

Delaware Chancery Court: Allegations That Directors Made Misrepresentations Concerning FDA Approval Prospects Were Insufficient to Plead Demand Futility Absent Plausible Allegations of Scienter

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On February 13, 2020, the Delaware Chancery Court dismissed a derivative action alleging that a pre-suit demand on the board of a biopharmaceutical company would have been futile because the directors faced a substantial likelihood of liability for either authorizing or failing to prevent alleged misstatements in a press release concerning FDA approval prospects for one of the company's products. [Owens v. Mayleben, 2020 WL 748023 \(Del. Ch. 2020\) \(Slights, V.C.\)](#). The court found plaintiff failed to meet his "burden to plead particularized facts that those board members knew the statements were false, but directed that they be disclosed to the market nevertheless."

The press release at issue reported that the FDA had informed the company during a recent meeting that it would permit a "fast tracked" regulatory approval process for the company's cholesterol drug. Several weeks after the issuance of that press release, the FDA released a summary of the same meeting. The FDA's summary "expressed doubt that [the company's cholesterol drug] had a 'clear regulatory path forward.'" Plaintiff alleged that the press release was materially misleading, and further alleged that the company's directors "contributed to and approved the allegedly misleading statements [in the press release] knowing they were false."

The court stated that "[w]henver directors communicate publicly or directly with shareholders about a corporation's affairs, with or without a request for shareholder action, directors have a fiduciary duty to shareholders to exercise due care, good faith and loyalty." The court explained that "[i]f the board of directors intentionally misleads stockholders about the business of the corporation it serves, then its members will be held liable for breach of fiduciary duty." The court specifically recognized that "directors who knowingly make materially misleading statements to stockholders may be considered to be interested for the purposes of demand."

The court found "the [c]omplaint pleads no facts that would allow a reasonable inference the [o]utside [d]irectors, individually or collectively, knew that anything included in the press release was false." The court noted that plaintiff did "not allege the [o]utside [d]irectors attended the FDA meeting or that any one of them knew what occurred at that meeting."

The court observed that it was "not surprising [p]laintiff has not pled particularized facts to support an inference of bad faith" given that there

was no “conceivable explanation of *why* any of the [d]efendants, let alone the [o]utside [d]irectors, would intentionally lie to the market knowing full well the official FDA minutes would contradict their statements in a matter of weeks.” The court pointed out that there were “no allegations that any of the [d]efendants engaged in insider trading or otherwise derived some benefit from having misled the market.” The court determined that it was therefore “not reasonable to infer bad faith” absent some rational “explanation for why [d]efendants would lie so openly, especially when they were virtually certain to be caught in the lie.”

Authors and
Contacts

Lynn Neuner

Partner

lneuner@stblaw.com

+1-212-455-2696

George Wang

Partner

gwang@stblaw.com

+1-212-455-2228

Cheryl Scarboro

Of Counsel

cscarboro@stblaw.com

+1-202-636-5529

