IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

HUBERT OWENS, Derivatively on Behalf of ESPERION THERAPEUTICS, INC.,	)	
Plaintiff,	)	
v.	)	**C.A. No. 12985-VCS**
TIM M. MAYLEBEN, ROGER S. NEWTON, MARY P. MCGOWAN, NICOLE VITULLO, DOV A. GOLDSTEIN, DANIEL JANNEY, ANTONIO M. GOTTO, JR., MARK E. MCGOVERN, GILBERT S. OMENN, SCOTT BRAUNSTEIN, and PATRICK G. ENRIGHT,	)	
Defendants,	)	
and	)	
ESPERION THERAPEUTICS, INC., a Delaware corporation,	)	
Nominal Defendant.	)	

MEMORANDUM OPINION

Date Submitted: November 6, 2019
Date Decided: February 13, 2020

Seth D. Rigrodsky, Esquire, Brian D. Long, Esquire and Gina M. Serra, Esquire of Rigrodsky & Long, P.A., Wilmington, Delaware and Brian J. Robbins, Esquire, Felipe J. Arroyo, Esquire and Shane P. Sanders, Esquire of Robbins Arroyo LLP, San Diego, California, Attorneys for Plaintiff Hubert Owens.

Rudolf Koch, Esquire and Sarah A. Clark, Esquire of Richards, Layton & Finger, P.A., Wilmington, Delaware and Deborah B. Birnbach, Esquire and Adam Slutsky, Esquire of Goodwin Procter LLP, Boston, Massachusetts, Attorneys for Defendants Tim M. Mayleben, Roger S. Newton, Mary P. McGowan, Nicole Vitullo, Dov A. Goldstein, Daniel Janney, Antonio M. Gotto, Jr., Mark E. McGovern, Gilbert S. Omenn, Scott Braunstein, and Patrick G. Enright, and Nominal Defendant Esperion Therapeutics, Inc.

SLIGHTS, Vice Chancellor

Nominal Defendant, Esperion Therapeutics, Inc. ("Esperion" or the "Company"), is an early-stage biopharmaceutical company that focuses on developing low-density lipoprotein cholesterol ("LDL-C") lowering therapies for patients with hypercholesterolemia, or high cholesterol. Like many early-stage biopharmaceutical companies, Esperion has almost no revenue. Its investors have gone "all in" on the prospect that Esperion's lead product in development, bempedoic acid, or ETC-1002, will be brought to market promptly. If Esperion succeeds in that endeavor, its investors will see significant returns; if it does not, its investors will see little to nothing by way of returns.

ETC-1002 is an oral, once-daily small-molecule drug designed to lower LDL-C levels in patients who cannot tolerate, or are on a maximally tolerated dose of, a HMG-CoA reductase inhibitor, or statin, a widely prescribed class of LDL-C lowering drugs. In August 2015, ETC-1002 was at a key stage in its development. The drug had just concluded Phase II clinical trials and Esperion's senior management and scientists were to meet with the United States Food and Drug Administration ("FDA") to determine ETC-1002's regulatory path forward. Current and potential investors were eager to hear what the FDA had to say.

After the meeting with the FDA, Esperion issued a press release to summarize the results of the meeting followed by a conference call with analysts and investors hosted by Esperion's President and CEO, Tim M. Mayleben. Both sources reported

good news. From Esperion's perspective, the FDA had advised the Company that it would allow ETC-1002 to follow a "fast track[ed]" regulatory approval process going forward. This meant the drug could be marketed to a certain segment of the population without having to go through a lengthy cardiovascular outcomes trial ("CVOT"). As reported by Esperion's CEO, the FDA had laid out a "clear regulatory path forward" for ETC-1002.

When the FDA released its summary of the meeting, investors were surprised to see that the FDA's report differed from what Esperion had previously reported. While the FDA did not rule out that ETC-1002's development could be streamlined, it expressed doubt that ETC-1002 had a "clear regulatory path forward." Investors got spooked and Esperion's stock price tumbled. Stockholders responded by initiating a securities class-action against Esperion and Mayleben in the United States District Court for the Eastern District of Michigan (the "Michigan Action").

In the wake of the Michigan Action, Plaintiff initiated this derivative action in which he asserts breach of fiduciary claims against certain Esperion executives and members of the Esperion board of directors. Unlike federal securities actions, however, plaintiffs filing derivative suits in Delaware must adequately plead demand futility to survive dismissal. As explained below, Plaintiff has failed to carry this heightened pleading burden. Accordingly, Defendants' Motion to Dismiss must be granted.

I. BACKGROUND

I have drawn the facts from the well-pled allegations in the Verified Stockholder Derivative Complaint ("Complaint"),[1] documents incorporated by reference or integral to the Complaint and those matters of which I may take judicial notice, including publicly available SEC documents.[2] All well-pled allegations in the Complaint, at this stage, are accepted as true.[3]

A. The Parties

Plaintiff, Hubert Owens, is, and was at all relevant times, an Esperion stockholder.[4] He brings derivative claims for breach of fiduciary duty on behalf of the Company.[5]

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[1] Citations to the Complaint are to "Compl. ¶ __."

[2] *Wal-Mart Stores, Inc. v. AIG Life Ins. Co.*, 860 A.2d 312, 320 (Del. 2004) (noting that on a motion to dismiss, the Court may consider documents that are "incorporated by reference" or "integral" to the complaint); *In re Gen. Motors (Hughes) S'holder Litig.*, 897 A.2d 162, 170 (Del. 2006) (holding that this Court may, when considering a Rule 12(b)(6) motion, take judicial notice of SEC documents not subject to reasonable dispute). Esperion produced documents to Plaintiff pursuant to 8 *Del. C.* § 220 ("Section 220 Documents"), and citations to those documents are to "ESPERION ___."

[3] *Gen. Motors*, 897 A.2d at 169.

[4] Compl. ¶ 10.

[5] Compl. ¶ 1.

Nominal Defendant, Esperion, is a Delaware corporation with its principal place of business in Ann Arbor, Michigan.[6] Esperion is a biopharmaceutical company focused on developing and commercializing therapies for treating patients with elevated levels of LDL-C.[7] The first iteration of Esperion was founded in 1998 ("Old Esperion"), and was sold to Pfizer Inc. for $1.3 billion in 2004.[8] Esperion's lead product candidate is ETC-1002, a once-daily oral LDL-C lowering drug that does not cause the side effects associated with other, currently available LDL-C lowering therapies.[9] As of the filing of this action, Esperion had no revenue and relied on debt and equity financing to fund its operations.[10] Esperion's future as a going concern depends almost entirely on the successful commercialization of ETC-1002.[11]

Defendant, Mayleben, has been Esperion's President and CEO since December 2012 and a member of Esperion's board of directors (the "Board") since

[6] Compl. ¶ 11.

[7] *Id.*

[8] Compl. ¶ 76.

[9] *Id.*

[10] Compl. ¶ 36.

[11] *Id.*

February 2010.[12] He was the COO and CFO of Old Esperion from 1998 until 2004.[13] Mayleben is a named defendant in the Michigan Action.[14]

Defendant, Roger S. Newton, is Esperion's Scientific Advisor.[15] He has been a member of the Board since 2010, was Esperion's Executive Chairman and Chief Science Officer from 2012 until late 2016 and was the Company's President and CEO from 2008 until 2012.[16] Newton was the co-founder, President and CEO of Old Esperion.[17]

Defendant, Mary P. McGowan, is Esperion's Chief Medical Officer.[18] She is the only Defendant who is not also a member of the Board.[19]

Defendant, Nicole Vitullo, has been Esperion's Lead Independent Director since 2015 and a director since 2008.[20] She is a partner at the venture capital firm,

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[12] Compl. ¶ 12.

[13] *Id.*

[14] *Id.*

[15] Compl. ¶ 13.

[16] *Id.*

[17] *Id.*

[18] Compl. ¶ 14.

[19] Compl. ¶ 23. I will refer to the other Defendants collectively as the "Director Defendants."

[20] Compl. ¶ 15.

Domain Associates, LLC ("Domain"), which was an early investor in both Old Esperion and Esperion.[21]

Defendant, Dov A. Goldstein, has been a member of the Board since 2008.[22] He was a member of the Company's Audit Committee during the time of the alleged wrongdoing.[23] Goldstein is the managing partner of Aisling Capital, LLC ("Aisling").[24]

Defendant, Daniel Janney, has served on the Board since 2012.[25] He was a member of the Audit Committee during the time of the alleged wrongdoing.[26] Janney is the managing partner of venture capital firm, Alta Partners, LP ("Alta"), which was an early investor in Old Esperion and Esperion.[27]

Defendant, Antonio M. Gotto, Jr., has been a member of the Board since 2014.[28] He was also a director of Old Esperion.[29]

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[21] Compl. ¶ 77.

[22] Compl. ¶ 16.

[23] *Id.*

[24] Compl. ¶ 78.

[25] Compl. ¶ 17.

[26] *Id.*

[27] Compl. ¶ 77.

[28] Compl. ¶ 18.

[29] *Id.*

Defendant, Mark E. McGovern, has served on the Board since 2014.[30]

Defendant, Gilbert S. Omenn, has served on the Board since 2014.[31] He was a member of the Company's Audit Committee during the time of the alleged wrongdoing.[32]

Defendant, Scott Braunstein, has served on the Board since 2015.[33] He is the current Chairman of Esperion's Audit Committee and sat on the Audit Committee during the time of the alleged wrongdoing.[34]

Defendant, Patrick G. Enright, served on the Board from 2013 until 2016.[35] He was the Chairman of Esperion's Audit Committee during the time of the alleged wrongdoing.[36]

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[30] Compl. ¶ 19.

[31] Compl. ¶ 20.

[32] *Id.*

[33] Compl. ¶ 21.

[34] *Id.* I will refer to Braunstein, Vitullo, Goldstein, Janney, Gotto, McGovern and Omenn collectively as the "Outside Directors."

[35] Compl. ¶ 22.

[36] *Id.*

B. ETC-1002's Development

Elevated LDL-C levels are a significant risk factor in cardiovascular disease.[37] So-called "statin therapies" are the drugs most frequently prescribed to lower LDL-C levels.[38] Statin therapies are highly prescribed; indeed, Lipitor, a statin therapy, is the best-selling prescription medication in history.[39]

Despite the widespread use of statins, a population of patients with elevated LDL-C levels cannot tolerate statins' side effects, which can include cognitive impairment and increased risk of elevated blood sugar.[40] ETC-1002 will treat this population.[41] In clinical studies, ETC-1002 has reduced LDL-C levels while being "well-tolerated" by statin-intolerant patients.[42] ETC-1002 is also therapeutic for patients who can tolerate statins, but are taking the maximum recommended dose of that therapy.[43] With these results in hand, Esperion intends to commercialize ETC-1002 by implementing a "dual strategy" targeting: (i) statin-intolerant patients; and (ii) patients suffering from heterozygous familial hypercholesterolemia ("HeFH")

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[37] Compl. ¶ 34.

[38] *Id.*

[39] *Id.*

[40] *Id.*

[41] Compl. ¶ 35.

[42] *Id.*

[43] *Id.*

and/or clinical atherosclerotic cardiovascular disease ("ASCVD") who can benefit from ETC-1002 as an "add-on therapy" and currently receive the maximally tolerated statin dose.[44] Esperion estimates approximately nine million patients fall into one of these two categories.[45]

C. The End of Phase IIb Clinical Trials

Newly developed pharmaceuticals must undergo extensive clinical trials to demonstrate safety and efficacy before the FDA will approve a New Drug Application ("NDA"), a necessary step before the drug can go to market.[46] By August 2015, Esperion had completed Phase IIb clinical trials for ETC-1002.[47] This was a crucial step in the development process as feedback from these trials would determine ETC-1002's regulatory next steps.[48] In this regard, ETC-1002 faced two very different paths to commercialization.[49] One would be more time consuming and less certain; the other would be streamlined and more likely to bring the drug to market promptly.

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[44] *Id.*

[45] *Id.*

[46] Compl. ¶¶ 2, 4.

[47] Compl. ¶ 37.

[48] Compl. ¶¶ 2–4.

[49] Compl. ¶ 4.

Esperion would have to walk the more difficult path if it were required to conduct a CVOT for ETC-1002 as a condition to the FDA's approval of the drug's NDA.[50] The CVOT would be designed to demonstrate clinically that ETC-1002 improves cardiovascular health in patients and would involve a time-consuming "long-term safety study."[51]

The alternative path would involve the FDA approving a less rigorous, less time-consuming trial for ETC-1002, where recorded lower LDL-C levels in patients taking the drug would function as a "clinical surrogate endpoint."[52] A clinical surrogate endpoint is a laboratory measure, like lower LDL-C levels, that researchers use as a substitute for an actual showing of improved patient health outcomes.[53] The FDA approves clinical surrogate endpoints under its Accelerated Approval Program for drugs that treat serious or life-threatening diseases where there is a current unmet medical need.[54] If the FDA approved lower LDL-C levels as a clinical surrogate endpoint for ETC-1002, Esperion would not be required to complete the

[50] *Id.*

[51] Compl. ¶ 44.

[52] Compl. ¶ 4.

[53] *Id.* at n.2.

[54] *Id.*

CVOT for the drug until after the NDA was approved.[55] At the time the relevant events unfolded, the FDA had never required an approved therapy that only targeted LDL-C lowering to complete a CVOT prior to NDA approval.[56]

D. Esperion's FDA Meeting, Press Release and Conference Call

Esperion executives attended the End-of-Phase II meeting with the FDA on August 11, 2015, to receive guidance on Phase III trials.[57] It is not alleged that any of the Outside Directors were present at this meeting. All of the meeting's participants knew that the FDA's "minutes" of the meeting, the official record of what transpired, would not be released until September.[58]

Despite not having the official FDA meeting minutes in hand, on August 17, 2015, Esperion issued a press release updating the market on ETC-1002's regulatory status.[59] The press release contained some very good news: Esperion confirmed that it would not need to complete a CVOT before ETC-1002 could be marketed to the HeFH and ASCVD patient populations.[60] The press release further reported, "LDL-

[55] Compl. ¶¶ 43, 45.

[56] Compl. ¶ 47; Ex. 2 (Esperion Registration Statement (S-1) May 14, 2013) at 81.

[57] Compl. ¶ 38.

[58] *Id.*

[59] Compl. ¶ 39.

[60] *Id.*

C remains an accepted clinical surrogate endpoint for the approval of an LDL-C lowering therapy such as ETC-1002 in patients with HeFH and/or patients with ASCVD."[61]

That same day, Esperion followed up the press release with an investor conference call.[62] Mayleben began the call by noting Esperion felt it was important for investors to know about the End-of-Phase II meeting before the official FDA minutes were released.[63] Mayleben then told investors, "the FDA confirmed for us that LDL-cholesterol lowering remains an acceptable clinical surrogate endpoint for the potential approval of a therapy such as [ETC-]1002 . . . [for] patients that have . . . [HeFH] and [ASCVD] or ASCVD patients who are already taking maximally tolerated statin therapy . . . ."[64] Mayleben later confirmed for investors, "[w]e know that [ETC-]1002 will not require a [CVOT] [] to be completed prior to approval in patients with [HeFH] and ASCVD . . . ."[65] In response to an analyst's question about why the Company was making the announcement before release of the official FDA minutes, Mayleben responded that Esperion thought telling

[61] *Id.*

[62] Compl. ¶ 40.

[63] *Id.*

[64] *Id.*

[65] Compl. ¶ 41.

investors that ETC-1002 "has a clear path to approval . . . warranted speaking about it sooner rather than later."[66]

While analysts expressed some disappointment that the approved patient population for ETC-1002 was narrower than expected, Mayleben's comments about the FDA's feedback were generally received as positive news.[67] One analyst noted the news "remove[d] a significant regulatory overhang on the stock," and that it helped "resolve some investor concerns, notably that there is a clear path forward for approval prior to having to show CVOT data."[68]

E. The FDA Releases Its Meeting Minutes

On September 28, 2015, after the close of the market, Esperion issued a press release providing updates on ETC-1002's Phase III strategy following receipt of the official FDA minutes.[69] Contrary to Esperion's August 17 press release and conference call, the September 28 release reported there was now uncertainty as to whether the FDA would continue its historical practice of using LDL-C lowering as a surrogate endpoint.[70]

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[66] *Id.*

[67] Compl. ¶ 43.

[68] *Id.*

[69] Compl. ¶ 44.

[70] Compl. ¶ 46.

On a follow-up investor conference call, analysts questioned Mayleben intensely about the discrepancy between the Company's August 17 statements and the FDA's official minutes.[71] Mayleben responded by explaining, "LDL has historically been an accepted surrogate . . . [but] just because that's been the way it's been in the past, there is no lead-pipe cinch guarantee that that's the way it will be in the future."[72] One analyst noted the FDA minutes were "worse than consensus expected, and even inexplicably inconsistent with the prior 17 August 2015 [] commentary. . . ."[73]

Esperion's stock closed at $35.09 per share on September 28. The next day, with news of the FDA minutes widely disseminated, the market priced Esperion's stock at $18.33 per share, a near 50% decline that erased over $376 million of the Company's market capitalization.[74] Nevertheless, Esperion remained hopeful that LDL-C lowering would continue to be an accepted surrogate endpoint.[75] That optimism was again challenged on June 28, 2016, when the Company was advised, and then reported, that the FDA still would not confirm that LDL-C lowering

[71] Compl. ¶ 47.

[72] Compl. ¶ 48.

[73] Compl. ¶ 49.

[74] Compl. ¶ 51.

[75] Compl. ¶¶ 52–55.

remained a surrogate endpoint and that "the regulatory pathway for an LDL-C lowering indication is not well defined at this time, due to the [FDA]'s view of a potentially evolving landscape."[76] The next day, Esperion's stock price declined again, this time by over 40% to $9.66 per share.[77]

F. Procedural History

Stockholders brought a securities class action against Esperion and Mayleben in the Eastern District of Michigan in 2016, and the Complaint was filed in this court months later, on December 14, 2016. Plaintiff did not make a pre-suit demand on the Board and alleges any such demand would have been futile.[78] Shortly after the Complaint was filed, the parties agreed to stay this case while a motion to dismiss was litigated in the federal securities action.[79] That stay was lifted in late 2018, and Defendants filed their Motion to Dismiss on February 8, 2019. The matter was submitted for decision on November 6, 2019.

The Complaint alleges breaches of fiduciary duty against each of the Defendants for their conduct surrounding the allegedly false and misleading

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[76] Compl. ¶ 56.

[77] Compl. ¶ 57. Although not relevant for purposes of this motion, the FDA eventually confirmed that LDL-C lowering is an acceptable clinical surrogate endpoint for ETC-1002. Ex. 11.

[78] Compl. ¶¶ 70–80.

[79] The case is currently ongoing in that venue.

comments regarding the FDA End-of-Phase II Meeting. Defendants have moved to dismiss under Court of Chancery Rule 23.1 for failure adequately to plead demand futility and Court of Chancery Rule 12(b)(6) for failure to state a claim.

II. ANALYSIS

Under Delaware law, the board of directors, not the stockholders, manages the affairs of a corporation.[80] Accordingly, the decision to initiate litigation derivatively on the company's behalf rests with the board.[81] Court of Chancery Rule 23.1 "exists at the threshold" to ensure that stockholders who seek to sue derivatively first make demand on the board.[82]

If a stockholder elects not to make a demand on the board to bring the derivative claims, then he must "allege with particularity . . . the reasons for [his] failure to obtain the action or for not making the effort."[83] Pleadings alleging demand futility under Rule 23.1 "are held to a higher standard" than this court's default notice pleading standard.[84] Specifically, allegations supporting demand futility "must comply with 'stringent requirements of factual particularity' and set

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[80] *See* 8 *Del. C.* § 141.

[81] *Spiegel v. Buntrock*, 571 A.2d 767, 773 (Del. 1990).

[82] *Aronson v. Lewis*, 473 A.2d 805, 811 (Del. 1984).

[83] Ch. Ct. R. 23.1(a).

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

forth 'particularized factual statements that are essential to the claim.'"[85] To comply with Rule 23.1, a plaintiff must make particularized allegations against each named defendant; he may not "rely on the 'group' accusation mode of pleading demand futility."[86]

When directors are sued for their affirmative actions, demand is futile if the plaintiff pleads facts that create a reasonable doubt that "the directors are disinterested and independent and [] the challenged transaction was otherwise the product of a valid exercise of business judgment."[87] When directors are sued for their failure to act, or where the conduct at issue involves a different board than the one in place at the time demand would be made, the court will excuse demand only when a plaintiff pleads particularized facts creating a reasonable doubt that a majority of the directors considering the demand would be able to do so impartially.[88] Although it is often true that the outcome of the demand futility analysis "would be no different" under either of the *Aronson* or *Rales* tests,[89] it is

[85] *Id.* at 120–21 (quoting *Brehm v. Eisner*, 746 A.2d 244, 254 (Del. 2000)).

[86] *Id.* at 121 n.36 ("Had plaintiffs provided individual allegations as to each of the director defendants, the outcome of this case may have been different.").

[87] *Aronson*, 473 A.2d at 814.

[88] *Rales v. Blasband*, 634 A.2d 927, 934 (Del. 1993).

[89] *In re Duke Energy Corp. Derivative Litig.*, 2016 WL 4543788, at *15 (Del. Ch. Aug. 31, 2016).

useful for the court to receive direction from the plaintiff as to which of the two tests the plaintiff seeks to invoke to demonstrate futility. Unfortunately, that direction is lacking here.[90] Given the lack of clarity in the parties' positions, and because it does appear (as explained below) that the Complaint attempts to plead a second-prong *Caremark* claim, I default to *Rales*.[91]

Plaintiff attempts to meet his heightened pleading burden in two ways. First, he argues that a majority of the Board face a substantial likelihood of liability and, therefore, could not have competently considered a litigation demand.[92] Alternatively, he argues the majority of the Board lack independence from interested fiduciaries and, therefore, would have been unable to exercise their "independent

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[90] Plaintiff has advanced theories under both *Aronson* and *Rales*: (1) that a majority of the Board faces liability for affirmative misstatements; and (2) that a majority of the Board faces oversight liability for a failure to correct Mayleben's alleged misstatements despite observing "red flags" that revealed their falsity. Compl. ¶¶ 12–22. For their part, Defendants maintain that Plaintiff has brought a classic *Caremark* oversight claim and, therefore, *Rales* applies. Oral Arg. on Defs.' Mot. to Dismiss the Verified Compl. ("OA") 18.

[91] *See In re Duke Energy Corp. Derivative Litig.*, 2016 WL 4543788, at *15 (defaulting to *Rales* when the plaintiffs were not clear on whether they were asserting claims of affirmative wrongdoing or a failure to exercise appropriate oversight). *See also In re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959 (Del. Ch. 1996) (Allen, C.) (holding that a director can be held liable for breach of fiduciary duty if the board either fails to have any oversight mechanism in place (prong one) or fails to use existing oversight mechanisms to respond to "red flags" revealing trouble (prong two)). For what it's worth, Plaintiff acknowledges the distinction does not matter here. OA 33–34.

[92] Compl. ¶ 75; *Rales*, 634 A.2d at 936 (citation omitted).

and disinterested business judgment" when considering a demand.[93] As explained below, Plaintiff has not met his pleading burden under either theory.

A. Plaintiff Has Not Well-Pled That A Majority of the Board Face a Substantial Likelihood of Liability

Demand is excused when a plaintiff sufficiently alleges that a majority of the demand board (i.e. the board in place at the time a demand would have been made) would face "a substantial likelihood" of liability if suit were filed.[94] Where, as here, the corporation's charter contains an exculpatory clause, as authorized under 8 *Del. C.* § 102(b)(7), "a substantial likelihood of liability may only be found to exist if the plaintiff pleads a non-exculpated claim against the directors based on particularized facts."[95]

To meet this burden, Plaintiff alleges a majority of the Board face a substantial likelihood of liability for either authorizing or failing to prevent the alleged misstatements.[96] As noted, while the Complaint contains classic *Caremark* language alleging a lack of board oversight and inadequate internal controls, Plaintiff denies

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[93] Compl. ¶ 78; *Rales*, 634 A.2d at 934.

[94] *Rales*, 634 A.2d at 936 (quoting *Aronson*, 473 A.2d at 815).

[95] *Teamsters Union 25 Health Servs. & Ins. Plan v. Baiera*, 119 A.3d 44, 62–63 (Del. Ch. 2015) (quotation omitted). At oral argument, Plaintiff's counsel confirmed Plaintiff is not pursuing a duty of care claim against Mayleben in his role as CEO. OA 50.

[96] Compl. ¶¶ 74–75.

he is pleading a *Caremark* claim and instead argues the majority of Esperion's Board actively contributed to the alleged misstatements.[97] The Complaint, however, does not raise a reasonable inference that a majority of Esperion's Board acted with *scienter*, and it contains not one particularized allegation of intentional misconduct as to a single Outside Director.

1. Plaintiff Has Not Adequately Pled the Director Defendants Made Intentional Misstatements

"Whenever directors communicate publicly or directly with shareholders about a 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."[98] If the board of directors intentionally misleads stockholders about the business of the corporation it serves, then its members will be held liable for breach of fiduciary duty.[99] It follows, therefore, that directors who knowingly make

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[97] *Compare* Compl. ¶¶ 12–22 (alleging each director "failed to ensure reliable systems of internal controls were in place at the Company") *and* Compl. ¶¶ 63–67 (alleging the directors ignored documents "establish[ing] that defendants knew as early as June 2015 that the FDA had signaled a change in its policy" towards accepted clinical surrogate endpoints) *with* Pl.'s. Answering. Br. in Opp'n to Defs.' Mot. to Dismiss ("AB") 35 ("Plaintiff does not plead a 'Caremark' claim based on ignorance of wrongdoing by employees."). This attempt to repackage clearly pled *Caremark* claims as something else, in response to a motion to dismiss, has undermined the credibility of Plaintiff's legal arguments.

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

[99] *Id.* at 14; *In re InfoUSA, Inc. S'holders Litig.*, 953 A.2d 963, 990 (Del. Ch. 2007).

materially misleading statements to stockholders "may be considered to be interested for the purposes of demand."[100]

Plaintiff alleges the Director Defendants contributed to and approved the allegedly misleading statements knowing they were false, that is, with *scienter*.[101] He maintains the Court can reasonably infer *scienter* because the Esperion Board "reviewed, edited and approved the August 17, 2015 press release."[102] These edits, credited broadly by Plaintiff to "the Board," added language to a draft press release that Plaintiff claims morphed true statements into material misstatements.[103]

Plaintiff's allegations fall well short of the particularity mark. While Plaintiff urges the Court to infer *scienter*, the Complaint pleads no facts that would allow a reasonable inference the Outside Directors, individually or collectively, knew that anything included in the press release was false. The Complaint does not allege the Outside Directors attended the FDA meeting or that any one of them knew what occurred at that meeting. Even assuming the Complaint allowed a reasonable inference that certain directors recommended inserting language into the final press release that ultimately was misleading, that inference cannot bear the weight of

[100] *InfoUSA*, 953 A.2d at 991.

[101] Compl. ¶ 58.

[102] Compl. ¶¶ 58–60.

[103] *Id.*

Plaintiff's burden to plead particularized facts that those board members knew the statements were false, but directed that they be disclosed to the market nevertheless.

It is not surprising Plaintiff has not pled particularized facts to support an inference of bad faith given that he has failed to plead any facts that would offer a conceivable explanation of *why* any of the Defendants, let alone the Outside Directors, would intentionally lie to the market knowing full well the official FDA minutes would contradict their statements in a matter of weeks.[104] The Complaint contains no allegations that any of the Defendants engaged in insider trading or otherwise derived some benefit from having misled the market. In the absence of *some* conceivable explanation for why Defendants would lie so openly, especially when they were virtually certain to be caught in the lie, it is not reasonable to infer bad faith.[105]

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[104] *See Ryan v. Armstrong*, 2017 WL 2062902, at *5 (Del. Ch. May 15, 2017) (refusing to credit allegations of bad faith absent credible motive).

[105] *See In re Novell, Inc. S'holder Litig.*, 2014 WL 6686785, at *7 (Del. Ch. Nov. 25, 2014) ("An analysis of motives is [] key to determining whether a fiduciary acted in bad faith."); *Armstrong*, 2017 WL 2062902, at *5 (same). Far more likely is that the Esperion officials who attended the meeting simply misinterpreted the FDA's comments, and the Outside Directors then relied on Mayleben's assessment of the meeting, as they are entitled to do under 8 *Del. C.* § 141(e). This is especially so when the facts relayed to the Board by Mayleben were consistent with the FDA's past practices. Compl. ¶ 47; OA 48–49.

In a last gasp to allege *scienter*, Plaintiff invokes what has become known as the "core operations" doctrine.[106] In making this argument, Plaintiff elides the scope and purpose of the doctrine. The core operations doctrine "is not sufficient *on its own* [to satisfy the heightened pleading burden imposed by Rule 23.1] in the context of generally pled allegations to establish scienter."[107] Instead, Plaintiff must plead other particularized facts that support an inference of director knowledge before the core operations doctrine may be invoked to enhance that inference.[108] Plaintiff has failed to plead those particularized facts here.

2. Plaintiff Has Not Adequately Alleged Oversight Liability

A director will face liability under *Caremark* where, in bad faith, he fails to oversee company operations.[109]

> Bad faith is established, under *Caremark*, when 'the directors [completely] fail[] to implement any reporting or information system

[106] AB 39–40. The core operations doctrine allows a court, in certain circumstances, to infer board knowledge of matters relating to a corporation's core product. *In re Fitbit, Inc. S'holder Derivative Litig.*, 2018 WL 6587159, at *15 n.179 (Del. Ch. Dec. 14, 2018) (citations omitted).

[107] *Id.*

[108] *Id.* Plaintiff summarily argues the Outside Directors' extensive experience in the pharmaceutical industry means they should have been alarmed by the "unusual step" of releasing a press release before the official FDA minutes were released. AB 41. But it is well-settled in Delaware that director experience, without additional pled facts, will not alone allow an inference of *scienter*. *See Citigroup*, 964 A.2d at 128 (rejecting the idea that director experience with previous scandals should have made them "especially sensitive" to red flags).

[109] *Marchand v. Barnhill*, 212 A.3d 805, 820 (Del. 2019).

> or controls[,] or . . . having implemented such a system or controls, consciously fail[] to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring their attention.'[110]

"Thus, to establish oversight liability a plaintiff must show the director *knew* they were not discharging their fiduciary obligations or that the directors demonstrated a *conscious* disregard for their responsibilities such as by failing to act in the face of a known duty to act."[111]

Having failed to well-plead that the Director Defendants knowingly released a misleading press release, Plaintiff must fall back and reset the battle line at *Caremark* ridge.[112] Where, as here, there is an exculpatory clause in the corporate charter, "it is not enough to allege that the misleading statements occurred on [the] directors' watch; nor is it enough to plead facts from which [the court] may infer negligence, or even gross negligence, in the directors' failure to cure the misimpression created by the statements."[113] Instead, Plaintiff must well-plead that

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[110] *Id.* at 821 (quoting *Stone ex rel. AmSouth Bancorp v. Ritter*, 911 A.2d 362, 370–72 (Del. 2006)).

[111] *Citigroup*, 964 A.2d at 123.

[112] *See Horman v. Abney*, 2017 WL 242571, at *7 (Del. Ch. Jan. 19, 2017) (describing a board knowing "of evidence of corporate misconduct . . . yet act[ing] in bad faith by consciously disregarding its duty to address that misconduct" as a *Caremark* claim.).

[113] *Ellis v. Gonzalez*, 2018 WL 3360816, at *11 (Del. Ch. July 10, 2018).

the directors acted in bad faith when they allowed the alleged misstatements to be made and then failed to correct them.[114]

Plaintiff points to minutes from an August 19, 2015 Board meeting that he says show the Board knew that the FDA advised the Esperion team at the August 11 meeting that a longer regulatory approval process might be necessary.[115] With this information in hand, the Director Defendants acted in bad faith, says Plaintiff, when they failed to issue a correction to the misleading press release.[116]

While I must "draw all inferences from [alleged] particularized facts in favor of the plaintiff, and not the defendant," I am not required to draw unreasonable inferences.[117] Plaintiff's showcase pleading of Board knowledge rests on a quote

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[114] *Id.*

[115] Compl. ¶¶ 61–66.

[116] *Id.*

[117] *See Del. Cty. Empls. Ret. Fund v. Sanchez*, 124 A.3d 1017, 1022 (Del. 2015); *Amalgamated Bank v. Yahoo! Inc.*, 132 A.3d 752, 798 (Del. Ch. 2016). The parties agreed, as a condition to the Section 220 production, that all documents produced would be deemed incorporated into the Complaint. Compl. at 1; AB 23. Thus, the parties have agreed that I may review documents cited in the Complaint "to ensure that the plaintiff has not misrepresented [their] contents and that any inference the plaintiff seeks to have drawn is a reasonable one." *Yahoo!*, 132 A.3d at 797. Plaintiff argues that I cannot weigh competing factual interpretations of incorporated documents on a motion to dismiss. That is true. But a plaintiff likewise "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). I am permitted to review incorporated documents "to ensure that the plaintiff cannot seize on a document, take it out of context, and insist on an unreasonable inference that the court could not draw if it considered related documents." *Id.* at 798. *See also In re Clovis Oncology, Inc. Derivative Litig.*, 2019 WL 4850188, at *14 n.216 (Del. Ch. Oct. 1, 2019) (noting that while

from a presentation delivered at the August 19 Board meeting, where the Board was advised, "[Esperion] expect[s] the FDA will likely continue to evolve policy on LDL-C lowering drug approvals."[118] On the very next slide, however, the Board was advised that Esperion considered the FDA meeting "successful" and that a CVOT trial would occur "post-approval."[119] The slide after that contains almost *exactly* the same message as the allegedly misleading press release and investor call: "LDL-C lowering drugs can be approved initially in high risk patients. Broader label now requires CVOT."[120] If anything, the document Plaintiff proffers as support for the inference of bad faith that he must well-plead actually supports the *opposite* inference.

B. The Complaint Does Not Create a Reasonable Doubt About the Independence of the Majority of the Esperion Board

When judging whether demand is excused because a majority of directors lack independence, this Court "counts heads" among the demand board to assess each

"Section 220 documents, hand selected by the company, cannot be offered to rewrite an otherwise well-pled complaint," they can be offered, and considered by the court, to ensure the plaintiff is not taking documents out of context). That is all I have done here.

[118] ESPERION 000382.

[119] ESPERION 000383.

[120] ESPERION 000384.

director's fitness to impartially manage the corporation's litigation asset.[121] If a majority of the board is interested, then demand is futile and excused.[122] If not, then demand is not excused.[123] When this suit was filed, Esperion's Board comprised nine members: Mayleben, Newton, McGovern, Omenn, Braunstein, Vitullo, Janney, Goldstein and Gotto.[124] To plead demand futility, Plaintiff must show five of these directors were unfit to consider his demand. Defendants concede that Mayleben and Newton are not independent for the purposes of this motion.[125] Plaintiff does not contest McGovern, Omenn or Braunstein's independence.[126] Therefore, Plaintiff must show that three of Vitullo, Janney, Goldstein and Gotto lack independence.

"In the demand futility context, directors are presumed to be independent."[127] To rebut this presumption, a plaintiff must plead facts alleging a director is so

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[121] *In re EZCORP Inc. Consulting Agmt. Derivative Litig.*, 2016 WL 301245, at *34 (Del. Ch. Jan. 25, 2016).

[122] *Id.*

[123] *Id.*

[124] Compl. ¶¶ 76–79. Although Defendant Enright was a director at the time of the alleged misconduct, he was not a director when the suit was filed.

[125] *See* OB 2.

[126] Plaintiff did not challenge these three directors' independence in his answering brief or at oral argument. "It is settled Delaware law that a party waives an argument by not including it in its brief." *Emerald P'rs v. Berlin*, 2003 WL 21003437, at *43 (Del. Ch. Apr. 28, 2003).

[127] *Baiera*, 119 A.3d at 59 (quotation omitted).

beholden to the interested director that his "discretion would be sterilized."[128] "A lack of independence turns on whether the plaintiffs have pled facts from which the director's ability to act impartially on a matter important to the interested party can be doubted because that director may feel either subject to the interested party's dominion or beholden to that interested party."[129]

Plaintiff's theory as to why Vitullo and Janney lack independence is that both Defendants, through their venture capital firms, profited handsomely from Pfizer's 2004 acquisition of Old Esperion.[130] He contends this fact, along with Alta and Domain's stakes in Esperion, allows an inference that these fiduciaries "will not do anything to jeopardize Newton and Mayleben."[131] He applies similar reasoning to Goldstein—Goldstein was trusted by Newton to join the Board and his venture capital firm has a stake in Esperion, therefore his independence can be reasonably doubted.[132]

The fact that a founder invited a director to join the company's board of directors, without more, does not support an inference that the director cannot

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[128] *Rales*, 634 A.2d at 936.

[129] *Marchand*, 212 A.3d at 818 (quotation omitted).

[130] AB 48–55.

[131] AB 54.

[132] *Id.*

exercise independent judgment in matters involving the founder.[133] Nor does our law infer a lack of director independence simply because that director owns stock in the company on whose board he sits; indeed, that dynamic is common and is generally regarded as a desirable alignment of incentives between fiduciaries and beneficiaries.[134] "If it were enough to plead director interestedness merely by alleging that the director's holdings *might be* devalued as a result of derivative litigation, it is difficult to imagine how a plaintiff would not carry his *heightened* burden to plead demand futility in nearly every derivative case."[135]

Plaintiff's allegations contesting Gotto's independence fare no better. Plaintiff focuses on Gotto's service on the boards of both Old Esperion and Esperion and alleges that Gotto earned $839,700 when Old Esperion was sold.[136] According

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[133] *See Khanna v. McGinn*, 2006 WL 1388744, at *15 (Del. Ch. May 9, 2006) (holding that plaintiffs failed to plead particularized facts that a director was "beholden" to the alleged controller, and that their generalized pleading of a lack of independence was "akin to the shorthand shibboleth which this Court has long rejected"); *In re W. Nat'l Corp. S'holders Litig.*, 2000 WL 710192, at *15 (Del. Ch. May 22, 2000) ("[A]s a preliminary matter, I note that even if [alleged controller] nominated some of the outside directors . . . such nomination, without more, does not mandate a finding that these directors were beholden to [alleged controller] . . . .").

[134] *Tilden v. Cunningham*, 2018 WL 5307706, at *12 (Del. Ch. Oct. 26, 2018).

[135] *Id.* (emphasis in original). Where, as here, the holdings creating the alleged conflict are not owned by the individual director, but by a firm where he is but one of several partners, any inference of interestedness is even weaker. Compl. ¶ 77.

[136] Compl. ¶ 76.

to Plaintiff, these pled facts reveal Gotto's "sense of owingness to [Mayleben and Newton] for his Old Esperion windfall and his continued directorship raises a reason to doubt that he could impartially consider a demand to sue Mayleben and Newton."[137]

These allegations are precisely the kind of "naked assertion[s] of a previous business relationship" that this court routinely deems insufficient to meet Rule 23.1's particularity standard.[138] The Complaint does not plead with particularity that Gotto's relationship with Mayleben and Newton involves the "very warm and thick personal ties of respect, loyalty, and affection" that would support an inference Gotto "would be more willing to risk his [] reputation than risk the relationship with the interested director."[139]

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As there are no reasonable doubts as to Vitullo, Janney, Goldstein or Gotto's independence, Plaintiff has not reached the required headcount to plead demand futility. Having determined that Plaintiff has failed to carry his burden to plead

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[137] AB 52.

[138] *Orman v. Cullman*, 794 A.2d 5, 26–27 (Del. Ch. 2002). *See also Khanna*, 2006 WL 1388744, at *20 (same); *Highland Legacy Ltd. v. Singer*, 2006 WL 741939, at *5 (Del. Ch. Mar. 17, 2006) (same); *Jacobs v. Yang*, 2004 WL 1728521, at *7 n.33 (Del. Ch. Aug. 2, 2004) (same).

[139] *Marchand*, 212 A.3d at 819; *Beam ex rel. Martha Stewart Living Omnimedia, Inc. v. Stewart*, 845 A.2d 1040, 1052 (Del. 2004).

demand futility with particularity, I need not reach Defendants' arguments under Rule 12(b)(6) that the Complaint fails to state viable claims.[140]

III. CONCLUSION

Based on the foregoing, Defendants' Motion to Dismiss with prejudice under Rule 23.1 must be **GRANTED**.

IT IS SO ORDERED.

[140] *In re LendingClub Corp. Derivative Litig.*, 2019 WL 5678578, at *18 (Del. Ch. Oct. 31, 2019).