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Inferences fail to support securities fraud class claim

Drug co. granted motion to dismiss

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A class action alleging securities fraud could not survive a motion to dismiss because the plaintiffs did not demonstrate that the defendant drug company's failure to disclose certain clinical test results was a "material omission that would have altered the total mix of information available," a U.S. District Court judge has determined.

At a hearing on the defendants' motion to dismiss, the plaintiffs alleged three specific instances of reasonable investors being misled by the omission of the test results.

However, Chief Judge Patti B. Saris noted that, as an initial matter, neither §10(b) of the Securities Exchange Act of 1934 nor SEC Rule 10b-5 creates an affirmative duty to disclose any and all material information to investors.

The plaintiffs asked the court to make an inference about the defendants possessing the key test results earlier than they had acknowledged. But Saris found that the plaintiffs had not offered enough support for her to make that leap, calling one theory premised on the disinterest of potential funders "farfetched."

By the time a reasonable inference could be made that the defendants possessed the negative test results, the company had duly reported out subsequent similarly negative results to investors.

The question, Saris said, was whether investors needed the earlier results, too, to render the later results "not misleading." She seized on the fact that the company's stock price had risen immediately after the negative later results were publicized.

"The release of the negative … results without consequence is fatal to Plaintiffs' allegations," Saris concluded.

The 25-page decision is *Emerson, et al. v. Genocea Biosciences, Inc., et al.*, Lawyers Weekly No. 02-592-18. The full text of the ruling can be found at masslawyersweekly.com.

Bar raised

Boston attorney Ian D. Roffman called *Emerson* a "classic stock-drop suit" of the type that was rampant nationwide more than 20 years ago. Investors, dismayed by plummeting stock prices, could generally find some evidence to allege securities fraud plausibly.

The Private Securities Litigation Reform Act of 1995 and subsequent decisions of the U.S. Supreme Court and lower courts changed the landscape, raising the bar for what a plaintiff must allege in order to survive a motion to dismiss, Roffman noted.

Judges in the District of Massachusetts, in particular, have been skeptical about stock-drop class actions, Roffman added.

"What this decision does is reaffirm a longstanding principle under securities law that this district has been very strong on," Roffman said. "In order to accuse someone of securities fraud, you need specific facts they did something wrong at the time you filed the complaint. It's not going to be enough to allege a set of circumstances that looks suspicious."

Boston lawyer Michael F. Connolly agreed and credited Saris for considering 35 documents in addition to the complaint at the motion-to-dismiss stage.

Connolly said he anticipated that the plaintiffs would follow Saris' decision to attempt to cure the defects and file an amended complaint, though he was unsure whether the plaintiffs had argued for leave to amend.

Louis M. Ciavarra said it was hard to tell if the decision reflected a deficiency at the pleading stage that could be addressed in an amended complaint.

"The court certainly gives a road map on where the gaps are," the Boston lawyer noted.

Ciavarra concurred that Saris' willingness to dismiss "demonstrates the high burden plaintiffs have when bringing private securities suits."

According to Roffman, Saris' decision in *Emerson* is a legal expression of an accepted concept in other contexts: Correlation is not causation.

"This is one area where it's well established that plaintiffs alleging correlation is not going to be enough," he said.

The court's protective posture is particularly important given the risks attendant to biotech businesses developing new drugs and devices, which are plentiful in Massachusetts, Roffman said.

"Along the way, there is going to be good news and bad news; it doesn't mean anybody has committed fraud," he said.

Nor was one corporate officer's decision to sell stock using the mechanism of a 10b5-1 plan evidence of anything untoward, Roffman said. Such plans exist to allow company officials to liquidate stocks while alleviating concerns about possible insider trading.

"As long as you stick to the plan, the transactions are fine," he said.

In an emailed statement, one of the defendants' attorneys, Randall W. Bodner of Boston, expressed satisfaction with Saris' decision, but he could not be reached for an interview.

None of the plaintiffs' attorneys responded to requests for comment.

Promising drug falls flat

Cambridge-based biopharmaceutical company Genocea researches, develops and brings to market T-cell vaccines to treat infectious diseases.

Between March 31, 2016, and Sept. 25, 2017, its only product in active clinical development was an immunotherapy treatment for genital herpes, GEN-003.

Genital herpes can remain latent in an infected person until it periodically and sporadically reactivates. While the virus is active and capable of being sexually transmitted, it travels to a patient's skin and mucus membrane in a process known as "viral shedding." During the active period, a patient sometimes — but not always — develops genital lesions.

Thus, when Genocea began testing GEN-003 against a placebo in 2012, it explored two properties of the drug: whether it could minimize or eliminate viral shedding and whether it could thwart outbreaks of lesions. Trial subjects were assessed immediately after given a dose of GEN-003 or a placebo, and then at six-month intervals thereafter.

Genocea announced that, in the third of three phases of a clinical trial, it planned to test a modified version of GEN-003 to ensure that, if it manufactured the drug using a commercial scalable process, it would not diminish its effectiveness.

On Sept. 29, 2016, Genocea initially announced positive viral shedding results for the period immediately post-dose in that third phase of testing.

On Nov. 3, 2016, CEO William D. Clark announced the company would depart from its established schedule for reporting clinical trial results. The viral shedding results measured six months post-dose would not be released concurrently with the six-month genital lesion results, he explained.

On Jan. 5, 2017, the company released positive news about GEN-003's six-month genital lesion results but, as planned, did not provide any information about the viral shedding results.

Shortly thereafter, Clark allegedly told employees at a company-wide meeting that potential funding partners had "no interest" in sponsoring the planned Phase 3 trials for GEN-003, according to two confidential witnesses. Clark stated that the company planned to shift gears to focus more heavily on its oncology program, the witnesses added.

In a required SEC filing three months later, Genocea still did not disclose the six-month viral shedding results, instead stating that the results were "expected in the middle of 2017." The company expressed optimism that GEN-003 would be ready for its next round of clinical trials in the fourth quarter of 2017.

At a July 2017 internal meeting, Clark announced the 12-month post-dosing results for both viral shedding and genital lesions, and the news about viral shedding was not good. That spawned outrage from company scientists, who demanded the still-undisclosed six-month viral shedding results from Clark.

Days later, the company issued a press release. The text did not highlight the negative 12-month test results, though they were divulged on an accompanying chart.

In an analyst call the same day, Chief Medical Officer Seth Hetherington downplayed the variability in shedding data, attributing it to the "small number of subjects" involved in the testing.

Genocea's stock price then increased to over $6 a share.

While neither Clark nor Hetherington sold any of their Genocea stock during the proposed class period, Chief Financial Officer Jonathan Poole did twice, once on May 8, 2017, and the second time on July 24, 2017, the same day Genocea issued its 12-month post-dosing results.

However, that second trade was executed pursuant to a 10b5-1 plan Poole had entered into back in May, authorizing his broker to sell shares when Genocea's stock price hit $6 per share.

After the financial markets had closed on Sept. 25, 2017, Genocea issued a press release announcing it would not be moving forward with the planned Phase 3 clinical trial of GEN-003 and instead would be "ceasing GEN-003 spending activities and reducing its workforce by approximately 40 percent."

The next day, Genocea's stock price fell more than 75 percent, from $5.33 a share to $1.25 a share.

A group of plaintiffs filed a class action against Genocea, alleging violations of Section 10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, as well as derivative claims against Clark, Pool and Hetherington, for allegedly misleading investors with their statements about the clinical test results.

The defendants moved to dismiss all counts for failure to state a claim, while the plaintiffs moved to strike certain exhibits and documents submitted in support of the defendants' motion to dismiss.

In deciding to grant the motion to dismiss, Saris said she had relied solely on uncontested documents, rendering the motion to strike moot.

Scienter theory weakened

The plaintiffs also asked Saris to find a strong inference of scienter from the omission of the six-month viral shedding results from Genocea's July 2017 report.

The defendants knew — or were reckless in not realizing — that failing to disclose the six-month viral shedding results would mislead investors about the prospects for the drug and the next phase of clinical trials, the plaintiffs argued.

However, "Genocea's own disclosure of the negative twelve month viral showing weakens any showing of scienter," Saris wrote.

The same disclosure was fatal to the plaintiffs' "core operations" theory: that the defendants intentionally withheld the Phase 2b six-month viral shedding results because GEN-003 was "core to Genocea's viability as a company."

If the plaintiffs' theory was true, the defendants would have had a similar motive to withhold the 12-month viral shedding results, Saris wrote.

Nor did Poole's stock sales bolster a strong inference of scienter, Saris found.

The use of 10b5-1 plans generally makes stock sales less suspicious and rebuts an inference of scienter, Saris noted.

"Therefore, while this evidence of insider trading is a concern, standing alone, it does not support a strong inference of scienter with respect to the six month data," Saris wrote.

Emerson, et al. v. Genocea Biosciences, Inc., et al.

THE ISSUE	Should a class action alleging securities fraud survive a motion to dismiss even though the claims are based on drawing speculative inferences from the defendant drug company's failure to disclose certain clinical test results?
DECISION	No (U.S. District Court)
LAWYERS	Amanda F. Lawrence, Beth A. Kaswan, Rhiana L. Swartz and Thomas L. Laughlin IV, of Scott & Scott, New York City and Colchester, Connecticut; Jason M. Leviton of Block & Leviton, Boston; Stephanie A. Bartone and Shannon L. Hopkins, of Levi & Korsinsky, Stamford, Connecticut; Katherine M. Lenahan, Sherief Morsy and Richard W. Gonnello, of Faruqi & Faruqi, New York City; Glen DeValerio and Daryl DeValerio Andrews, of Andrews DeValerio, Boston (plaintiffs) Randall W. Bodner, Elizabeth Downing Johnston, Kristi Lynn Jobson and Nicholas Pisegna, of Ropes & Gray, Boston (defense)

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— Ian D. Roffman, Boston