

Southern District of New York: Dismisses Class Action Alleging That a Drug Company Failed to Disclose Drug Trial Information (Securities Law Alert)

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On September 12, 2022, the Southern District of New York dismissed with prejudice a putative securities fraud class action alleging that a drug company that was developing a COVID-19 vaccine failed to disclose information about its Phase II/III clinical trials in violation of Section 10(b) of the Exchange Act. *In re AstraZeneca plc Sec. Litig.*, 2022 WL 4133258 (S.D.N.Y. 2022) (*Oetken, J.*). The court held that plaintiffs failed to identify any misleading statement, determining that the challenged statements were not actionable because they “merely recite historical fact.” The court disagreed that the challenged statements were misleading—on the ground that they created the impression that the trials were producing positive results and experienced no significant setbacks—stating that there is no generalized duty to disclose negative facts.

In 2020, the company began to develop a COVID-19 vaccine and conducted Phase II/III clinical trials. Plaintiffs alleged that the company failed to disclose, among other things, that some trial participants received half doses, that the clinical trials suffered from widespread flaws in design, errors in execution, that the clinical trials did not follow applicable protocols and guidelines, and that as a result the drug was unlikely to be approved for commercial use in the U.S. Plaintiffs commenced this action after a series of stock drops that were allegedly caused by various corrective disclosures. Defendants moved to dismiss under Federal Rules of Civil Procedure 8, 9(b), and 12(b)(6), as well as the PSLRA.

After concluding that the complaint failed to identify any misleading statement under Section 10(b), the court further determined that the complaint should be dismissed “under the PSLRA because it falls short of the PSLRA’s ‘particularity threshold.’” Explaining that the PSLRA obligates a plaintiff to “demonstrate with specificity why and how” each statement is materially false or misleading, the court held that the complaint did not adequately do so. The court pointed out that the complaint merely identified various defendant statements and repeated a “copy-and-pasted list of omissions.” Citing *In re Alcatel Sec. Litig.*, 382 F. Supp. 2d 513 (S.D.N.Y. 2019), the court stated that such allegations did not specify why and how each statement was misleading because they do not specify what understanding each statement left investors, and how that understanding was inconsistent with alleged omissions.

The court further concluded that the complaint failed to state a claim “because it does not identify any statement made misleading by any alleged omission.” As to plaintiffs’ claim that defendants failed to disclose that some Phase II/III trial participants received half doses; that

some received late second doses; and that the trial reflected “a patchwork of disparate patient subgroups, each with subtly different treatments” the court stated that “an omission is actionable under the securities laws only when the corporation is subject to a duty to disclose the omitted facts.” *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94 (2d Cir. 2015). The court stated that plaintiffs “have not identified any inaccurate, misleading, or incomplete statement relating to” the Phase II/III dosing. As to company statements, such as the one highlighting “the start of a Phase II/III UK trial of AZD1222 in about 10,000 adult volunteers” the court stated that plaintiffs “identified only accurate statements describing the launch and historical progression of the Phase II/III clinical trials.” Plaintiffs argued that these statements, even if literally truthful, were still misleading. However, the court stated that plaintiffs failed to allege “any relevant context to create a misleading impression.” According to the court, plaintiffs’ argument—that the statements alone created a misleading impression that the trials were proceeding as expected, producing positive results, and experiencing no significant setbacks or unusual issues—was the same as stating that the absence of a negative disclosure gave the impression that there were no negative facts. The court cautioned that if this were the standard then every omission would be actionable. Instead, the court explained, “there is no generalized duty to disclose negative facts.” *In re Philip Morris Int’l Inc. Sec. Litig.*, 2021 WL 4135059 (S.D.N.Y. Sept. 10, 2021).

Plaintiffs also alleged that defendants put the “conduct of the trials at issue” when they mentioned the Phase II/III trials because under *In re Vivendi Securities Litigation*, 838 F.3d 223 (2d Cir. 2016) “once a company speaks on an issue or topic, there is a duty to tell the whole truth.” However, the court disagreed finding that defendants’ statements were “at such a high level of generality, and the alleged omitted facts so granular, that there is no violation of that principle here.”

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