

# Court of Chancery Applies Well-Settled Principles To Dismiss *Malone/Caremark* ‘Hybrid’ Claims

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> See page 4 for key points

## Introduction

The Delaware Court of Chancery recently dismissed a “hybrid” of *Malone*<sup>1</sup> false disclosures and *Caremark* oversight claims brought by two stockholder plaintiffs. In *In re FibroGen, Inc. Derivative Litigation*,<sup>2</sup> Vice Chancellor Sam Glasscock III analyzed what were essentially securities fraud claims repurposed as claims for breach of fiduciary duty under two theories: (i) knowingly misleading stockholders in disclosures (*Malone* claims) and (ii) failure of oversight (*Caremark* claims). The court, applying well-settled principles, dismissed the plaintiffs’ claims due to their failure to plead any facts from which the court could reasonably infer that any director acted in bad faith.

## Background

FibroGen, Inc. is a biopharmaceutical company involved in developing Roxadustat, a drug to treat anemia. FibroGen had an agreement with a commercial partner to develop the drug, and its revenue was primarily derived from this agreement. The drug development and clinical trials ran for several years. The U.S. Food and Drug Administration (FDA), however, ultimately did not approve the drug for any patient population, and FibroGen’s commercial partner ceased funding and development.

On April 12, 2021, FibroGen stockholders brought a securities class action claim against FibroGen and certain members of its management. The securities plaintiffs alleged that the defendants previously had made false and misleading disclosures regarding the drug and FibroGen’s FDA approval process. After a motion to dismiss those claims was denied in part, the parties agreed to settle the litigation for \$28.5 million.

Subsequently, the plaintiffs brought a derivative action in the Court of Chancery against FibroGen’s directors and officers for, among other things, breaches of fiduciary duty under *Malone* and *Caremark* theories.

The plaintiffs took issue with three types of communications. First, the plaintiffs alleged that members of FibroGen’s management made false statements in conference calls and press releases regarding Roxadustat’s safety results and the FDA’s approval process (the management claims). The plaintiffs alleged that FibroGen board members were aware — or could have been aware — of facts contrary to management’s statements, and that these statements misled investors into believing that the FDA would approve Roxadustat without special warnings.

Second, the plaintiffs claimed that FibroGen issued Forms 10-Q containing allegedly misleading statements about contents of its new drug application to the FDA (the 10-Q claims), and the plaintiffs alleged that FibroGen’s directors were aware of facts indicating the filings were misleading.

<sup>1</sup> *Malone v. Brincat*, 722 A.2d 5 (Del. 1998). A *Malone* claim alleges that a fiduciary knowingly disseminated false information “that results in corporate injury or damage to an individual stockholder” outside the context of a stockholder vote. *Id.* at 9.

<sup>2</sup> *In re FibroGen, Inc. Deriv. Litig.*, C.A. No. 2022-0331-SG (Del. Ch. Oct. 2, 2024).

Finally, the plaintiffs alleged that FibroGen's 2019 and 2020 Forms 10-K — which were signed by a majority of the board — contained misleading, post hoc manipulated data about Roxadustat and the approval process (the 10-K claims). The defendants moved to dismiss for failure to plead demand futility as required under Court of Chancery Rule of Civil Procedure 23.1 and for failure to state a claim.

### The Court's Analysis

Under Delaware law, a *Malone* claim arises when a fiduciary knowingly disseminates false information in the absence of a request for stockholder action “that results in corporate injury or damage to an individual stockholder.”<sup>3</sup> A so-called “prong-two” *Caremark* oversight claim arises where directors, “having implemented [oversight] system or controls, consciously failed to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring their attention.”<sup>4</sup> Here, the court stated that the plaintiffs, “[p]erhaps sensing the weakness of the [*Malone*] disclosure allegations,” presented a “hybrid” claim that asked the court to “consider the facts under the lens of a *Caremark* oversight claim.” As the court explained, the plaintiffs’ “syllogism ran thus: Management communicated false and misleading statements to investors and the FDA; even if Plaintiffs have not adequately alleged that a majority of the Director Defendants participated in that dissemination knowingly or intentionally, these Director Defendants’ failure to investigate and intervene, in the face of ‘red flags’ indicating management wrongdoing, amounts to bad faith under a *Caremark* analysis.” The court referred to this hybrid *Malone/Caremark* claim as a “*FibroGen*” claim.

In dismissing the complaint, the court first noted that the plaintiffs’ claims required them to plead with particularity facts

from which the court could reasonably infer that asking the FibroGen’s board to consider whether any wrongdoing had occurred — a so-called “demand” on the board — would have been futile. The plaintiffs argued that such a demand would have been futile because a majority of the board faced a substantial likelihood of liability for breaching their fiduciary duties under the plaintiffs’ allegations. The court held that the particularized pleading standard “differ[s] substantially from . . . permissive notice pleadings” and places a higher pleading burden on the plaintiffs. The court then separately analyzed the *Malone* and *Caremark* aspects of the hybrid claim, treating them as separate claims.

Analyzing the *Malone* claims, the court emphasized that the plaintiffs had to plead “specific facts indicating that [each] director ‘prepared’ the challenged language or was ‘directly responsible for the misstatements or omissions,’ that the statements were false or misleading, and that the director knew that the statements were false or misleading, or intended that they be so.”

The court first analyzed the management claims. The court found that the plaintiffs had failed to allege with particularity that any member of the board had approved, prepared, caused or were otherwise involved with the purportedly false underlying statements. The court also rejected the plaintiffs’ alternative argument that the board failed to correct the statements because the plaintiffs failed to plead with particularity that any director reviewed or even knew about the allegedly false statements.

Next, the court analyzed the 10-Q claims. Here, too, the court found that the plaintiffs had failed to plead particularized facts that any director knew about the statements included in the Forms 10-Q, let alone that any director had played any role in issuing the statements.

<sup>3</sup> *Malone*, 722 A.2d at 9.

<sup>4</sup> *Stone v. Ritter*, 911 A.3d 362, 370 (Del. 2006).

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Finally, the court analyzed the 10-K claims. Unlike the Forms 10-Q, a majority of the board signed the Forms 10-K at issue. However, the court found that the plaintiffs again failed to plead facts from which the court could reasonably infer that a majority of directors were involved in preparing the Forms 10-K or that they knew that the facts regarding Roxadustat differed from those stated in the Forms 10-K. Simply signing the 10-K was not grounds for director liability.

Analyzing the *Caremark* claims next, the court held that the plaintiffs failed to plead with particularity facts from which the court could reasonably infer that a majority of directors consciously ignored red flags identifying management’s alleged misconduct in issuing misleading disclosures.

The plaintiffs identified what they believed were the two most prominent red flags: (i) a July 2020 board meeting in which the board learned that a black box warning would likely be required for Roxadustat, and (ii) the FDA’s extension of the review period and requests for additional safety analyses. As to the black box warning claim, the court found that such a warning would signal

to the board at most that the FDA viewed Roxadustat as comparable to a competitor drug, which itself had a black box warning. Such information was therefore not clear enough to put the board on notice that management was issuing false or misleading public disclosures. Regarding the FDA’s requests and extension, the court stated that although it might have been prudent for the board to investigate more fully after the FDA’s actions, those actions did not give rise to red flags because they did not provide clear evidence that FibroGen management was disseminating allegedly false or misleading information.

The court also held that the plaintiffs had failed to clearly identify a corporate trauma — in other words, even if the board had been presented with “red flags,” “none of the wrongdoing alleged against FibroGen itself caused the FDA’s rejection of [Roxadustat] — that is, a failure of oversight did not lead to a ‘mission critical’ corporate trauma.” The lack of any “mission critical” corporate trauma further undercut a reasonable inference that the board allegedly acted in bad faith by ignoring red flags of purported misconduct.

## Key Points

- Although the plaintiffs' argument was framed as a hybrid of *Malone* and *Caremark* claims, the Court of Chancery treated the respective *Malone* and *Caremark* aspects as separate claims, and applied settled Delaware law to dismiss them.
- *FibroGen* reaffirms that board members cannot be held liable for public statements simply because they signed a public filing or an employee they oversee made the statements. To survive a motion to dismiss, a plaintiff must plead particularized facts making it reasonable to infer that a director either (i) knew about the falsity or misleading nature of the statements and did not act, or (ii) approved, prepared, caused or were otherwise involved with the false or misleading statements.
- Both directors and officers should regularly consult with counsel to ensure the accuracy of public statements issued outside the context of a stockholder vote, and to understand any litigation risks related to a corporation's public statements.

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Special thanks to **Stephen F. Arcano**.

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