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District of Massachusetts Finds Optimistic Statements Do Not Amount to Actionable Securities Fraud

Securities Litigation Quick Read

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A recent decision out of the U.S. District Court for the District of Massachusetts (District of Massachusetts) reaffirms the ability of pharmaceutical companies to make optimistic public statements about clinical trials without undue fear of liability in shareholder litigation. In *In re Karyopharm Therapeutics, Inc. Securities Litigation*, the District of Massachusetts dismissed a complaint brought by shareholders, alleging that Karyopharm and its officers and directors made material and misleading statements and omissions about selinexor, a drug candidate for the treatment of multiple myeloma and other advanced cancers.[1] The lead plaintiff, Dr. Myo Thant, alleged that Karyopharm and the individual defendants overstated the likelihood of selinexor's FDA approval and misrepresented the results of clinical trials. The court dismissed the complaint, finding that Karyopharm's statements were not misleading and lacked the requisite scienter.

In 2012, Karyopharm started its first phase of clinical trials for selinexor, a drug targeted toward patients with advanced cancers. The first phase revealed that selinexor caused significant adverse effects among patients due to the drug's high toxicity. Despite this, however, Karyopharm proceeded to a second phase of trials, which consisted of two separate trials — the "SOPRA" trial and the "STORM" trial, with each having different target groups and methodologies. The company also supplied real-world data (RWD) to the FDA in support of selinexor's approval. The plaintiffs alleged that Karyopharm made material misstatements and omissions relating to the SOPRA and STORM trials, as well as the RWD.

Regarding the SOPRA trial and the RWD, the plaintiffs alleged that the company misled investors by overstating the efficacy of selinexor. The court, however, found that the plaintiffs selectively quoted Karyopharm's press releases and that, when read in context, "no reasonable investor would have understood the SOPRA press release to be claiming that the trial showed a better overall survival rate for selinexor-treated patients."[2] The court reasoned that Karyopharm, while it had framed the results optimistically, did not materially misstate the results of the trial. "That the company … cast its trial results in a positive light does not detract from its disclosures, as a defendant does not have a duty to cast the descriptions of its business in the most negative light."[3] Additionally, differences in interpretation for the RWD "consitute[d] a non-actionable scientific disagreement" rather than a material misstatement of the data.[4]

Regarding the STORM trial, on the other hand, the court found that the plaintiffs plausibly alleged material omissions relating to certain potential adverse effects of selixnor. While the company had disclosed the most common side effects, such as nausea and fatigue, it had omitted that over half of the patients experienced severe side effects, and "more than 25% of patients permanently discontinued the drug due to its side effects."[5] On this

basis, the company's disclosures "were arguably incomplete for failing to fully reveal the drug's toxicity."[6]

But while certain statements may ultimately be actionable, the court found that the plaintiffs still had not adequately alleged scienter as required under the PSLRA. Karyopharm's omissions, though plausibly alleged to be materially misleading, did not reflect "either a conscious intent to defraud investors or a high degree of recklessness."[7] The court first noted that, of the scienter-specific allegations, "not one mentions investors," and only one mentioned a stock price (which was outdated).[8] This, the court reasoned, did not show an intent to defraud investors. Nor did the court find the alleged omissions sufficiently reckless to support scienter because the defendants offered a "plausible, nonculpable explanation" for not disclosing toxicity data — namely that they believed it was not necessary given the target patient groups suffered from advanced cancers so side effects would be measured relatively against that context.[9] "As a result, no reasonable investor would interpret [Karyopharm's] statement that selinexor's safety profile was 'predictable' and 'manageable' to mean the drug was benign," and contemporaneous analyst reports came to the same conclusion.[10]

In addition to the claims under Section 10(b) of the Exchange Act, the lead plaintiff also brought a claim under Section 11 of the Securities Act. The court found that the lead plaintiff lacked standing to bring a Section 11 claim, however, because he could not show that the shares he bought were traceable to a public offering. The court found that allegations of traceability based "upon information and belief" were insufficient to create standing for a Section 11 claim. The court focused on the large number of previously traded shares in circulation and the fact that none of the plaintiff's purchases occurred on the offering dates or at offering prices. This, the court reasoned, meant that the plaintiff's allegations of traceability "do not exclude the possibility that he purchased common stock from the pool of previously issued shares."[11]

The decision in *Karyopharm* — especially significant for publicly traded pharmaceutical companies or others in highly technical or heavily regulated industries — further illustrates that in some instances, companies may frame disclosures in a positive light, and that legitimate disagreements between companies and industry regulators do not necessarily amount to misrepresentations. And even then, if misstatements are sufficiently alleged to be material, allegations of scienter still must show a specific intent *to mislead investors*. Ultimately, the court dismissed all the claims against Karyopharm, reaffirming that optimism in the face of disappointing results does not necessarily amount to securities fraud.

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[1] No. 19-11972-NMG, 2021 WL 3079878 (D. Mass. July 21, 2021).

[2] *Id.* at *7.

[3] *Id.* (quoting *Corban v. Sarepta Therapeutics, Inc.*, No. 14-cv-10201, 2015 WL 1505693, at *6 (D. Mass. Mar. 31, 2015)).

[4] *Id.* at *8.

[5] *Id.*

[6] *Id.*

[7] *Id.* at *9 (quoting *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 58 (1st Cir. 2008)).

[8] *Id.* at *9.

[9] *Id.*

[10] *Id.*

[11] *Id.* at *11.

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