Delaware Court of Chancery Sustains Failure to Monitor Caremark Claim

October 22, 2019

In an important decision regarding the pleading requirements to state a *Caremark*[1] claim, the Delaware Court of Chancery ruled on October 1 in *In re Clovis Oncology, Inc. Derivative Litigation* that shareholders had adequately pled the board of directors acted in bad faith by ignoring red flags that management was reporting inaccurate clinical trial testing results for one of the company's three drugs in development.[2] The court sustained the Plaintiffs' failure-to-monitor claim notwithstanding the company having a system of reporting and compliance controls in place, through which the board received regular reports regarding the company's central compliance issues. Focusing instead on the board allegedly ignoring red flags as to a product that was "intrinsically critical to the Company's business operation" and in a heavily regulated industry, the court found that the board's failure to object or ask questions when it received reports of the inaccurate clinical trial metrics amounted to bad faith, sufficient to plead oversight liability.[3]

The ruling marks a rare instance in which a complaint has survived a motion to dismiss despite the board having implemented a system of targeted controls and reporting requirements, but where the alleged failure was in the monitoring of those controls (i.e., the second prong of *Caremark*). The opinion's focus on the company having one "mission critical" product subject to FDA regulations suggests that boards operating in the midst of positive legal obligations may face greater scrutiny for failure to pay attention to relevant regulatory requirements, particularly with respect to developments that might impact significant products or operations. While it remains to be seen how the decision will apply in other cases, and whether the holding will stand if appealed,[4] the decision underscores the importance of boards understanding and overseeing compliance with regulatory mandates, especially where companies operate in highly regulated industries.

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

2 *In re Clovis Oncology, Inc. Deriv. Litig.*, 2019 WL 4850188, at *1 (Del. Ch. Oct. 1, 2019).

3 *Id.* at 2, 32.

4 Defendants' appeal, if any, is due to be filed by October 31, 2019.

Legal Background

Under *In re Caremark International Inc. Derivative Litigation*, and as explicated by the Delaware Supreme Court in *Marchand v. Barnhill*[5] earlier this year, a board of directors may be liable for failure to oversee where derivative plaintiffs have alleged "particularized facts 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."[6] In *Marchand*, shareholders of Blue Bell Creameries USA, Inc. ("Blue Bell") alleged Blue Bell's board of directors breached its duty of loyalty by knowingly disregarding food safety risks in Blue Bell's ice cream factories and failing to oversee Blue Bell's food-making operations, which ultimately led to a widespread *listeria* outbreak. Chief Justice Strine of the Delaware Supreme Court reversed the lower court's dismissal of the plaintiffs' complaint, finding the "onerous" pleading standard imposed by *Caremark* was met as to the first *Caremark* prong because plaintiffs pleaded particularized facts suggesting (i) "no reasonable compliance system and protocols were established as to the obviously most central consumer safety and legal compliance issue facing the company," (ii) "the board's lack of efforts resulted in it not receiving official notices of food safety deficiencies for several years," and (iii) "as a failure to take remedial action, the company exposed consumers to *listeria*-infected ice cream, resulting in the death and injury of company customers." Central to this holding was the fact that Blue Bell had one product ice cream and operated a heavily regulated industry, making food safety "mission critical" to the company's success.[7]

Factual Background. Clovis Oncology, Inc. ("Clovis") is a biopharmaceutical company that, between February 2014 and April 2016, was developing a drug called Rociletinib ("Roci") to treat a previously-untreatable strain of lung cancer. Roci was one of three drugs Clovis had in development, but was considered the most "promising."[8] Roci was competing with one other drug in development, Tagrisso, in a race for New Drug Application ("NDA") approval by the U.S. Food and Drug Administration ("FDA"), in order to enter a potential $3 billion market for drugs of this type.[9] As part of this process, Roci was undergoing clinical trials that incorporated a standardized industry protocol called "RECIST,"[10] which involved measuring an "objective response rate" ("ORR") in

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

6 *Id.* at 821 (quoting *Stone v. Ritter*, 911 A.2d 362, 370-72 (Del. 2006)).

7 *Id.* at 824.

8 2019 WL 4850188, at *1.

9 *Id.* at *10-*13.

10 RECIST stands for "Response Evaluation Criteria in Solid Tumors," and RECIST guidelines provide a standardized approach to solid tumor measurement along with definitions for objective assessment of changes

patients using patient scans that were "confirmed" by subsequent scans for tumor shrinkage.[11]

In a verified complaint filed by holders of Clovis stock during the relevant period on March 2017, Plaintiffs alleged that the Clovis board of directors "received reports indicating Clovis was improperly calculating Roci's ORR" by using "unconfirmed" responses.[12] Plaintiffs alleged the board knew FDA regulations and the RECIST protocol required the use of only "confirmed" responses, and the board's inaction in the face of these red flags amounted to a breach of its fiduciary duties under *Caremark*.[13] Defendants—members of the Clovis board, Clovis and certain current and former officers—moved to dismiss under Delaware Court of Chancery Rule 12(b)(6).[14]

The Decision

On October 1, Vice Chancellor Slights denied Defendants' motion to dismiss the complaint, finding that Plaintiffs had adequately pled that the board failed to monitor the compliance and reporting system surrounding Roci's clinical trials and ignored multiple red flags indicating that management was providing the board with a skewed ORR. In particular, Vice Chancellor Slights pointed to Plaintiffs' allegations that "(i) the Board knew the TIGER-X protocol incorporated RECIST; (ii) RECIST requires reporting only confirmed responses;[15] (iii) industry practice—and FDA guidance require that the study managers report only confirmed responses; (iv) management was publicly reporting unconfirmed responses to keep up with Tagrisso's response rate; and

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in tumor size. The full RECIST guidelines may be found at https://ctep.cancer.gov/protocolDevelopment/docs/recist_guideline.pdf.

11 *Id.*

12 These reports included management presentations to the board in which ORRs were presented with the caveat that they would change "as patients get to their second and third scans," ORRs were noted as "*Unconfirmed," and management noted they would be citing "the unconfirmed investigator assessed response rate" in meetings with the FDA regarding Roci's NDA. *Id.* at *13-*24.

13 Plaintiffs also brought insider trading and unjust enrichment claims, which were dismissed. 2019 WL 4850188, at *43-*50.

14 *Id.* at 33. Defendants also moved to dismiss under Delaware Court of Chancery Rule 23.1, which the court denied, finding Plaintiffs adequately pled demand futility because they pled "particularized facts to support a reasonable inference the Board Defendants face a substantial likelihood of liability on Count I," the *Caremark* claim. *Id.* at *30.

15 Defendants disputed Plaintiffs' allegations that "confirmed" responses were a black-letter requirement of the RECIST protocol and FDA regulations and that the directors understood this to be required. *Id.* at *38 n.201 & *39 n.210. Vice Chancellor Slights discussed this factual issue at some length but ultimately ruled that, due to the procedural posture of the case, the court was obligated to construe all factual allegations and reasonable inferences drawn therefrom in Plaintiffs' favor. *Id.* As such, the court accepted that the directors knew RECIST required confirmed responses, finding "these regulations, and the reporting requirements of the RECIST protocol, were not nuanced." *Id.* at *39.

(v) the Board knew management was incorrectly reporting responses but did nothing to address this fundamental departure from the RECIST protocol."[16] Applying the criteria set forth in *Marchand* and *Stone*, Vice Chancellor Slights acknowledged that "a *Caremark* claim is among the hardest to plead and prove" but found that the "high bar" was met because 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."[17] This, the court found, was sufficient to plead the second prong of *Caremark*—that the board failed to "make a good faith effort" to "monitor" its oversight system.[18]

Vice Chancellor Slights emphasized that "as fiduciaries, corporate managers must be informed of, and oversee compliance with, the regulatory environments in which their businesses operate" and that a *Caremark* claim is more likely to survive dismissal where it is alleged that "the company operates in the midst of obligations imposed upon it by positive law," including "regulatory mandates," yet "fails to monitor existing compliance systems."[19] Vice Chancellor Slights also stressed the importance of "the board's oversight function when the company is operating in the midst of 'mission critical' regulatory compliance risk," citing *Marchand*.[20] "[W]here externally imposed regulations govern [a company's] 'mission critical' operations, the board's oversight function must be rigorously exercised," which "entails a sensitivity to 'compliance issues intrinsically critical to the company.'"[21] Here, Clovis was operating in a highly regulated space, and compliance with FDA regulations and FDA approval of Roci's NDA was "intrinsically critical to the Company's business operation."[22] Against this backdrop, the board ignoring "multiple warning signs" that management was not complying with the mandates of FDA regulations and RECIST, so as to endanger the approval of Roci's NDA, was sufficient to adequately plead a *Caremark* claim.[23]

Takeaways

Clovis makes clear that boards of directors must calibrate the nature of their oversight activities to the relationship between a company's operations and its regulatory environment, specifically, the extent to which a company has significant products or

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16 *Id.* at *38-*39 (internal quotation marks omitted).

17 *Id.* at *2.

18 *Id.*

19 *Id.* at *34-*35.

20 *Id.*

21 *Id.* at *36 (quoting *Marchand*, 212 A.3d at 822).

22 *Id.*

23 *Id.*

operations in a highly regulated industry must inform the way boards should react to regulatory compliance risks and any corresponding red flags. While red flags are assessed under *Caremark* with regards to their "visib[ility] to the careful observer,"[24] *Clovis* makes clear that "the careful observer is one whose gaze is fixed on the company's mission critical regulatory issues."[25]

The court's sustaining of the Plaintiffs' claim under the second *Caremark* prong is also particularly notable here given the requirement that "the directors knew that they were not discharging their fiduciary obligations" and had a "known duty to act."[26] Here, the central issue regarding the board's knowledge as to whether only "confirmed" responses could be used to calculate ORR under FDA regulations and the RECIST protocol was vigorously disputed, and resolved in favor of the Plaintiffs due in part to the procedural posture of the case. The court's acceptance of allegations regarding the board's knowledge of FDA requirements and industry protocols signals that directors of companies with one or few primary products will be expected to have a greater firsthand understanding of the obligations imposed by "positive law"[27] and may less readily rely on representations by management in this respect.[28]

Clovis also represents a rare instance of a *Caremark* claim surviving even where the company had internal controls in place, and these controls were largely functioning. Unlike in *Marchand*, where Blue Bell had a singular product yet no board-level food safety controls in place, here, Clovis had in place two committees dealing with biopharmaceutical compliance.

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Please do not hesitate to contact us with any questions.

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[24] *Wood v. Baum*, 953 A.2d 136, 144 (Del. 2008) (internal citations omitted); *In re Citigroup Inc. S'holders Litig.*, 2003 WL 21384599, at *2 (Del. Ch. June 5, 2003) (internal quotation marks omitted).

[25] 2019 WL 4850188, at *38.

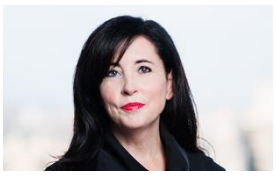
[26] *Stone*, 911 A.2d at 370.

[27] 2019 WL 4850188, at *35.

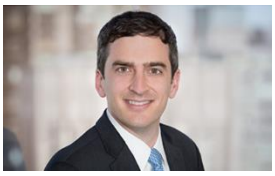
[28] *Id.* at *40 n.210 ("the Complaint alleges circumstances where any reliance on Clovis' management regarding ORR reporting would be unreasonable in light of the Board presentations and the competitive pressure Roci faced from Tagrisso—rendering a reliance defense under 8 Del. C. § 141(e) inappropriate, at least at this stage").

NEW YORK

Mark P. Goodman
mpgoodman@debevoise.com



Maura Kathleen Monaghan
mkmonaghan@debevoise.com



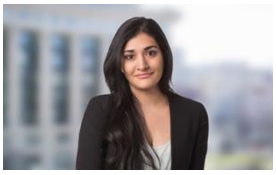
Jacob W. Stahl
jwstahl@debevoise.com

WASHINGTON, D.C.

Paul D. Rubin
pdrubin@debevoise.com

Jonathan R. Tuttle
jrtuttle@debevoise.com

Ada Fernandez Johnson
afjohnson@debevoise.com



Tara P. Ganapathy
tpganapathy@debevoise.com