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Board's Failure to Adhere to Best Practices in Drug Clinical Trial Does Not Excuse Stockholder Demand as Futile

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In *Wilkin v. Narachi, et al., and Orexigen Therapeutics, Inc.,* Civil Action No. 12412-VCMR (Del. Ch. February 28, 2018), the Delaware Court of Chancery granted a motion to dismiss brought by defendants ("Defendants"), directors and officers of biopharmaceutical company Orexigen Therapeutics, Inc. ("Orexigen"), for failure to plead demand futility under Court of Chancery Rule 23.1. The Court ruled that the plaintiff, a stockholder of Orexigen ("Plaintiff"), did not plead sufficient facts to show that a substantial likelihood of liability prevented the directors from exercising independent and disinterested business judgment when considering a demand to bring a lawsuit on behalf of the corporation.

Plaintiff brought a derivative suit claiming that Defendants breached their fiduciary duties and wasted corporate assets in connection with Orexigen's application for expedited market approval of its drug Contrave (designed to help obese and overweight adults manage their weight) by the U.S. Food and Drug Administration ("FDA").

The FDA expressed concerns about Contrave's cardiovascular safety and required Orexigen to conduct a related initial clinical trial. The FDA agreed to grant Contrave expedited market approval if the data available a quarter of the way through the initial trial (the "25% Results") met a preset threshold for cardiovascular safety. It was essential to the ongoing viability of the initial trial that the 25% Results not be learned by trial participants or those conducting the trial. To allay these confidentiality concerns, Orexigen approved a data access plan to limit access to the 25% Results to select individuals.

After the initial trial reached the quarter way mark, the FDA granted Contrave initial market approval based on the 25% Results. However, the FDA determined that more than 100 individuals, including those with business interest in the study, had knowledge of or access to the 25% Results. The FDA concluded that this over-dissemination of the 25% Results tainted the remainder of the initial trial for purposes of satisfying Contrave's post-marketing requirements. The FDA also expressed concern about the prospect for the remainder of the initial trial because too many participants had left the study.

The initial trial was terminated at the halfway point, and the clinical trial researchers issued a press release stating that the results did not confirm the cardiovascular benefits suggested by the 25% Results. The market reacted to this news and Orexigen's stock price dropped by 27%. Subsequently, Orexigen conducted a further clinical trial of Contrave required by the FDA.

Prior to filing his complaint, Plaintiff did not demand that the directors bring a lawsuit on behalf of Orexigen. Plaintiff argued that making this demand is excused as futile because seven of the eight directors "knowingly and/or intentionally caus[ed] the Company to violate regulations and breach its confidentiality obligations with respect to the 25% [R]esults" and "knowingly allow[ed] the company to make (or themselves ma[de]) improper public statements." Claiming that these decisions and actions related to the Contrave clinical trial breached Defendants' fiduciary duties and wasted corporate assets, Plaintiff also contended that demand is excused as futile because the directors' decisions and actions were not a valid exercise of the business judgment rule.

The Court acknowledged that the directors' actions may have violated best practices, but went on to hold that Plaintiff failed to establish that the directors violated any legal obligation. The Court first addressed Plaintiff's argument that demand was futile because the directors had a substantial likelihood of personal liability for breaching their duty of loyalty by disclosing the 25% Results. Plaintiff asserted that the directors violated "positive law" by knowingly and intentionally disseminating confidential data (i.e., the 25% Results), which resulted in Orexigen incurring additional costs associated with a new trial. The Court, however, held that Plaintiff's vague and conclusory references to U.S. federal law authorizing the FDA to require confidential trials and impose fines were insufficient to show a substantial likelihood of liability. Similarly, the Court was unpersuaded by Plaintiff's mention of legal rules governing the FDA's approval of new drugs and his argument that the directors violated FDA guidance, noting that Plaintiff did not specify how these rules were violated and explaining that such guidance is not binding positive law. Finding that the FDA's conclusion about disclosure of the 25% Results only affected the prospect for continuing the initial trial, not the expedited market approval based on the 25% Results, the Court also rejected Plaintiff's claim that Defendants violated Orexigen's agreement with the FDA that applied to the portion of the initial clinical trial on which the 25% Results were based.

Next, the Court reframed Plaintiff's argument that demand was futile because the directors had a substantial likelihood of personal liability for breaching their duty of loyalty due to public statements made by representatives of Orexigen. As the Court explained, "the issue 'is whether [the directors] breached their more general fiduciary duty of loyalty and good faith by knowingly disseminating to the stockholders false information . . . about the company.'" Following this analysis, the Court determined that Plaintiff failed to adequately allege and plead facts indicating that Plaintiff received and relied upon false communications from the directors who were deliberately misinforming stockholders about the business of the corporation, which would be necessary to successfully state a duty of loyalty claim. On this basis, the Court concluded that the directors did not face a substantial likelihood of liability for a breach of the duty of loyalty such that making a demand would be excused as futile.

Finally, the Court addressed Plaintiff's argument that the directors failed to exercise sound business judgment, causing Orexigen to waste its assets. According to Plaintiff, the breach of confidentiality with respect to the 25% Results served no legitimate business purpose and provided Orexigen with no benefit in return for the otherwise avoidable cost of conducting a new clinical trial. The Court first observed that, in order to prevail on a waste claim, Plaintiff must overcome the general presumption of good faith on behalf of the directors and show that the directors' decision was "so egregious or irrational that it could not have been based on a valid assessment of the corporation's best

interests." The Court was unwilling to conclude that disclosure of the 25% Results served no legitimate business purpose. Citing the concerns raised by the FDA about the initial trial's continuing viability due to the loss of participants, the Court found that it was not reasonable to infer that a new study was an otherwise avoidable cost absent the confidentiality concerns. Defendants' motion to dismiss was granted.

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