Statements of Opinion as Actionable Securities Law Violations after *Omnicare*

By Jennifer Wagner


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Debates about whether statements of opinion can be a basis for a misrepresentation span centuries. For example, in 1884, Lord Justice Bowen opined that the sellers of a property could be held liable for a statement that Mr. Fleck was "a most desirable tenant," when, in fact, the sellers knew that Mr. Fleck paid his rent "by driblets." *Smith v. Land and House Prop. Corp.*, 28 Ch. D. 7 (1884).

Not to be outdone by Lord Justice Bowen, let alone a disagreement among the circuit courts, the U.S. Supreme Court considered when a statement of opinion can form the basis of a claim under Section 11 of the Securities Act of 1933 (the "Securities Act") in *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318 (2015). The Court held that an issuer's opinion statement may give rise to liability if: (1) the issuer omits to disclose material facts regarding the basis for its opinion, and (2) the omitted facts conflict with what "a reasonable investor would take from the statement" (for example, where an issuer announces that it is in compliance with applicable law, but fails to disclose that it has not consulted legal counsel). *Id.* at 1329.

Omnicare was a victory for investors because it rejected a rule that would have insulated overly-optimistic opinion statements from liability. In *Tongue v. Sanofi*, 816 F.3d 199 (2nd Cir. 2016), however, the Second Circuit released its first decision interpreting *Omnicare* and placed a heavy burden on investors seeking to hold issuers liable for misleading opinions. While *Omnicare* remains a promising decision for plaintiffs, only time will tell whether it will prove to be a meaningful victory.

The Decision

Omnicare arose out of a registration statement that the company filed in connection with a public offering. In the registration statement, Omnicare stated: (1) "[w]e believe our contract arrangements … are in compliance with applicable federal and state laws," and (2) "[w]e believe that our contracts with pharmaceutical manufacturers are legally and economically valid … ." 135 S. Ct. at 1323.

Subsequent *qui tam* lawsuits, however, alleged that Omnicare had violated anti-kickback laws. *See id.* at 1324. Further, the *Omnicare* plaintiffs alleged that one of Omnicare's attorneys had warned of potential violations. *Id.* Thus, plaintiffs alleged that the registration statement was false and misleading because Omnicare had no "reasonable grounds" for believing that the opinions expressed were "truthful and complete." *Id.* Plaintiffs filed suit against Omnicare asserting claims under Section 11 of the Securities Act (15 U.S.C. § 77k(a)), which imposes liability on an issuer if a registration statement: (1) "contain[s] an untrue statement of a material fact," or (2) "omit[s] to state a material fact … necessary to make the statements therein not misleading."

The district court granted Omnicare's motion to dismiss on the basis that the opinion statements as to legal compliance were considered "soft" information that did not give rise to liability. *Indiana State Dist. Council of Laborers and HOD Carriers Pension and Welfare Fund v. Omnicare, Inc.*, 2012 WL 462551, *4 (E.D. Ky. 2012), *aff'd in part, rev'd in part*, 719 F.3d 498 (6th Cir. 2013), *vacated and remanded*, 135 S. Ct. 1318 (2015). The district court further held that statements of belief are actionable only if the speaker knows they are untrue. *Omnicare*, 135 S. Ct. at 1324.

The Sixth Circuit reversed. *Omnicare*, 719 F.3d at 510. The Sixth Circuit noted that, in contrast to a claim under Section 10(b) of the Securities and Exchange Act of 1934 (the "Exchange Act"), which requires proof of scienter, a Section 11 claim provides for strict liability. Therefore, the Sixth Circuit held that plaintiffs needed only to allege that the stated belief was objectively false, and did not need to allege that the opinion was disbelieved. *Id.* at 506-07.

The Supreme Court granted certiorari and vacated the Sixth Circuit's decision. *Omnicare*, 135 S. Ct. at 1324-25. The Court first distinguished statements of fact and statements of opinion. Based on the distinction, the Court determined that a statement of opinion is not actionable under the first clause of Section 11, providing liability for untrue statements of *fact*, simply because the opinion turns out to be erroneous. *Id.* at 1325-26. The Court held that statements of opinion are actionable as untrue statements of fact only if the speaker does not actually believe the opinion expressed,[1] or the opinion contains an embedded statement of fact. *Id.* at 1326-27.

While the Court ruled that a sincerely-held opinion cannot give rise to liability as an alleged false fact, the Court went on to hold that such opinion statements are not immune from liability under Section 11's omissions clause. The Court determined that a reasonable investor may fairly understand an opinion statement to convey certain information about how the speaker formed the opinion. The Court held that if a "statement omits material facts about the issuer's inquiry into or knowledge concerning a statement of opinion, and if those facts conflict with what a reasonable investor would take from the statement itself, then § 11's omissions clause creates liability." *Id.* at 1329.

The Court considered an opinion statement to the effect that "We believe our conduct is lawful." *Id.* at 1328. The Court noted that such a statement may be misleading if the issuer failed to consult with a lawyer or undertake any meaningful inquiry in expressing the opinion. The Court further recognized that the statement could be misleading if the issuer made the statement despite receiving contrary legal advice. *Id.* at 1329.

The Court recognized that an opinion may be misleading if it is not "fairly align[ed]" with the information in the issuer's possession. *Id.* However, the Court went on to make clear that an opinion is not rendered misleading simply because the issuer is aware of "some fact cutting the other way." *Id.*

Omnicare argued that allowing inquiry into an issuer's basis for its opinions was "unpredictable" and would have a chilling

effect on an issuer's willingness to make opinion statements (thus "depriving investors of potentially helpful information"). *Id.* at 1331. In response to Omnicare's concerns, the Court noted that stating a claim was "no small task for an investor." *Id.* at 1332.

> The investor must identify particular (and material) facts going to the basis for the issuer's opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context. *Id.*

Finally, the Court seemed unconcerned that its decision could have a chilling effect on issuers. The Court noted that in order to avoid liability, an issuer need only qualify or explain the basis for its opinion. *Id.* The Court also held that to the extent its decision "chill[ed] *misleading* opinions, that is all to the good: In enacting §11, Congress worked to ensure better, not just more, information." *Id.* (emphasis in original).

The Court remanded the case for reconsideration in light of its holding.

The Second Circuit Weighs In

The Second Circuit issued its first opinion interpreting *Omnicare* in *Tongue v. Sanofi*, 816 F.3d 199 (2nd Cir. 2016). The opinion places a high bar on plaintiffs seeking to hold issuers liable for opinion statements.

Investors alleged that Sanofi and its predecessor, Genzyme Corporation, made misrepresentations and omissions regarding the Food and Drug Administration's ("FDA") anticipated approval of the drug Lemtrada. Investors asserted claims both under Section 11 of the Securities Act and also under Section 10(b) of the Exchange Act. Consistent with the majority of courts that have addressed the issue since *Omnicare*, the Second Circuit (without discussion) applied *Omnicare*'s rulings both to the Section 11 and Section 10(b) claims. *See Sanofi*, 816 F.3d at 209.

Investors alleged that Genzyme had misled investors by expressing optimism regarding the timing of Lemtrada's FDA approval, while failing to disclose that the FDA had repeatedly raised significant concerns regarding the structure of Lemtrada's clinical trials. *Id.* at 211. Instead of using a double-blind study (a study in which both the patient and the researcher are unaware of what drug is being administered), Genzyme used only a single-blind study.

As early as 2002, the FDA had expressed concerns about the use of a single-blind trial for Lemtrada. *Id.* at 203. Despite its expressed concerns, the FDA permitted the company to enroll patients in Phase III trials (the final phase before approval for public use). In 2007, the FDA indicated that a single-blind trial might "potentially" be accepted if the trials "reveal[ed] an extremely large effect." *Id.* at 203-04. During Phase III, in March of 2010, the FDA expressed that "the bias introduced by unblinding physicians and patients remains a significant problem which will cause serious difficulties in interpreting the results of the trial." *Id.* at 204. In early 2011, the FDA informed the company that "the lack of blinding remains a major concern." *Id.*

In April of 2011, Sanofi initiated a tender offer to acquire Genzyme. As part of the merger, Genzyme's shareholders would receive a cash payment plus contingent value rights (CVRs). *Sanofi*, 816 F.3d at 204. The CVRs entitled the holders to cash payment upon achievement of certain milestones. The "Approval Milestone" provided a payment to CVR holders if the FDA approved Lemtrada by March 31, 2014. *Id.* at 204.

The offering materials incorporated opinion statements relating to Lemtrada to the effect that the company "[e]stimated a 90% probability that Lemtrada would achieve the Approval Milestone," and further that the company "anticipat[ed] product approval in the United States in the second half of 2012." *Id.* at 204-05.

Lemtrada, however, did not receive approval by the second half of 2012. The FDA announced it would hold a hearing regarding Lemtrada in November of 2013. In advance of the hearing, briefing materials were released in which physicians reviewing Lemtrada determined that the single-blind trials were not sufficient to support the effectiveness of Lemtrada. *Id.* at 206-07. After the release of the briefing materials, the value of the CVRs dropped by more than 62 percent. *Id.* In December of 2013, Sanofi announced that the FDA formally rejected the application and that the company did not anticipate the Approval Milestone would be met. This announcement caused a further decline in the value of the CVRs. *Id.*

Under *Omnicare*, the fact that the company's opinions, regarding the timing of Lemtrada's approval, turned out to be incorrect does not give rise to liability. Instead, the question addressed by the Second Circuit was whether the company's statements of optimism in 2011 (including the company's statement expressing a 90 percent probability of approval by a particular date) "fairly aligned" with the information available to the company at that time.

The investors argued that the company's statements of optimism were misleading, because the company failed to disclose material facts regarding the FDA's repeated expressions of concern over the single-blind trials. *Id.* at 211. The Second Circuit disagreed. First, the court held that the FDA's statements suggesting that it potentially would accept a single-blind trial that revealed an "extremely large effect" made it impossible for the investors to plausibly allege that the company's later statements of optimism were misleading. *Id.*

The court did not rest on this ruling alone, and instead went on to announce a number of additional grounds for dismissal of the claims. One of the most notable aspects of the Second Circuit's opinion is that it analyzed whether the statements were misleading from the perspective of a "sophisticated investor." *Id.* In *Omnicare*, the Court reiterated that the inquiry into whether a statement is misleading is an "objective" one, and asks whether a statement is "misleading to an *ordinary investor*." *Omnicare*, 135 S. Ct. at 1327-28 (emphasis added).

Without commenting on this apparent divergence from *Omnicare*, the Second Circuit went on to opine that "sophisticated investors" (such as plaintiffs) who were "accustomed" to the practices of the industry must have expected that the company and the FDA were in a dialogue regarding the application

process. *Sanofi*, 816 F.3d at 211. The court further indicated its belief that such sophisticated investors would understand that differing views were "inherent" in the nature of the dialogue. *Id.* In the court's view, this dialogue did not prevent the company from issuing statements of "exceptional optimism" regarding the likelihood of drug approval. *Id.* The court further rejected plaintiffs' argument that the relevant test should be whether the company failed to disclose a risk above and beyond the normal risk associated with drug approval. *Id.* at 212.

Finally, the Second Circuit determined that the company's statements were not misleading because "sophisticated investors" were charged with the knowledge of the FDA's public preference for double-blind trials. "Especially 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." *Id.* at 212-13.

In sum, *Sanofi* places a high burden on investors alleging claims based on opinion statements even after *Omnicare*. However, the opinion's emphasis on whether the statements were misleading to *sophisticated* investors gives plaintiffs the opportunity to argue that the holding is limited to its facts and does not apply outside of cases involving complex securities.[2]

Mixed Results in the District Courts

In the district courts, investors have invoked *Omnicare* in opposing motions dismiss with mixed results. *Compare, e.g., City of Westland Police and Fire Ret. Sys. v. Metlife, Inc.*, 129 F. Supp. 3d 48, 68-77 (S.D.N.Y. 2015) (granting motion to dismiss claims based on allegedly misleading opinion statements); *West v. Ehealth, Inc.*, 2016 WL 948116, *7-8 (N. D. Cal. 2016) (same); *In re Velti PLC Sec. Litig.*, 2015 WL 5736589 (N.D. Cal. 2015) (same); *with In re Genworth Fin. Inc. Sec. Litig.*, 103 F. Supp. 3d 759, 776-79 (E.D. Va. 2015) (denying motion to dismiss claims based on allegedly misleading opinion statements); *In re Bioscrip, Inc. Sec. Litig.*, 95 F. Supp. 3d 711, 728-32 (S.D.N.Y. 2015) (same).

Further, in at least two cases, *Omnicare* has helped investors survive motions for summary judgment. *See In re Lehman Bros. Sec. and ERISA Litig.*, 131 F. Supp. 3d 241, 250-59 (S.D.N.Y. 2015); *In re Merck & Co., Inc. Sec., Derivative & ERISA Litig.*, 2015 WL 2250472, n.7 (D.N.J. 2015) (finding *Omnicare* instructive as to the scienter analysis under Section 10(b) of the Exchange Act).

The Outlook Going Forward

While *Sanofi* gives issuers some cover, *Omnicare* should continue to make issuers think twice before expressing overly-optimistic opinions affecting stock price. Further, investors seeking to hold issuers liable for opinion statements should heed the Supreme Court's caution that pleading such a claim is "no small task." Investors are likely to be successful only where they can point to specific material facts that call into question whether an issuer's optimism is fairly aligned with the information in its possession, something akin to the most desirable Mr. Fleck paying by driblets.

(Endnotes)

1 Consistent with the Court's prior holding in *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083 (1991), the Court acknowledged that Section 11 does not impose liability on the issuer in the "rare" circumstance in which an issuer expresses an opinion that is not sincerely-held, but in fact turns out to be accurate. *Omnicare,* 135 S. Ct. at n.2.

2 The Private Securities Litigation Reform Act ("PSLRA") provides a statutory safe harbor for forward-looking statements that meet certain criteria. 15 U.S.C. § 77z-2; 15 U.S.C. § 78u-5. The Second Circuit acknowledged that the district court ruled that the opinion statements at issue were protected by the PSLRA safe harbor. *Sanofi*, 816 F.3d at 208. However, the Second Circuit affirmed without discussing the PSLRA safe harbor or its interplay with *Omnicare* in the context of forward-looking statements of opinion.

In Case You Missed It: Amendments to the Federal Rules of Civil Procedure

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The Federal Rules of Civil Procedure were amended in 2015, effective December 1, 2015. The following summary is a summary, not a substitute for reading the amendments (a redline is available for download at *http://www.uscourts.gov/rules-policies/current-rules-practice-procedure/federal-rules-civil-procedure*). The Local Rules of Civil Procedure (LR) for the United States District Court for the District of Oregon were also recently amended, effective March 1, 2016. Recent changes to the Local Rules are summarized below and in greater detail at *https://ord.uscourts.gov/local-rules/civil-procedure*.

Rule 1: *The parties and the court* are responsible to construe, administer, and employ the rules of procedure to secure the just, speedy, and inexpensive determination of every action. From the Advisory Committee Notes: Effective advocacy is consistent with—and indeed depends upon—cooperative and proportional use of procedure.

Rule 4: The time limit for serving a complaint is *90 days* (no longer 120).

Rule 16(b): The court's deadline to issue a scheduling order is *reduced by 30 days* (the earlier of 90 days after service of a defendant or 60 days after appearance of a defendant). Exceptions are not permitted *unless the judge finds good cause for delay*. Permitted contents of the scheduling order are expanded expressly to permit an order *to preserve ESI*, *to incorporate claw-back agreements for privileged information (see FRE 502)*, and *to require a conference with the court before making a discovery motion*.

LR 26-3: New Practice Tip reminds lawyers that their assigned judge may require a court conference prior to filing a motion to compel.