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Second Circuit Addresses Two Questions of First Impression on Falsity in Securities Fraud Cases

On December 26, 2023, the Second Circuit in *In re Philip Morris Int'l Inc. Securities Litigation* issued a decision on two matters of first impression relating to falsity in the securities fraud context. [1] First, the court held that statements in which a securities-fraud defendant asserts in "general and inherently subjective terms" that its scientific studies complied with a "published and internationally recognized" standard should be analyzed as statements of opinion, not fact.[2] Second, the court held that statements in which a securities-fraud defendant interprets data in a way that is ultimately endorsed by the Food and Drug Administration (FDA) are per se "reasonable" as a matter of law.[3] The decision likely expands the scope of defenses available to securities-fraud defendants who contest falsity at the motion to dismiss stage.

Background

The plaintiffs, a putative class of investors in the tobacco company Philip Morris International Inc. ("PMI"), allege that PMI made false and misleading statements about IQOS, its line of smoke-free tobacco products.[4] Between late 2016 and early 2017, PMI sought FDA approval to market IQOS as a lower-risk alternative to cigarettes.[5] In its application to the FDA, PMI submitted data from many studies it had commissioned about the health risks of IQOS relative to cigarettes.[6] In a series of public statements, PMI represented that the studies were "conducted according to Good Clinical Practice ('GCP')," an international quality standard for clinical trials.[7] PMI further represented that "the evidence generated to[ ]date supports [PMI's] conclusion that IQOS has the potential to reduce the risk of smoking-related diseases in adult smokers who switch to it completely."[8]

While PMI's FDA application was pending, two articles were published. The first, in *Reuters*, questioned the PMI studies' compliance with GCP standards. The second, in *The New York Times*, reported that an FDA advisory panel had issued nonbinding recommendations concluding that PMI's studies did not sufficiently link IQOS with reduced health risks. Plaintiffs alleged that the articles caused stock price declines and brought suit, claiming PMI defrauded investors by (1) misrepresenting the studies' compliance with GCP standards, and (2) mischaracterizing the extent to which the studies supported the conclusion that IQOS

[1] *In re Philip Morris Int'l Inc. Sec. Litig*., No. 21-2546, 2023 WL 8883457 (2d Cir. Dec. 26, 2023).

[2] *Id.* at *1.

[3] *Id*.

[4] Id.

[5] *Id*. at *2.

[6] *Id*.

[7] *Id*. at *2, *4.

[8] *Id*. at *6.

reduced the risk of long-term smoking-related illness. After the complaint was filed, the FDA authorized PMI to market IQOS as a "reduced-exposure" product, finding that "[a]lthough [PMI] ha[d] not *demonstrated* that [IQOS] . . . will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users," IQOS does offer "dramatic changes in exposure relative to combusted cigarettes [that] are reasonably likely to . . . translate to lower risk of tobacco-related morbidity and mortality."[9]

Opinion

In February 2020, Judge Abrams of the U.S. District Court for the Southern District of New York granted PMI's motion to dismiss the complaint with prejudice, finding, among other things, that the plaintiffs failed to adequately plead falsity.[10] The plaintiffs appealed.

On appeal, the Second Circuit first addressed whether PMI defrauded investors by claiming that its IQOS studies were conducted in accordance with GCP. Plaintiffs argued that because "'GCP' is a technical term [that] investors consider to be a verifiable fact that can be relied upon," PMI's claims that its studies complied with GCP standards were false.[11] PMI argued that the GCP standards are "inherently subjective," and therefore any representation about GCP compliance must be understood as a statement of opinion, not fact.[12] The Second Circuit agreed with PMI, highlighting that GCP does not offer "hard and fast rules" but rather general standards.[13] For example, GCP provides that "clinical trials should be scientifically sound" and that "[t]he investigator should have adequate resources to properly conduct the trial[ ] [and] should be thoroughly familiar with the appropriate use of the investigational product(s)."[14] Given this broad and subjective language, the Second Circuit held that PMI's GCP-related statements should not be assessed as statements of fact for purposes of a falsity inquiry.

The Second Circuit then analyzed whether PMI's "statements about the long-term health effects [of IQOS] that could be inferred from the totality of the evidence collected in PMI's . . . studies" were false or misleading.[15] Plaintiffs contended that PMI's representations could not be reconciled with the FDA advisory panel's nonbinding conclusion, as reported by *The New York Times*, that the studies did not show that IQOS reduced the risk of smoking-related illnesses.[16] The Second Circuit rejected this argument, applying its longstanding rule that "so long as [the defendants] conducted a meaningful inquiry and in fact held th[e] view they expressed [about how to interpret the data in the studies], the statements will not be deemed to mislead in a manner that is actionable."[17] Extending this principle further, the court announced a rule that "where the FDA eventually accept[s] a [d]efendant['s] interpretation of the data, that interpretation is per se reasonable as a matter of law."[18] Because the FDA ultimately agreed with PMI that the studies suggest IQOS is likely to reduce smoking-related health risks, PMI's publicly stated interpretations of the data could not have been false or misleading.

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[9] *Id*.

[10] *In re Philip Morris Int'l Inc. Sec. Litig*., 437 F. Supp. 3d 329, 348–58 (S.D.N.Y. 2020).

[11] *In re Philip Morris*, 2023 WL 8883457 at *4.

[12] *Id*. at *5.

[13] *Id*.

[14] *Id*.

[15] *Id.* at *6.

[16] *Id*.

[17] *Id.* at *7.

[18] *Id.*

Implications

The Second Circuit's decision in *In re Philip Morris* likely expands the scope of defenses available to securities-fraud defendants who contest falsity at the motion to dismiss stage. The decision may significantly undercut the ability of plaintiffs to allege fraud where companies make statements that they have satisfied certain subjective standards. Perhaps more significantly, the decision grants defendants an absolute defense against claims that they have made statements that unreasonably interpret data if their interpretation is ultimately adopted by the FDA. Notably, this defense may be available *even if* the interpretation had not been adopted by the FDA at the time the statements were made, so long as the FDA and the defendant base their conclusion on the same data. The case may also serve as a persuasive precedent for cases involving data interpretations set forth by other regulatory agencies; while the per se rule adopted here does not on its face extend to agencies other than the FDA, the decision does not identify any basis to limit it to only that agency.

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This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues addressed in this memorandum should be directed to:

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