Applying *Omnicare*: The Second Circuit Weighs in on Statement of Opinion Liability Post-*Omnicare*

March 23, 2016

On March 4, 2016, the Court of Appeals for the Second Circuit issued *Tongue v. Sanofi*[1]—the Second Circuit's first published opinion interpreting and applying the Supreme Court's opinion in *Omnicare Inc. v. Laborers District Council Construction Industry Pension Fund*.[2] *Omnicare* addressed the circumstances under which a company issuing securities (an "issuer") is liable for statements of opinion or belief.[3]

Under the prior controlling authority in the Second Circuit, *Fait v. Regions Financial Corp.*, an issuer could only be liable if an opinion was both (1) objectively false and (2) disbelieved by the speaker at the time it was made.[4] Now, under *Omnicare*, an issuer may also be liable if the speaker omits information which renders the opinion misleading to a reasonable investor.[5] *Sanofi* makes clear that whether an omission renders an opinion misleading depends largely on context, underscoring the Supreme Court's admonition that, despite this new basis for liability, pleading such a claim is "no small task for an investor[.]"[6]

The Supreme Court's 2015 *Omnicare* Decision

In *Omnicare,* the Supreme Court set forth the test for determining whether a statement of opinion or belief is actionable under Section 11 of the Securities Act of 1933 (the "Securities Act").[7] The Court ruled that a sincerely held statement of opinion does not constitute an untrue statement of fact simply because the opinion ultimately proves incorrect.[8] But the Court further held that if a registration statement omits material facts about the issuer's inquiry into (or knowledge concerning) even an ultimately correct statement of opinion, liability may lie under Section 11 if the omitted facts conflict with what a reasonable investor, reading the statement fairly and in context, would take from the statement.[9] After all, an investor "expects not just that the issuer believes the opinion (however irrationally), but that it fairly aligns with the information in the issuer's possession at the time."[10]

Thus, under *Omnicare*, issuers' statements of opinion, though sincerely held and otherwise true as a matter of fact, may nonetheless be actionable if the speaker omits information which makes the statement misleading to a reasonable investor.[11] The *Omnicare* Court, however, emphasized that meeting the standard for imposing Section 11 liability "is no small task for an investor."[12] Reasonable investors, the Court explained, "understand that opinions sometimes rest on a weighing of competing facts," and therefore reasonable investors do "not expect that ***every*** fact known to an issuer supports its opinion statement."[13]

The Second Circuit's March 2016 Application of *Omnicare* in *Tongue v. Sanofi*

In *Sanofi*, the Second Circuit applied *Omnicare* to claims for misleading statements of opinion brought under Section 11 of the Securities Act and expressly extended *Omnicare* to Section 10 of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.[14] *Sanofi* involved a group of investors who sued a pharmaceutical company, its predecessor, and three executives ("Sanofi") for allegedly making misleading statements regarding clinical testing of a breakthrough drug, Lemtrada.[15]

When Sanofi acquired Genzyme Corporation ("Genzyme"), the prior owner of Lemtrada, it issued contingent value rights ("CVRs") to Genzyme shareholders.[16] The publicly-traded CVRs entitled the holder to cash payouts if certain milestones, such as Food and Drug Administration ("FDA") approval of Lemtrada, were met.[17] After the acquisition, Sanofi made statements in the offering materials for the CVRs, and then to the market as a whole, that it expected the FDA to approve Lemtrada and that the clinical trials were progressing well.[18] But, privately, the FDA had repeatedly warned that the lack of double-blind studies in the Lemtrada clinical trials was a "major concern," but that it might nevertheless accept the results if the single-blind studies showed "an extremely large effect[.]"[19]

Prior to a hearing on Lemtrada's application, the FDA publicly released briefing materials noting its concerns about Sanofi's failure to use double-blind studies,[20] and detailing its prior communications of those concerns to Sanofi.[21] Upon the release of the briefing materials, the CVRs lost over half their value.[22] Then the FDA formally rejected Lemtrada's application, and the CVRs' value dropped even lower.[23] The FDA eventually approved Lemtrada without further clinical trial, but only after the deadline for CVR milestone payments based on FDA approval had long passed.[24]

Two groups of CVR holders sued, alleging Sanofi misled investors by failing to disclose the FDA's repeated concerns over Sanofi's use of single-blind studies.[25] Applying the old standard set forth in *Fait*, the district court dismissed both groups' complaints for failure to state a claim.[26] On appeal, the Second Circuit affirmed under the new *Omnicare* standard.[27]

In its *Sanofi* opinion, the Second Circuit analyzed three categories of statements of opinion: (1) statements relating to the expected timing of FDA approval; (2) statements relating to the timing of the launch of Lemtrada; and (3) statements relating to Lemtrada's trial results.[28]

As to the first category, the Second Circuit found there was no plausible allegation that the FDA's interim feedback conflicted with Sanofi's expectation for FDA approval.[29] Although the FDA expressed concerns about Sanofi's testing methodology, it also stated those concerns could be overcome if the results showed an "extremely large effect"—and it was undisputed that Lemtrada's treatment effect was large.[30]

The court further found that the challenged omissions did not render the statements materially misleading. Emphasizing "the need to examine the context" of the allegedly misleading opinion, the court observed—***without explanation***—that the CVR holders were "sophisticated investors" who were (1) aware that Sanofi's projections were synthesized from a wide variety of information (some of which may have been conflicting); and (2) familiar with the pharmaceutical industry, including the FDA's custom and practice of engaging in ongoing dialogues during clinical trials.[31] Additionally, because the offering materials contained numerous caveats, a reasonable investor would have considered the statements "in light of all the surrounding text, including hedges, disclaimers, and apparently conflicting information."[32] Further, per the *Sanofi* court, *Omnicare* did not require Sanofi to disclose the FDA's feedback merely because it tended to undermine their optimistic projections.[33]

Regarding the second category of statements, the Second Circuit observed that the FDA's concerns over Sanofi's testing methodology did not conflict with statements that Sanofi felt "relaxed" or "satisfied" with their progress.[34] According to the court, a reasonable investor would not have inferred from mere statements of confidence that the FDA had not engaged in industry-standard dialogue about potential deficiencies in the testing methodology or the drug itself.[35] Moreover, Sanofi's belief as to when the FDA would approve the drug did not conflict with the information available to Sanofi at the time.[36]

As to the third category, the Second Circuit explained that the CVR holders failed to show any conflict between Sanofi's statement about the general effectiveness of Lemtrada and the FDA's feedback.[37] Sanofi's statements about the effectiveness of Lemtrada could not be misleading merely because the FDA disagreed with the conclusion—so long as Sanofi conducted a meaningful inquiry and in fact held that view, the statements could not give rise to omissions liability.[38]

Takeaways and Conclusions

The following are takeaways which might be considered by issuers:

- ***Context matters*** to the analysis of whether an issuer's opinion statement is materially misleading to a reasonable investor. As the Second Circuit emphasized in *Sanofi*, even if a company's "exceptional optimism" about its likelihood of success is later deflated, a plaintiff's Section 11 claims will likely fail in the absence of any "serious conflict" between existing information and a defendant's optimistic (though later incorrect) statements.[39] As *Sanofi* recognized, "issuers must be forthright with their investors, but securities law does not impose on them an obligation to disclose every piece of information in their possession."[40] Accordingly (and even if an issuer is aware of some potentially conflicting information), liability for allegedly misleading opinion statements may not lie unless an issuer's opinion is in direct conflict with clear, known factual information.

- Post-*Sanofi,* ***sophistication may be a factor***. Without any explanation or briefing, the Second Circuit assumed that the *Sanofi* investors were sophisticated, and therefore held them to a higher burden with respect to collecting and synthesizing available information and weighing the accuracy of the issuer's opinion statements. Considering the lack of briefing at the district and circuit court levels, the Second Circuit's statements about sophisticated investors beg many questions. For example, what makes an investor sophisticated for purposes of the analysis? Might a class be defeated based upon a combination of sophisticated and "unsophisticated" investors? Is it the defendant's burden to plead and prove sophistication as a defense?
- When determining whether an opinion statement is materially misleading, courts will scrutinize what information was known to the issuer (and, perhaps more importantly, what information was discounted or ignored) at the time the statement was made. As explained in *Sanofi*, the mere fact that some conflicting information exists does not necessarily make an issuer's statement misleading. Rather, the key question regarding Section 11 liability is ***whether the issuer has conducted a meaningful inquiry and has a reasonable basis upon which to make a particular assertion***.[41] Under this standard, issuers need not drown investors with all available information in an attempt to avoid liability. Instead, issuers should realistically assess the available information and avoid making opinion statements that are too far-reaching or one-sided. Obviously, companies should not willfully blind themselves to available information that undermines statements made.
- ***Caveats and disclaimers are as important as ever.*** In *Sanofi*, the Second Circuit pointed to the issuer's offering statement, which "made numerous caveats to the reliability of the projections."[42] In addition, the court tasked the sophisticated *Sanofi* investors with reviewing publicly available FDA reports and journal articles, which contained information contrary to the complained-of opinions. Thus, the *Sanofi* court explained, a reasonable investor should have understood the potential for differing opinions and should not have been misled by the issuer's statements. While it is not clear whether other courts might similarly charge plaintiffs with an affirmative obligation to look at contradictory information outside of an issuer's public filings, *Sanofi*'s reasoning emphasizes that an issuer can point to its own disclaimers and caveats to undercut a plaintiff's Section 11 or Section 10(b) claims.
- Post-*Sanofi*, the *Omnicare* standards for investors seeking to challenge an issuer's opinions under an omissions theory have now been applied to Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder.

If you would like more information about this subject or other litigation-related topics, please contact your Andrews Kurth representative in the Litigation Practice Section.

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1. *See* Nos. 15-588-cv & 15-623-cv, --- F.3d ---, 2016 WL 851797 (2d Cir. Mar. 4, 2016).

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

3. *Omnicare*, 135 S. Ct. at 1327-32.

4. 655 F.3d 105, 109-10 (2d Cir. 2011) (citing *Virginia Bankshares v. Sandberg*, 501 U.S. 1083, 1095-96, 111 S. Ct. 2749, 115 L.Ed.2d 929 (1991)).

5. *Omnicare*, 135 S. Ct. at 1332.

6. *Sanofi*, 2016 WL 851797, at *8 (quoting *Omnicare*, 135 S. Ct. at 1332).

7. 135 S. Ct. 1318 (2015).

8. *Omnicare*, 135 S. Ct. at 1327-28.

9. *Id*. at 1329.

10. *Id.*

11. *Id*. at 1332.

12. *Id.*

13. *Id.* at 1329 (emphasis in original).

14. *Sanofi*, 2016 WL 851797, at *1.

15. *Id.*

16. *Id*. at *2-3.

17. *Id*. at *2.

18. *Id*. at *3-4.

19. *Id*. at *2.

20. *Id.* at *4.

21. *Id*. at *5.

22. *Id*.

23. *Id*.

24. *Id*.

25. *Id*. at *1.

26. *Id*. at *6.

27. *Id*. at *1.

28. *Id.* at *8.

29. *Id*.

30. *Id*.

31. *Id*. at *9 (citing *Omnicare*, 135 S. Ct. at 1330). The *Sanofi* court further noted that the FDA had long made public its preference for double-blind trials, while Sanofi had publicly stated that they were relying on single-blind studies. *Id*. at *10.

32. *Id*. (brackets and internal quotations omitted).

33. *Id*.

34. *Id*.

35. *Id*.

36. *Id*.

37. *Id*. at *11.

38. *Id*.

39. 2016 WL 851797 at *9.

40. *Id.* at *12.

41. *Id.* at *11.

42. *Id.* at *9.