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Memorandum

Second Circuit: Decides Two Matters of First Impression Concerning Challenged Statements on Scientific Studies and Data Interpretation

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On December 26, 2023, the Second Circuit affirmed the dismissal of a putative securities fraud class action against a tobacco products manufacturer and certain of its executives alleging that they made various false and misleading statements about the company's smoke-free products in violation of Section 10(b) and Rule 10b-5. *In re: Philip Morris Int'l Sec. Litig.*, 2023 U.S. App. LEXIS 34122 (2d Cir. 2023) (Sullivan, J.). Notably, the panel decided two matters of first impression in the Second Circuit. First, the court held that a securities fraud defendant's challenged statements that its scientific studies complied with a methodological standard that is published and internationally recognized, but stated in general and inherently subjective terms, were properly analyzed as statements of opinion rather than fact. Second, the court held that where a securities fraud defendant's challenged statements express an interpretation of scientific data, which is ultimately endorsed by the FDA, such statements are per se reasonable as a matter of law under *Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016).

Background

Around 2014, the company began the process of seeking FDA authorization to generally market its smokeless tobacco product in the U.S., or to be able to market it as a "reduced-exposure" tobacco product and/or as a "reduced-risk" tobacco product.[1] In support of its FDA applications, the company submitted a variety of clinical and non-clinical studies it had commissioned to assess the product's toxicological profile and effects on human users. In 2019, the FDA authorized the company to market the product in the U.S. and in 2020 the FDA further authorized it to market it with reduced—exposure claims. Subsequently, investor plaintiffs alleged that defendants had made false or misleading statements regarding the methodology and results of its scientific studies. In 2021, the district court dismissed the complaint with prejudice finding that plaintiffs had failed to adequately plead falsity or scienter and concluding that each such finding provided an alternate basis for dismissal of the claims.

Statements of Compliance With Good Clinical Practice Are Properly Analyzed as Statements of Opinion Rather Than Fact

On appeal, plaintiffs challenged the district court's conclusion that defendants' statements—that the company's studies were "conducted according to Good Clinical Practice" ("GCP")—were inactionable statements of opinion.

[1] A reduced-exposure tobacco product is one that reduces exposure to harmful chemicals. A reduced-risk tobacco product is one that reduces the risk of tobacco-related diseases.

Citing *Omnicare v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175 (2015), plaintiffs argued that because defendants did not couch their statements with words like "we think" or "we believe" that they were statements of fact, not opinion. The Second Circuit stated that plaintiffs' "reliance on *Omnicare* is misplaced." In *Omnicare*, the Supreme Court rejected a securities-fraud plaintiff's argument that a defendant stating that "we believe we are following the law conveys that we in fact are following the law." The Second Circuit explained that "[c]onsidered in that context, the Court's point was that language like 'we believe' or 'we think' is *sufficient* – not *necessary* – to render a statement one of opinion rather than fact." (emphasis in original). The Second Circuit stated that *Omnicare* clarified that if a statement expresses an "inherently subjective" assessment then that is also sufficient to render it pure opinion. The court explained that, therefore, the materiality of defendants' statements about compliance with GCP turned on whether the statements were "inherently subjective."

The Second Circuit agreed with defendants that GCP could be analogized to "generally accepted auditing standards whose general and often inherently subjective nature is such that an auditor's statement of compliance with [them] cannot properly be characterized as a statement of fact." The Second Circuit noted that this view was confirmed by the complaint, which defined the requirements of GCP to be that clinical trials should be "scientifically sound," individuals conducting a trial should be "qualified" and the investigator should have "adequate resources." The court concluded that whether these requirements were met—and the ultimate question of whether the clinical trials complied with GCP—were "all questions that require inherently subjective assessments, and thus do not lend themselves to resolution as matters of objective fact."

Statements Interpreting Scientific Data Are Per Se Reasonable as a Matter of Law When They Are Ultimately Endorsed by the FDA

On appeal, plaintiffs argued that it was error for the district court to rely on the FDA's 2020 findings concerning the company's scientific studies to assess the contemporaneous falsity of defendants' statements that had been made years before 2020. In essence, plaintiffs objected to the district court relying on the FDA's later endorsement when they alleged that defendants' interpretation of scientific data had been false from the beginning. However, the Second Circuit pointed out that "we are dealing not with statements of fact, but with statements about the proper interpretation of data." The court continued that "the question before us is not whether Defendants' statements were factually false when made, but whether they expressed an interpretation of the data that was objectively irrational or unreasonable when they were made." Citing *Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016)[2], the court held that where the FDA eventually accepts a defendant's challenged statements expressing an interpretation of scientific data, that interpretation is per se reasonable as a matter of law.

[2] In *Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016), the Second Circuit "rejected the proposition that a mere dispute about the proper interpretation of data can form a basis for liability under section 10(b) and Rule 10b-5."

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