

## First Circuit: Disclosure of FDA Concerns Undercuts Any Inference of Scienter

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On April 9, 2020, the First Circuit affirmed the dismissal of a securities fraud action alleging that a biopharmaceutical company failed to disclose “material facts about [the company’s] manufacturing problems and the impact those problems were likely to have on the FDA’s approval” of the company’s ocular pain drug. *Mehta v. Ocular Therapeutix, 2020 WL 1808366 (1st Cir. 2020) (Stahl, C.J.)*. The First Circuit found it significant that defendants fully disclosed the FDA’s concerns regarding certain manufacturing issues. The court held that these disclosures belied any inference of scienter.

Plaintiffs challenged statements in the company’s 2016 and 2017 Forms 10-K representing that the company manufactured its ocular pain drug “using current Good Manufacturing Practices [cGMP]”, as well as an executive’s May 2017 statements describing the company’s drug manufacturing process as “fully developed.” Plaintiffs argued “that a strong inference of scienter can be drawn from those alleged misstatements because defendants made them despite having received” Forms 483 from the FDA in February 2016 and May 2017 that “apprised defendants of [the company’s] manufacturing problems.”

The First Circuit held that plaintiffs’ “allegations do not give rise to a strong inference of scienter.” The court noted that the 2016 and 2017 Forms 10-K “disclosed receipt of the February 2016 Form 483, described its relevance to [the company’s] manufacturing capabilities, and warned of its implications.” The 2016 and 2017 Forms 10-K also specifically warned investors that resolution of the issues identified in the February 2016 Form 483 was a prerequisite for FDA approval. The First Circuit found “[t]hese informative disclosures about the nature and consequences of the February 2016 Form 483 undercut any inference that defendants intentionally or recklessly misled investors” concerning the company’s compliance with cGMP regulations. Rather than inferring scienter, the court determined that “the more reasonable inference of nonfraudulent intent is that defendants were [simply] stating their intention to comply with cGMP regulations as the governing standards for their drug product manufacturing operations.”

As to the May 2017 statements concerning the “fully developed” nature of the company’s manufacturing processes, the First Circuit noted that a company executive specifically disclosed the receipt of a Form 483 from the FDA one day earlier and discussed its ramifications. The First Circuit found that these disclosures “made pellucid that [the company’s] manufacturing process was considered deficient by the FDA.” The court also credited defendants’ representation that in the FDA approval context, the phrase “fully developed” refers to a process that “has surpassed the concept or piloting stage but must still be tested and validated to determine whether the process works as intended and meets

the necessary standards.” The court determined that “[i]n light of that term of art and [the executive’s] disclosures during the conference call that contravene[d] plaintiffs’ characterization of his statements, the more reasonable and compelling inference drawn from the complaint’s allegations is that [the executive] spoke with nonfraudulent intent in describing [the company’s] manufacturing process as ‘fully developed.’”

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