Cooley

In re Nektar Therapeutics: Ninth Circuit Affirms Dismissal of Securities Class Action Arising from Failure of Clinical Drug Trial

June 6, 2022

Summary

On May 19, 2022, a panel of the Ninth Circuit unanimously affirmed the district court's dismissal of a putative securities fraud class action accusing Nektar Therapeutics and several of its executives of misleading investors about the results of a clinical drug trial. The court held that even if Nektar had relied on outlier data in statements about the trial's interim results, the plaintiffs failed to sufficiently articulate what the trial would have showed without the outlier data or why that difference would have been material to investors. The court also held that plaintiffs failed to plead loss causation based on the results of a later-stage clinical trial or an anonymous short-sellers' report. More broadly, the opinion underscores and provides comfort that even where an experimental drug yielded promising results in early clinical trials, the later disclosure of disappointing data—without more—does not suffice to state a securities fraud claim.

Background

Nektar Therapeutics is a biopharmaceutical company that develops drugs to treat cancer, autoimmune diseases, and chronic pain. Its flagship drug candidate NKTR-214 was a modified version of a human protein that activates the body's production of cancer-fighting "CD8+" T cells, which kill infected or malignant cells.

Nektar carried out a Phase 1 clinical trial (the EXCEL trial) to test NKTR-214's effectiveness. In the EXCEL trial, 28 patients were treated with NKTR-214 every two or three weeks. The Company reported interim data as the trial progressed. In 2017, Nektar's CEO presented a bar graph of data from the EXCEL trial at a healthcare conference. That graph—referred to as the "30-fold chart"—showed that among 10 patients treated with NKTR-214, cancer-fighting cells increased by about 30-fold, on average.

Based on the promising results of the Phase 1 EXCEL trial, Nektar launched a Phase 1/2 trial called PIVOT. The PIVOT trial evaluated the effectiveness of NKTR-214 when dosed with a second cancer drug, Opdivo. In June 2018, Nektar released disappointing data from the PIVOT trial showing that the response rate had declined by 35% as compared to interim PIVOT results the Company had previously disclosed. Nektar's stock price then fell by about 42%.

Some four months later, anonymous short-sellers released a report (the "Plainview Report") suggesting that NKTR-214 was less effective than Nektar had claimed. The Plainview Report focused on a second chart from the EXCEL trial ("Figure 6"), which compared data from seven patients in EXCEL. Figure 6 reflected that one EXCEL patient (Patient 14) saw an outsized 300-fold increase in CD8+ T cells as compared to the other six patients. The Plainview Report asserted that the 30-fold chart included data from Patient 14 and thus provided a misleading picture of the EXCEL results. But the authors of the Plainview Report also declared that they were making "no representation, express or implied, as to the accuracy, timeliness, or completeness of information" in the report. Nektar's stock price fell another seven percent the day the Plainview Report was published.

In October 2018, two pension funds filed suit against Nektar and certain current and former employees on behalf of a putative class of investors who purchased stock in Nektar between 2017 and 2018. The funds alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5. In mid-2020, the district court dismissed the complaint without prejudice, and the funds filed an amended complaint. The district court held that the amended complaint failed to adequately allege falsity, scienter, and loss causation, and dismissed it with prejudice.

The Decision

The Ninth Circuit affirmed, holding that the plaintiffs failed to allege falsity and loss causation.

No Materially False or Misleading Statements: The Ninth Circuit held that the plaintiffs failed to plead falsity based on Nektar's use of the 30-fold chart to show the efficacy of NKTR-214 because they "fail to specify why the chart would have deceived a reasonable investor under § 10(b) or Rule 10b-5."

First**,** the court held that even if Patient 14's data was included in the 30-fold chart, the complaint did not "allege with specificity what the Phase 1 EXCEL results would have been without the outlier data" or "provide context about why investors would have felt misled had they received Phase 1 EXCEL results without the outlier data."

While the plaintiffs tried to explain what the EXCEL results would have been without the outlier data, the court held they did not meet the heightened pleading standard of Rule 9(b) and the PSLRA. The court rejected all of the plaintiffs' attempts to show what the extent of the change—or fold change—in CD8+ T cells would have been without Patient 14's data, which included:

- Cherry-picking data from several patients in Figure 6 of the Plainview Report and calculating what the fold change for *those* patients would have been (without justifying why they selected those patients or pleading that any patients from Figure 6 were even included in the 30-fold chart);
- Pointing to an anonymous confidential witness's "vague and hyperbolic assertions" about what the results would have been without Patient 14's data (without providing the specificity needed to meet the PSLRA's heightened pleading standard, particularly given the "highly technical task of evaluating scientific studies and their impact on investment decisions"); and
- Relying on statistical analysis by an outside expert who made a series of what the court called "questionable assumptions" to "estimate" that, without the outlier data, the fold change of the other patients in the 30-fold chart would have been no more than 5.55.

The court further found that the plaintiffs failed to adequately plead why a lower fold change would have been material to investors. The court explained that "context matters in determining the falsity of statements based on highly technical information" and held that the complaint "failed to plead sufficient facts to provide context that would allow us to assess the alleged falsity of Nektar's statements."

Second**,** the court similarly rejected the plaintiffs' attempt to plead that a statement about dosing frequency was materially false. The plaintiffs alleged that two patients in the 30-fold chart were dosed with NKTR-214 every two weeks, but Nektar "falsely claimed" patients were dosed every three weeks.Again, the court found the plaintiffs had pled "no facts" supporting why this alleged one-week difference "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." The court recognized that one could infer that "needing a higher frequency of dosing suggests a lower potency of the drug," but still found this fell short because "it is unclear how that relates to the viability of NKTR-214 on the market" or Nektar's "attractiveness as an investment."

No Loss Causation: The Ninth Circuit also held that the complaint failed to plead loss causation based on the results of the PIVOT trial or the Plainview Report.

First**,** the court rejected the claim that the PIVOT trial data exposed the falsity of Nektar's statements about the EXCEL trial. The complaint alleged that Nektar misleadingly incorporated outlier results into its reporting on the EXCEL trial, thus inflating the Company's stock price, and that the disclosure of the PIVOT trial data revealed the falsity of the prior statements and caused the stock price to fall. But the court found only a "tenuous causal connection" between Nektar's statements about the two trials. It highlighted distinctions between the trials, namely that the EXCEL trial tested NKTR-214 alone and measured biomarker data, while the PIVOT trial tested the use of NKTR-214 together with Opdivo and measured tumor shrinkage. In considering whether the plaintiffs had traced their losses "back to the very facts about which the defendant lied," the court observed that the announcement of the PIVOT data did not "correct or revise previous patient data" or otherwise suggest that the EXCEL data was manipulated or flawed. Rather, the PIVOT data merely introduced new information on NKTR-214 that was not as promising as the earlier, more limited data. The court explained that the plaintiffs' allegations "most plausibly suggest that relatively disappointing test results, not any revelation of earlier falsehoods, caused Nektar's share price to plunge."

Second**,** the court held that the Plainview Report failed to establish loss causation. It reaffirmed its recent ruling that to adequately allege that reports by "self-interested and anonymous short-sellers" are corrective disclosures, plaintiffs must meet a "high bar." To start, such reports typically rely on publicly available information, but corrective disclosures must necessarily reveal *new* information to investors. Short-seller reports *might* function as corrective disclosure where they "required extensive and tedious research involving the analysis of far-flung bits and pieces of data, . . . mak it plausible that provided new information to the market," even where the "underlying data" was already public. The court held that the Plainview Report might have provided investors new information because its analysis assembled "disparate sources and connected data in ways that were not plainly obvious." Nevertheless, the court concluded that the Plainview Report was not a corrective disclosure because it was authored by short-sellers with a "financial incentive to convince others to sell" and who disclaimed its accuracy and completeness. Therefore, it was implausible that reasonable investors would perceive the Plainview Report as revealing the falsity of the defendants' prior statements because investors would have

taken its “contents with a healthy grain of salt.”

Implications

The Ninth Circuit’s decision contains some important takeaways:

- Where the initial results of a clinical trial are promising but the drug later experiences setbacks, that does not necessarily mean that pharmaceutical company executives committed securities fraud. Experimental drug candidates often fail to “live up to their potential”—indeed, “hat is the nature of the industry.” To plead a viable claim for securities fraud, plaintiffs must point to something more.
- Plaintiffs cannot satisfy the PSLRA’s heightened pleading standard through “vague and hyperbolic assertions” and “conclusory adjectives” from anonymous confidential witnesses. With respect to clinical drug trials, this means that a plaintiff cannot rely on a confidential witness’s generalized claim that a statement about the clinical trial was “deceitful” or “lacked scientific integrity.” Rather, “n 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.”
- Nor can plaintiffs meet the PSLRA’s “exacting” standards by simply citing an outside expert’s analysis that is “based on questionable assumptions and unexplained reasoning.” A court should evaluate whether the expert’s *assumptions* support the expert’s *conclusions*, and whether the expert allegations are sufficient to clear the high pleading bar under the PSLRA.
- Context is critical when analyzing whether statements about “highly technical information” are materially false. A plaintiff must plead sufficient facts to show why the difference between what a defendant said about the technical information and the alleged truth would have been material to an average investor.
- An announcement preceding a stock drop is not enough to allege loss causation merely because the announcement was disappointing compared to earlier, rosier statements. Pleading loss causation requires a plaintiff to allege that the disclosure revealed that the earlier statements were fraudulently misleading, not that it merely introduced investors to new information.
- Plaintiffs must overcome a high bar to adequately allege that a report published by short-sellers was a corrective disclosure, because such reports are typically based on publicly available information and do not introduce new facts to the market. But even where plaintiffs can show that a short-seller report did present novel facts or analysis, it might not be corrective where: (1) the short-sellers have a financial incentive to persuade investors to sell, and (2) the report disclaims the accuracy or completeness of its contents. These incentives and disclaimers are exceedingly common in short seller reports. The court must determine whether investors would actually perceive the report as revealing the falsity of prior statements, or merely take it with “a healthy grain of salt.”

Notes

In re Nektar Therapeutics Sec. Litig., 2022 WL 1573821, at *2 (9th Cir. May 19, 2022).

Id.; *see also Mulquin v. Nektar Therapeutics*, 510 F. Supp. 3d 854, 859 (N.D. Cal. 2020).

Nektar, 2022 WL 1573821, at *3.

According to the district court opinion, the Plainview Report also acknowledged that its authors “have short positions in and may own option interests on the stock of , and stand to realize gains in the event that the price of the stock decreases.” *Mulquin*, 510 F. Supp. 3d at 858.

Nektar, 2022 WL 1573821, at *3; *In re Nektar Therapeutics*, 2020 WL 3962004, at *1 (N.D. Cal. July 13, 2020).

See 15 U.S.C. § 78j(b), 78t; 17 C.F.R. § 240.10b-5.

Nektar, 2020 WL 3962004, at *1.

Mulquin, 510 F. Supp. 3d at 868, 870, 873.

Nektar, 2022 WL 1573821, at *4.

Id.

“Fold change measures how much a quantity changes between an initial and final measurement. It is derived by dividing

the final measurement by the initial measurement." *Id.* at *2 & n.2.

Id. at *5.

Id. at *6.

Id. (quoting *In re Atossa Genetics Inc. Sec. Litig.*,868 F.3d 784, 795 (9th Cir. 2017)).

Id.

Id. at *7.

Id. (quoting in part *Mineworkers' Pension Scheme v. First Solar Inc*., 881 F.3d 750, 753 (9th Cir. 2018)).

Id.

Id. at *8 (citing *In re Bofl Holding, Inc. Sec. Litig.*, 977 F.3d 781 (9th Cir. 2020)).

Id. at *7 (quoting *Bofl*, 977 F.3d at 797).

Id. at *8.

Id. at *8 (quoting *Bofl*, 977 F.3d at 797).

Id. (quoting *Bofl*, 977 F.3d at 797).

Id. at *1, *8.

Id. at *5.

Id.

Id.

See id. at *5 & n.5 (questioning the basis of one of the plaintiffs' expert's assumptions and observing that "sing the same logic as the expert, choosing a starting count somewhere between 11 and 50 would mean that the fold change experienced by the other patients in the 30-fold chart could be anywhere from ~8-fold to ~27-fold").

Id. at *6.

Id. at *8 (quoting *Bofl*, 977 F.3d at 797).

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