Delaware Court Denies Another Motion to Dismiss a *Caremark* Claim Against Directors

On October 1, 2019, in *In re Clovis Oncology, Inc. Derivative Litigation*,[1] the Court of Chancery of Delaware denied a motion to dismiss a claim against members of the board of Clovis Oncology, Inc. ("Clovis" or the "Company") alleging that the directors breached their fiduciary under *Caremark*[2] by failing to oversee the Company's clinical drug trials. The Court found that the plaintiffs satisfied the *Caremark* standard, which requires a plaintiff to provide particularized facts in a well-pled complaint "that either (i) the directors completely failed to implement any reporting or information system or controls or (ii) having implemented such a system or controls, consciously failed to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring their attention."[3]

I. Facts

Clovis, a small biopharmaceutical company, had no drugs on the market and did not have sales revenue. Clovis had a developmental drug, Rociletinib ("Roci"), which was designed to treat a type of lung cancer.[4] In order to obtain U.S. Food and Drug Administration ("FDA") approval, Clovis had to prove Roci's "efficacy and safety in clinical trials."[5] Before commencing the clinical trials, the FDA required Clovis to agree to "certain standards that define how the trial will be conducted, how the trial data will be analyzed and . . . how success in the trial will be measured" (these standards are known as the "clinical trial protocol").[6] Clovis selected the clinical trial protocol known as RECIST, as this was "the most widely used system for assessing response in cancer clinical trials."[7]

RECIST's "success defining metric is called the objective response rate" ("ORR").[8] The ORR function "measures the percentage of patients who experience meaningful tumor shrinkage when" being treated with Roci.[9] The FDA uses the ORR metric in determining whether to approve a drug.[10] Physicians also use the ORR metric as an important factor in determining whether to prescribe a drug.[11] The board of directors of Clovis (the "Clovis Board") was highly focused on Roci's ORR and "knew investors would not view an ORR incorporating *unconfirmed* responses as 'meaningful,'" nor would the FDA accept such results as "approvable."[12]

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[1] *In re Clovis Oncology, Inc. Deriv. Litig.*, No. 2017-0222-JRS, 2019 WL 4850188 (Del. Ch. Oct. 1, 2019).

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

[3] *Id.* at *12.

[4] *Id.* at *1, *4. Roci was one of three developmental drugs that Clovis was developing for clinical trials. *Id.* at *4. Because the estimated market of a drug of Rocis's type was estimated to be $3 billion and the Clovis Board knew that AstraZeneca's competing drug, Tagrisso, was also in clinical trials seeking FDA approval, the Clovis Board was focused on Roci and "'spent hours at Board Meetings discussing Roci' and were 'regularly apprised' of the drug's progress" *Id.* at 3*4 (citations omitted).

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] *Id.* at *5.

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Id.* (emphasis added) (citations omitted). "[E]ach of the Board Defendants appreciated the FDA 'could only make its

Throughout the clinical trials, Clovis was reporting to regulators that the "confirmed ORR" was around 60% "per RECIST."[13] However, as early as June 12, 2014, the Clovis Board had received reports indicating that Roci's ORR metric was based in part on unconfirmed responses.[14] Further, on December 3, 2014, the Clovis Board received a report stating that by March 2015, Roci would have a response rate of less than 60% and that it could ultimately be less than 50%.[15] In February 2015, certain defendants signed Clovis's 2014 Annual Report, which allegedly "reaffirmed previous, inflated ORR reports and omitted that Clovis was relying on partially unconfirmed responses."[16] Further, in April 2019, the Clovis Board received a presentation from management which revealed that the ORR was as high as 53.3% for the highest group of test patients and as low as 37.1% for other subgroups.[17] Lastly, in June 2015, certain defendants received data regarding Roci's ORR that was nearly final, which showed the ORR was around 45%, and then a few days later that the ORR was only 42%.[18] The following month, Clovis conducted a secondary offering of shares and the entire Clovis Board signed the registration statement which disclosed that Roci's ORR was 60%.[19]

Among other counts, based in part on the foregoing alleged facts, the plaintiffs claimed that the defendants who were members of the Clovis Board (the "Board Defendants") "breached their fiduciary duties under *Caremark* by their 'actions and inactions in connection with the [Roci] trial.'"[20] In particular, the plaintiffs alleged that either (i) "the Board Defendants failed to institute an oversight system for the [Roci] trial or (ii) the Board Defendants consciously disregarded a series of red flags related to the [Roci] trial."[21]

II. The Delaware Court's Decision

In analyzing the plaintiffs' claims, the Court of Chancery explained that the *Caremark* decision and its progeny distinguish between the fiduciary duty generally owed by the board in the *management of business risk* from the "board's oversight of the company's *compliance with positive law* – including regulatory mandates."[22] Recently, the Delaware Court noted that the "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 (1) fails to implement compliance systems, or (2) fails to monitor existing compliance systems," resulting in a violation of law and liability.[23]

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decisions . . . to approve Roci based on *confirmed* responses.'" *Id*. (emphasis added) (citations omitted).

[13] *Id*.

[14] *Id*. at *6.

[15] *Id*. (citations omitted).

[16] *Id*. at *7.

[17] *Id*.

[18] *Id*.

[19] *Id*. Throughout the *Clovis* opinion, there were several other red flags that the Clovis Board was apprised of, including undisclosed side effects.

[20] *Id*. at *10 (citations omitted).

[21] *Id*.

[22] *Clovis*, 2019 WL 4850188, at *12 (emphasis added). *See In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959 (Del. Ch. 1996); *Stone v. Ritter*, 911 A.2d 362 (Del. 2006).

[23] *In re Facebook, Inc. Sec. 220 Litig.*, 2019 WL 2320842, at *14 (Del. Ch. May 31, 2019). In *Facebook*, the court further explained that "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 courts of its operations*. *Id*. (emphasis added).

In *Marchand v. Barnhill*, the Delaware Supreme Court further underscored the importance of board oversight "when the company is operating in the midst of 'mission critical' regulatory compliance risk."[24] The *Marchand* Court made clear that "when a company operates in an environment where externally imposed regulations govern its 'mission critical' operations, the board's oversight function must be rigorously exercised."[25]

The *Clovis* Court explained that the *Caremark* standard for breach of fiduciary duty "is among the hardest to plead and prove," as implicit in the standard "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.'"[26]

The *Clovis* Court found that the plaintiffs met the heavy pleading burden set by *Caremark* and denied the motion to dismiss.

III. Significance of the Decision

This opinion is the most recent denial of a motion to dismiss a *Caremark* claim alleging that board defendants failed to adequately monitor compliance systems in a highly-regulated industry. It reinforces the *Marchand* Court's decision to allow a *Caremark* claim to proceed against directors for allegedly failing to implement any compliance system and extends the potential for liability to claims against directors that implement a compliance system, but fail to adequately monitor it.

The case emphasizes the relevance of *Caremark*'s standard to board oversight of products that are "instinctually critical to the company's business operations."[27] The *Clovis* Court made clear that oversight must be "more rigorously exercised" where a company's 'mission critical' operations are subject to "externally imposed regulations."[28] Taken together, *Clovis* and *Marchand* suggest that directors are more likely to face *Caremark* liability in highly-regulated industries, monoline companies, or where the court reasonably infers that a board is comprised of "experts" that "would have appreciated" signals of non-compliance, but instead operated with "hands on their ears to muffle the alarms."[29] In inferring the board's expert composition, the *Clovis* Court considered the directors' previous participation on the boards of other pharmaceutical companies, health-care focused firms, advisory roles held in related medical industries and involvement in Roci's development since the Company's inception. Importantly, the *Clovis* decision widens plaintiffs' ability to establish an inference of scienter at the pleading stage of a *Caremark* claim. It suggests future *Caremark* claims can survive the pleading stage if the court reasonably infers that board defendants *did* understand (or should have understood) incidents involving the

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

[25] *Clovis*, 2019 WL 4850188, at *13 (quoting *Marchand*, 212 A.3d at 824). In reviewing the *Marchand* decision, the *Clovis* Court explained that key to the *Marchand* Court's "analysis was the fact that food safety was the "*most central safety and legal compliance issue facing the company*." *Clovis*, 2019 WL 4850188, at *12 (emphasis added) (quoting *Marchand*, 212 A.3d at 822).

[26] *Clovis*, 2019 WL 4850188, at *12 (quoting *In re Massey Energy Co.*, No. 5430-VCS, 2011 WL 2176479, at *22 (Del. Ch. May 31, 2011)) (citing *Stone*, 911 A.2d at 370). In order for a plaintiff to survive dismissal when pleading an allegation of breach of fiduciary duty under *Caremark*, the case requires "well-pled allegations of bad faith" – a standard of wrongdoing "qualitatively different from, and more culpable than . . . gross negligence." *Clovis*, 2019 WL 4850188, at *12 (quoting *Stone*, 911 A.2d at 372).

[27] *Id.* at *1.

[28] *Clovis*, 2019 WL 4850188, at *13 (quoting *Marchand*, 212 A.3d at 821).

[29] *Clovis*, 2019 WL 4850188, at *7 (citations omitted).

company's non-compliance with positive law – including regulatory mandates.[30] Important to the *Clovis* Court's reasoning were well-pled allegations that the Board Defendants provided false reports about Roci's safety and efficacy to the FDA, approved misinformation in an annual report and securities offerings and "did nothing to address … fundamental departure[s] from [positive law]."[31] In reaching its decision, the Court considered the expert composition of the Board an important factor.

The *Clovis* Court cautioned that *Caremark* "does not demand omniscience," but rather a good faith effort to implement an oversight system and then to monitor it."[32] Avoiding *Caremark* liability at the pleading stage "entails sensitivity to compliance issue[s] intrinsically critical to the company."[33] Therefore, when implementing and monitoring compliance-oversight systems, directors should take care to adhere to industry protocols and regulatory mandates. This caution particularly applies to board oversight systems in highly-regulated businesses and monoline companies.

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If you have any questions about the issues addressed in this memorandum, or if you would like a copy of any of the materials mentioned in it, please do not hesitate to call or email Helene Banks at 212.701.3439 or hbanks@cahill.com; Bradley J. Bondi at 202.862.8910 or bbondi@cahill.com; Charles A. Gilman at 212.701.3403 or cgilman@cahill.com; Elai Katz at 212.701.3039 or ekatz@cahill.com; Geoffrey E. Liebmann at 212.701.3313 or gliebmann@cahill.com; Ross Sturman at 212.701.3831 or rsturman@cahill.com; or Eboney J. Hutt at 212.701.3259 or ehutt@cahill.com; or Paul Rafla at 212.701.3388 or prafla@cahill.com.

[30] *Id*. at *14.
[31] *Id*. at *13.
[32] *Id*. at *13 (quoting *Marchand*, 212 A.3d at 821).
[33] *Id*.