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Second Circuit's First Published Opinion Applying *Omnicare* Adopts Strong Contextual Approach to Opinion Statement Liability

In *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 135 S.Ct. 1318 (2015) ("*Omnicare*"), the Supreme Court pronounced the standard for determining whether a statement of opinion is actionable under Section 11 of the Securities Act of 1933 (the "Securities Act"). The Second Circuit's first published opinion applying *Omnicare, In re Sanofi Securities Litigation, AG Funds, L.P. v. Sanofi*, Nos. 15-588-cv, 15-623-cv (2d Cir. Mar. 4, 2016) ("*Sanofi*"), applies *Omnicare* to claims challenging statements of opinion under Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), and reflects a rigorous, context-focused application of *Omnicare* that underscores the hurdles to pleading federal securities law claims based on omissions in connection with a statement of opinion. Concluding that the omitted facts did not, in context, render defendants' statements of opinion materially misleading, the Second Circuit affirmed the dismissal of claims under Sections 11 and 12 of the Securities Act and Section 10(b) of the Exchange Act.

Background

In *Omnicare*, the Supreme Court held that even a sincerely held opinion could be actionable under Section 11's "omissions rendering an affirmative statement materially misleading" prong if the investor could identify "particular (and material) facts going to the basis for the issuer's opinion … whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context."[1] This holding modified the standard for opinion liability in the Second Circuit, which previously had required proof of subjective falsity for all forms of opinion liability.[2]

Sanofi is the first published opinion from the Second Circuit addressing *Omnicare*'s newly recognized form of opinion liability. The *Sanofi* case concerns defendants' multiple sclerosis treatment drug Lemtrada. In April 2011, Sanofi acquired Genzyme, the biotechnology company that owned Lemtrada. As part of that acquisition, Sanofi issued contingent value rights ("CVRs") to Genzyme shareholders. The CVRs, which were publicly traded, entitled the holder to cash payouts if certain milestones, such as FDA approval of Lemtrada, were met. Between 2011 and 2013, Sanofi made statements in the offering materials for the CVRs, and subsequently to the market as a whole, to the effect that it expected the FDA to approve Lemtrada and that the clinical trials were progressing well.

Privately, the FDA had repeatedly expressed to Sanofi and Genzyme a "major concern" about the lack of double-blind studies in the Lemtrada clinical trials. The FDA had noted, however, that if the single-blind studies

[1] *Omnicare*, 135 S. Ct. at 1331.

[2] *See Fait v. Regions Fin. Corp.*, 655 F.3d 105 (2d Cir. 2011). The Ninth Circuit too had required proof of subjective falsity. *See Rubke v. Capitol Bancorp Ltd.*, 551 F.3d 1156 (9th Cir. 2009).

"reveal[ed] an extremely large effect, then the FDA [might] potentially accept" the results of such studies.[3] In November 2013, in connection with the upcoming hearing on Lemtrada's application, the FDA released briefing materials that included physicians' concerns about the failure to use double-blind studies. Upon the release of those materials, the value of the CVRs dropped more than 62%. In December 2013, Sanofi announced that the FDA had formally rejected Lemtrada, resulting in a further drop in the CVRs' value. Although the FDA eventually approved Lemtrada without further clinical trials, by then the deadline for CVR milestone payments based on that approval had passed.

Two categories of CVR holders filed suit: (1) a putative class of those who had purchased CVRs between March 6, 2012 and November 7, 2013, who alleged violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5; and (2) corporations that had either opted out of the class or had acquired CVRs outside of the class period, who asserted Exchange Act claims and also alleged violations of Sections 11 and 12(a)(2) of the Securities Act. Both categories of plaintiffs alleged that defendants' failure to disclose the FDA's concerns about the lack of double-blind studies rendered statements regarding the likelihood of meeting the approval milestone, upon which the CVRs' value partially depended, materially misleading.

The district court, in an opinion pre-dating *Omnicare*, dismissed both complaints for failure to state a claim.[4] With regard to defendants' allegedly false or misleading statements of opinion, the district court held that there had been no showing of objective falsity and, invoking the pre-*Omnicare* standard from *Fait v. Regions Financial Corp.*, 655 F.3d 105 (2d Cir. 2011), held that plaintiffs had failed to allege any facts suggesting that defendants "did not genuinely believe what they were saying at the time they said it."[5] The Second Circuit affirmed, and wrote "principally to examine the impact of the Supreme Court's decision in *Omnicare*,"[6] which "altered the standard announced [by the Second Circuit previously] in *Fait*."[7]

The *Sanofi* Decision

The *Sanofi* opinion addressed (1) statements in the CVR offering materials that the FDA would approve Lemtrada before the approval milestone, and (2) defendants' subsequent statements to the market about the FDA approval process, including statements that defendants were "very satisfied with where the progress is going" and "pretty relaxed." The Second Circuit held that plaintiffs had not adequately alleged that either category of opinion statements was materially misleading.

As to the first category of challenged opinions, the Second Circuit found that there was "no plausible allegation that the FDA's interim feedback conflicted with any reasonable interpretation of Defendants' statements about FDA

[3] *Sanofi*, No. 15-588-cv, slip op. at 6.

[4] *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510 (S.D.N.Y. 2015).

[5] *See id.* at 531-33.

[6] *Sanofi*, No. 15-588-cv, slip op. at 5.

[7] *Id.* at 17.

approval."[8] This was so because, although the FDA had expressed concerns about the lack of double-blind studies, it also had stated that those concerns could be overcome if the results showed an "extremely large effect," and it was undisputed that Lemtrada's treatment effect was large.[9]

The more interesting aspects of the *Sanofi* decision concern the Court's approach to assessing whether the challenged omissions could nevertheless be considered materially misleading. First, the Second Circuit emphasized "the need to examine the context of an allegedly misleading opinion."[10] In this regard, the *Sanofi* court stressed plaintiffs' sophistication—something apparently not considered by the district court or argued in the parties' appellate briefs. Specifically, the *Sanofi* court concluded that, as sophisticated investors, plaintiffs were (i) aware that issuers' projections are synthesized from a wide variety of information, some of which may be in tension with the ultimate projection set forth by the issuer; and (ii) familiar with the customs and practices of the relevant industry, including that defendants and the FDA were engaged in a dialogue—necessarily including differing views—about the sufficiency of various aspects of the clinical trials.[11] Moreover, the Court added, the offering materials "made numerous caveats to the reliability of the projections."[12] Thus, "[w]hile a layperson, unaccustomed to the subtleties and intricacies of the pharmaceutical industry and registration statements, may have misinterpreted Defendants' statements as evincing assurance of success, Plaintiffs here can claim no such ignorance."[13]

Second, the *Sanofi* court rejected out-of-hand the suggestion that *Omnicare* required defendants to disclose the FDA's feedback merely because it tended to undermine their optimistic projections. Thus, even though plaintiffs "[c]ertainly … would have been interested in knowing about the FDA feedback, and perhaps would have acted otherwise had the feedback been disclosed," *Omnicare* "does not impose liability merely because an issuer failed to disclose information that ran counter to an opinion expressed in the registration statement."[14] In further support of this conclusion, the *Sanofi* court noted that the FDA had long made public its preference for double-blind trials, while defendants had publicly stated that they were relying on single-blind studies, adding: "[e]specially where a complex financial instrument whose value is tied to FDA approval is involved, investors may be expected to keep themselves apprised of the FDA's public positions on testing methodology."[15]

As to the next category of challenged opinions about the FDA approval process—those that post-dated the CVR offering materials—the Second Circuit concluded that they failed to support a claim "for many of the same reasons"

[8] *Id.* at 19-20.

[9] *Id.* at 20.

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] *Id.* at 21.

[14] *Id.*

[15] *Id.* at 22.

that the statements about FDA approval that were in the offering materials failed to support a claim.[16] Specifically, the Court stated that, "whatever the implication" of defendants' statements that they were feeling "relaxed" or "satisfied" with the process, "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 in either the testing methodology or the drug itself."[17]

The Significance of *Sanofi*

Sanofi is important by virtue of its being the Second Circuit's first published opinion applying *Omnicare*, and potentially even more so to issuers given its strict adherence to the Supreme Court's admonition that pleading viable opinion omission claims should be "no small task for an investor."[18] *Sanofi* holds that *Omnicare* requires only that statements of opinion "fairly align with the information in the issuer's possession at the time," and does not require that all information conflicting with that opinion be disclosed.[19]

Also noteworthy is the *Sanofi* court's consideration of the sophistication of CVR investors in analyzing whether omitted information could be considered to have rendered an opinion materially misleading. In order to guard against an "overly expansive" application of the *Omnicare* standard,[20] the *Sanofi* court charged the initial CVR holders, as sophisticated investors, with responsibility for taking into consideration caveats to defendants' opinions that the court concluded should fairly have been understood or implied in light of the industry and circumstances involved. Even more interesting, perhaps, was the court's apparent application of similar reasoning to those investors who acquired CVRs later, on the public market, and might not necessarily have been "sophisticated." In this regard, the court appears to have held those investors to a similar standard as the initial CVR holders.[21] How this particular aspect of *Sanofi* may be developed or applied in future cases will be interesting to observe, but, regardless, issuers should be heartened by the fact that the Second Circuit's first published opinion discussing *Omnicare* suggests that the Second Circuit will continue to narrowly limit potential opinion liability based on omissions and expect investors to understand that opinion statements are not misleading for failing to disclose allegedly contradictory facts that are not "out of the ordinary, or . . . of the kind normally confronted by pharmaceutical companies seeking FDA approval."[22]

[16] *Id.* at 23.

[17] *Id.* The Court also rejected plaintiffs' challenge to defendants' positive statements regarding Lemtrada's clinical trial results, noting that there was (i) no relationship between the FDA's critical feedback and defendants' statements touting the results of Lemtrada's trials and, moreover (ii) no conflict between the two. *See id.* at 23-25.

[18] *Omnicare*, 135 S. Ct. at 1332.

[19] *Sanofi*, No. 15-588-cv, slip op. at 18.

[20] *Id.*

[21] The Court did not explain its reasoning in this regard. It may be by virtue of plaintiffs' having decided to invest in what the court termed a "complex financial instrument," *id.* at 22, or, perhaps, because they must be charged with implicit knowledge in light of the presence of sophisticated investors in an allegedly efficient marketplace.

Finally, *Sanofi* is also significant because the Second Circuit applied *Omnicare* to claims challenging statements of opinion under Section 10(b) of the Exchange Act, employing the same analysis it used for plaintiffs' claims under Section 11 of the Securities Act. *Omnicare* addressed only the Securities Act, so applying it to Section 10(b) claims reflects an extension of the Supreme Court's reasoning beyond the statute in question in *Omnicare*. Many courts have taken *Omnicare* into account in connection with Section 10(b) claims, however—with some courts holding that *Omnicare* actually applies to Section 10(b) claims and others holding that it can provide instructive or persuasive authority for such claims. The question whether, after *Omnicare*, subjective falsity continues to be required to challenge statements of opinion under Section 10(b) in light of the statute's scienter requirement remains live, and was not definitively resolved by the Second Circuit in *Sanofi*. The *Sanofi* court did not expressly address the issue—finding that no material omission had been pleaded under either the Securities Act or the Exchange Act, and not referring to scienter.

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[22] Sanofi at 21-22.