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ALERT MEMORANDUM

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# In Sanofi, the Second Circuit Applies Omnicare's Standard for Liability for Statements of Opinion Under Section 11 for the First Time and Affirms Dismissal

On Friday, March 4, 2016, the Second Circuit ruled in In re Sanofi Securities Litigation, AG Funds, L.P. v. Sanofi,[1] finding that statements of opinions that allegedly failed to disclose certain contradictory facts did not constitute material misstatements or omissions in light of the context of those statements. The ruling represents the first time that the Second Circuit has meaningfully interpreted the standards for liability for statements of opinion set out in the Supreme Court's 2015 decision in Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund.[2]

## Background

Sanofi is a pharmaceutical company that acquired another pharmaceutical company, Genzyme, in 2011. Genzyme had developed a drug named Lemtrada that had not yet been approved by the FDA, but that had potential as a successful treatment for multiple sclerosis. At the time of Genzyme's acquisition by Sanofi, Lemtrada's market worth was estimated to be $14 billion worldwide. As part of Sanofi's acquisition of Genzyme, Genzyme shareholders received compensation in the form of a contingent value right ("CVR"), a financial instrument that entitled each shareholder to payouts upon the achievement of certain milestones tied to the development of Lemtrada.

One of these milestones was FDA approval of Lemtrada for treatment, prior to March 31, 2014. The FDA had expressed concerns about the use of single-blind (as opposed to double-blind) studies for Lemtrada as early as 2002. However, it had also stated that single-blind studies might be sufficient if the effect of the drug was large. On October 6, 2013, the FDA rejected Lemtrada's initial application for approval, causing Sanofi to announce to its shareholders that it was unlikely that the CVR milestone would be reached. Thereafter, Sanofi shareholders filed two class action complaints (later consolidated) alleging that by failing to disclose the FDA feedback about single-blind studies, Sanofi had misled investors in violation of the Exchange Act, the Securities Act, and state blue sky laws.[3]

[1] 15-588-cv, 15-623-cv (2d Cir. Mar. 4, 2016).

[2] 135 S. Ct. 1318 (2015).

[3] Sanofi, 15-588-cv, 15-623-cv at 13-14.

Sanofi moved to dismiss these complaints on the basis that they did not allege any materially false or misleading statements. The U.S. District Court for the Southern District of New York granted Defendant's motion to dismiss, holding that Plaintiffs had failed to allege any false or materially misleading statements.[4] After that January 2015 decision, the Supreme Court issued its opinion in Omnicare addressing the standard for analyzing whether a statement of opinion is materially misleading under the federal securities laws.

In resolving a prior circuit split, Omnicare identified three circumstances where statements of opinion can create liability for the speaker: (1) where the speaker does not actually hold the disclosed opinion; (2) where the opinion includes embedded facts that are untrue; or (3) where the opinion omits facts about the speaker's basis for the opinion that differ from what a reasonable investor would understand about that basis from the opinion itself.[5]

On appeal, the plaintiffs in Sanofi argued that certain of the company's statements of opinion concerning the expected timing of FDA approval, the timing of the launch of Lemtrada, and Lemtrada's trial results fell into Omnicare's third category of actionable statements, because those statements failed to disclose the FDA's negative feedback about single-blind trials.[6]

**Analysis**

The Second Circuit separately examined each subset of statements identified by plaintiffs as materially misleading and concluded that none of them were actionable under the Omnicare standard.

With respect to the statements concerning the expected timing of FDA approval, including that the company expected FDA approval prior to March 31, 2014, the court highlighted two reasons why the plaintiffs failed to plead an omission claim under Omnicare. First, the court noted that the allegedly omitted facts regarding the FDA's concerns did not "conflict with what a reasonable investor would take from the statement itself" because: (a) the FDA stated that the deficiencies it identified could be overcome under certain circumstances; and (b) the context of the disclosed opinion– including that investors would be aware "that projections provided by issuers are synthesized from a wide variety of information," that investors know "that some of the underlying facts may be in tension with the ultimate projection set forth by the issuer," that "the customs and practices of the relevant industry" would include a dialogue

[4] Id. at 14-15, citing lower court opinion 87 F. Supp. 3d 510, 537-47 (S.D.N.Y. 2015).

[5] Omnicare, 135 S. Ct. at 1332.

[6] See Sanofi, 15-588-cv, 15-623-cv at 19.

between the issuer and the FDA, and that "the Offering Materials themselves made numerous caveats to the reliability of the projections"–demonstrated that the plaintiffs would not "have misinterpreted Defendants' statements as evincing assurance of success."[7] Second, the court reiterated that "Omnicare does not impose liability merely because an issuer failed to disclose information that ran counter to an opinion expressed in the registration statement." The court therefore rejected the plaintiffs' proposed "bright-line disclosure rule" that would hold a defendant liable if it "failed to disclose a risk above and beyond the normal risks associated with drug approval" as unsupported by Omnicare.[8]

With respect to the challenged statements of opinion regarding the timing of the launch of Lemtrada, including that the company was "very satisfied" and "feeling pretty, pretty relaxed" with its progress, the court concluded that "[s]uch a generalized statement of subjective optimism arguably does not even convey facts about how the speaker has formed the opinion" as required to establish omission liability under Omnicare.[9] Even if it did, however, the court further held that: (a) "no reasonable investor would have inferred that mere statements of confidence suggested that the FDA had not engaged in industry-standard dialogue with Defendants about potential deficiencies"; and (b) the challenged statement "did not conflict with the information available to [the company] at the time."[10]

Finally, with respect to the challenged opinions regarding Lemtrada's trial results, including that the company was "very pleased with the results" and that they demonstrated "strong and robust treatment effect," the court rejected the plaintiffs' argument "that Sanofi had no reason to comment on Lemtrada's Phase III success except to build investor anticipation about FDA approval" as having "no merit," because "Sanofi had an interest in building global interest in Lemtrada" and "[s]tatements lauding the effectiveness of Lemtrada, when taken in the context of a global rollout plan, do not suggest any special approval (or likelihood of approval) from the regulators of a single country."[11] The court also stressed that "Defendants' statements about the effectiveness of Lemtrada cannot be misleading merely because the FDA disagreed with the conclusion—so long as Defendants conducted a 'meaningful' inquiry and in fact

[7] Id. at 19-21.

[8] Id. at 21-22.

[9] Id. at 23.

[10] Id.

[11] Id. at 23-24.

held that view." In other words, "Defendants' statements were not misleading simply because the FDA [later] disagreed with Defendants' interpretation of the data."[12]

**Implications**

Sanofi represents one of the first applications of Omnicare's holdings by an appellate court. It is clear from this decision that while Omnicare may have expanded the potential bases for liability for statements of opinion, satisfying that standard remains "no small task for an investor."[13] Sanofi also confirms that "issuers need not disclose a piece of information merely because it cuts against their projections"[14] and that, in assessing whether a plaintiff has adequately alleged omission liability for a statement of opinion, a court must consider at the motion to dismiss stage (and before any discovery has been conducted) whether the undisclosed information conflicts with what a reasonable investor would take from the disclosed opinion itself by considering the full context of the opinion, including any caveats or disclaimers concerning the opinion, the customs and practices of the relevant industry, the sophistication of the parties, and whether there is an actual conflict between the omitted information and the disclosed opinion.

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Please call any of your regular contacts at the firm or any of the partners and counsel listed under Litigation and Arbitration in the Practices section of our website (www.clearygottlieb.com) if you have any questions.

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[12] Id. at 24-25.

[13] Id. at 17.

[14] Id. at 25.

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