March 9, 2016

Second Circuit Interprets *Omnicare* Narrowly, Holding That Issuers Need Not Disclose Information Merely Because It Cuts Against Their Opinions or Projections

On March 4, 2016, in *Tongue* v. *Sanofi,*[1] the Second Circuit interpreted and applied for the first time the Supreme Court's decision in *Omnicare Inc.* v. *Laborers Dist. Council Const. Indus. Pension Fund*,[2] which addressed the circumstances under which issuers can be liable for statements of opinion or projections. The Second Circuit acknowledged that the *Omnicare* ruling has altered the law in the Circuit, as set forth in *Fait* v. *Regions Financial Corp.*,[3] which allowed for liability only if the opinion was both (1) objectively false and (2) the speaker did not believe the statement at the time it was made. The Second Circuit observed that, under *Omnicare,* a plaintiff can alternatively allege that an opinion statement is false by pleading that the speaker omitted information that would render the opinion misleading to a reasonable investor.

The Second Circuit made clear that plaintiffs face a difficult burden to plead that an opinion is false by virtue of an omission of fact. In particular, the Court held that Sanofi's predictions that the Federal Drug Administration (FDA) would approve the drug Lemtrada by a certain date were not false even though Sanofi had repeatedly been warned by the FDA that the agency was concerned by Sanofi's use of single-blind studies and that this study design would negatively impact its willingness to approve the drug. In reaching this holding, the Second Circuit underscored how difficult it will be for plaintiffs to plead and prove that a statement of opinion is misleading merely because the speaker possessed, but did not disclose, contrary information. Further, the Second Circuit found that, in determining whether the opinion is misleading to a reasonable investor, it is appropriate to consider the sophistication of the plaintiffs.

Background

The multiple sclerosis drug Lemtrada was developed and owned by defendant Genzyme Corporation and, following a 2011 acquisition, Sanofi. Beginning in 2002, the FDA expressed concern that the use of single-blind studies in the clinical trials of Lemtrada—as opposed to the more commonly used double-blind studies—would devalue the clinical trial efficacy results necessary to obtain FDA approval. The FDA suggested that if the study revealed an "extremely large effect" of the drug, the design may be accepted by

[1] No. 15-588, 2016 WL 851797 (2d Cir. Mar. 4, 2016).

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

[3] 655 F.3d 105 (2d Cir. 2011).

the FDA, but communicated that the failure to blind both patients and physicians was a "major concern." The FDA's concerns were communicated repeatedly between 2002 and 2011.

In 2011, in connection with Sanofi's merger with Genzyme, Genzyme stockholders were provided both cash and financial instruments tied to the value of Lemtrada, called CVRs, which would be traded on the NASDAQ exchange. The CVR holders were entitled to additional payments if certain Lemtrada-related milestones were achieved by various dates, including a $1 payment per share if the FDA approved Lemtrada by March 31, 2014.

The registration statement provided to shareholders estimated a 90% probability that Lemtrada would achieve this milestone. The registration statement, as well as subsequent public filings by Sanofi in 2012 and 2013, also contained optimistic projections about the results of the ongoing clinical trials and the likelihood for product approval. Among other things, management described the clinical trial data as "nothing short of stunning" and told analysts that Sanofi was "in [a] good position to launch Lemtrada."

In November 2013, the FDA rejected Lemtrada's initial application. Two of the reviewing physicians cited the failure to use double-blind studies, finding that "troublesome design issues and the presence of bias in trials prevents reliance on [the] results" and that the design "confounds interpretation of [the] ostensible results." The value of the CVRs dropped in value from $2.00 to $.32 per share.

Class action lawsuits were filed by CVR shareholders against Sanofi and related defendants, asserting claims under both the Securities Exchange Act of 1934 and the Securities Act of 1933. Plaintiffs claimed that, by failing to disclose the FDA's concerns over the use of single-blind studies, defendants had misled the investors about the likelihood that Lemtrada would be approved by the FDA and meet the CVR milestones. The United States District Court for the Southern District of New York (Engelmayer, J.) dismissed the complaint, holding, *inter alia,* that plaintiffs had failed to allege subjective and objective falsity as to defendants' projections and statements of opinion. Plaintiffs appealed.

Second Circuit Decision

In a decision written by Judge Barrington D. Parker and joined by Judges Lohier and Carney, the Second Circuit affirmed the District Court's ruling below, and expressly stated that it wrote principally to examine the impact of *Omnicare,* which had been decided by the Supreme Court during the pendency of the appeal.

In applying *Omnicare,* the Second Circuit focused on several key concepts:

First, the Court examined whether the omitted facts conflicted with what a reasonable investor would take from the statement itself. Mindful of the Supreme Court's directive to examine context, the Court observed that the plaintiffs were sophisticated investors, who were "no doubt aware that projections

provided by issuers are synthesized from a wide variety of information, and that some of the underlying facts may be in tension with the ultimate projection set forth by the issuer." Among other things, investors would have been aware that there is a continuous dialogue between the FDA and any proponent of a new drug, and that "inherent in the nature of a dialogue are differing views." The Court concluded that "[w]hile a layperson, unaccustomed to the subtleties and intricacies of the pharmaceutical industry and registration statements, may have misinterpreted [the alleged misstatements] as evincing assurance of success, Plaintiffs here can claim no such ignorance."

The Court thus embraced the proposition that shareholders are well-informed about the industry and company in which they have invested, and applied that assumption at the motion to dismiss stage in determining whether the omitted facts directly conflict with the challenged opinion.

Second, the Court rejected plaintiffs' argument that a statement of opinion necessarily becomes misleading if defendants fail to disclose a fact that, if known, would have undermined defendants' optimistic projection. The Second Circuit explained, "Defendants need not have disclosed the FDA feedback merely because it tended to cut against their projections . . . . Certainly, Plaintiffs would have been interested in knowing [it], and perhaps would have acted otherwise had the feedback been disclosed, but *Omnicare* does not impose liability merely because an issuer failed to disclose information that ran counter to an opinion expressed in the registration statement." In reaching this holding, the Court observed that the omitted information was not different from the kind normally confronted by pharmaceutical companies seeking FDA approval, and also noted that the FDA has long publicly disclosed its preference for double-blind studies.

Analysis

Sanofi is significant because it is the first Second Circuit case interpreting the portion of *Omnicare*'s holding that allows projections and statements of opinion to be challenged on the basis that the speaker was aware of information that contradicted the challenged statement. Since nearly all opinions and projections reflect a multitude of inputs—not all of which point in the same direction—this prong of *Omnicare*, if improperly analyzed, had the potential to increase defendants' exposure to securities claims premised on statements of opinion.

But the Second Circuit has now made clear that a securities claim may not lie even where defendants are aware of significant information that undercuts the challenged opinion or projection. In *Sanofi,* the very agency charged with approving drugs for sale, the FDA, had repeatedly expressed concern about the single-blind design of the Lemtrada clinical trials, but defendants had nonetheless publicly predicted a 90% chance of regulatory approval by a certain date. The Court accepted that investors would certainly have wanted to know about the FDA's concerns, and that the information may even have influenced their investment decisions. Nonetheless, such an omission did not suffice to allege a misleading statement of opinion.

Finally, it is significant that, in conducting this analysis, the Court deemed plaintiffs to be "sophisticated" and held them to a higher standard than a layperson. While the Court did not explain precisely how it drew that conclusion, the decision suggests that investors are charged with a certain level of diligence and industry knowledge by virtue of having decided to purchase securities in the company—even if they do not have prior experience with drug trials or pharmaceutical industry expertise. This aspect of *Sanofi* will be helpful to defendants in future cases in numerous other contexts outside of the pharmaceutical industry. It also may create opportunities for defendants to oppose class certification because investors in a putative class often have varying levels of sophistication, and investors' differing abilities to appreciate the risks that underlie the challenged opinion may create individualized issues or give rise to an argument that the named plaintiff is atypical.

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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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