaintiff objects to this exhibit in his Answering Brief by arguing that this exhibit was unimportant to, or only indirectly referenced in, the Complaint. This exhibit is Contrave's United States patent application. Plaintiff discusses the contents of the patent application in paragraphs 88 and 119 of the Complaint. Plaintiff also advances the theory in the Complaint that the Director Defendants conspired to use the patent process to publicly disclose the 25% Results. Therefore, the patent application is both incorporated-by-reference and integral to the Complaint.

89 Defs.' Opening Br. Ex. K.

90 *Id.*

91 Defs.' Opening Br. Ex. L.

92 Defs.' Opening Br. Ex. K.

board authorized the payment of an issuance fee to the USPTO, also necessitated by the WIPO application.[93] On January 20, 2015, Orexigen paid the fee.[94] The projected publication date of the patent application was June 11, 2015.[95]

9. The 25% Results are publicly disclosed

On March 3, 2015, three months before the projected application publication date, the USPTO issued the approved patent for Contrave.[96] Orexigen responded by filing a Current Report Form 8-K the same day (the "8-K").[97] The 8-K disclosed that the USPTO had "issued U.S. Patent No. 8,969,371 (the "371 Patent") and made publicly available provisional patent applications (U.S. Application No. 61/913216, U.S. Application 61/914938 and U.S. Application No. 61/984580) (the "Provisional

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93 Pl.'s Answering Br. Ex. T.

94 Defs.' Opening Br. Ex. K.

95 *Id.*

96 Defs.' Opening Br. Ex. J. Plaintiff objects to this exhibit in his Answering Brief by arguing that this exhibit was unimportant to, or only indirectly referenced in, the Complaint. This exhibit is the published United States patent for Contrave. Plaintiff alleges that the disclosure of the 25% Results in this patent was a knowing and intentional violation of the law by the Director Defendants. Plaintiff also discusses the published patent in paragraphs 97, 109, and 129 of the Complaint. Therefore, this document is incorporated-by-reference and integral to the Complaint. Moreover, the Court only relies on this exhibit as evidence that the patent was published, and the Court can take judicial notice of the publication of patents. *See Microstrategy, Inc. v. Acacia Research Corp.*, 2010 WL 5550455, at *4 (Del. Ch. Dec. 30, 2010).

97 Defs.' Opening Br. Ex. P.

Patent Applications") to which the 371 Patent claims priority."[98] The 8-K also stated that "[t]he 371 Patent and the Provisional Patent Applications contain claims related to a positive effect of Contrave on [cardiovascular] outcomes. The observed effects on [cardiovascular] outcomes were unexpected and appear to be unrelated to weight change."[99] The 8-K also included data from the 25% Results. That data was followed by a reiteration that "[i]t is important to emphasize" two things.[100] First, "[t]he U.S. package insert for Contrave states that the effect of Contrave on CV morbidity and mortality has not been established."[101] And second, "[t]he 25% Interim Analysis was prospectively designed to enable an early and preliminary assessment of safety to support regulatory approval. A larger number of MACE are required to precisely determine the effect of Contrave on [cardiovascular] outcomes."[102] Finally, the 8-K disclosed that "[a] second, large, randomized, placebo-controlled clinical trial evaluating the effect of Contrave on [cardiovascular]

98 *Id.* at 2.

99 *Id.*

100 *Id.* at 4.

101 *Id.*

102 *Id.*

outcomes is planned to start later this year. Orexigen expects this trial to be completed by 2022."[103]

10. The second interim analysis

At the February 19, 2015 board meeting, the Director Defendants learned that "the Light Study has reached the 50% interim analysis point, which is underway."[104] At the March 1, 2015 board meeting Dr. Klassen "described to the Board the status of the 50% interim analysis of the Light Study."[105]

11. Orexigen and Takeda terminate the Light Study and the Cleveland Clinic discloses the 50% Results

On March 26, 2015, the Steering Committee voted to halt the Light Study and disclose the 50% Results to the public.[106] On May 12, 2015, Takeda and Orexigen announced that they had accepted the recommendation of the Steering Committee for the early termination of the Light Study.[107] Also on May 12, 2015, without

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103 *Id.*

104 Compl. ¶ 96.

105 *Id.* ¶ 99. It is unclear from the Complaint when the Data Monitoring Committee completed the second interim analysis and made the data (the "50% Results") available. All that can be ascertained from the Complaint is that the Steering Committee knew the 50% Results sometime before or on March 26, 2015. *Id.* ¶ 133. The Complaint does not allege sufficient facts to state or infer when the Director Defendants knew the 50% Results.

106 *Id.*

107 *Id.* ¶ 139; Defs.' Opening Br. Ex. S. Plaintiff objects to the exhibit in his Answering Brief as unimportant or only indirectly referenced in the Complaint. This exhibit is a press release announcing the termination of the Light Study. Plaintiff addresses

approval from Takeda or Orexigen, Dr. Nissen and the Cleveland Clinic issued a press release disclosing the 50% Results.[108] This press release included a quote from Dr. Nissen: "The [] [50%] results do not confirm cardiovascular benefits of Contrave claimed by Orexigen in the patent application based on the data obtained at the 25 percent time point in the trial."[109] The markets reacted to the news. Orexigen's stock dropped 27% on May 12, 2015.[110]

12. This litigation

On May 28, 2015, Plaintiff sent Orexigen a demand to inspect certain books and records pursuant to 8 *Del. C.* § 220.[111] Orexigen provided documents in response to the demand on August 17, 2015.[112] Plaintiff filed the original complaint in this action on June 3, 2016. Defendants moved to dismiss on October 31, 2016. Plaintiff filed the Complaint on January 13, 2017. Defendants again moved to dismiss on

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this press release and its contents in paragraphs 139 and 140 of the Complaint. Plaintiff also contends that the Director Defendants made misrepresentations about when the Light Study was terminated. Therefore, this document is incorporated-by-reference and integral to the Complaint.

108 Compl. ¶ 139.

109 *Id.* (alteration in original).

110 *Id.* ¶ 142.

111 Pl.'s Answering Br. 3.

112 *Id.*

March 27, 2017. The Court heard oral argument on the Motion to Dismiss on November 17, 2017.

II. ANALYSIS

Defendants move to dismiss the Complaint for failure to adequately plead demand futility under Court of Chancery Rule 23.1 and for failure to state a claim under Rule 12(b)(6). For the reasons that follow, I find that the Complaint fails to adequately plead demand futility under Court of Chancery Rule 23.1.

A. Standard of Review Under Court of Chancery Rule 23.1

"[D]irectors are empowered to manage, or direct the management of, the business and affairs of the corporation."[113] This necessarily includes the right to bring lawsuits on behalf of the corporation; "the right of a stockholder to prosecute a derivative suit [therefore] is limited . . . ."[114] For a derivative suit to proceed, "the complaint must allege with particularity that the board was presented with a demand and refused it wrongfully or that the board could not properly consider a demand, thereby excusing the effort to make demand as futile."[115] Here, Plaintiff has only pled that demand is futile.

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113 *Rales v. Blasband*, 634 A.2d 927, 932 (Del. 1993) (citing 8 *Del. C.* § 141(a)).

114 *Id.*

115 *La. Mun. Police Empls.' Ret. Sys. v. Pyott*, 46 A.3d 313, 339–40 (Del. Ch. 2012), *rev'd on other grounds* 74 A.3d 612 (Del. 2013).

Pleadings under Court of Chancery Rule 23.1 "must comply with stringent requirements of factual particularity that differ substantially from the permissive notice pleadings governed solely by Chancery Rule 8(a)."[116] In other words, the complaint "must set forth particularized factual statements that are essential to the claim" of demand futility.[117] "Rule 23.1 is not satisfied by conclusory statements or mere notice pleading,"[118] nor is "mere speculation or opinion . . . enough."[119] "In evaluating whether demand is excused, [however,] the Court must accept as true the well pleaded factual allegations in the Complaint,"[120] "as well as 'all reasonable inferences that logically flow from [those] facts.'"[121]

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116 *Brehm v. Eisner*, 746 A.2d 244, 254 (Del. 2000).

117 *Id.*

118 *Id.*

119 *In re Walt Disney Co. Deriv. Litig.*, 825 A.2d 275, 285 (Del. Ch. 2003).

120 *In re Citigroup Inc. S'holder Deriv. Litig.*, 964 A.2d 106, 120 (Del. Ch. 2009).

121 *Melbourne Mun. Firefighters' Pension Tr. Fund ex rel. Qualcomm, Inc. v. Jacobs*, 2016 WL 4076369, at *7 (Del. Ch. Aug. 1, 2016) (quoting *Postorivo v. AG Paintball Hldgs., Inc.*, 2008 WL 553205, at *4 (Del. Ch. Feb. 29, 2008)), *aff'd* 158 A.3d 449 (Del. 2017). Of course, "[i]f these principles were applied mindlessly . . . a plaintiff could describe a document or take a handful of words out of context and claim that the court was required to accept the plaintiff's pleading-stage characterization." *Amalgamated Bank v. Yahoo! Inc.*, 132 A.3d 752, 797 (Del. Ch. 2016). "A plaintiff may not reference certain documents outside the complaint and at the same time prevent the court from considering those documents' actual terms." *Winshall v. Viacom Int'l, Inc.,*76 A.3d 808, 818 (Del. 2013). Therefore, "[t]he incorporation-by-reference doctrine permits a court to review the actual document to ensure that the plaintiff has not misrepresented its contents and that any inference the plaintiff seeks to have drawn is a reasonable one." *Amalgamated Bank*, 132 A.3d at 797.

The seminal demand futility cases in Delaware are *Aronson v. Lewis*[122] and *Rales v. Blasband*. In *Aronson*, the Delaware Supreme Court held that a stockholder who challenges an action taken by the board considering the demand must allege particularized facts sufficient to raise a reasonable doubt that: "(1) the directors are disinterested and independent [or] (2) the challenged transaction was otherwise the product of a valid exercise of business judgment."[123] Under *Rales*, a derivative plaintiff who does not challenge actions taken by a majority of the board members considering demand must allege particularized facts sufficient to "create a reasonable doubt that, as of the time the complaint is filed, the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand."[124] This Court recently stated that *Aronson* and *Rales*

The doctrine of incorporation-by-reference applies equally in the Rule 23.1 and Rule 12(b)(6) context. *Id.*; *Reiter ex rel. Capital One Fin. Corp. v. Fairbank*, 2016 WL 6081823, at *5 (Del. Ch. Oct. 18, 2016).

122 *Aronson v. Lewis*, 473 A.2d 805 (Del. 1984), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000).

123 *Rales*, 634 A.2d at 933 (alteration in original) (quoting *Aronson*, 473 A.2d at 814). For a majority of the board to be disinterested and independent, "the board must be able to act free of personal financial interest and improper extraneous influence." *Id.* at 935.

124 *Id.* at 934.

both address the same question of whether the board can exercise its business judgment on the corporate behalf in considering demand.[125]

Relying on *Louisiana Municipal Police Employees' Retirement System v. Pyott*, Plaintiff contends that demand is excused under either *Aronson* or *Rales* because a majority of the Board faces a substantial likelihood of liability for breaching the duty of loyalty by causing Orexigen to violate positive law.[126] "[B]ecause sophisticated and well-advised individuals do not customarily confess knowing violations of law, a plaintiff following this route effectively must plead facts and circumstances sufficient for a court to infer that the directors knowingly violated positive law."[127]

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125 *In re Duke Energy Corp. Deriv. Litig.*, 2016 WL 4543788, at *14 (Del. Ch. Aug. 31, 2016); *see also Kandell ex rel. FXCM, Inc. v. Niv*, 2017 WL 4334149, at *11 (Del. Ch. Sept. 29, 2017) (quoting *In re China Agritech, Inc. S'holder Deriv. Litig.*, 2013 WL 2181514, at *16 (Del. Ch. May 21, 2013)) ("The tests articulated in *Aronson* and *Rales* are 'complementary versions of the same inquiry.'").

126 Pl.'s Answering Br. 32-33. "[T]he fiduciary duty of loyalty is not limited to cases involving a financial or other cognizable fiduciary conflict of interest. It also encompasses cases where the fiduciary fails to act in good faith." *Stone ex rel. AmSouth Bancorp. v. Ritter*, 911 A.2d 362, 370 (Del. 2006). The Delaware Supreme Court has articulated situations when a fiduciary fails to act in good faith, including when "the fiduciary acts with the intent to violate applicable positive law." *Id.*

127 *Pyott*, 46 A.3d at 341. "[D]irectors' 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." *Id. at* 340 (quoting *Stone*, 911 A.2d at 373). But, "[w]ithout a connection to the board, a corporate calamity will not lead to director liability. Without a substantial threat of director liability, a court has no reason to doubt the board's ability to evaluate a demand." *Id.* In order "[t]o plead a sufficient connection between the corporate trauma and

B. Demand Is Not Excused as Futile

Plaintiff argues that demand is excused because seven of the eight directors on the board "knowingly and/or intentionally caus[ed] the Company to violate regulations and breach its confidentiality obligations with respect to the 25% [R]esults"[128] and "knowingly allow[ed] the Company to make (or themselves ma[de]) improper public statements."[129] Plaintiff further contends that demand is excused because the Director Defendants' decisions and actions were not a valid exercise of the business judgment rule.[130]

A review of Plaintiff's allegations shows the main deficiency in the entirety of Plaintiff's demand futility analysis. Plaintiff attempts to plead knowing and intentional violations of the law without any violation of the law. Instead, Plaintiff paints a picture of directors who, at worst, failed to follow best practices. But, a

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the board, the plaintiff's first and most direct option is to allege with particularity actual board involvement in a decision that violated positive law." *Id.* "In *Caremark*, Chancellor Allen framed the test as whether the directors 'knew or . . . should have known' about illegality. In *Stone*, the Delaware Supreme Court tightened the test to require actual knowledge: '[I]mposition of liability requires a showing that the directors knew they were not discharging their fiduciary obligations.'" *Id.* at 340–41 (quoting *In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959, 971 (Del. Ch. 1996) and *Stone*, 911 A.2d at 370)).

128 Pl.'s Answering Br. 34; s*ee also* Compl. ¶¶ 151-52.

129 Compl. ¶ 154.

130 *Id.* ¶¶ 155-58.

failure to follow best practices does not create a substantial likelihood of liability. For this and the other reasons explained below, I hold that demand is not excused as futile.

1. Plaintiff fails to raise a reason to doubt that the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand

"The analysis of whether a majority of the board faces a substantial likelihood of personal liability 'is conducted on a claim-by-claim basis.'"[131] "The complained-of conduct must 'be so egregious on its face' that the board could not have exercised its business judgment in responding to a stockholder demand to pursue those claims."[132] In essence, Plaintiff argues that demand is futile due to the Director Defendants' substantial likelihood of liability for two reasons: (1) that the Director Defendants face a substantial likelihood of personal liability for breaching their duty of loyalty due to the disclosure of the 25% Results; and (2) that the Director Defendants face a substantial likelihood of personal liability for breaching their duty of loyalty due to public statements made by representatives of Orexigen. I address each of these arguments in turn.

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131 *Melbourne Mun. Firefighters' Pension Tr. Fund ex rel. of Qualcomm, Inc. v. Jacobs*, 2016 WL 4076369, at *6 (Del. Ch. Aug. 1, 2016) (quoting *Teamsters Union 25 Health Servs. & Ins. Plan v. Baiera*, 119 A.3d 44, 58 n.71 (Del. Ch. 2015)), *aff'd* 158 A.3d 449 (Del. 2017).

132 *Id.* at *6 (quoting *Aronson*, 473 A.2d at 815).

a. Plaintiff fails to plead that a majority of the directors face a substantial likelihood of personal liability for allowing the dissemination of confidential interim data

Plaintiff asserts that the Director Defendants "act[ed] with the intent to violate applicable positive law" by knowingly and intentionally disseminating confidential interim data related to the 25% Results in violation of FDA regulations and in breach its agreement with the FDA.[133] Plaintiff's theory of the case, as best I can discern, is that Orexigen suffered a corporate trauma when the FDA determined a new CVOT, costing around $200 million, would be necessary to fulfill the post-marketing requirement for Contrave. But, it is unclear to me exactly what law or agreement Plaintiff plead Orexigen violated.[134] Nonetheless, I attempt to address below all the various allegations made by Plaintiff.

The only statute or regulation the Complaint references is the Food and Drug Administration Amendments Act of 2007 (the "2007 Act").[135] The Complaint

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133 Pl.'s Answering Br. 32.

134 The Complaint does not address the FDA's statements that the new CVOT also was necessary due to the number of participants who had left the study. Defs.' Opening Br. Ex. A Reference ID: 3625465, at 8. Additionally, Plaintiff rejects Defendants' suggestion that they have attempted to plead failure of oversight claims. Rather, they state, "Plaintiff does not plead a failure of oversight and instead alleges that the Individual Defendants consciously breached their fiduciary duty of loyalty by intentionally causing Orexigen to violate its agreement with the FDA." Pl.'s Answering Br. 34.

135 Compl. 29 n.6.

mentions the 2007 Act four times. First, the Complaint states that under the 2007 Act, "the FDA has the authority to require a drug-specific, risk evaluation mitigation strategy to ensure the benefits of the drug outweighs its risks."[136] Second, the Complaint alleges "[t]he FDA, through the [2007 Act], has broad discretion to enforce confidentiality of interim results, including fining a sponsoring company for breach of its confidentiality obligations or even withdrawing approval of the drug underlying the CVOT."[137] Third, the Complaint cites the 2007 Act as authority for the proposition that "the FDA has authority to fine or withdraw approval where a company does not meet its CVOT obligations." Finally, the Complaint quotes from a March 2015 Forbes article that discussed the 2007 Act.[138] The Forbes article discussed the 2007 Act in relation to the public dissemination of the 25% Results through the patent process not the "confidentiality breaches" that lead to the new CVOT requirement:

> [The FDA] told Orexigen when Contrave was approved that it would need to do a second big study, because Orexigen had not kept the data fire walled, instead letting over 100 people, including people outside the company and Orexigen's CEO, learn about the results, according to FDA documents. Now, because of the release of data via a press release, some experts question whether doctors or

136 *Id.*

137 *Id.* ¶ 45.

138 *Id.* ¶ 131. This Forbes article is cited by the Complaint in footnotes 42, 43, 45 and discussed in paragraph 131.

> patients will be willing to participate in that second trial. What if it can't be completed?
>
> [John Jenkins, the director of the Office of New Drugs at the FDA] said he wouldn't engage in "a hypothetical" and referred me to the FDA's guidance. I asked him to explain what the guidance means in a generic case, not specifically related to Orexigen.
>
> "Congress passed a law in 2007, [the 2007 Act]," Jenkins said. "They gave us the authority to require these trials. If companies are not meeting their obligations there are fines, there are civil money penalties, there's a possibility for seizure, and there's even a possibility for initiating withdrawal procedures."[139]

Plaintiff's first three references to the 2007 Act include conclusory statements about the FDA's ability to require confidential trials and to impose penalties for violations of "confidentiality." Plaintiff, however, does not allege with particularity any facts to suggest that the FDA ever determined that Orexigen violated anything or issued any fines whatsoever to Orexigen. The relevance of the fourth reference is unclear since the FDA already had determined a new CVOT was required when

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[139] Matthew Herper, *Top FDA Official Says Orexigen Study Result Unreliable, Misleading*, FORBES, Mar. 5, 2015, https://www.forbes.com/sites/matthewherper/2015/03/05/top-fda-official-says-orexigen-data-unreliable-likely-false/#365923a36af8. "The Complaint here extensively cites to and quotes from documents [Plaintiff] obtained from the Company through a books and records inspection demand under 8 *Del. C.* § 220." *Reiter ex rel. Capital One Fin. Corp. v. Fairbank*, 2016 WL 6081823, at *5 (Del. Ch. Oct. 18, 2016). The Complaint also extensively cites to and quotes from a myriad of other documents including certain news articles. "Accordingly, I may apply the incorporation-by-reference doctrine with respect to the documents referenced in the Complaint in evaluating the sufficiency of the Complaint's allegations to demonstrate demand futility." *Id.* at *6.

the 25% Results were disclosed by the patent application. I cannot infer based on these four statements that Defendants violated the 2007 Act and, therefore, face a substantial likelihood of liability such that they cannot consider demand. A vague reference to a law that allows fines does not explain how the Director Defendants violated that law by disregarding internal documents and procedures. Nor does a veiled reference to the disclosure of information in the patent application explain how the patent disclosures relate to the new CVOT requirement.

Plaintiff also mentions 21 U.S.C. §§ 355, 355-1 and 21 C.F.R. § 312.50 in his Answering Brief. These statutes and regulations generally govern FDA approval of new drugs and drug trial sponsors' responsibilities. Section 355 alone is 37 pages long, yet Plaintiff points to no specific section that Orexigen violated nor alleges any particular facts in relation to these statutes and regulations. Merely discussing these statutes in vague, broad terms does not support an inference that Director Defendants' decisions somehow violated these statutes.[140]

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[140] *See, e.g.*, *Desimone v. Barrow*, 924 A.2d 908, 928 (Del. Ch. 2007) ("But I do not accept cursory contentions of wrongdoing as a substitute for the pleading of particularized facts. Mere notice pleading is insufficient to meet the plaintiff's burden to show demand excusal in a derivative case.").

Plaintiff's brief and the Complaint also discuss, and quote from, various FDA guidance.[141] All of the guidance is just that—guidance. This is obvious from the notation on the top of every page of each document that says "Contains Nonbinding Recommendations."[142] Pleading violations of nonbinding recommendations does not constitute pleading a violation of positive law such that the board faces a substantial likelihood of liability and cannot consider demand.[143]

Finally, the Complaint often repeats the conclusory statement that the Defendants violated their agreement with the FDA. The only agreement between Orexigen and the FDA supported by particularized facts is the agreement related to expedited market approval. As the Summary Review explains, Defendants

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141 *E.g.*, Compl. 60 n.30. (citing U.S. Dep't of Health and Human Servs. Food and Drug Admin., *Guidance for Clinical Trial Sponsors Establishment and Operation of Clinical Trial Data Monitoring Committees* (2006)).

142 U.S. Dep't of Health and Human Servs. Food and Drug Admin., *Guidance for Clinical Trial Sponsors Establishment and Operation of Clinical Trial Data Monitoring Committees* (2006).

143 The Plaintiff's Answering Brief also states: "Even more curious is Defendants' argument that Orexigen did not have 'a legal or other duty to comply with the [the First or Second Plan].' If that is the case, then why have a [data action plan] if it can be unilaterally violated for any reason or no reason at all? Why bother subsequently revising the [First Plan] to reflect the Company's true confidentiality obligations to the FDA?" Pl.'s Answering Br. 35-36 (internal citations omitted). The First and Second Plan, which were incorporate by reference in the Complaint and submitted by Defendants, are on their face internal guidance documents only. Plaintiff fails to explain how a violation of internal guidance documents would mean the board faces a substantial likelihood of liability and cannot consider demand.

"originally submitted a new drug application (NDA 200063) for Contrave on 31 March 2010." The FDA's response to this application addressed concerns about a "statistically significant higher mean systolic and diastolic blood pressure and heart rate among naltrexone/bupropion-treated subjects compared with placebo-treated subjects."[144] The FDA's response informed Defendants that, to assuage these concerns, "before your application can be approved, you must conduct a randomized, double-blind, placebo-controlled trial of sufficient size and duration to demonstrate that the risk of major adverse cardiovascular events in overweight and obese subjects treated with naltrexone/bupropion does not adversely affect the drug's benefit-risk profile."[145]

After receiving the FDA's response, Defendants submitted formal dispute resolution requests to several subsets of the FDA. Eventually, the Office of New Drugs sent a letter to Defendants expressing that it "supported the conduct of an interim analysis to support approval with a final analysis to occur after approval."[146] The letter from the Office of New Drugs recommended that "the interim analysis was to exclude a hazard ratio (HR) of 2.0 (upper bound of the 95% confidence

144 Defs.' Opening Br. Ex. A Reference ID: 3625465, at 2.

145 *Id.*

146 *Id.* at 2-3.

interval [CI]) and the final analysis was to exclude a HR of 1.4."[147] The Light Study was designed to allow these two analyses to be conducted. The 25% Results would be the basis of FDA approval, and the final analysis would be used for the post-marketing requirement.[148]

The FDA approved Contrave based on the 25% Results in September 2014. The Summary Review issued with the approval addressed confidentiality concerns regarding the Light Study, but confirmed that because "the concerns regarding dissemination of unblinded data arose after the interim analysis, there is no debate among the review team that the upper bound of the 95% CI for MACE is less than 2.0; therefore, the interim data can be used to rule out the agreed-upon pre-approval risk margin."[149] The Summary Review made clear that "[t]he review team has serious concern [sic] about the ability to maintain the integrity of the ongoing trial such that the final results could, on their own, reliably assess the HR risk margin of 1.4,"[150] because the FDA was "not confident that [it] would ultimately be able to detect or exclude the possibility that the [Orexigen]'s activities may have biased the

147 *Id.* at 3.

148 *Id.* at 3; *see id*. at 8.

149 *Id.* at 7.

150 *Id.* at 6.

[Light Study]'s results or otherwise compromised its integrity."[151] This ultimately meant that the Light Study results could not be used to show Contrave met the post-marketing requirement for cardiovascular safety.[152]

Plaintiff does not argue that the FDA concluded that there was any violation of any agreement with the FDA. In fact, the Summary Review, which Plaintiff incorporated by reference in the Complaint and relied on extensively, reflects that the only concern the FDA raised was that the Light Study's results *after* the 25% Results could be compromised. This meant the FDA required a new study for Contrave to fulfill its post-marketing requirements but not that Contrave's market approval was at risk. Plaintiff has not pled any particularized facts for the Court to infer differently, and thus, Plaintiff has not adequately pled a violation of positive law such that the board faces a substantial likelihood of liability and cannot consider demand.[153]

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151 *Id.* at 8.

152 *Id.*

153 The allegations in the Complaint are not organized in chronological order, which makes it unclear what exact causal connections Plaintiff is attempting to plead. To the extent Plaintiff is trying to plead that the new CVOT was required due to the patent process disclosures, this case presents an even clearer application of the business judgment rule. In that case, the board faced a business decision. They could comply with the Second Plan, an internal protocol developed without any input from the FDA, and risk not having patent protection for a potentially lucrative drug. Alternatively, they could not comply with the Second Plan and risk the cost of a second trial, but preserve and protect Orexigen's intellectual property. Plaintiff has not adequately alleged that either of these options was illegal, or in violation of

b. Plaintiff fails to plead that a majority of the directors face a substantial likelihood of personal liability for knowingly allowing the dissemination of false information to stockholders[154]

"Whenever directors communicate publicly or directly with shareholders about the corporation's affairs, with or without a request for shareholder action, directors have a fiduciary duty to shareholders to exercise due care, good faith and loyalty."[155] Thus, "[i]t follows *a fortiori* that when directors communicate publicly or directly with shareholders about corporate matters the *sine qua non* of directors' fiduciary duty to shareholders is honesty."[156] "The issue in this case is not whether [the] directors breached their duty of disclosure."[157] Instead, the issue "is whether they breached their more general fiduciary duty of loyalty and good faith by

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some agreement with the FDA. The board therefore was free to exercise their business judgment. The board chose to pursue patent protection, and the FDA required a new CVOT to fulfill the post-marketing requirements.

154 Three federal securities actions were filed against Orexigen on March 10 and 11, 2015. Defs.' Opening Br. Ex. G, at 12. These three actions were consolidated on June 22, 2015. *Id.* at 13. The allegations in the federal securities action significantly overlapped with the allegations related to the disclosure claims in this litigation. *See id.* at 22-31. The consolidated action was dismissed, partially with prejudice and partially without, on May 19, 2016. *Id.* at 36.

155 *Malone v. Brincat*, 722 A.2d 5, 10 (Del. 1998).

156 *Id.*

157 *Id.* As the Delaware Supreme Court explained in *Malone v. Brincat*, there is a difference between the duty of disclosure in the context of requesting stockholder action and the more general requirement to communicate honestly with stockholders under the duty of loyalty and good faith. *Id.*

knowingly disseminating to the stockholders false information about . . . the company.

"To successfully state a duty of loyalty claim against directors for providing information in the absence of a request for shareholder action, a stockholder must allege that he received 'false communications' from directors who were 'deliberately misinforming shareholders about the business of the corporation.'"[158] Under *Malone v. Brincat*, "[w]hen shareholder action is absent, plaintiff must show reliance, causation, and damages" in order to establish a breach of the duty of loyalty.[159] "The decision by the Supreme Court to set a high bar for *Malone*-type claims was not . . . inadvertent."[160] The purpose was "to ensure that [Delaware] law was not discordant

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158 *Orloff v. Shulman*, 2005 WL 3272355, at *14 (Del. Ch. Nov. 23, 2005) (quoting *Jackson Nat'l Life Ins. Co. v. Kennedy*, 741 A.2d 377, 389 (Del. Ch. 1999)).

159 *A.R. DeMarco Enters., Inc. v. Ocean Spray Cranberries, Inc.*, 2002 WL 31820970, at *4 n.10 (Del. Ch. Dec. 4, 2002); *see also Dubroff v. Wren Holdings, LLC*, 2010 WL 3294219, at *1 (Del. Ch. Aug. 20, 2010) ("Because no shareholder approval was sought through the challenged disclosure, Delaware requires that reliance and causation be alleged and proven."); *Anglo Am. Sec. Fund, L.P. v. S.R. Global Int'l Fund L.P.*, 2006 WL 1494360, at *3 (Del. Ch. May 24, 2006) ("[I]f a complaint does not allege statements made to shareholders in conjunction with a request for shareholder action, a plaintiff cannot rely on a 'rebuttable presumption of reliance.'"); *Alessi v. Beracha*, 849 A.2d 939, 944 (Del. Ch. 2004) (explaining that when there is no request for shareholder action, stockholders cannot rely on the fraud on the market theory under Delaware law).

160 *Metro Commc'n Corp. BVI v. Advanced Mobilecomm Techs. Inc.*, 854 A.2d 121, 158 (Del. Ch. 2004).

with federal standards."[161] This also helps ensure that Delaware law does "not encourage a proliferation of disclosure claims outside the discretionary vote or tender context by exposing corporate directors to an additional host of disclosure claims that did not involve the need to show reliance or scienter."[162]

In the Complaint, Plaintiff takes issue with three instances where Defendant Narachi and other members of Orexigen's senior management shared information with the public: a call with analysts on September 11, 2014,[163] the 8-K and related public statement issued on March 3, 2015,[164] and an earnings call on May 8, 2015.[165] I have serious doubts about whether any of the statements made by Orexigen's representatives on these three occasions reflect a knowing dissemination of false information.[166] Regardless, Plaintiff has failed to sufficiently plead all the necessary

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161 *Id.*

162 *Id.*

163 Compl. ¶¶ 104-07.

164 *Id.* ¶¶ 108-10, 126-29.

165 *Id.* ¶¶ 137-38.

166 Moreover, Plaintiff only pled a connection to a majority of the Director Defendants in one instance—the 8-K. The board "reviewed and approved the public disclosure of the 25% Results via Current Report on Form 8-K, along with a script of expected questions and answers." *Id.* ¶ 108. There is no basis for attributing any statements on the calls on September 11 and May 8 to the Director Defendants, other than Defendant Narachi, such that a majority of the board would face a substantial likelihood of liability for a breach of the duty of loyalty. *Desimone v. Barrows*, 924 A.2d 908, 943 (Del. Ch. 2007) ("Delaware law does not permit the wholesale

elements of his disclosure claim; thus, the Director Defendants cannot face a substantial likelihood of liability for a breach of the duty of loyalty such that demand would be excused. [167]

In *Wood v. Baum*, the Delaware Supreme Court considered a case where "the plaintiff attempted to create a 'reasonable doubt' that the Board would have properly exercised its business judgment by alleging that the Board was disabled because of a substantial risk of liability."[168] The Supreme Court described the issue before it as "whether the Complaint alleges particularized facts that, if proven, would show that 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."[169] The Supreme Court held "that the plaintiff's factual allegations [were] insufficient to

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imputation of one director's knowledge to every other for demand excusal purposes.").

167 *Wood v. Baum*, 953 A.2d 136, 142 (Del. 2008). Moreover, a failure to plead any facts related to a particular element warrants dismissal under Court of Chancery Rule 12(b)(6). *Loudon v. Archer-Daniels-Midland Co.*, 700 A.2d 135, 147 (Del. 1997) ("In every case, a plaintiff stating a claim against directors for violation of the duty of disclosure must set forth in a well-pleaded complaint allegations sufficient to warrant the remedy sought."); *DiRienzo v. Lichtenstein*, 2013 WL 5503034, at *10 (Del. Ch. Sept. 30, 2013) ("[F]ailure to plead an element of a claim precludes entitlement to relief and, therefore, is grounds to dismiss that claim.").

168 *Wood*, 953 A.2d at 140-41.

169 *Id.* at 141.

establish demand futility,"[170] because "the Complaint [did] not even purport to state a cause of action for fraud, let alone plead the specific facts required to support such a claim," and "[t]he Complaint alleges many violations of federal securities and tax laws but does not plead with particularity the specific conduct in which each defendant 'knowingly' engaged."[171]

The same is true here. Plaintiff has not pled a single fact related to an element of his claim—individual reliance. The only facts Plaintiff has pled that are remotely related to reliance are (1) analysts reacted "enthusiastically" to the 8-K;[172] (2) Orexigen's stock price went up nearly 50% after the 8-K was issued;[173] and "Orexigen's stock price reached its apex on April 10, 2015, topping off at $81.10 a share, as adjusted to reflect a 1-for-10 reverse stock split in 2016 to maintain the Company's listing on NASDAQ."[174] But, none of these alleged facts, or even all of these facts taken together, show or infer reasonable, individual reliance. And "if a complaint does not allege statements made to shareholders in conjunction with a request for shareholder action, a plaintiff cannot rely on 'a rebuttable presumption

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170 *Id.* at 144.

171 *Id.* at 141, 142.

172 Compl. ¶ 111.

173 *Id.*

174 *Id.* ¶ 132.

of reliance'" [175] i.e. "the fraud on the market theory."[176] As reflected in *Wood*, a failure to plead an element of a claim precludes a finding that the directors face a substantial likelihood of liability for that claim such that demand is excused. Therefore, Plaintiff cannot show that a majority of the Director Defendants face a substantial likelihood of personal liability for knowingly allowing the dissemination of false information to stockholders.

2. Plaintiff fails to plead that the board's actions were so egregious that they are not a valid exercise of the business judgment rule

Plaintiff contends that "[a] pre-suit demand on the Orexigen Board is also excused because [seven of the eight Board members] did not exercise valid business judgment in connection with their decisions, actions, and transactions"[177] in three ways.[178] First, Plaintiffs allege that the Director Defendants "failed to act with loyalty and due care by knowingly or recklessly allowing the Company to make (or

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175 *Alessi*, 849 A.2d at 944.

176 *Id.*

177 Compl. ¶ 155.

178 Plaintiff mentions the Director Defendants' duty of care twice in the Complaint as part of the broad allegations against the Director Defendants but abandoned these claims in his briefing. Presumably this is because Orexigen's certificate of incorporation includes a Section 102(b)(7) provisions that exculpates the directors for personal liability to the fullest extent allowed under Delaware law.

themselves making) improper public statements."[179] This allegation was addressed at length in Section II.B.1.b. above. Second, Plaintiffs allege that the Director Defendants "failed to act with loyalty and due care by knowingly or recklessly making decisions and taking actions that caused or allowed Orexigen to breach its confidentiality obligations with respect to the 25% Results, forcing the Company to abandon the Light Study and bear the expenses of a new CVOT . . . ."[180] This allegation was addressed at length in Section II.B.1.a. above. Finally, Plaintiff alleges that the Director Defendants "failed to exercise valid business judgment in connection with causing the Company to waste its assets."[181]

"A board of directors enjoys a presumption of sound business judgment, and its decisions will not be disturbed if they can be attributed to any rational business purpose. A court under such circumstances will not substitute its own notions of what is or is not sound business judgment."[182] "Irrationality is the outer limit of the business judgment rule. Irrationality may be the functional equivalent of the waste

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179 *Id.* ¶ 156.

180 *Id.* ¶ 157.

181 *Id.* ¶ 158.

182 *Sinclair Oil Corp. v. Levien*, 280 A.2d 717, 720 (Del. 1971).

test or it may tend to show that the decision is not made in good faith, which is a key ingredient of the business judgment rule."[183]

"[T]o excuse demand on grounds of waste the Complaint must allege particularized facts that lead to a reasonable inference that the director defendants authorized 'an exchange that is so one sided that no business person of ordinary, sound judgment could conclude that the corporation has received adequate consideration.'"[184] In order "[t]o prevail on a waste claim ... the plaintiff must overcome the general presumption of good faith by showing that the board's decision was so egregious or irrational that it could not have been based on a valid assessment of the corporation's best interests."[185]

Plaintiff argues that the "breach of the confidentiality obligations was unnecessary, served no legitimate business purpose, and provided [Orexigen] with virtually no benefit in return for the substantial, otherwise avoidable costs incurred by the breach and from carrying out a new CVOT".[186] But, as Plaintiff points out, the 25% Results, while preliminary and unreliable, showed that Contrave could be

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183 *Brehm v. Eisner*, 746 A.2d 244, 264 (Del. 2000).

184 *In re Citigroup Inc. S'holder Deriv. Litig.*, 964 A.2d 106, 136 (Del. Ch. 2009) (quoting *Brehm*, 746 A.2d at 263).

185 *White v. Panic*, 783 A.2d 543, 554 n.36 (Del. 2001).

186 Compl. ¶¶ 158, 165.

"one of the most effective cardiovascular drugs in history."[187] Plaintiff also points out that Contrave was Orexigen's "primary drug and best business prospect."[188] In light of these realities, the Court cannot reasonably conclude, even at the motion to dismiss stage, that there was *no* legitimate business purpose for the disclosures. Additionally, based on the facts in the Complaint, and the Summary Review, it is not a reasonable inference that the new CVOT was an otherwise avoidable cost absent the confidentiality concerns. Both the Data Monitoring Committee and the FDA raised concerns about the Light Study's continuing viability due to loss of participants.[189] At the very least, the Light Study would have required a new cohort of trial subjects to continue. Plaintiff has failed to plead particularized facts that show the Director Defendants' actions were "so egregious or irrational that it could not have been based on a valid assessment of the corporation's best interests." Thus, demand is not excused.

III. CONCLUSION

For the foregoing reasons, the Motion to Dismiss is GRANTED.

IT IS SO ORDERED.

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187 *Id.* ¶ 119.

188 *Id.* ¶ 37.

189 *White*, 783 A.2d at 554 n.36.