

Ninth Circuit panel rejects claim that Nektar Therapeutics misled investors

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On May 19, 2022, the Ninth Circuit affirmed dismissal of a case claiming securities fraud in the life sciences space, confirming that disappointing results are insufficient to plead fraud. The panel found that the defendants' positive statements about a study of a pipeline cancer drug were not rendered false or misleading simply because a second, larger study eventually showed less promise.

On May 19, 2022, the Ninth Circuit issued a decision rejecting claims that Nektar Therapeutics misled investors about a promising drug. The case involved a relatively common fact pattern in the life sciences space: an early study shows more promise than a later one, causing sharp stock price movements up and later down. Plaintiffs claim fraud, and courts must carefully assess the disclosure record for evidence of misconduct. Here, the panel affirmed the dismissal of the complaint and observed that “[e]xperimental drug candidates do not always live up to their potential But . . . that does not mean that a pharmaceutical company has defrauded the investing public.” (Op. at 3.)

The case related to a Nektar cancer drug. In 2017, after a small initial clinical trial (called EXCEL) yielded promising results, Nektar presented the results at various conferences. In particular, Nektar used a chart in various presentations that showed that “cancer-fighting cells increased an average of about 30-fold among 10 patients after taking Nektar’s drug.” (Op. at 7.)

Nektar thereafter launched a second trial (called PIVOT). It used a different treatment protocol and did so in a larger patient population. When Nektar released the PIVOT results, which showed lower patient response rates, its stock price dropped by more than 40%.

A few months later, an anonymous short-seller issued a report claiming that the EXCEL results were skewed by a single patient who had a particularly strong reaction to the drug, and that it was misleading for Nektar not to disclose the existence of the alleged outlier. Upon release of the report, Nektar’s stock declined by a further 7%.

Two pension funds then sued Nektar and certain executives alleging securities fraud under Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and Rule 10b-5. The plaintiffs alleged that Nektar misled investors by touting promising results that included outlier data, and by failing to disclose the inclusion of the outlier data. The district court dismissed the case, finding that the plaintiffs had failed to adequately plead falsity, scienter, or loss causation.

On appeal, the Ninth Circuit affirmed. The panel concluded that the plaintiffs did not adequately show that Nektar had made any misstatement or material omission, focusing in particular on the plaintiffs’ failure to show that the information that they claimed should have been disclosed would have been material to a reasonable investor. The panel also found that the plaintiffs could not show loss causation—i.e., that the release of the PIVOT results, or of the short-seller report, corrected any prior Nektar misstatement or omission.

On the topic of falsity, the panel concluded that the plaintiffs failed to show how the chart showing a 30-fold average increase in cancer-fighting cells for patients involved in EXCEL would have deceived a reasonable investor. Among other issues, the plaintiffs did not specify what the trial results would have been *without* the data from the alleged outlier patient. Without such information, the panel concluded that there was no basis to assess the significance of that patient

to the overall results.

More generally, the panel explained that “in the highly technical task of evaluating scientific studies and their impact on investment decisions, plaintiffs must provide some specificity to anchor their contentions that investors would find one study outcome to be meaningfully different from another.” (Op. at 14.) The panel offered a hypothetical analogy to a situation involving smartphone microprocessor processing speeds. If a company disclosed to investors that its new chip was 300 times faster than its prior chip, but exclusion of an outlier test would have meant that the new chip in fact was only *200 times* faster than the older chip, a court would require more than just those figures to assess the materiality of the difference. The panel wrote:

It may well be that consumers cannot tell the difference between 200 times and 300 times faster in real-life because 200 times is blazingly fast for any conceivable task on a smartphone. And in such a scenario, the average investor may not care whether the new microchip is 200 times or 300 times faster because it makes no material difference to consumers. (Op. at 15.)

The panel thus declined to find that Nektar’s disclosures regarding the EXCEL results were misleading, even if the inclusion of a single patient may have impacted the overall data.

On the topic of loss causation, the panel held that neither the PIVOT trial nor the short-seller report constituted a corrective disclosure that revealed that the EXCEL results were false. Acknowledging that the PIVOT results “somewhat took the shine off of the” EXCEL results, the panel also found that nothing about the PIVOT results suggested that the EXCEL results were “manipulated” or that the study methodology or analysis had been “flawed.” (Op. at 17-18.) “Rather, it merely showed that results from a different and more comprehensive test were not as promising as those from the more limited Phase 1 EXCEL data.” (Op. at 18.)

The panel also reaffirmed prior Ninth Circuit guidance that takes a dim view of using anonymous, self-interested reports from short-sellers as the hook to try to establish loss causation. The panel found that, particularly given that the short-seller report disclaimed any representation as to the accuracy of the information provided, the plaintiffs could not tie any stock price movement upon its release to new information released to the market.

The decision was written by Circuit Judge Kenneth K. Lee, and was joined by Circuit Judges Milan D. Smith, Jr. and Danielle J. Forrest.

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