EFiled: Oct 01 2019 01:59PM EDT
Transaction ID 64260437
Case No. 2017-0222-JRS

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

IN RE CLOVIS ONCOLOGY, INC. DERIVATIVE LITIGATION	))	**CONSOLIDATED C.A. No. 2017-0222-JRS**

MEMORANDUM OPINION

Date Submitted: July 1, 2019
Date Decided: October 1, 2019

Seth D. Rigrodsky, Esquire, Brian D. Long, Esquire and Gina M. Serra, Esquire of Rigrodsky & Long, P.A., Wilmington, Delaware; Nicholas I. Porritt, Esquire, Adam M. Apton, Esquire and Adam C. McCall, Esquire of Levi & Korsinsky, LLP, Washington, D.C.; Kip B. Shuman, Esquire of The Shuman Law Firm, San Francisco, California; and Rusty E. Glenn, Esquire of The Shuman Law Firm, Denver, Colorado, Attorneys for Plaintiffs Carl McKenry and Juzet Macalinao on behalf of Clovis Oncology, Inc.

Gregory P. Williams, Esquire, Blake Rohrbacher, Esquire and Robert L. Burns, Esquire of Richards Layton & Finger, P.A., Wilmington, Delaware, Attorneys for Defendants Brian G. Atwood, M. James Barrett, James C. Blair, Keith T. Flaherty, Ginger L. Graham, Paul H. Klingenstein, Edward J. McKinley and Thorlef Spickschen.

William M. Lafferty, Esquire and Ryan Stottmann, Esquire of Morris, Nichols, Arsht & Tunnell LLP, Wilmington, Delaware and Tariq Mundiya, Esquire, Todd G. Cosenza, Esquire and Charles Dean Cording, Esquire of Willkie Farr & Gallagher LLP, New York, New York, Attorneys for Defendants Patrick J. Mahaffy, Erle T. Mast and Nominal Defendant Clovis Oncology, Inc.

SLIGHTS, Vice Chancellor

Like many upstart biopharmaceutical companies, nominal defendant, Clovis Oncology, Inc. (or the "Company"), had one drug among its drugs under development, Rociletinib (or "Roci"), that was especially promising. Roci, a therapy for the treatment of lung cancer, performed well during the early stages of its clinical trial. But data from later stages of the trial revealed the drug likely would not be approved for market by the Food and Drug Administration ("FDA"). Plaintiffs, Clovis stockholders, allege members of the Clovis board of directors (the "Board") breached their fiduciary duties by failing to oversee the Roci clinical trial and then allowing the Company to mislead the market regarding the drug's efficacy.[1] These breaches, it is alleged, caused Roci to sustain corporate trauma in the form of a sudden and significant depression in market capitalization. Plaintiffs also allege that certain members of the Board and a member of senior management engaged in unlawful stock trades before the market was apprised of Roci's failure.[2]

Defendants have moved to dismiss each of Plaintiffs' derivative claims under Court of Chancery Rules 23.1 and 12(b)(6) for failure to plead demand futility with particularity and failure to state viable claims. As explained below, Plaintiffs have well-pled that Defendants face a substantial likelihood of liability under *Caremark*

[1] *See In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959 (Del. Ch. 1996).

[2] *See Brophy v. Cities Serv. Co.*, 70 A.2d 5 (Del. Ch. 1949).

and our Supreme Court's recent explication of *Caremark* in *Marchand v. Barnhill*.[3] Clovis conducted its clinical trial of Roci subject to strict protocols and associated FDA regulations. Yet, assuming the pled facts are true, the Board ignored red flags that Clovis was not adhering to the clinical trial protocols, thereby placing FDA approval of the drug in jeopardy. With the trial's skewed results in hand, the Board then allowed the Company to deceive regulators and the market regarding the drug's efficacy.

As explained in *Marchand*, "to satisfy their duty of loyalty, directors must make a good faith effort to implement an oversight system and then *monitor it*."[4] This is especially so when a monoline company operates in a highly regulated industry.[5] Here, Plaintiffs have well-pled Roci was "intrinsically critical to the [C]ompany's business operation," yet the Board ignored multiple warning signs that management was inaccurately reporting Roci's efficacy before seeking confirmatory scans to corroborate Roci's cancer-fighting potency—violating both internal clinical trial protocols and associated FDA regulations.[6] In other words, Plaintiffs have well-pled a *Caremark* claim.

---

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

[4] *Id.* at 821 (emphasis supplied).

[5] *Id.* at 809.

[6] *Id.* at 822.

The same cannot be said for Plaintiffs' attempt to plead *Brophy* and unjust enrichment claims.[7] Specifically, with respect to *Brophy*, Plaintiffs have failed to plead facts that allow a reasonable inference of scienter. The allegedly unlawful trades were so small in relation to each fiduciary's Clovis stock holdings as to defy any inference of the bad intent required to state a claim. And Plaintiffs' unjust enrichment claim, when reduced to its essence, rests on their deficient *Brophy* claim.

I. FACTUAL BACKGROUND

I draw the facts from the allegations in the Supplemental Consolidated Verified Shareholder Derivative Complaint (the "Complaint"), documents incorporated by reference or integral to that pleading and judicially noticeable facts.[8]

[7] *Brophy*, 70 A.2d 5.

[8] *See Wal-Mart Stores, Inc. v. AIG Life Ins. Co.*, 860 A.2d 312, 320 (Del. 2004) (quoting *In re Santa Fe Pac. Corp. S'holder Litig.*, 669 A.2d 59, 69 (Del. 1995)) (noting that on a motion to dismiss, the Court may consider documents that are "incorporated by reference" or "integral" to the complaint); D.R.E. 201–02 (codifying Delaware's judicial notice doctrine). *See also Amalgamated Bank v. Yahoo! Inc.*, 132 A.3d 752, 797 (Del. Ch. 2016), *abrogated on other grounds*, 2019 WL 3683525 (Del. Aug. 7, 2019) (noting that where, as here, the nominal defendant has produced documents in response to a demand for books and records under 8 *Del. C.* § 220 on the condition that such documents be deemed incorporated by reference in any complaint that might be filed, the court may consider the documents in their entirety rather than rely only the portions "cherry-picked" by the plaintiff).

For purposes of this motion to dismiss, I accept as true the Complaint's well-pled factual allegations and draw all reasonable inferences in Plaintiffs' favor.[9]

A. Parties and Relevant Non-Parties

Plaintiffs, Carl McKenry and Juzet Macalinao, are Clovis stockholders.[10] They have held Clovis common stock since March 26, 2014 and January 1, 2014, respectively.[11]

Nominal Defendant, Clovis, is a biopharmaceutical firm focused on acquiring, developing and commercializing cancer treatments.[12] During the Relevant Period,[13] Clovis had no drugs on the market but did have three drugs in development. Of these, Roci was the most promising.[14]

Plaintiffs bring this derivative action against all nine members of the Board (collectively, the "Board Defendants"), each of whom was a member of the Board

[9] *Marchand*, 212 A.3d at 813 ("At this stage of the case, we are bound to draw all fair inferences in the plaintiff's favor from the well-pled facts.").

[10] Suppl. Consol. Verified S'holder Deriv. Compl. ("Compl.") (D.I. 37) ¶¶ 27–28.

[11] Compl. ¶¶ 27–28, 247.

[12] Compl. ¶ 29.

[13] The Complaint defines the "Relevant Period" as the start of the phase II Roci trial on February 26, 2014, through the initiation of this litigation. Compl. ¶ 7.

[14] Compl. ¶¶ 63, 68.

during the Relevant Period.[15] Defendant, Erle Mast, is Clovis' former Executive Vice President and Chief Financial Officer ("CFO").[16] Defendants collectively owned upwards of 17.4% of the Company's stock.[17]

The Board has two relevant sub-committees. The Nominating and Corporate Governance Committee is charged with developing and overseeing the effectiveness of Clovis' legal, ethics and regulatory compliance matters.[18] The Audit Committee oversees typical audit functions and, importantly, reviews earnings reports with management before release to the market.[19]

Defendant, Brian G. Atwood, has served on the Board since Clovis' inception in 2009.[20] He served as a member of the Audit Committee and the Nominating and Corporate Governance Committee for fiscal years 2013–2015.[21] Atwood had

---

[15] Compl. ¶¶ 1, 257.

[16] Compl. ¶ 38.

[17] Compl. ¶¶ 30, 41.

[18] Compl. ¶¶ 56–57. The Nominating and Corporate Governance Committee is also charged with providing "general compliance oversight," receiving "updates about the compliance program," and reviewing "the status and effectiveness of [Clovis'] compliance programs with respect to non-financial regulatory requirements, including . . . Federal health care program requirements and [FDA] requirements (and similar non-U.S. requirements, as applicable)." Compl. ¶ 279.

[19] Compl. ¶ 58.

[20] Compl. ¶ 30.

[21] *Id.*

previous experience as co-founder of a biotechnology company and as a managing director for a healthcare-focused venture capital firm.[22]

Defendant, M. James Barrett, Ph.D., has served on the Board since Clovis' inception.[23] He serves as Chairman of the Board and as Chairman of the Nominating and Corporate Governance Committee.[24] Additionally, Barrett has held positions as a general partner in a healthcare venture capital firm and as the chairman, CEO and founder of a medical technology company.[25]

Defendant, James Blair, Ph.D., has served on the Board since Clovis' inception.[26] He is a member of the Nominating and Corporate Governance Committee and serves as Chairman of the Compensation Committee.[27] Blair has over thirty years of experience as a general partner in a life sciences venture capital management company.[28] Some of his other experience includes serving on the

[22] *Id.*

[23] Compl. ¶ 31.

[24] *Id.*

[25] *Id.*

[26] Compl. ¶ 32.

[27] *Id.*

[28] *Id.*

boards of over 40 life science companies as well as the advisory board of the Department of Molecular Biology at Princeton University.[29]

Defendant, Keith Flaherty, M.D., has served on the Board since 2013.[30] He is a member of the Nominating and Corporate Governance Committee.[31] Additionally, Flaherty is an Associate Professor of Medicine at Harvard Medical School and has been a principal investigator for numerous first-in-human clinical trials with novel, targeted therapies.[32]

Defendant, Ginger Graham, has served on the Board since 2013.[33] She is a member of the Compensation Committee.[34] Graham has previous experience as the president and CEO of a biopharmaceutical company and has served on the boards of multiple healthcare firms.[35]

---

[29] *Id.*

[30] Compl. ¶ 33.

[31] *Id.*

[32] *Id.*

[33] Compl. ¶ 34.

[34] *Id.*

[35] *Id.*

Defendant, Paul Klingenstein, has served on the Board since Clovis' inception.[36] He is a member of the Audit Committee.[37] Klingenstein has additional experience as a managing partner of a healthcare venture capital firm, which he formed in 1999.[38] And he has served on the boards of multiple pharmaceutical companies.[39]

Defendant, Patrick J. Mahaffy, is one of Clovis' co-founders and has been Clovis' CEO, President and a member of the Board since Clovis' inception.[40] Mahaffy previously served as the president and CEO of two biopharmaceutical companies—one of which he also founded.[41]

Defendant, Edward J. McKinley, has served on the Board since Clovis' inception.[42] He is a member of the Audit Committee.[43]

---

[36] Compl. ¶ 35.

[37] *Id.*

[38] *Id.*

[39] *Id.*

[40] Compl. ¶ 36.

[41] *Id.*

[42] Compl. ¶ 37.

[43] *Id.*

Defendant, Thorlef Spickschen, has served on the Board since Clovis' inception.[44] He is a member of the Compensation Committee.[45] Before joining Clovis, he served as the chairman of a publicly-traded biotechnology company, as well as Eli Lilly & Co.'s managing director for Germany and Central Europe.[46]

Defendant, Erle T. Mast, is a Clovis co-founder and served as Executive Vice President and CFO from the Company's inception in 2009 until his resignation in March 2016.[47] Mast was not a member of the Board during the Relevant Period.[48]

Non-party, Dr. Andrew Allen, served as Clovis' Chief Medical Officer ("CMO") during the Relevant Period.[49] Non-party, AstraZeneca PLC, is a pharmaceutical company based in the United Kingdom. AstraZeneca manufactures Tagrisso (described below), which would have directly competed with Roci had Roci made it to market.[50]

---

[44] Compl. ¶ 38.

[45] *Id.*

[46] *Id.*

[47] Compl. ¶ 40.

[48] *Id.*

[49] Compl. ¶ 13.

[50] Compl. ¶ 76.

B. Clovis Initiates Roci's Clinical Trial

At the beginning of the Relevant Period, Clovis had no products on the market and generated no sales revenue.[51] Accordingly, Clovis "reli[ed] solely on investor capital for all [] operations."[52] The Company's prospects rested largely on one of its three developmental drugs, Roci, a cancer drug designed to treat a previously-untreatable type of lung cancer.[53] Because of the estimated $3 billion annual market for drugs of its type, Clovis expected Roci to generate large profits if Clovis could secure FDA approval for the drug and shepherd it to market.[54]

As the Roci clinical trial began, the Board knew time was of the essence. AstraZeneca's competing drug, Tagrisso, was also in the race for FDA approval.[55] Appreciating Roci's importance to Clovis' success, the Board was hyper-focused on the drug's development and clinical trial.[56] Indeed, it is alleged the Board

---

[51] Compl. ¶¶ 63, 68.

[52] Compl. ¶ 68.

[53] Compl. ¶ 71 ("[P]rior to the Relevant Period (and the approval of competitor drug Tagrisso), no targeted therapies were approved for the treatment of tumors with the T790M resistance mutation.").

[54] Compl. ¶¶ 71–72.

[55] Compl. ¶¶ 72, 76, 79, 101.

[56] Compl. ¶¶ 8, 20, 101. *See, e.g.*, Compl. ¶ 20 ("Clovis' internal documents confirm that the Board was regularly apprised of the ongoing [Roci clinical trial] and spent hours at Board meetings discussing [Roci's] trial status and competitor drugs, particularly

Defendants "spent hours at Board meetings discussing [Roci]" and were "regularly apprised" of the drug's progress.[57]

To obtain FDA approval, new drugs like Roci and Tagrisso must prove their efficacy and safety in clinical trials.[58] Before commencing a clinical trial, the FDA requires a drug's sponsor to agree to certain standards that define how the trial will be conducted, how the trial data will be analyzed and, most relevant here, how success in the trial will be measured.[59] These agreed-upon standards become the "clinical trial protocol."[60] If the drug's sponsor fails to adhere to the clinical trial protocol, the FDA will not approve a new drug for market.[61]

Clovis named its Roci clinical trial "TIGER-X."[62] TIGER-X incorporated a standardized and well-known clinical trial protocol called "RECIST."[63] Clovis

---

Tagrisso.") (citing Compl. Ex. A at 00120–00126; 00180–00181; 00371–00372; 00494–00495; 00732–00733; 00870; 00873; 001069; 01073).

[57] Compl. ¶ 20.

[58] Compl. ¶ 77.

[59] Compl. ¶¶ 81–82.

[60] Compl. ¶ 81 (citing Friedman, et al., *Fundamentals of Clinical Trials* 3–8 (4th ed. 2010) (describing clinical trial protocols as "a written agreement between the investigator [the drug company], the participant, and the scientific community.")).

[61] Compl. ¶¶ 81, 99.

[62] Compl. ¶¶ 65–67.

[63] Compl. ¶¶ 82, 84, 88, 89. "RECIST" stands for "Response Evaluation Criteria in Solid Tumors." Compl. ¶ 83.

chose RECIST instead of a lesser-known or bespoke clinical trial protocol because RECIST "has become the most widely used system for assessing response in cancer clinical trials, and is the preferred and accepted system for use in new drug applications to regulatory agencies."[64] By selecting RECIST, Clovis was able to "give investors confidence in the Company's reported results" by facilitating "comparisons between [Roci] and competing therapies."[65]

One of RECIST's important functions is to establish the "criteria defining success" for the clinical trial.[66] This success-defining metric is called the objective response rate (or "ORR").[67] ORR measures the percentage of patients who experience meaningful tumor shrinkage when treated with the drug.[68] This metric

---

[64] Compl. ¶ 83 (quoting Manola et al., *Assessment of Treatment Outcome, in* UICC MANUAL OF CLINICAL ONCOLOGY 40, 44 (Brian O'Sullivan et al. eds., 9th ed. 2015)).

[65] Compl. ¶ 85.

[66] Compl. ¶ 82.

[67] Compl. ¶¶ 8, 82.

[68] Compl. ¶ 8. Importantly, RECIST "unequivocally requires each instance of tumor shrinkage (a response) to be 'confirmed.' This means that any initial observation . . . [of tumor shrinkage] must have been observed in a subsequent scan before it can be included in the calculation of ORR." Compl. ¶¶ 82, 83, 86, 97–98. Indeed, "[m]embers of the medical and scientific communities view response confirmation as the key metric to guaranteeing the reliability, soundness, and reproducibility of claimed efficacy results." Compl. ¶ 97 (citing Eisenhaur, et al., *New response evaluation criteria in solid tumors: Revised RECIST guideline (version 1.1)*, 45 EUROPEAN J. CANCER, 228, 236 (2009)). Defendants assert that, during the time Clovis was submitting data to the FDA, it was not clear the FDA required confirmed responses because the FDA had granted Roci "[a]ccelerated [a]pproval" for which confirmation was not required for "interim results." *See* Defs.' Br. in Supp. of Their Mot. to Dismiss Pls.' Consol. Verified S'holder Compl.

is important both to the FDA in its approval process and to physicians in deciding whether to prescribe the drug.[69] Not surprisingly, then, the "[Board] was laser-focused on [Roci's] ORR."[70]

As Roci's clinical trial progressed, the Board knew investors would not view an ORR incorporating unconfirmed responses as "meaningful," nor would the FDA accept such results as "approvable."[71] Indeed, each of the Board Defendants appreciated the FDA "could only make its decision . . . to approve Roci based [] on confirmed responses."[72]

C. TIGER-X Trial's Undisclosed Failure to Follow RECIST Standards

Ostensibly intending to follow RECIST, the TIGER-X protocol specifically required and set out a schedule for confirmation scans.[73] And throughout the

("DOB") (D.I. 16) at 11–12, 14, 28. Plaintiffs respond by pointing to RECIST guidelines stating, "confirmation [of responses] is required." *See* Pls.' Answering Br. in Opp'n to Defs.' Mot. to Dismiss ("PAB") (D.I. 23) at 9. Of course, at this stage, I cannot resolve this or any other factual dispute; I am obliged to "accord the plaintiff the benefit of all reasonable inferences." *Marchand*, 212 A.3d at 820.

[69] Compl. ¶¶ 8, 120, Ex. A at 00371.

[70] Compl. ¶ 8. *See also* Compl. ¶ 78 ("The single most critical metric that the [Board] Defendants, regulators, medical professionals, and investors focused on during the phase II trials was [Roci's] [ORR]. Oncologists and researchers view ORR as the critical measure of a cancer drug's efficacy.").

[71] Compl. ¶ 97.

[72] Compl. ¶¶ 99–100 (citing FDA guidance documents).

[73] Compl. ¶¶ 87–91, 99–100.

Relevant Period, Clovis' press releases, investor calls, Securities and Exchange Commission ("SEC") filings and statements to medical journals reinforced the belief that Clovis was reporting a confirmed ORR of about 60% "per RECIST."[74] Mindful of the race to market, Clovis' management consistently represented that Roci's ORR was at least as encouraging as Tagrisso's.[75]

Despite these public signals, as early as June 12, 2014, the Board received reports indicating Clovis was improperly calculating Roci's ORR.[76] Specifically, these reports suggested that, while the clinical trial protocol required Clovis to calculate ORR based only on confirmed responses, Clovis was actually calculating ORR, in part, based on unconfirmed responses.[77] For example, on June 12, 2014, the Board reviewed management's presentations from a May 31, 2014 medical conference (the "ASCO conference").[78] That data indicated Roci's ORR was

---

[74] *See, e.g.*, Compl. ¶¶ 80, 90, 91–99, 102–103, 106, 112, Ex. A at 00296 (symposium presentation slide showing responses "per RECIST"), 00302 (same), 01004 (board slide deck showing response "per RECIST"). *See also* Compl. ¶ 95 (describing a medical paper that republished data originally disclosed by Clovis' Chief Medical Officer) (citing Sequist, et al., *Rociletinib in EGFR-Mutated Non-Small-Cell Lung Cancer*, 372 NEW ENG. J. MED. 1700, 1704 (2015)).

[75] Compl. ¶¶ 102–03, 112.

[76] Compl. ¶¶ 103–104, 224. *See, e.g.*, Compl. ¶ 224 ("[T]he [Board] Defendants were well aware that the ORR data was 'immature' and based on both unconfirmed and confirmed responses.") (citing Compl. Ex. A at 00162, 00246, 00371, 00495, 01021).

[77] Compl. ¶¶ 103–104, 106–08, 201.

[78] Compl. ¶ 104.

"58 percent" (the "ASCO ORR").[79] At the same meeting, management told the Board the ASCO ORR would improve "as patients get to their second and third scans."[80] By definition, then, the ASCO ORR was partially based on unconfirmed results (i.e., it was not RECIST compliant).[81] Notwithstanding this revelation, the Board did nothing.

Mahaffy continued publicly to report Roci's ORR at 58% in investor calls,[82] and on August 7, 2014, Clovis issued a press release restating this inflated number.[83] Soon after, the Board viewed another report signaling that Clovis' management was calculating Roci's ORR with unconfirmed responses and that only "80% of unconfirmed [responses] convert to confirmed."[84]

---

[79] Compl. ¶¶ 12, 16, 103–104, Ex. A at A0060, A0074, A0108; *see also* the SEC's settlement agreement and subsequent settlement consent decree confirming that the 60% ORR presented at the ASCO conference included unconfirmed responses while the actual ORR, including only confirmed responses, was only 40%. Compl. ¶ 128.

[80] Compl. ¶ 104, Ex. A at 00120.

[81] *See* Compl. ¶ 10 ("RECIST unequivocally requires each instance of tumor shrinkage (a response) to be 'confirmed.'"). Plaintiffs allege that an ORR including unconfirmed scans is, by definition, *not* an "ORR" because ORR can only be calculated with confirmed scans. Compl. ¶ 105.

[82] Compl. ¶ 107.

[83] Compl. ¶¶ 107–08, 201; Clovis, Current Report (Form 8-K) (Aug. 7, 2014).

[84] Compl. ¶¶ 107–08, Ex. A at 00162.

On September 9, 2014, Clovis closed a critical $287 million private placement of convertible senior notes in order to finance ongoing operations.[85] The Board relied heavily upon the market's positive reaction to Roci's publicly reported ORR to make its case for further investment in the Company.[86]

As the Company was touting Roci's prospects, management gave a presentation to the Board explicitly comparing Roci's 63% mixed ORR to Tagrisso's confirmed 70%.[87] Another Board presentation from the same time period showed that management was reporting Roci's ORR using partially unconfirmed responses by noting that Roci's ORR was "**Unconfirmed*."[88]

As TIGER-X progressed, Clovis' public statements regarding Roci remained upbeat. Roci was Clovis' champion and it was prepared to do battle with Tagrisso. On September 9, 2014, Mahaffy told a securities analyst that Roci and Tagrisso had "similar response rate[s]," and on November 18, 2014, Clovis issued a press release stating that Roci's ORR was 67%.[89]

---

[85] Compl. ¶ 110.

[86] Compl. ¶¶ 110–11.

[87] Compl. ¶¶ 12–13, 101, 112, Ex. A at 00231; *see also* Letter to Vice Chancellor Slights from Brian D. Long, Esq., on behalf of Pls.' Resp. to Questions Posed by the Ct. at the June 19, 2019 Hr'g in this Matter ("Pls.' Letter") (D.I. 61) at 2–3.

[88] Compl. ¶¶ 13, 224, 259, Ex. A at 00246; Pls.' Letter at 2–3.

[89] Compl. ¶¶ 112–13.

The Board, however, continued to receive signals that management was not vigilantly following RECIST. On December 3, 2014, the Board reviewed a report stating, "in mid-March, we will have a response rate of less than 60% (could be less than 50%)."[90] The same report revealed the Company was waiting on "data maturity" and that at least some patients had not received a second scan at that time, indicating continued non-compliance with RECIST.[91]

With hands on their ears to muffle the alarms, on February 27, 2015, Defendants Mahaffy, Mast, Atwood, Barrett, Blair, Flaherty, Graham, Klingenstein, McKinley and Spickschen signed Clovis' 2014 Annual Report.[92] The report reaffirmed previous, inflated ORR reports and omitted that Clovis was relying on partially unconfirmed responses.[93]

On April 29, 2015, management updated the Board by presenting a series of slides depicting that the highest ORR for any subgroup of Roci patients was 53.3% and revealing the numbers were as low as 37.1% for other groups.[94] The next day,

---

[90] Compl. ¶ 120, Ex. A at 00371.

[91] *Id.* ("We really want to get to at least 2 scans on every patient and to more than 2 on as many as we can.").

[92] Compl. ¶¶ 206–07.

[93] *Id.*

[94] Compl. ¶ 16, Ex. A at 00633, 00640, 00717, 00724, 00726. *See also* Pls.' Letter at 3–4.

Clovis management and CMO Allen published data from the TIGER-X trial in the *New England Journal of Medicine* ("NEJM").[95] The NEJM article showed Roci's ORR at 59% as "assessed according to . . . [RECIST]."[96] At about this time, in the spring of 2015, Clovis statisticians had already informed "senior clinical personnel" that there was "a 'divergence between the confirmed and unconfirmed ORR'" for Roci.[97]

Approximately one month later, on June 9, 2015, Clovis officials met with the FDA regarding Roci's critical New Drug Application ("NDA").[98] The NDA filing necessarily included the Company's disclosure of TIGER-X data for final FDA approval.[99] At the meeting, management reported an ORR of 50% without informing the FDA that this ORR included unconfirmed responses.[100] Notwithstanding its report to the FDA, management continued to report a 60% ORR in public statements.[101]

---

[95] Compl. ¶ 123.

[96] Compl. ¶¶ 124, 208.

[97] Compl. ¶ 126.

[98] Compl. ¶ 129.

[99] *Id.*

[100] *Id.*

[101] Compl. ¶¶ 128–29.

On June 19, 2015, Mahaffy, Mast and other members of senior management received "close to final" data from the TIGER-X trial.[102] The data showed an ORR of 45.1% for the 500mg dose (significantly lower than the 60% ORR the Company had been disclosing to the market).[103] Mahaffy wrote to another Clovis executive that the data "[s]eems worrying."[104] Three days later, on June 22, CMO Allen resigned without warning.[105] On July 7, Clovis' management received the "final" TIGER-X data showing that Roci's ORR was only 42%.[106]

On July 14, 2015, Clovis conducted a secondary offering of 4.1 million shares and raised more than $316 million.[107] The prospectus for the offering was signed by the entire Board and disclosed a "'60 percent ORR' at the 'recommended dose of 500mg.'"[108] It did not disclose that the ORR included unconfirmed responses.[109]

---

[102] Compl. ¶ 130.

[103] *Id.*

[104] *Id.*

[105] Compl. ¶ 131.

[106] Compl. ¶ 137.

[107] Compl. ¶ 133.

[108] Compl. ¶¶ 134, 136.

[109] Compl. ¶ 136.

The FDA requested additional data in support of the NDA in October 2015.[110] In response, Clovis disclosed that Roci's current *confirmed* ORR was between 28% and 34%.[111] At the same time, management presented a slide to the Board to illustrate how Roci was stacking up against Tagrisso.[112] The slide clearly showed an ORR of 46% that was "(Unconf + Conf)" while Tagrisso's ORR was "Confirmed."[113] Management advised the Board in connection with the NDA that "[w]e will cite the unconfirmed investigator assessed response rate of ~46%."[114] The public continued to hear a different story, however. For instance, a November 5, 2015 press release and earnings call announced third quarter results and cited presentations from medical conferences claiming Roci's ORR was 60%.[115]

D. The Fallout

The conflicting reports regarding Roci's ORR eventually prompted the FDA to ask questions and to call for a meeting with Clovis executives on November 9,

---

[110] Compl. ¶ 140.

[111] Compl. ¶¶ 140–41.

[112] Compl. ¶ 143, Ex. A at 01021; Pls.' Letter at 45.

[113] *Id.*

[114] Pls.' Letter at 4–5; Compl. Ex. A at 01069.

[115] Compl. ¶¶ 144–45, 215.

2015.[116] During the meeting, the FDA emphasized it would credit only confirmed responses on the NDA[117] and insisted Clovis comply with TIGER-X's stated protocol (which had explicitly incorporated RECIST).[118] Mahaffy updated the Board on this most recent FDA meeting the following week.[119]

The public was finally informed of Roci's true ORR when, on November 16, 2015, Clovis issued a press release stating the correct *confirmed* ORR was as low as 28–34%.[120] Clovis' stock price immediately dropped 70%, wiping out more than $1 billion in market capitalization.[121]

On April 8, 2016, the FDA voted to delay action on Clovis' NDA until the Company could provide concrete evidence of a risk/benefit profile meriting approval.[122] On this news, Clovis' stock price fell another 17%.[123] On May 5, 2016,

---

[116] Compl. ¶¶ 17, 146.

[117] *Id*.

[118] Compl. ¶¶ 80, 82.

[119] Compl. Ex. A at 01073 (containing minutes from a special Board meeting on November 15, 2015).

[120] Compl. ¶¶ 222–23.

[121] Compl. ¶¶ 18, 223.

[122] Compl. ¶ 228.

[123] Compl. ¶ 227.

Clovis withdrew its NDA for Roci and terminated enrollment in all ongoing Roci studies.[124]

E. Undisclosed Side Effects and Other TIGER-X Protocol Violations

In addition to the Company's refusal properly to report ORR, the Board was advised that Roci had serious, undisclosed side effects and that the TIGER-X trial had been compromised by other clinical trial protocol violations during the Relevant Period.[125] FDA regulations and internal Clovis policies required Clovis to abide by certain informed consent, patient eligibility, data reliability, recordkeeping and adverse event reporting practices.[126] The Company routinely missed these marks throughout the TIGER-X trial.[127]

For example, on August 17, 2015, a research associate notified senior Clovis management of protocol violations involving patient informed consent, patient enrollment, adverse event reporting, data alteration and missing data.[128] Management received a similar report ten days later.[129] The following month, on

[124] Compl. ¶ 229.

[125] Compl. ¶¶ 1, 19, 22, 149–96.

[126] Compl. ¶¶ 149–68.

[127] Compl. ¶ 171.

[128] *Id.*

[129] *Id.*

September 17, 2015, Clovis management identified 238 protocol deviations.[130] On October 14, 2015, in a notice letter (Form 483) to the Company, the FDA identified a failure to report two serious adverse events, approximately twelve patient eligibility violations and various failures to maintain case history and informed consent records.[131] It was also discovered that the clinical trial administrators had failed to monitor other medications enrollees were taking while participating in the trial.[132] The Board was notified of several of these clinical trial protocol violations on December 10, 2015, and likely received additional information about the problems "at regularly scheduled board meetings" where "hours of discussion occurred . . . regarding [Roci]."[133]

Protocol violations were not the only problems with the Roci clinical trial. The Board also learned that one of the drug's side effects, QT prolongation, was more common than management publicly reported.[134] Specifically, the Board received a report on April 29, 2014, that a grade 3 out of 4 (indicating a severe

[130] *Id.*

[131] *Id.*

[132] Compl. ¶¶ 173, 175–176.

[133] Compl. ¶¶ 174, 259.

[134] Compl. ¶ 189.

response) QT prolongation occurred in 6.2% of patients.[135] Nevertheless, the Board sat idle as the Company reported a "manageable side effect profile" throughout May 2014.[136] On October 7, 2014, Board materials indicated that a grade 3 QT prolongation occurred in 2.5% of patients.[137] The same results were reported in forecasts the Board received from management in December of 2014.[138]

The Company's misleading reports regarding Roci's side effects continued into 2015. In February and July of 2015, Clovis disclosed that Roci's only grade 3 adverse event "of note" was hyperglycemia.[139] The prospectus for the July 2015 secondary offering made a similar disclosure.[140] Although an August 6, 2015 press release mentioned the QT prolongation side effect, it emphasized that the only grade 3 adverse event identified in more than 5% of patients was hyperglycemia.[141] Mahaffy and Mast made public statements in September and November of 2015 that Roci did not have "typical side effects" and that the "only grade 3 or 4 adverse event

---

[135] Compl. ¶ 179.

[136] Compl. ¶ 103.

[137] Compl. ¶ 180.

[138] Compl. ¶ 181.

[139] Compl. ¶¶ 122, 136.

[140] Compl. ¶ 136 ("[T]he only common grade 3 [side effect] was hyperclycemia.") (alteration in original).

[141] Compl. ¶ 211.

that has been identified in more than ten percent of patients is hyperglycemia."[142] By this time, however, Clovis had already reported data to the FDA indicating that Roci had a 12% incidence of grade 3 or higher QT prolongation.[143] And, by April 2016, management had informed the Board that the FDA was going to require a "Boxed Warning" (the strongest of the FDA warnings) because it had concluded Roci significantly increased the risk of QT prolongation.[144]

F. Defendants' Stock Sales and Related Litigation

As the TIGER-X tribulations unfolded, three members of the Board, Defendants Barrett, Blair and Spickschen, along with CFO Mast, sold small percentages of their Clovis stock holdings.[145] These trades, and their timing relative to the November 16, 2015 fall in Clovis' stock price, are depicted in the chart below.[146]

[142] Compl. ¶¶ 139, 148, 216.

[143] Compl. ¶¶ 148, 216.

[144] Compl. ¶¶ 184, 226.

[145] Compl. ¶ 31 (Barrett's sales), ¶ 38 (Spickschen's sales), ¶ 40 (Mast's sales), ¶ 354 (Blair's sales).

[146] Compl. ¶ 354.

Name	Date	Shares	Price	Proceeds
Barrett	5/15/15	2,424	$92.22	**$223,536**
Blair	3/5/15	8,528	$77.70	**$662,625**
Spickschen	5/15/15	4,309	$85.00	**$366,269**
Mast	3/9/15	9,000	$79.58	**$716,202**
	4/1/15	3,000	$72.26	**$216,786**
	5/1/15	3,000	$82.25	**$246,744**
	6/1/15	3,000	$86.69	**$266,064**
	7/1/15	3,000	$86.59	**$259,761**
	8/03/15	3,000	$86.12	**$258,369**
	9/1/15	3,000	$79.09	**$237,258**
	10/1/15	3,000	$90.77	**$272,304**
	11/2/15	3,000	$104.18	**$312,543**
		33,000		**$2,786,031**
	Total:	**48,261**		**$4,038,461**

At first glance, the trades appear to be significant. But it is undisputed that each of the Director Defendants retained between 96% and 99.9% of their total holdings throughout the Relevant Period.[147]

After news of the failed TIGER-X trial broke, and the value of Clovis' stock fell precipitously, Clovis, Mahaffy and Mast were each named as defendants in a series of securities fraud class actions.[148] One of these cases was settled for

[147] Tr. of Oral Arg. on Defs.' Mot. to Dismiss (D.I. 63) at 35:3–5; Transmittal Aff. of Robert L. Burns, Esq. in Supp. of Defs.' Mot. to Dismiss Pls.' Consol. Verified S'holder Deriv. Compl., ("Burns Aff.") (D.I. 19) Ex. O at 45 (showing the Board Defendants' stock holdings as of April 13, 2015); Clovis, Proxy Statement (Schedule 14A) (Apr. 30, 2015) (showing the Board Defendants' stock holdings as of April 13, 2015).

[148] Compl. ¶¶ 26, 231. *See, e.g.*, *Medina v. Clovis Oncology, Inc., et al.*, Civil Action No. 1:15-cv-2546 (reported in Westlaw as 2016 WL 660133).

$142 million in cash and Clovis stock.[149] The SEC's September 18, 2018 complaint against Clovis, Mahaffy and Mast led to the entry of an onerous consent decree requiring the three defendants to pay $20 million, $250 thousand and $100 thousand in civil penalties, respectively.[150] Additionally, Mast was required to disgorge $454,154 (representing his unjust profits from selling Clovis stock).[151] The FDA also launched its own investigation of Clovis relating to the TIGER-X trial.[152]

G. Procedural Posture

On May 31, 2016 and December 15, 2016, Plaintiffs served the Company with demands to inspect books and records under 8 *Del. C.* § 220 in response to which they received approximately 3,000 pages of documents.[153] Plaintiffs filed their first complaint on March 23, 2017.[154] They amended the complaint on May 18, 2017.[155]

---

[149] Compl. ¶ 239.

[150] Compl. ¶¶ 240–41, 245.

[151] Compl. ¶ 245.

[152] Compl. ¶ 232.

[153] Compl. ¶¶ 43–44.

[154] *See* Verified S'holder Deriv. Compl. (D.I. 1); Compl. ¶¶ 43, 250.

[155] D.I. 8.

Defendants moved to dismiss the first amended complaint under Court of Chancery Rules 23.1 and 12(b)(6) on August 1, 2017.[156]

As noted, on September 18, 2018, the SEC filed a complaint against Clovis, Mahaffy and Mast that resulted in consent decrees and civil penalties.[157] After the SEC settlements, Plaintiffs moved to amend their complaint again on November 19, 2018, to add allegations regarding the SEC enforcement actions.[158] After this Court granted leave to amend, the parties supplemented their briefing on Defendants' motions to dismiss.[159] Following oral argument and post-argument filings, the motion to dismiss was submitted for decision on July 1, 2019.

II. ANALYSIS

The Complaint comprises three counts.[160] Count I is a derivative claim for breach of fiduciary duty against the Board Defendants.[161] Specifically, Plaintiffs allege the Board Defendants breached their fiduciary duties under *Caremark* by their

[156] D.I. 15–16.

[157] Compl. ¶¶ 240–43, 245.

[158] D.I. 34, 36–37.

[159] D.I. 46, 50, 54.

[160] Compl. ¶¶ 341–360. Count I has received the most attention. *See, e.g.*, PAB (D.I. 23) at 58, 62–63 (devoting approximately three total pages to the *Brophy* and unjust enrichment claims).

[161] Compl. ¶¶ 342–44.

"actions and inactions . . . in connection with the TIGER-X trial."[162] In this regard, Count I alleges either that (i) the Board Defendants failed to institute an oversight system for the TIGER-X trial or (ii) the Board Defendants consciously disregarded a series of red flags related to the TIGER-X trial.[163]

Count II asserts a derivative claim against the Board Defendants for unjust enrichment, and Count III asserts a derivative claim for breach of fiduciary duty against Barrett, Blair, Mast and Spickschen under *Brophy*, which permits a corporation to recover from its fiduciaries for harm caused by improper stock trades.[164]

As for Count I, Plaintiffs have pled particularized facts that "create a reasonable doubt that, as of the time the complaint [was] filed, the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand."[165] Specifically, Plaintiffs have well-pled that the Board

---

[162] Compl. ¶¶ 344–45; *Caremark*, 698 A.2d 959.

[163] *See* PAB (D.I. 23) at 31 ("Defendants Face a Substantial Likelihood of Personal Liability for Failing to Prevent or Correct Clovis from Providing Shareholders and the FDA with Misleading Study Data Results."), 44 ("The [Board] Defendants Also Face a Substantial Likelihood of Personal Liability for Failing to Implement Any System of Internal Controls to Ensure Compliance with Study Protocol or Receive Notice of Study Protocol Violations.").

[164] *Brophy*, 70 A.2d 5; Compl. ¶¶ 349–60.

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

ignored red flags that the Company was violating—perhaps consciously violating—the RECIST protocol and then misleading the market and regulators regarding Roci's progress through the TIGER-X trial. Because Plaintiffs have pled particularized facts to support a reasonable inference the Board Defendants face a substantial likelihood of liability on Count I, Defendants' motion to dismiss Count I under Rule 23.1 must be denied. Having so concluded, *a fortiori*, I deny the Motion to Dismiss under Rule 12(b)(6) as well.[166]

Regarding Counts II and III, Plaintiffs have failed to plead particularized facts showing that the Defendants face a substantial likelihood of personal liability as to either count. Defendants' motion to dismiss Counts II and III, therefore, must be granted.

A. The Applicable Rule 23.1 Standard

There is no dispute that each of the Complaint's three counts purports to state a derivative claim.[167] As Justice Moore emphasized in his seminal *Aronson* decision, 8 *Del. C.* § 141(a) codifies a bedrock of Delaware corporate law—the board of

[166] *See McPhadden v. Sidhu*, 964 A.2d 1262, 1270 (Del. Ch. 2008) ("[A] complaint that survives a motion to dismiss pursuant to Rule 23.1 will also survive a 12(b)(6) motion to dismiss[.]"); *Ryan v. Gifford*, 918 A.2d 341, 357 (Del. Ch. 2007) ("[W]here plaintiff alleges particularized facts sufficient to prove demand futility under the second prong of *Aronson*, that plaintiff *a fortiori* rebuts the business judgment rule for the purpose of surviving a motion to dismiss pursuant to Rule 12(b)(6).").

[167] Compl. ¶¶ 347–48, 351–52, 359–60; DOB (D.I. 16) at 1.

directors, not stockholders, manages the business and affairs of the corporation, including the decision to cause the corporation to sue.[168] With this in mind, our law has established procedural imperatives to ensure that shareholders do not "imping[e] on the managerial freedom of directors."[169] To wrest control over the litigation asset away from the board of directors, the stockholder must demonstrate that demand on the board to pursue the claim would be futile such that the demand requirement should be excused.[170]

Plaintiffs acknowledge they did not make a pre-suit demand on the Board.[171] It is settled, therefore, that their Complaint must "comply with stringent requirements of factual particularity that differ substantially from the permissive notice pleadings" of Chancery Rule 8 in order to demonstrate that demand upon the Board would have been futile.[172] Where, as here, a plaintiff challenges board inaction—as opposed to a business decision of the Board—the court analyzes

---

[168] *Aronson v. Lewis*, 473 A.2d 805, 811 (Del. 1984), *overruled on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000) (citing 8 *Del. C.* § 141(a)).

[169] *Aronson*, 473 A.2d at 811.

[170] *See Beam ex rel. Martha Stewart Living Omnimedia, Inc. v. Stewart*, 845 A.2d 1040, 1044 (Del. 2004).

[171] Compl. ¶ 250.

[172] *Brehm*, 746 A.2d at 254 (noting that conclusory statements or mere notice pleading are insufficient to satisfy Rule 23.1).

demand futility under the well-known and "well-balanced" *Rales* standard.[173] This standard requires plaintiffs to plead facts regarding demand futility with particularity but balances that requirement with a mandate that the court draw all reasonable inferences in the plaintiffs' favor.[174]

Demand futility turns on "whether the board that would be addressing the demand can impartially consider [the demand's] merits without being influenced by improper considerations."[175] Such improper influence arises if a majority of the board's members (i) are "compromised" because they face "a 'substantial likelihood' of personal liability" with respect to at least one of the alleged claims or (ii) lack independence because they are beholden to an interested person.[176]

---

[173] *Rales*, 634 A.2d at 932–34; *Marchand*, 212 A.3d at 818 (citing *Del. Cty. Empls.' Ret. Fund v. Sanchez*, 124 A.3d 1017, 1022 (Del. 2015) (explaining that the *Rales* test is "well balanced")).

[174] *Rales*, 634 A.2d at 934 (requiring "particularized factual allegations"); *Marchand*, 212 A.3d at 818 (requiring "reasonable inferences" to be drawn in plaintiff's favor).

[175] *Rales*, 634 A.2d at 934.

[176] *Guttman v. Huang*, 823 A.2d 492, 501 (Del. Ch. 2003) (quoting *Rales*, 634 A.2d at 936); *In re Goldman Sachs Gp., Inc. S'holder Litig.*, 2011 WL 4826104, at *18 (Del. Ch. Oct. 12, 2011). The parties agree the first prong in the *Rales* analysis applies where, as here, a plaintiff challenges board inaction such as when a board is alleged to have consciously disregarded its oversight responsibilities. *See Wood v. Baum*, 953 A.2d 136, 140 (Del. 2008); DOB (D.I. 16) at 18; PAB (D.I. 23) at 28.

B. Plaintiffs Have Well-Pled the Board Faces a Substantial Likelihood of Liability Under *Caremark* (Count I)

The parties agree that Count I implicates *Caremark*, *Stone v. Ritter* and their progeny.[177] These cases require well-pled allegations of bad faith to survive dismissal—i.e., allegations "the directors knew that they were not discharging their fiduciary obligations," a standard of wrongdoing "qualitatively different from, and more culpable than . . . gross negligence."[178] Given this high bar, it is now indubitably understood, and oft-repeated, that a *Caremark* claim is among the hardest to plead and prove.[179] At the pleadings stage, this means Plaintiffs must allege particularized facts that either (i) "the directors completely fail[ed] to implement any reporting or information system or controls, or . . . [(ii)] having implemented such a system or controls, consciously fail[ed] to monitor or oversee its operations thus disabling themselves from being informed of risks or problems

[177] *See Marchand*, 212 A.3d at 820–21 (discussing the *Caremark* progeny); *Caremark*, 698 A.2d at 970; *Stone v. Ritter*, 911 A.2d 362 (Del. 2006).

[178] *Stone*, 911 A.2d at 369–70 (citing *In re Walt Disney Co. Deriv. Litig.*, 906 A.2d 27 (Del. 2006)).

[179] *See Stone*, 911 A.2d at 372 ("[A] claim that directors are subject to personal liability for employee failures is possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment.") (internal quotation marks omitted); *Guttman*, 823 A.2d at 506 ("A *Caremark* claim is a difficult one to prove."); *Caremark*, 698 A.2d at 967 ("The theory here advanced is possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment.").

requiring their attention."[180] Implicit in these standards is the requirement that plaintiffs plead particular facts allowing a reasonable inference the directors acted with scienter, which "requires proof that a director acted inconsistent with his fiduciary duties and, most importantly, that the director *knew* he was so acting."[181]

Caremark rests on the presumption that corporate fiduciaries are afforded "great discretion to design context- and industry-specific approaches tailored to their companies' businesses and resources."[182] Indeed, "[b]usiness decision-makers must operate in the real world, with imperfect information, limited resources, and uncertain future. To impose liability on directors for making a 'wrong' *business decision* would cripple their ability to earn returns for investors by taking *business risks*."[183] But, as fiduciaries, corporate managers must be informed of, and oversee compliance with, the regulatory environments in which their businesses operate. In this regard, as relates to *Caremark* liability, it is appropriate to distinguish the board's oversight of the company's *management of business risk* that is inherent in its business plan from the board's oversight of the company's *compliance with*

[180] *Marchand*, 212 A.3d at 821 (quoting *Stone*, 911 A.2d at 370–72).

[181] *In re Massey Energy Co.*, 2011 WL 2176479, at *22 (Del. Ch. May 31, 2011) (citing *Stone*, 911 A.2d at 370) (emphasis in original).

[182] *Marchand*, 212 A.3d at 821.

[183] *In re Citigroup Inc. S'holder Deriv. Litig.*, 964 A.2d 106, 126 (Del. Ch. 2009) (emphasis supplied).

positive law—including regulatory mandates. As this Court recently noted, "[t]he legal academy has observed that Delaware courts are more inclined to find *Caremark* oversight liability at the board level when the company operates in the midst of obligations imposed upon it by positive law yet fails to implement compliance systems, or fails to monitor existing compliance systems, such that a violation of law, and resulting liability, occurs."[184]

Our Supreme Court's recent decision in *Marchand v. Barnhill* underscores the importance of the board's oversight function when the company is operating in the midst of "mission critical" regulatory compliance risk.[185] The regulatory compliance risk at issue in *Marchand* was food safety and the failure to manage it at the board level allegedly allowed Blue Bell Creameries to distribute mass quantities of ice cream tainted by *listeria*.[186] The Court held that Blue Bell's board had not made a "good faith effort to put in place a reasonable system of monitoring and reporting"

---

[184] *In re Facebook, Inc. Sec. 220 Litig.*, 2019 WL 2320842, at *14 (Del. Ch. May 31, 2019). The court explained: "In other words, it is more difficult to plead and prove *Caremark* liability based on a failure to monitor and prevent harm flowing from risks that confront the business in the ordinary course of its operations. Failure to monitor compliance with positive law, including regulatory mandates, is more likely to give rise to oversight liability." *Id.* (collecting authorities).

[185] *Marchand*, 212 A.3d at 824 (applying *Caremark*, 698 A.2d 959).

[186] *Id.* at 809.

when it left compliance with food safety mandates to management's discretion rather than implementing and then overseeing a more structured compliance system.[187]

As *Marchand* makes clear, when a company operates in an environment where externally imposed regulations govern its "mission critical" operations, the board's oversight function must be more rigorously exercised.[188] Key to the Supreme Court's analysis was the fact that food safety was the "most central safety and legal compliance issue facing the company."[189] To be sure, even in this context, *Caremark* does not demand omniscience. But it does demand a "good faith effort to implement an oversight system and then monitor it."[190] This entails a sensitivity to "compliance issue[s] intrinsically critical to the company[]."[191]

1. *Caremark*'s First Prong

The so-called first prong of *Caremark* requires Plaintiffs to well-plead that the Board "completely fail[ed] to implement any reporting or information system or

---

[187] *Id.* at 823–24.

[188] *Id.* at 824 ("food safety was essential and mission critical" and the "most central consumer safety and legal compliance issue facing the company"). *See also id.* at 822 (observing that food safety "has to be one of the most central issues at the company" and "a compliance issue intrinsically critical to the company's [monoline] business operation").

[189] *Id.*

[190] *Id.* at 821.

[191] *Id.* at 822.

controls[.]"[192] But Plaintiffs acknowledge the Board's Nominating and Corporate Governance Committee was "specifically charged" with "provid[ing] general compliance oversight . . . with respect to . . . Federal health care program requirements and FDA requirements."[193] And they further acknowledge "[t]he Board . . . reviewed detailed information regarding [Roci's] TIGER-X trial at each Board meeting."[194] Given these acknowledged facts, it is difficult to conceive how Plaintiffs would prove the Board had no "reporting or information system or controls[.]"[195]

2. *Caremark*'s Second Prong

Caremark's second prong is implicated when it is alleged the company implemented an oversight system but the board failed to "monitor it."[196] To state a claim under this prong, Plaintiffs must well-plead that a "red flag" of non-compliance waived before the Board Defendants but they chose to ignore it.[197]

---

[192] *Id.* at 821.

[193] Compl. ¶ 279.

[194] Compl. ¶ 16. Plaintiffs also allege Clovis maintained extensive policies addressing the alleged deviations from the clinical study protocol. *See* Compl. ¶¶ 150 (protocol on recordkeeping), 146 (informed consent protocol), 154, 158 (regarding FDA regulations), 67 (regarding reporting adverse events).

[195] *Marchand*, 212 A.3d at 821.

[196] *Id.*

[197] *See South v. Baker*, 62 A.3d 1, 16–17 (Del. Ch. 2012).

In this regard, the court must remain mindful that "red flags are only useful when they are either waived in one's face or displayed so that they are visible to the careful observer."[198] But, as *Marchand* makes clear, the careful observer is one whose gaze is fixed on the company's mission critical regulatory issues.[199] For Clovis, this was Roci's TIGER-X trial and the clinical trial protocols and related FDA regulations governing that study.

Plaintiffs have alleged particularized facts supporting reasonable inferences that: (i) the Board knew the TIGER-X protocol incorporated RECIST;[200] (ii) RECIST requires reporting only confirmed responses;[201] (iii) industry practice and FDA guidance require that the study managers report only confirmed responses;[202] (iv) management was publicly reporting unconfirmed responses to

---

[198] *Wood*, 953 A.2d at 143 (internal citations omitted); *In re Citigroup Inc. S'holders Litig.*, 2003 WL 21384599, at *2 (Del. Ch. June 5, 2003) (internal quotes omitted).

[199] *Marchand*, 212 A.3d 805.

[200] Compl. ¶¶ 82, 84, 88, 89. Indeed, the Company elected to adopt RECIST even though it could have incorporated other clinical trial protocols. Compl. ¶¶ 80, 83.

[201] Compl. ¶ 86. As noted, Defendants vigorously dispute whether RECIST requires only confirmed responses to be included in ORR. *See, e.g.*, DOB (D.I. 16) at 14, 28. While Defendants may ultimately prove that their interpretation of RECIST is correct, they cannot rewrite Plaintiffs' Complaint on a motion to dismiss. *See* Compl. ¶ 86, Ex. B (D.I. 37) at 1 (RECIST guidelines stating that "[*c*]*onfirmation of response* is required for trials . . .") (emphasis in original). *See also Vanderbilt Income & Growth Assocs., L.L.C. v. Arvida/JMB Managers, Inc.*, 691 A.2d 609, 613 (Del. 1996) (emphasizing the trial court cannot ignore well-pled allegations in a complaint on a motion to dismiss).

[202] Compl. ¶ 99–100 (citing FDA guidance documents).

keep up with Tagrisso's response rate;[203] and (v) the Board knew management was incorrectly reporting responses but did nothing to address this fundamental departure from the RECIST protocol.[204] When Clovis' serial non-compliance with RECIST was finally revealed to the regulators, Roci was doomed.[205] And when the drug's failure was revealed to the market, Clovis' stock price tumbled.[206]

ORR was the crucible in which Roci's safety and efficacy were to be tested.[207] Roci was Clovis' mission critical product.[208] And the Board knew, upon completion of the TIGER-X trial, the FDA would consider only confirmed responses when determining whether to approve Roci's NDA per the agency's own regulations.[209] As pled, these regulations, and the reporting requirements of the RECIST protocol, were not nuanced.[210] The Board was comprised of experts and the RECIST criteria

---

[203] *See, e.g.*, Compl. ¶¶ 16, 104, 120, 134, 136, 143, 206–07, 259.

[204] Compl. ¶¶ 104, 107–08, 120, 259; Compl. Ex. A at 00120, 00162, 00246, 00371.

[205] Compl. ¶¶ 223, 228.

[206] Compl. ¶¶ 18, 222–23.

[207] Compl. ¶ 8 ("ORR was the "primary endpoint"—the key measure of success—in the TIGER-X trial.").

[208] Compl. ¶¶ 8, 20, 101; *see also* Compl. ¶ 63 (Clovis had no drugs on the market).

[209] Compl. ¶ 99.

[210] *See* Compl. ¶ 10 ("RECIST unequivocally requires each instance of tumor shrinkage (a response) to be 'confirmed.'"). Defendants attack Plaintiffs' assertions that (i) the Board understood RECIST and (ii) ORR was more than a mere "nuts and bolts" requirement. *See* Defs.' Reply Br. in Supp. of Their Mot. to Dismiss Pls.' Consol. Verified S'holder

are well-known in the pharmaceutical industry.[211] Moreover, given the degree to which Clovis relied upon ORR when raising capital, it is reasonable to infer the Board would have understood the concept and would have appreciated the distinction between confirmed and unconfirmed responses.[212] The inference of Board knowledge is further enhanced by the fact the Board knew that even after FDA approval, physicians (i.e., future prescribers) would evaluate Roci based on its ORR.[213]

Deriv. Compl. (D.I. 27) at 16 (there are "no well-pled allegations even suggesting the [Board] Defendants understood (or should have understood) that ORR results were reported (allegedly) incorrectly based on the highly technical detail on which Plaintiffs focus."). Plaintiffs have alleged sufficient facts to support an inference that the Board Defendants *did* understand (or should have understood) that Clovis was reporting ORR results incorrectly. For example, Board slides explicitly warn that ORR numbers are "[u]nconfirmed." Compl. Ex. A at 00162, 00246. Tagrisso was compared with Roci by highlighting their respective ORRs with the caveat that Roci's ORR was "(Unconf + Conf)" while Tagrisso's was "Confirmed." Compl. Ex. A at 01021. Additionally, Plaintiffs point to scholarly publications indicating that "confirmation [of responses] is the 'industry standard.'" Compl. ¶ 97. Since Roci was such an important product for the Company, it is reasonable to infer that the Board presentations regarding ORR, at the least, should have prompted questions—if not objections—from the Board. Furthermore, the Complaint alleges circumstances where any reliance on Clovis' management regarding ORR reporting would be unreasonable in light of the Board presentations and the competitive pressure Roci faced from Tagrisso—rendering a reliance defense under 8 *Del. C.* § 141(e) inappropriate, at least at this stage.

[211] Compl. ¶¶ 30–38; *see also* Compl. ¶ 83 (quoting Manola et al., *Assessment of Treatment Outcome, in* UICC MANUAL OF CLINICAL ONCOLOGY 40, 44 (Brian O'Sullivan et al. eds., 9th ed. 2015).

[212] Compl. ¶¶ 110–11.

[213] Compl. ¶¶ 8, 120, Ex. A at 00371.

Defendants argue the FDA blessed Clovis' plan to report unconfirmed responses for "interim" results because Roci was on an accelerated approval track.[214] Additionally, Defendants claim FDA guidance was not as clear as the Complaint depicts.[215] But, again, that is not what the Complaint alleges.[216] Whether Plaintiffs'

---

[214] *See, e.g.*, DOB (D.I. 16) at 14. Defendants cite to Compl. Ex. A (D.I. 37) at 00001069. This document is an October 7, 2015 Board report stating "a few highlights" "in terms of the FDA review so far." One of those highlights was that "[w]e will cite the unconfirmed investigator assessed response rate of [] 46%." *Id.* Defendants claim this means that the FDA did not have an "issue" with reporting unconfirmed results. DOB (D.I. 16) at 30. This report might be interpreted as suggesting either that (i) the FDA implicitly condoned reporting unconfirmed responses or (ii) the FDA did not notice or was not specifically told that Clovis reneged on a promise to use only confirmed responses. Which interpretation will carry the day remains to be seen. At this point, I cannot ignore that the Complaint contradicts the assertion that the FDA knew about and blessed reliance on unconfirmed results. Compl. ¶ 129 ("Documents publicly released by the FDA on April 8, 2016 demonstrate that at that June 9, 2015 meeting, the [Board] Defendants privately reported an ORR of 50% (without informing the FDA that the ORR was unconfirmed)[.]"). On this point, my conclusion at this stage is similar to Judge Moore's in the related federal securities litigation, *Medina v. Clovis Oncology, Inc.*, 215 F.Supp. 3d 1094, 1112 (D. Colo. 2017) (stating, after an extensive review of RECIST requirements, that he "agrees with plaintiffs' interpretation of RECIST" "at this stage" that RECIST "requires that responses be confirmed."). Like Judge Moore, I note that my conclusion is a reflection of the applicable standard of review, fully acknowledging that "Defendants [might] present evidence at summary judgment indicating that their interpretation of RECIST was reasonable and that the FDA would accept [] unconfirmed responses." *Id.* at 1117.

[215] DOB (D.I. 16) at 14.

[216] Compl. ¶ 86 ("RECIST unequivocally requires each instance of tumor shrinkage (a response) to be 'confirmed.'"). *See also Sanchez*, 124 A.3d at 1020 ("all reasonable inferences from the pled facts must . . . be drawn in favor of the plaintiff in determining whether the plaintiff has met its burden under *Aronson.*"). I acknowledge the parties' agreement that the Company's Section 220 documents would be deemed incorporated in the Complaint whether cited there or not. This is a now-standard form of agreement and it serves the laudable purpose of eliminating the need for parties and the court to address whether referring to Section 220 documents has converted a motion to dismiss into a motion for summary judgment. *See Yahoo!*, 132 A.3d at 797 (confirming parties can agree that Section 220 documents are deemed incorporated by reference in the complaint without

allegations hold up during discovery, at summary judgment or at trial remains to be seen.

Drawing all reasonable inferences in Plaintiffs' favor, I am satisfied they have well-pled that the Board consciously ignored red flags that revealed a mission critical failure to comply with the RECIST protocol and associated FDA regulations. Additionally, at this stage, Plaintiffs' allegation that this failure of oversight caused monetary and reputational harm to the Company is sufficient to provide a causal nexus between the breach of fiduciary duty and the corporate trauma.[217] Therefore,

---

altering the Rule 12(b)(6) standard of review). But incorporating documents that might not square with a complaint's otherwise well-pled allegations is a far cry from providing the court with an undisputed factual predicate upon which judgment as a matter of law may rest. In other words, Section 220 documents, hand selected by the company, cannot be offered to rewrite an otherwise well-pled complaint. This view of the so-called *Yahoo!* agreement is entirely consistent with the "incorporation by reference doctrine," whereby the court may "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." *Id.* The doctrine "limits the ability of the plaintiff to take language out of context because the defendants can point the court to the entire document." *Id.* "In the end, the only effect of the Incorporation Condition (within the parties' agreement) will be 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. Mindful of this purpose, our courts must regulate how far down the road of incorporation by reference a defendant may go when plaintiff has well-pled something as fact (*e.g.*, that the Board understood ORR), even if another document might suggest the facts are otherwise. Section 220 documents may or may not comprise the entirety of the evidence on a particular point. Until that is tested, Defendants cannot ask the court to accept their Section 220 documents as definitive fact and thereby turn pleading stage inferences on their head. That is not, and should not be, the state of our law.

[217] Compl. ¶ 21. With this said, Plaintiffs' causation case will be challenging. It appears Roci was not what Clovis hoped it would be. If that proves true, then Plaintiffs may have difficulty connecting the oversight failure(s) to the corporate trauma. It might well be that Roci simply did not work and nothing the Board did or did not do would change that.

Defendants' motion to dismiss Count I (Plaintiffs' *Caremark* claim) under Rules 23.1 and 12(b)(6) must be denied.

C. Plaintiffs Fail to State a *Brophy* Claim (Count III)

Generally, "corporate officers and directors may purchase and sell the corporation's stock at will, without any liability to the corporation."[218] Indeed, Delaware law recognizes that it is good when fiduciaries align their interests with the company through stock ownership, a dynamic facilitated by the fact that many directors and officers are compensated in stock.[219] With the desirability of aligned incentives in mind, our law sets the bar for stating a claim for breach of fiduciary duty based on insider trading very high.[220]

"[A]n insider's trade may be deemed a breach of the fiduciary duty of loyalty, when: (1) 'the corporate fiduciary possessed material, nonpublic information'; and

---

For now, questions of causation are fact intensive and, as such, cannot be addressed at the pleading stage. *In re Massey Energy Co. Deriv. & Class Action Litig.*, 160 A.3d 484, 506 (Del. Ch. 2017).

[218] *Tuckman v. Aerosonic Corp.*, 1982 WL 17810, at *11 (Del. Ch. May 20, 1982).

[219] *See In re Oracle Corp.*, 867 A.2d 904, 930 (Del. Ch. 2004), *aff'd*, 872 A.2d 960 (Del. 2005) ("[T]he use of equity as a compensation tool is a legitimate choice under our law and Delaware statutory law permits and its common law creates incentives for stockholders to serve as directors and officers.").

[220] *See Guttman*, 823 A.2d at 502 ("[I]t is unwise to formulate a common law rule that makes a director 'interested' [for demand futility purposes] whenever a derivative plaintiff cursorily alleges that he made sales of company stock in the market at a time when he possessed material, non-public information.").

(2) 'the corporate fiduciary used that information improperly by making trades because she was motivated, in whole or in part, by the substance of that information.'"[221] In other words, Plaintiffs must plead facts that support an inference that Barrett, Blair, Mast and Spickschen acted with scienter.[222]

At the pleading stage, by necessity, a *Brophy* claim usually rests on circumstantial facts and a successful claim typically includes allegations of unusually large, suspiciously timed trades that allow a reasonable inference of scienter.[223] While the fact a fiduciary sells stock near the time he learns of material, nonpublic information might be evidence of the seller's motive, temporal proximity alone generally is insufficient to support an inference of scienter that will survive a motion to dismiss.[224] The other important piece of circumstantial evidence that, along with timing, might support an inference of scienter is the size of the trade

---

[221] *Tilden v. Cunningham*, 2018 WL 5307706, at *19 (Del. Ch. Oct. 26, 2018) (quoting *In re Oracle*, 867 A.2d at 934).

[222] *Guttman*, 823 A.2d at 505; *Brophy*, 70 A.2d 5.

[223] *See, e.g.*, *In re Fitbit, Inc. S'holder Deriv. Litig.*, 2018 WL 6587159, at *1 (Del. Ch. Dec. 14, 2018) (finding that plaintiffs adequately alleged that insiders sold substantial amounts of their holdings in an initial public offering and a secondary offering after voting to waive lock-up agreements intended to prevent insiders from selling more shares after the initial public offering).

[224] *See Guttman*, 823 A.2d at 502; *Rattner v. Bidzos*, 2003 WL 22284323, at *10, *12 (Del. Ch. Sept. 30, 2003) (noting that a complaint seeking an inference based on the "timing and size of [] sales" should plead facts to "assist in determining whether the pattern of executed trades was the product of an orchestrated scheme to defraud the market . . . or good faith adherence to Company policy or consistent with prior individual practices.").

relative to the defendant's overall stock holdings.[225] If a defendant sells only a small portion of her holdings and retains a "huge stake in the company[,]" then it is difficult reasonably to infer she was "fleeing disaster or seeking to make an unfair buck[.]"[226]

Plaintiffs allege three of the Director Defendants each traded one time, six months or more before Clovis disclosed the lower ORR results, with each trade representing a very small fraction of the trader's overall stake in the Company.[227] Specifically, each of the directors named in Count III retained between 96% and 99.9% of their total holdings as of April 13, 2015 (i.e., after the alleged improper trades).[228] In other words, in large measure, notwithstanding their alleged knowledge of the corporate trauma soon to come, each of these Defendants rode

[225] *See, e.g.*, *In re Oracle*, 867 A.2d at 954 (analyzing the size of stock sales relative to defendants' overall holdings, and concluding that, even though the dollar values generated from sales were large (nearly $1 billion), the fact that the sales were between 7% and 2% of defendants' overall holdings was inconsistent with a "rational inference of scienter.").

[226] *Id.*

[227] Compl. ¶¶ 222–23 (stock price decline was on 11/16/15), 354 (stock trades were on 5/15/15 (Barrett), 3/5/15 (Blair), 5/15/15 (Spickschen)); Burns Aff. (D.I. 19) Ex. O at 45 (showing shares owned as of April 13, 2015).

[228] Compl. ¶ 354; Clovis, Proxy Statement (Schedule 14A) (Apr. 30, 2015) (showing that, as of April 13, 2015, Barrett owned more than 2,300,000 shares, Blair owned more than 2,200,000 shares and Spickschen owned more than 116,000 shares. These Defendants sold approximately 2,424; 8,528; and 4,309 shares, respectively yielding a percent of total holdings sold of approximately .1%; .5%; and 4% respectively). Compl. ¶ 354.

over the falls with the rest of Clovis' stockholders when the corporate storm hit the Company.

Regarding Mast, Plaintiffs allege he traded nine times in a consistent pattern (selling about 3,000 shares on the first of every month), which is inconsistent with an inference that he sold because insider knowledge allowed him to anticipate a decline.[229] While Mast sold a larger percentage of his overall holdings when compared with the other Defendants named in Count III, he still retained approximately 90% of his holdings throughout the Relevant Period.[230]

Noticeably absent from the Complaint are any well-pled facts that the trades at issue represented a deviation from the sellers' past trading practices.[231] To the contrary, the alleged selling patterns are inconsistent with a rational inference that

[229] Compl. ¶¶ 222–23 (stock decline was on 11/16/15), 354 (between 3/9/15 and 11/2/15, Mast's trades occurred early in the month and, with one exception, were for 1,000 shares each.). The nature of the stock trades in this case make it distinguishable from other cases involving numerous insiders unloading significant portions of their stock. *See, e.g.*, *Silverberg ex rel. Dendreon Corp. v. Gold*, 2013 WL 6859282, at *15 (Del. Ch. Dec. 31, 2013) (denying a motion to dismiss where directors sold between 77% and 58% of their holdings within a day of FDA approval milestone and these sales were the first time that the directors had sold any of their shares despite owning them for more than a decade).

[230] Burns Aff. (D.I. 19) Ex. O at 45; Clovis, Proxy Statement (Schedule 14A) (Apr. 30, 2015) (showing that, as of April 13, 2015, Mast owned more than 330,000 shares). Mast sold 33,000 shares from March until November of 2015—yielding a percentage of total holdings sold of approximately 10%). Compl. ¶ 354.

[231] *See Rattner*, 2003 WL 22284323, at *12; *Guttman*, 823 A.2d at 503–04 (declining to draw an inference of scienter from the unusual timing of trades where the complaint did not plead facts related to sellers' past trading practices).

these Defendants were motivated to sell based on their knowledge of Roci's true ORR.

After carefully reviewing the Complaint, I am satisfied it is not reasonably conceivable that these four defendants—who sold only a sliver of their holdings and suffered approximately the same decrease in net worth as other Clovis stockholders—made their trades with the requisite scienter required to sustain a *Brophy* claim. Therefore, Defendants' motion to dismiss under Rule 12(b)(6), and by extension Rule 23.1, is granted.

D. Plaintiffs Fail to State an Unjust Enrichment Claim (Count II)

In Count II, Plaintiffs attempt to state a derivative claim for unjust enrichment in addition to their *Caremark* and *Brophy* claims.[232] As "representatives of Clovis," they seek "restitution from the Board Defendants" and an order requiring Defendants to disgorge "all profits, benefits and other compensation obtained . . . from their wrongful conduct and fiduciary breaches."[233]

Unjust enrichment is the "unjust retention of a benefit to the loss of another, or the retention of money or other property of another against the fundamental

[232] Compl. ¶¶ 349–52.

[233] Compl. ¶ 351.

principles of justice or equity and good conscience."[234] "The elements of unjust enrichment are: (1) an enrichment, (2) an impoverishment, (3) a relation between the enrichment and impoverishment, (4) the absence of justification, and (5) the absence of a remedy provided by law."[235]

Even with Section 220 documents in hand, Plaintiffs have not attempted to connect the Board Defendants' enrichment to alleged wrongdoing beyond their *Brophy* claim.[236] In search of an enrichment, Plaintiffs can point only to the Board Defendants' regular compensation and the profits obtained by some of the Board Defendants who sold stock. Because I have determined Plaintiffs have failed to state a viable *Brophy* claim, the only potential "enrichment" that remains is the Board Defendants' regular compensation.

Not surprisingly, Plaintiffs fail to connect the Board Defendants' "benefits and other compensation" with the alleged wrongdoing (i.e., oversight failures).[237]

---

[234] *Nemec v. Shrader*, 991 A.2d 1120, 1130 (Del. 2010) (citing *Fleer Corp. v. Topps Chewing Gum, Inc.*, 539 A.2d 1060, 1062 (Del. 1988)).

[235] *Id.*

[236] Of course, *Brophy* is a species of unjust enrichment that does not require a showing of actual harm to the corporation, but instead focuses "on the public policy of preventing unjust enrichment based on the misuse of confidential corporate information." *Kahn v. Kolberg Kravis Roberts & Co., L.P.*, 23 A.3d 831, 840 (Del. 2011) (citing *Brophy*, 70 A.2d 5). Therefore, I have analyzed Plaintiffs' allegations of enrichment associated with the alleged improper stock trades under *Brophy*'s rubric with respect to Count III.

[237] Compl. ¶ 351.

In apparent recognition of this pleading gap, Plaintiffs cite *Caspian Select Credit Master Fund Ltd. v. Gohl* for the general proposition that an unjust enrichment claim that is duplicative of a breach of fiduciary duty claim can survive a motion to dismiss if the fiduciary duty claim survives.[238] But that general proposition is not helpful here. In *Caspian*, a controlling shareholder allegedly engaged in self-dealing by being on both sides of a stock issuance.[239] There was a clear enrichment tied to an alleged breach of the fiduciary duty of loyalty.[240] Where, as here, the underlying breach arises from a *Caremark* violation, it is difficult to discern how that breach would give rise to an enrichment, and Plaintiffs have not well-pled that connection here.

Defendants' motion to dismiss Count II is granted under Rule 12(b)(6) for failure to state a viable claim and, by extension, under Rule 23.1 for failure to plead particular facts that would allow an inference that a majority of the Board faces a substantial likelihood of liability for unjust enrichment.

---

[238] PAB (D.I. 23) at 62 (citing *Caspian Select Credit Master Fund Ltd. v. Gohl*, 2015 WL 5718592, at *16 (Del. Ch. Sept. 28, 2015)).

[239] *Id.*

[240] *Id.*

III. CONCLUSION

Based on the foregoing, Defendants' motion to dismiss Plaintiffs' Complaint is DENIED as to Count I but GRANTED as to Counts II and III.

IT IS SO ORDERED.