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In re Clovis: Considering *Caremark* Claims after *Marchand*

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In *In re Clovis Oncology Inc. Derivative Litigation*,[1] the Delaware Court of Chancery construed the Delaware Supreme Court's opinion in *Marchand v. Barnhill*[2] to mean that the board's duty of oversight under *Caremark*[3] "must be more rigorously exercised" for corporations operating "in an environment where externally imposed regulations govern its 'mission critical' operations."[4] The *Clovis* Court stated that, for purposes of adequately pleading that the board failed to monitor effectively its compliance system or controls, the plaintiff must show that "red flags" of non-compliance had been waved in such a manner that they become apparent to a careful observer. The Court concluded, however, that the "careful observer is one whose gaze is fixed on the company's mission critical regulatory issues."[5] While the Court's opinion in *Clovis* does not purport to change longstanding principles involving the duty of oversight under *Caremark*, it does provide substantial guidance regarding the manner in which the Delaware courts will assess whether a plaintiff has met its pleading-stage burden to demonstrate that the board failed to effectively monitor risks.

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Background

Clovis Oncology Inc. is a biopharmaceutical firm focused on developing and commercializing cancer treatments.[6] During the relevant period at issue,[7] Clovis had three drugs in development, but no commercial products or revenue. To fund its operations, Clovis relied on investor capital. One of the three drugs under development, Rociletinib (Roci), a drug designed to treat lung cancer, was particularly important to Clovis in light of the size of its potential market.

To obtain Food and Drug Administration (FDA) approval, Clovis had to undergo clinical trials to demonstrate the efficacy and safety of Roci. For purposes of the trial, Clovis elected to use a standard protocol known as RECIST. One of RECIST's key functions is to establish the criteria for success in the trial,

known as the objective response rate (ORR), which measures the percentage of patients who experience tumor shrinkage through treatment. During the 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.'"[8]

Despite these statements, the Court found that the plaintiffs had pled that as early as June 12, 2014, Clovis's board of directors (Board) had received reports indicating that Clovis was improperly calculating the ORR. That is, the plaintiffs had pled facts showing that the Board had received reports containing information from which the Board could have inferred that the ORR calculations were based in part on unconfirmed responses. To this end, the Court pointed to, among other things, a management presentation given to the Board stating that the ORR was 58 percent. At that meeting, however, management advised the Board that the ORR would improve as patients get second and third scans—which advisement, according to the Court, apparently would have alerted the Board to the fact that the ORR as reported was based at least in part on unconfirmed results and therefore not RECIST-compliant.[9] The Court also noted that, later in 2014, the Board received a report showing that management was reporting the ORR using partially unconfirmed results by noting that it was "'**Unconfirmed*.'"[10]

By late 2014, the Board received from management a report stating that, by mid-March of the following year, the ORR would be less than 60 percent and perhaps below 50 percent. Not long thereafter, Clovis was advised that the FDA would not be approving Roci. Once the news that Roci would not be approved was released, Clovis's stock price declined. As Clovis had sought and obtained investor capital in the period leading up to the failed trial, it was named as a defendant in a series of securities fraud class action suits, one of which was settled for a sizable sum. In addition, an action brought by the SEC precipitated the entry of a consent decree, resulting in Clovis paying civil penalties.

Analysis

After seeking and obtaining books and records under Section 220 of the Delaware General Corporation Law, the plaintiffs brought suit, alleging, among other things, that the directors breached their fiduciary duties under *Caremark*. Specifically, the plaintiffs claimed that the directors failed to institute an oversight system for the Roci clinical trial or consciously disregarded their oversight duties by ignoring so-called red flags that emerged during the clinical trial. The defendants moved to dismiss under Rule 23.1, claiming that the plaintiffs had not adequately pled that a pre-suit litigation demand was futile, and under Rule 12(b)(6), claiming that the plaintiffs had not stated viable claims against the directors.

The Court denied the defendants' motion to dismiss under Rule 23.1. In this regard, the Court found that the plaintiffs had pled adequately that the defendants faced a substantial likelihood of liability on the duty of oversight claims under *Caremark*, as construed with the recent gloss supplied by the Delaware Supreme Court's opinion in *Marchand v. Barnhill*, which the Court found to render demand futile. As a result of this ruling, the Court found that the defendants' motion under Rule 12(b)(6) also failed. In reaching its key conclusion, the Court reiterated the key mandates of *Caremark*—namely, that the board of directors must implement an oversight system for key risks and must monitor the system. With respect to the imposition of liability on a *Caremark* claim, the Court stated that it was important to distinguish between oversight of business risk, on the one hand, and oversight of legal and regulatory compliance, on the other, and cited to the statements of the Delaware Supreme Court in *Marchand* which the Court read to impose a heightened oversight obligation with respect to the latter.[11]

The Court rejected the plaintiffs' argument that Clovis had not instituted an oversight system. The Court noted that Clovis's nominating and governance committee expressly was delegated the duty of overseeing compliance oversight, including with respect to FDA requirements. Moreover, as the plaintiffs' complaint made clear, the Board regularly received reports containing significant information regarding the Roci trial. But, as to the claims that the Board failed to monitor its oversight system, the Court found that the plaintiffs had pled adequately that "red flags" of non-compliance had been waved before the Board and that the directors chose to ignore them. While the Court recognized that red flags must be waved so as to be visible to the "careful observer," given what the Court found to be the centrality of Roci to Clovis's otherwise limited operations, it held the directors to a fairly high level of perspicacity under the circumstances. The Court found that the plaintiffs sufficiently had alleged facts supporting reasonable inferences that the directors knew the protocol on which the Roci trial was based, that management was incorrectly reporting the results, and that the Board did not take measures to remedy the incorrect deficiencies. The Court then stated that, once the incorrect reports were revealed, "Clovis's stock price tumbled" and that at the pleading stage, there was a sufficient "causal nexus" between the alleged oversight failures and resulting harms for the oversight claims to proceed.[12]

Key Takeaways

The *Clovis* opinion signals that, post-*Marchand*, the Delaware courts, in assessing *Caremark* claims at the pleading stage, may hold boards operating in highly regulated industries to a somewhat elevated standard for monitoring and assessing compliance with mission-critical regulatory regimes. Even if it holds certain directors to a higher standard, however, the suggestions of the *Clovis* Court do not strip directors of the protections they traditionally are afforded under Delaware law. Although the focus on regulatory compliance in this context has been the subject of increased discussion and debate following *Marchand* and *Clovis*, its roots date back to the original *Caremark* opinion, in which the Court of Chancery observed that

> [f]inancial and organizational disasters . . . raise the question, what is the board's responsibility with respect to the organization and monitoring of the enterprise to assure that the corporation functions within the law to achieve its purposes?[13]

In answering this question in *Caremark*, the Court of Chancery characterized the claims before it as "extremely weak" based, in part, on the fact that "the Board appear[ed] to have been informed by experts that the company's practices while contestable, were lawful" and "[t]here [wa]s no evidence that reliance on such reports was not reasonable."[14] In doing so, the Court implicitly acknowledged the protections directors are entitled to under Section 141(e) of the Delaware General Corporation Law, under which directors are "fully protected" for their good faith reliance upon corporate records and information, opinions, reports, or statements presented by corporate officers or employees, committees of the board, or any other person as to matters the director "reasonably believes are within such other person's professional or expert competence and who has been selected with reasonable care by or on behalf of the corporation."[15]

While the *Clovis* Court found a defense premised on Section 141(e) premature at the pleading stage in light of the plaintiffs' allegations that reliance on management to report ORR would be "unreasonable in light of the Board presentations and the competitive pressure Roci faced,"[16] Section 141(e) ultimately should protect directors of corporations operating in highly regulated industries from liability when they rely on corporate records, officers, or employees, or on legal or regulatory advisors selected with

reasonable care on matters reasonably believed to be within their professional or expert competence, so long as such reliance is in good faith.[17] Just as "independent directors are entitled to rely in good faith on advice from the auditors that corporate books and records are accurate and GAAP-compliant,"[18] they can rely in good faith on technical metrics and data presented to them by officers and qualified expert advisors.

But at the pleading stage, a board's principal line of defense to a claim that it did not adequately monitor key legal and regulatory risks will stem from the minutes and other board-level materials. *Clovis* and other recent cases highlight the tight-rope that practitioners walk in preparing these items. On the one hand, in *Clovis*, less thorough board-level materials could have provided the plaintiffs with less of a basis upon which to allege that the Board should have known of the red flags identified by the Court. On the other hand, drafting minutes and board materials in a more robust manner that tends to show that the board was apprised of any deficiencies or concerns in respect of key regulatory matters and directed some action to remedy or address those deficiencies and concerns can establish the adequacy of the board's reporting mechanisms and responses to potential red flags.[19] Generally speaking, evidencing such satisfaction of the board's fiduciary duties will be of utmost importance at the pleading stage. The *Clovis* Court, despite recognizing that "*Caremark* does not demand omniscience," did impute a fair degree of knowledge and expertise to the Board for purposes of assessing the plaintiffs' allegations.[20] If directors are held to this type of standard, it stands to reason that more, and not less, detailed minutes generally will provide better evidence of the type of deliberations expected from those with this level of expertise, at least for purposes of dismissing claims at the pleading stage. Accordingly, in situations where board books highlight areas of key regulatory compliance matters, corporations and their counsel should take care to ensure that those materials or the minutes are sufficiently robust—and that they reflect the board's actions or directives in response to those matters, along with their bases for doing so.

Notes

1. In re Clovis Oncology Inc. Derivative Litig., 2019 WL 4850188 (Del. Ch. Oct. 1, 2019).
2. Marchand v. Barnhill, 212 A.3d 805 (Del. 2019); s*ee generally* John Mark Zeberkiewicz & Robert B. Greco, "*Marchand v. Barnhill*: Addressing & Monitoring Corporate Risk," 33 *Insights* 1, 11 (July 2019).
3. In re Caremark Int'l Inc. Deriv. Litig., 698 A.2d 959 (Del. Ch. 1996).
4. *Clovis*, 2019 WL 4850188, at *13.
5. Id.
6. The summary of the facts presented herein, and any characterization thereof, is based solely on the *Clovis* Court's opinion, which was decided solely on the basis of the defendants' motion to dismiss. In this regard, it is important to recognize that the Court, in considering the defendants' motion to dismiss under Rule 23.1 on the grounds that the plaintiffs had not made a pre-suit demand nor shown that demand was futile, was applying the *Rales* standard, which "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." *Id.* at *11.
7. The Court defined the relevant period to be from the commencement of the phase II *Roci* trial on February 26, 2014 through the initiation of the litigation.
8. *Id.* at *5.
9. *Id.* at *6.
10. Id.
11. *Id.* at *13.
12. *Id.* at *13–15.
13. *Caremark*, 698 A.2d at 968–969.
14. *Id.* at 971–972.
15. 8 *Del. C.* § 141(e).
16. *Clovis*, 2019 WL 4850188, at *14 n.210.
17. *See* In re Rural Metro Corp., 88 A.3d 54, 86 n.13 (Del. Ch. 2014) ("[I]f the directors followed a process or reached a result falling outside the range of reasonableness, but did so in reliance on the advice of experts, they could be found to have breached their fiduciary duties under the

applicable standard of review and yet be 'fully protected' against liability under Section 141(e) of the DGCL.").

18. In re Am. Int'l Grp., Inc., 965 A.2d 763, 828–829 n.246 (Del. Ch. Feb. 10, 2009), *aff'd sub nom.* Teachers' Ret. Sys. of La. v. PricewaterhouseCoopers LLP, 11 A.3d 228 (Del. 2011) (TABLE).
19. *See* Zeberkiewicz & Greco, *supra* n.2 at 14; *see generally* John Mark Zeberkiewicz & Robert B. Greco, "Drafting Minutes & Preparing Disclosures in the Post-Corwin Era," 33 *Insights* 1, 15 (Mar. 2019).
20. *Clovis*, 2019 WL 4850188, at *13.