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CAREMARK CLAIMS: "MISSION CRITICAL" COMPLIANCE RISKS AND A BOARD'S DUTY TO MONITOR

In two recent cases the Delaware courts have allowed Caremark *claims to proceed, raising the question whether the courts are lowering the high pleading bar to such cases. The authors discuss the cases, finding that extreme facts rather than lowering requirements are responsible for the decisions. Their takeaways include three central points that bear on whether a* Caremark *claim will survive a motion to dismiss; and they conclude that corporate boards should identify "mission critical" compliance risks and have — and use — mechanisms for monitoring those risks.*

By Maeve O'Connor, Elliot Greenfield and Tristan M. Ellis *

Derivative claims based on directors' oversight obligations – known as *Caremark* claims – present "possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment."[1] Indeed, in the more than 20 years since *Caremark*, only a handful of cases have survived a motion to dismiss. Twice in the past year, however, in *Marchand v. Barnhill* and *In re Clovis Oncology, Inc. Derivative Litigation* ("*Clovis*"), Delaware courts have allowed *Caremark* claims to proceed past the pleading stage, raising the question of whether these decisions represent a trend towards lowering the bar.[2] Notably, in both cases, the plaintiffs relied heavily on board minutes and materials obtained through Section 220 "books-and-records" demands, which allowed them to make particularized factual allegations regarding board oversight activity.[3]

Careful review of *Marchand* and *Clovis* indicates that the outcome of those cases merely reflects the extreme sets of facts on which they were based rather than an easing of the "onerous pleading burden" that plaintiffs bear when it comes to *Caremark* claims.[4] Other recent decisions confirm that Delaware courts remain deferential to directors' judgment in carrying out their oversight obligations and will find a breach of fiduciary duty adequately pleaded only in cases involving egregious, bad-faith conduct.[5] Nonetheless, corporate

[1] *In re Caremark Int'l Inc. Derivative Litig.* ("*Caremark*"), 698 A.2d 959, 967 (Del. Ch. 1996).

[2] *Marchand v. Barnhill*, 212 A.3d 805 (Del. 2019); *In re Clovis Oncology, Inc. Derivative Litig.*, 2019 WL 4850188 (Del. Ch. Oct. 1, 2019).

[3] 8 Del. C. § 220; *Marchand*, 212 A.3d at 822; *Clovis*, 2019 WL 4850188, at *9.

[4] *Marchand*, 212 A.3d at 824.

[5] *See, e.g.*, *In re LendingClub Corp. Derivative Litig.*, 2019 WL 5678578, at *8-14 (Del. Ch. Oct. 31, 2019); *Rojas ex rel. J.C. Penney Co., Inc. v. Ellison*, 2019 WL 3408812, at *8-14 (Del. Ch. July 29, 2019).

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boards should heed the lesson of *Marchand* and *Clovis*, which make clear that this deference has its limits: courts will step in when they perceive a complete failure to monitor, particularly in the context of "mission critical" compliance risks.

I. PLEADING A *CAREMARK* CLAIM

A *Caremark* claim is the mechanism under Delaware law by which a company, or a stockholder with standing to sue derivatively on behalf of a company, may challenge the failure of a board of directors to oversee management. Consistent with the presumption that directors are faithful to their fiduciary duties and the Delaware courts' hesitancy to second-guess their business judgments or impose liability for mere inattention or negligence, the *Caremark* court emphasized the difficulty a plaintiff faces in pleading a breach of fiduciary duty based on failure to monitor: "only a sustained or systematic failure of the board to exercise oversight . . . will establish the lack of good faith that is a necessary condition to liability."[6]

Subsequent decisions have further clarified that liability for failure to adequately oversee a company's affairs requires that a board of directors either (*i*) "utterly 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" – *i.e.*, "that the directors knew that they were not discharging their fiduciary obligations."[7]

With respect to the first prong of *Caremark*, the mere failure to put in place *adequate* controls is not sufficient. Courts have rejected claims based on allegations that reporting systems were faulty or that certain information should have been reported to the board.[8] Rather, allegations that would pass muster "might take the form of facts that show the company entirely lacked an audit committee or other important supervisory structures, or that a formally constituted audit committee failed to meet."[9] This framework respects boards' business judgment regarding how best to construct relevant reporting systems; it simply requires that they not entirely fail to do so.

As to the second prong, a plaintiff must allege particularized facts indicating "actual director involvement in a decision or series of decisions that violated positive law" or that "the board consciously failed to act after learning about evidence of illegality – the proverbial 'red flag.'"[10] By requiring that a "red flag" make the board aware of a violation by the company of "positive law" – and not simply business risk – the Delaware courts substantially limit the scope of issues that fall within the *Caremark* framework and may give rise to liability.[11]

In light of these stringent pleading requirements, it comes as no surprise that very few complaints asserting *Caremark* claims have survived a motion to dismiss. The two cases that recently did make it past the pleading stage – *Marchand* and *Clovis* – do not appear to represent a sea change in the law and instead illustrate the extreme factual allegations that Delaware courts require to find a breach of fiduciary duty for failure to monitor adequately pleaded.

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[6] *Caremark*, 698 A.2d at 971.

[7] *Stone ex rel. AmSouth Bancorp. v. Ritter*, 911 A.2d 362, 370 (Del. 2006).

[8] *See, e.g.*, *In re Gen. Motors Co. Derivative Litig.*, 2015 WL 3958724, at *14-15 (Del. Ch. June 26, 2015), *aff'd*, 133 A.3d 971 (Del. 2016) (unpublished table disposition).

[9] *David B. Shaev Profit Sharing Account v. Armstrong*, 2006 WL 391931, at *5 (Del. Ch. Feb. 13, 2006) (footnote omitted), *aff'd*, 911 A.2d 802 (Del. 2006) (unpublished table disposition).

[10] *South v. Baker*, 62 A.3d 1, 14-15 (Del. Ch. 2012).

[11] *Id.* at 6; *see also, e.g.*, *In re Facebook, Inc. Section 220 Litig.*, 2019 WL 2320842, at *14 & n.150 (Del. Ch. May 30, 2019) (observing that "Delaware courts are more inclined to *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"); *cf. Wilkin ex rel. Orexigen Therapeutics, Inc. v. Narachi*, 2018 WL 1100372, at *12 (Del. Ch. Feb. 28, 2018) ("Pleading violations of nonbinding recommendations does not constitute pleading a violation of positive law such that the board faces a substantial likelihood of liability and cannot consider demand.").

II. *CAREMARK* PRONG ONE: *MARCHAND V. BARNHILL*

In *Marchand*, the Supreme Court of Delaware held that the plaintiff met his "onerous pleading burden" because he alleged that Blue Bell Creameries USA, Inc., which manufactured ice cream, lacked *any* "compliance system and protocols" related to food safety – "the obviously most central consumer safety and legal compliance issue facing the company."[12] That failure meant that the board was unaware of critical food safety deficiencies, which ultimately led to *listeria* contamination in Blue Bell's ice cream that caused the death of three of the company's customers and injured others.[13] The *listeria* outbreak also forced the company to recall all of its products, lay off over a third of its employees, and stop production at all of its plants.[14]

Marchand turned on the first prong of *Caremark*: whether the Blue Bell board had "utterly failed to adopt or implement any reporting and compliance systems."[15] In the years preceding the *listeria* outbreak, Blue Bell's management allegedly had been aware of serious health safety issues at the company's production facilities, including numerous positive tests indicating the presence of *listeria* above legal limits.[16] Despite the growing severity of these serious, life-threatening food safety issues, management allegedly did not present this information to the board until after the discovery of *listeria* in samples of Blue Bell's ice cream forced the company to issue a recall.[17] Indeed, aside from a single reference to an audit related to sanitation issues, prior to the recall there was no reference in the board minutes "of *any* board-level discussion regarding food safety."[18]

The plaintiff's allegations indicated that Blue Bell had "no board committee charged with monitoring food safety," and that "Blue Bell's full board did not have a process where a portion of the board's meetings each year . . . were specifically devoted to food safety compliance" or "a protocol requiring or . . . any expectation that management would deliver key food safety compliance reports or summaries of these reports to the board on a consistent and mandatory basis."[19] In holding that the plaintiff adequately pleaded a *Caremark* claim, the court observed that whether the company's sole product was safe for consumption was "one of the most central issues at the company."[20]

The allegations in *Marchand* clearly present an extreme case. The court repeatedly emphasized that "*Caremark* is a tough standard for plaintiffs to meet,"[21] and it made clear that Delaware law gives boards "great discretion to design context- and industry-specific approaches" to board-level oversight that are "tailored to their companies' businesses and resources."[22] That deference means that a *Caremark* claim must be dismissed "even when illegal or harmful company activities escaped detection," so long as the board made a "good faith effort to put a reasonable compliance and reporting system in place."[23]

Nevertheless, allegations supporting "an inference that a board has undertaken *no efforts* to make sure it is informed of a compliance issue *intrinsically critical* to the company's business operation" adequately pleads "that the board has not made the good faith effort that *Caremark* requires."[24] A board that makes no effort to monitor a "mission critical" compliance risk is susceptible to a *Caremark* claim.[25]

III. *CAREMARK* PRONG TWO: *IN RE CLOVIS ONCOLOGY, INC. DERIVATIVE LITIGATION*

Clovis is another extreme case but, unlike *Marchand*, it turned on the second prong of *Caremark* – allegations that the board, having implemented reporting systems or controls, ignored "red flags" of noncompliance.[26] *Clovis* involved a biopharmaceutical company that had no drugs on the market and three in development, one of which – referred to as "Roci" – was the most promising

[12] *Marchand*, 212 A.3d at 824.

[13] *Id.* at 812-14.

[14] *Id.* at 807.

[15] *Id.* at 808 (internal quotation marks omitted); *see also id.* at 821 ("[O]ur focus here is on the key issue of whether the plaintiff has pled facts from which we can infer that Blue Bell's board made no effort to put in place a board-level compliance system.").

[16] *Id.* at 811-12.

[17] *Id.* at 812-14.

[18] *Id.* at 812-13.

[19] *Id.* at 813.

[20] *Id.*at 822.

[21] *Id.*; *see also id.* at 820, 824 (using similar language).

[22] *Id.* at 821.

[23] *Id.*

[24] *Id.* at 822 (emphasis added).

[25] *Id.* at 824.

[26] *Clovis*, 2019 WL 4850188, at *13.

and thus allegedly "intrinsically critical" to the company's business.[27] Nonetheless, the Clovis board allegedly "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."[28]

According to the complaint, the Clovis board knew how important Roci was to the company's success and "was hyper-focused on the drug's development and clinical trial," spending hours of board meetings discussing Roci and receiving regular updates on the drug's progress.[29] The board also allegedly knew that FDA approval of Roci hinged on the drug's "objective response rate," or "ORR," which is "the percentage of patients who experience meaningful tumor shrinkage when treated with the drug," and was thus "laser-focused" on it.[30]

Based on the particularized facts alleged in the complaint – which included multiple reports to the board suggesting that the company was improperly calculating and reporting Roci's ORR[31] – the court found it reasonable to infer that the board knew that management was reporting inflated ORR figures to keep up with the response rate of a competitor drug but took no corrective action.[32] Accordingly, the court held that the plaintiffs had adequately pleaded that the board "consciously ignored red flags that revealed a mission critical failure to comply with the [clinical trial] protocol and associated FDA regulations."[33]

Notably, the court rejected the defendants' argument that the plaintiff had not adequately alleged that the board understood the "highly technical detail" of ORR, pointing to board presentations – obtained through Section 220 demands – that explicitly warned that reported ORR figures were unconfirmed.[34] Based on the board members' expertise in the field, the court inferred that the board knew that those unconfirmed ORR figures were noncompliant with FDA regulations and Roci's clinical trial protocol.[35] The court might have reached a different conclusion if Roci were less material to the company's prospects and outlook, but, because Roci was a make-or-break drug for the company, the court found it reasonable to infer that the board was closely scrutinizing management's presentations, especially reports regarding ORR.

In reaching its conclusion, the court emphasized that boards "must be informed of, and oversee compliance with, the regulatory environments in which their businesses operate."[36] The court also reiterated the crucial distinction between a "board's oversight of the company's *management of business risk* that is inherent in its business plan" and its "oversight of the company's *compliance with positive law* – including regulatory mandates."[37] As in *Marchand*, "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."[38]

IV. KEY TAKEAWAYS

Neither *Marchand* nor *Clovis* appears to indicate a trend towards relaxing the onerous pleading burden that *Caremark* imposes. However, these decisions provide a useful reminder that a *Caremark* claim, though difficult to plead, is not a "chimera."[39] *Marchand* and *Clovis* reiterate and emphasize three central points that bear on whether a *Caremark* claim will survive a motion to dismiss. *First*, because a *Caremark* claim involves a breach of the duty of loyalty, a plaintiff must allege particularized facts showing that directors acted in *bad faith*: a "good faith effort to implement an oversight system and then monitor it" will not give rise to liability.[40] Factual allegations giving rise to an inference of bad faith typically involve egregious conduct amounting to a complete abdication of a director's oversight obligations or even complicity in the misconduct. *Second*, Delaware courts continue to draw a bright line between oversight of *business* risks and oversight of *legal compliance* risks, giving broad deference to boards on the former and exercising tighter

[27] *Id.* at *1-2, *4 (internal quotation marks omitted).

[28] *Id.* at *1.

[29] *Id.* at *4.

[30] *Id.* at *5 (internal quotation marks omitted).

[31] *Id.* at *6-7.

[32] *Id.* at *13.

[33] *Id.* at *15.

[34] *Id.* at *14 n.210 (internal quotation marks omitted).

[35] *Id.* at *14 & n.210.

[36] *Id.* at *12.

[37] *Id.*

[38] *Id.* at *13.

[39] *Marchand*, 212 A.3d at 824.

[40] *Id.* at 821.

control over the latter.[41] *Third*, a *Caremark* claim is more likely to survive when it involves a "mission critical" compliance risk[42] and the corporation at issue is "a monoline company" that "operates in a highly regulated industry."[43]

In light of this framework, corporate boards would be well advised to take stock and identify their "mission critical" compliance risks and ensure that they have in place – and use – mechanisms for monitoring those risks. Such a review should take place periodically, as risks evolve over time and new risks emerge. For example, companies that host a large volume of customers' personally identifiable information or medical records should consider whether it is prudent to create a board committee charged with overseeing data security issues and require board-level reporting on data security risks. More broadly, boards looking to forestall potential *Caremark* liability should put in place systems to ensure that material adverse information regarding legal compliance – in any area of the company's operations – is promptly brought to the board's attention. Regardless of the particular compliance risk at issue, boards should be mindful of *Caremark*'s "bottom-line requirement" that they "make a good faith effort – *i.e.*, try – to put in place a reasonable board-level system of monitoring and reporting."[44]

Additionally, the expanded pre-lawsuit use of "books-and-records" demands under Section 220 means that plaintiffs are often armed with the company's board and committee minutes and materials. As noted above, a key allegation in *Marchand* was the startling lack of board-level discussion of food safety issues, at least as reflected in board minutes. Boards therefore should ensure that their risk-monitoring activity and discussions are fully reflected in company records. ■

[41] *Clovis*, 2019 WL 4850188, at *12.

[42] *Marchand*, 212 A.3d at 824; *Clovis*, 2019 WL 4850188, at *12-13, *15.

[43] *Clovis*, 2019 WL 4850188, at *1; *see also Marchand*, 212 A.3d at 809-11.

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