In the
United States Court of Appeals
for the Second Circuit

August Term, 2015

No. 15-588-cv

GEN. PARTNER GLENN TONGUE, DEERHAVEN CAPITAL MANAGEMENT,

Plaintiffs-Appellants,

JOHN SOLAK, individually and on behalf of all others similarly situated,

Plaintiff,

VINCENT STASIULEWICZ, individually and on behalf of all others similarly situated,

Consolidated Plaintiff,

v.

SANOFI,

Defendant-Appellee,

CHRISTOPHER VIEHBACHER, DAVID MEEKER, JEROME CONTAMINE,

Defendants-Consolidated Defendants-Appellees,

SANOFI PHARMACEUTICALS, INC.,

Consolidated Defendant.

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2
3 No. 15-623-cv
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5 AG FUNDS, L.P., AG MM, L.P., AG SUPER FUND INTERNATIONAL, L.P.,
6 AG PRINCESS, L.P., NUTMEG PARTNERS, L.P., AG SUPER FUND, L.P.,
7 ARISTEIA HORIZONS, L.P., WINDERMERE IRELAND FUND PLC, COMPASS
8 ESMA, L.P., COMPASS TSMA, L.P., XEROPOLIS L.L.C., OZ ELS MASTER
9 FUND, LTD., OZ MASTER FUND, LTD., OZ EUREKA FUND, L.P., GORDEL
10 CAPITAL LIMITED, OZ EUROPE MASTER FUND, LTD., OZ GLOBAL
11 SPECIAL INVESTMENTS MASTER FUND, L.P., OZ SELECT MASTER FUND,
12 LTD., OZ GLOBAL EQUITY OPPORTUNITIES MASTER FUND, OZ
13 ENHANCED MASTER FUND, LTD., SAPELO LLC, WHITEBOX
14 CONCENTRATED CONVERTIBLE ARBITRAGE PARTNERS, L.P., WHITEBOX
15 CREDIT ARBITRAGE PARTNERS, L.P., WHITEBOX ASYMMETRIC PARTNERS,
16 L.P., WHITEBOX MULTISTRATEGY PARTNERS, L.P., PANDORA SELECT
17 PARTNERS, L.P., WHITEBOX INSTITUTIONAL PARTNERS, L.P., WHITEBOX
18 SPECIAL OPPORTUNITIES FUND SERIES B PARTNERS, L.P., WHITEBOX
19 SPECIAL OPPORTUNITIES FUND, SERIES O,
20
21 *Plaintiffs-Appellants*,
22
23 GOLDMAN SACHS PROFIT SHARING MASTER TRUST, MERRILL LYNCH
24 INVESTMENT SOLUTIONS OCH-ZIFF EUROPEAN MULTI-STRATEGY UCITS
25 FUND, OZEA, L.P.,
26
27 *Plaintiffs*,
28
29 *v.*
30
31 SANOFI, GENZYME CORPORATION, CHRISTOPHER VIEHBACHER, DAVID
32 MEEKER, JEROME CONTAMINE,
33
34 *Defendants-Appellees*.
35 _____

Appeal from the United States District Court
for the Southern District of New York.
Nos. 13 Civ. 8806 (PAE), 14 Civ. 2211 (PAE) — Paul A. Engelmayer, *District Judge*.

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Argued: October 7, 2015
Decided: March 4, 2016

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Before: PARKER, LOHIER, and CARNEY, *Circuit Judges*.

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In these related cases, Plaintiffs appeal from a judgment of the United States District Court for the Southern District of New York (Engelmayer, Paul A., *J.*) granting Defendants' motion to dismiss the complaints for failure to state a claim upon which relief may be granted. *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510 (S.D.N.Y. 2015). Plaintiffs allege that Defendants made materially false or misleading statements or omissions regarding the clinical testing of Defendants' drug, Lemtrada. Specifically, Plaintiffs allege that Defendants misled investors by failing to disclose that the FDA had expressed concern regarding the use of single-blind (as opposed to double-blind) clinical studies. We affirm the decision of the district court. We write here primarily to examine the impact of the Supreme Court's intervening decision in *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 135 S. Ct. 1318 (2015). We conclude that even under the Supreme Court's revised approach to allegations of materially misleading opinions, Plaintiffs have failed to meet the standards applicable under Fed. R. Civ. P. 12(b)(6). Affirmed.

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CHRISTOPHER L. NELSON (James M. Ficaro, Brett D. Stecker, *on the brief*), The Weiser Law Firm, P.C., Berwyn, PA, Daniella Quitt, Harwood Feffer LLP, New York, NY, *on the brief, for Plaintiffs-Appellants Gen. Partner Glenn Tongue, Deerhaven Capital Management*.

JOHN B. ORENSTEIN (Harry N. Niska, *on the brief*), Ross Orenstein & Baudry LLC, Minneapolis, MN, *for Plaintiffs-Appellants AG Funds, L.P. et al.*

JOHN NEUWIRTH (Joshua S. Amsel, Caroline Hickey Zalka, Justin D. D'Aloia, *on the brief*), Weil, Gotshal & Manges LLP, New York, NY, *for Defendants-Appellees*.

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BARRINGTON D. PARKER, *Circuit Judge*

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In these related cases, Plaintiffs allege that the pharmaceutical company Sanofi, along with its predecessor and three company executives, made materially false or misleading statements regarding its breakthrough drug, Lemtrada, designed to treat multiple sclerosis ("MS"). Plaintiffs allege that while Lemtrada was undergoing Phase III clinical trials prior to FDA approval, Sanofi misled investors by failing to disclose that the FDA had repeatedly expressed concern with Sanofi's use of single-blind studies and had encouraged Sanofi to use double-blind studies in its clinical trials. Plaintiffs allege that these omissions misled investors and artificially inflated the value of Plaintiffs' contingent value rights ("CVRs"), specialized financial instruments whose value is tied to the achievement of certain "milestones."

Plaintiffs' allegations are predicated on §§ 10(b), 18, and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78a *et seq.* (the "Exchange Act"); §§ 11 and 12 of the Securities Act of 1933, 15 U.S.C. §§ 77a *et seq.* (the "Securities Act"); and state blue sky laws. Before the Court is Plaintiffs' appeal from the district court's grant of Defendants' motion to dismiss under Fed. R. Civ. P. 12(b)(6) for failure to state a claim. Because we agree with the district court's reasoning and holding, we write principally to examine the impact of the Supreme Court's decision in *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 135 S. Ct. 1318 (2015), decided after the district court rendered its decision.

BACKGROUND

A. Development of Lemtrada

Prior to 2011, Defendant Genzyme Corporation ("Genzyme") was the owner of a promising drug called Lemtrada. Lemtrada had not yet been approved by the FDA, but had shown potential as a treatment for victims of MS. The advantage of Lemtrada comes partially from its unique treatment cycle. While traditional MS treatments require a daily or weekly dosing regimen, Lemtrada only requires two annual treatment courses.

In part because of Lemtrada's unique treatment design, Genzyme used a single-blind study in its early clinical trials. In a single-blind study, either the researcher or the patient does not know which drug was administered. By contrast, in a double-blind study, neither the patient nor the investigator knows which drug was administered. Lemtrada's biannual treatment regimen effectively precluded the use of double-blind studies, as patients would realize they were being required to undergo treatment far less frequently than under their normal drug. In what appears to have been among its earliest public reports on its Lemtrada clinical studies, Genzyme stated in the New England Journal of Medicine in 2008 that it was relying solely on single-blind studies for the trials.

At least as far back as 2002, the FDA expressed concern about the use of single-blind studies for Lemtrada, telling ILEX (the then-owner of Lemtrada that was acquired by Genzyme in 2004) in a teleconference that the use of single-blind studies in Lemtrada's early clinical trials would "not provide substantial support for a BLA."[1] Joint App'x at 43. In 2004, the FDA again informed ILEX in another teleconference that "[b]ecause of study design issues (open-label, small sample size) the [clinical trial] is unlikely to provide substantial support for an sBLA."[2] *Id.* After Genzyme acquired ILEX, the FDA reiterated in a telephone call that the early clinical trial "will not be a pivotal study to support a license application." *Id.*

In 2006, the FDA expressed more optimism for the drug's approval based on the single-blind studies, saying that "a rater blinded (but patient not blinded) study may be adequate if the effect is large," though the FDA again noted that it would "prefer double-blinded, controlled studies, especially for the pivotal trials." *Id.* at 78. In 2007, the FDA sent a letter "strongly recommend[ing]" that Genzyme "use a double-dummy placebo control in your pivotal trials," adding that "[t]he acceptability of your rater-blinded study will be a matter of review. If your study results reveal an extremely large effect, then FDA may potentially accept this rater-blinded design for the pivotal trials." *Id.* Notwithstanding this feedback, the FDA permitted Genzyme to enroll patients in Phase III clinical trials that were only single-blind studies. (Phase III is the final phase of trials prior to submission of the drug for FDA approval for public usage.)

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[1] Biologics License Application. According to the FDA, a BLA "is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce." FDA, *Biologics License Applications (BLA) Process (CBER)*, http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/default.htm (last visited Mar. 1, 2016).

[2] Supplemental Biologics License Application.

The FDA's concerns regarding the use of single-blind studies continued and were expressed to Genzyme during the Phase III trials. According to the FDA's minutes of a meeting with Genzyme, the FDA expressed in March 2010 that it "was concerned by the potential bias introduced by the absence of blinding of patients," and 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 43. And in 2011, the FDA reiterated in a meeting with Genzyme that "the lack of double-blinding has consistently concerned us. The lack of blinding remains a major concern." *Id.* at 43–44. The FDA added that "despite these previous concerns that have been communicated to you, there was little discussion of the unblinded design of the trials in the meeting material." *Id.* at 44.

B. Sanofi Acquires Genzyme

Defendant Sanofi is a global pharmaceutical company engaged in the research, development, manufacturing, and marketing of healthcare products. In 2010, Sanofi began an effort to acquire Genzyme. At the time, Lemtrada's market worth was estimated at $14 billion worldwide. Genzyme initially rejected Sanofi's offers, arguing that Sanofi undervalued Lemtrada's business potential. Partially as a result of this contention, Genzyme and Sanofi began to negotiate a deal whereby Genzyme's stockholders would be partially compensated by a financial instrument tied to the value of Lemtrada. The two parties eventually agreed that each shareholder would receive a cash payment of $74 per share, plus one CVR per share. The parties agreed to the terms of the acquisition and executed a Merger Agreement on February 16, 2011.

Each CVR entitled the holder to cash payouts upon achievement of certain "milestones" connected to the success of Lemtrada. The first milestone, called the "Approval Milestone," entitled CVR holders to $1 per CVR if the FDA approved Lemtrada for treatment of MS by March 31, 2014. The four other milestones,

called the "Product Sales Milestones," entitled CVR holders to similar cash payments if Lemtrada achieved certain levels of global net sales. In addition, the second Product Sales Milestone, if met, compensated CVR holders an additional $1 per CVR if Lemtrada had failed to meet the Approval Milestone. The CVRs also contained a $1 per share payout for production milestones related to other drugs.

Sanofi initiated a tender offer on April 1, 2011, consisting of the $74 per share and one CVR per share. The tender offer was followed by a short-form merger on April 8, 2011. The offer and merger were conducted pursuant to a Form F-4 Registration Statement and a 424B3 Prospecture (together, the "Offering Materials"). The Offering Materials incorporated, by reference, a number of Genzyme's prior SEC filings containing statements regarding Lemtrada, its clinical results, and its potential approval by the FDA. Specifically:

1) 14D-9 (filed March 7, 2011)

- Estimated a 90% probability that Lemtrada would achieve the Approval Milestone. *Id.* at 45.
- "The Approval Milestone is designed to trigger a payment to CVR holders in the event that the Company receives FDA approval of alemtuzumab[3] for treatment of MS by March 31, 2014. Company management currently anticipates product approval in the United States in the second half of 2012." *Id.*

2) Form 10-K (filed March 1, 2011)

- "We are currently developing alemtuzumab for the treatment of Relapsing-Remitting MS, or

[3] "Alemtuzumab" is the scientific name for Lemtrada.

> RRMS, the most common form of MS. . . . We have completed enrollment in two phase 3 clinical trials of alemtuzumab vs. Rebif® (a standard of care therapy) for the treatment of RRMS, from which we expect to obtain results in 2011. Five-year follow up data from our phase 2 study continues to show durable treatment benefit. In 2010, the FDA granted alemtuzumab 'fast track' status for the treatment of RRMS. We anticipate product approval in the United States in the second half of 2012." *Id.* at 46.

3) Form 8-K (filed January 11, 2011)

- "Within Genzyme's late-stage product pipeline, three product approvals are expected by the end of 2013 [including] alemtuzumab for multiple sclerosis . . . ." *Id.*

4) Form 8-K (filed February 16, 2011)

- "Based on promising phase 2 data, alemtuzumab has the potential to become a new standard of care for multiple sclerosis treatment, a market that is expected to reach $13 billion by 2012. Two phase 3 trials are fully enrolled; results of the trial in treatment-naïve patients are expected mid-year, and results of the trial in treatment-experienced patients are expected during the second half of this year. Genzyme anticipates U.S. approval of the treatment in the second half of 2012." *Id.* at 47.

C. Sanofi's Statements Following the Acquisition

Following its acquisition of Genzyme, Sanofi continued to speak optimistically about Lemtrada. In its November 14, 2011 Form

6-K filing, Sanofi announced its "Successful Phase III Results for Alemtuzumab (LEMTRADA™) in Multiple Sclerosis." *Id.* The CEO of Genzyme added that "[w]e are very pleased with the results of the [Phase III clinical trials] which are unprecedented . . . . Based on these positive results, we are on track to submit LEMTRADA™ for review to US and EU regulatory authorities in the first quarter of 2012." *Id.* at 47–48. Sanofi later averred, in its March 5, 2012 Form 20-F:

> The two Phase III studies demonstrating the safety and efficacy of alemtuzumab were completed in 2011. The first study . . . demonstrated strong and robust treatment effect on the relapse rate co-primary endpoint vs Rebif. . . . The second study . . . demonstrated that relapse rate and SAD[4] were significantly reduced in MS patients receiving alemtuzumab as compared with Rebif. In both cases, safety results were consistent with previous alemtuzumab use in MS and adverse events continued to be manageable. The dossier is scheduled to be submitted to FDA review in the second quarter of 2012.

Id. at 48, 936.

Sanofi continued to make similar statements endorsing the effectiveness of Lemtrada, saying that patients taking Lemtrada "were more than twice as likely to experience a sustained reduction in disability over two years," *id.* at 49, and "two pivotal Phase III studies demonstrating the safety and efficacy of alemtuzumab were completed in 2011," *id.* at 50. In a conference call with analysts on April 27, 2012, Sanofi's CEO noted that with regard to Lemtrada, "the data are nothing short of stunning." *Id.* at 87. In another conference call with analysts on October 25, 2012, Sanofi's CFO stated that "this will continue and probably somewhat amplify in the

[4] "Sustained accumulation of disability." Joint App'x at 981.

coming quarters as we prepare for the launch of Lyxumia, thereafter for the launch of Lemtrada," and Sanofi's CEO added, "look at Lemtrada . . . . I would say I'm actually very satisfied with where the progress is going." *Id.* at 90.

On January 28, 2013, Sanofi announced that the FDA had accepted its sBLA filing seeking approval of Lemtrada. Shortly thereafter, on February 7, 2013, Sanofi's CEO told analysts:

> So I think it augurs well because this also says that we have a team, that should be in good position to launch Lemtrada. It is obviously a huge opportunity that we have to be able to put 2 significant new medicines into an important area like MS. This is a market of some $14 billion worldwide.

Id. at 1099. On October 30, 2013, Sanofi's CEO told analysts: "But quite honestly, I'm feeling pretty, pretty relaxed because if I look at our Phase III pipeline, there's an awful lot of really good stuff in there . . . . We've got Aubagio and Lemtrada rolling out."[5] *Id.* at 98.

D. The FDA Rejects Lemtrada's Initial Application

On October 16, 2013, the FDA announced it would conduct a hearing on November 13, 2013 regarding Lemtrada's application. On November 8, 2013, the FDA Advisory Committee on Peripheral and Central Nervous System Drugs released the materials for the November 13 hearing (the "Briefing Materials").[6] The three

[5] We do not attempt here to recite each and every allegedly false or misleading statement identified by Plaintiffs in their respective complaints, but the statements above provide an adequate sampling.

[6] Plaintiffs in the consolidated class action allege that a separate "Background Package" was released on November 13, detailing the FDA's past comments to Genzyme and Sanofi regarding the use of single-blind trials. A review of the documents themselves reflects that these comments were, in fact, included in the original Briefing Materials, released on November 8, as alleged by the plaintiffs in the *AG Funds* action. Where a document is referenced in a complaint, "the documents control and this Court need not accept as true the allegations in the amended complaint." *Rapoport v. Asia Elecs. Holding Co.*, 88 F. Supp. 2d 179, 184 (S.D.N.Y. 2000). In any event, the timing of the disclosure is immaterial for purposes of this appeal.

physicians reviewing Lemtrada's application in advance of the hearing all expressed concerns regarding Lemtrada, and two of them referenced the failure to use double-blind studies:

> In particular, Dr. Marler has grave concerns that the failure to blind patients and treating physicians in the open-label design of the trials introduced bias that confounds interpretation of their ostensible results. Because of these issues, Dr. Marler finds that the applicant has not submitted evidence from adequate and well-controlled studies to support the effectiveness of alemtuzumab for treating multiple sclerosis. . . .
>
> . . . Dr. Yan also feels that troublesome design issues and the presence of bias in trials prevents reliance on their results, and that a valid, accurate, and interpretable effect on the two main clinical outcomes of interest, relapse rate and sustained accumulation of disability, has not been established. Dr. Yan finds, like Dr. Marler, that the applicant has not provided evidence from adequate and well-controlled studies in this application and that such studies still need to be conducted to establish the effectiveness of alemtuzumab for the treatment of patients with multiple sclerosis.

Id. at 53–54.[7] The Briefing Materials also detailed the FDA's communications with Genzyme and Sanofi regarding the use of single-blind clinical trials.

Upon release of the Briefing Materials on November 8, the value of the CVRs dropped from $2.00 per share to $0.77 share, or more than 62%.

[7] The third physician was primarily concerned with the safety of the drug, and did not discuss the reliability of the clinical trials. As Plaintiffs' claims relating to the safety of Lemtrada have been abandoned on appeal, we need not consider the impact of his statements here.

On December 30, 2013, Sanofi announced that it had received formal rejection of Lemtrada from the FDA and acknowledged that it did "not anticipate that the CVR milestone of U.S. approval of Lemtrada by March 31, 2014 will be met." *Id.* at 54. The value of the CVRs dropped further on the news, falling to $0.32 per share.

Sanofi's CEO said in a January 23, 2014 interview that the rejection "wasn't a total surprise," but added, "[t]hat having been said, this is a drug that's been approved by 30 countries in the world. We're seeing patients who have gone five years without a relapse. So we believe that the drug actually is working and it's important for patients." *Id.* at 1235.

In April of 2014, Sanofi announced that it was engaged in discussions with the FDA regarding Lemtrada's application, and on May 30, 2014, Sanofi announced that the FDA had accepted Lemtrada for resubmission.[8] On November 14, 2014, the FDA approved Lemtrada for treatment of MS, well after the deadline for the Approval Milestone had passed.

E. Procedural History

Two class action complaints were filed against Defendants in December 2013. The complaints were consolidated in February 2014, and a Consolidated Amended Complaint was filed on April 28, 2014 (the "CAC"). The putative class comprised all persons, other than Defendants, who purchased CVRs between March 6, 2012 and November 7, 2013. The CAC alleged violations of § 10(b) (and SEC Rule 10b-5 promulgated thereunder) against all defendants, and § 20(a) of the Exchange Act against the individual defendants.

On March 28, 2014, 32 corporations filed a separate complaint (the AG Funds Complaint, or "AGC") alleging claims arising out of the same set of facts. These plaintiffs had either opted out of the class action or had acquired CVRs outside the class period. In

[8] At oral argument, counsel for all parties agreed that the record did not reflect what amendments were made to the submission, but that Sanofi did not conduct new Phase III trials for Lemtrada.

addition to violations under §§ 10(b) and 20(a) of the Exchange Act, the AGC alleges violations under § 18 of the Exchange Act, §§ 11 and 12(a)(2) of the Securities Act, and state blue sky laws. For purposes of this appeal, the operative differences between the complaints are:

(1) The CAC only alleges violations of the Exchange Act, requiring a showing of scienter, and

(2) The AGC's Securities Act claims encompass statements made by Genzyme and Sanofi in the Offering Materials.

Both complaints allege, among other things, that by failing to disclose the feedback from the FDA regarding the use of single-blind studies, Defendants misled investors as to the likelihood of meeting the Approval Milestone, upon which the CVRs' value partially depended, thereby artificially inflating the value of the CVRs.[9] The district court accepted these cases as related.[10]

On June 27, 2014, Defendants moved to dismiss both complaints for failing to state a claim, arguing that the complaints did not allege any materially false or misleading statements, there were no sufficient allegations of scienter, and their statements were protected as forward-looking statements. On January 28, 2015, the district court granted Defendants' motion.

F. The Opinion Below

The district court (Engelmayer, *J.*) held in a thorough and thoughtful opinion that Plaintiffs had failed to allege false or materially misleading statements. *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510 (S.D.N.Y. 2015). With regard to the allegedly false or misleading statements of opinion, the court held, invoking the standard in *Fait v. Regions Financial Corp.*, 655 F.3d 105 (2d Cir. 2011), that Plaintiffs had failed to allege any facts suggesting that

[9] The CVRs are publicly traded on the NASDAQ exchange.

[10] Though each complaint sets out slightly different allegations, we address the complaints together and refer to Plaintiffs collectively.

Defendants "did not genuinely believe what they were saying at the time they said it," and that there similarly had been no showing of objective falsity. 87 F. Supp. 3d at 531–33. The court came to the same conclusion for each group of allegedly false or misleading statements of opinion. *See id.* at 537–47.

The court additionally held that, insofar as it was required, Plaintiffs had failed to adequately allege scienter, saying that "[a]t all relevant times, and without the benefit of hindsight, Sanofi did not have reason to know that its public statements omitted or misrepresented material facts." *Id.* at 545. The court also held that, in any event, Defendants' forward-looking statements were protected by the Private Securities Litigation Reform Act Safe Harbor provision, as they were accompanied by cautionary language and not made with actual knowledge of falsity. *See*, *e.g.*, *id.* at 535–36.[11]

After dismissing Plaintiffs' federal claims, the court declined to exercise its discretionary jurisdiction over Plaintiffs' remaining claims under state blue sky laws. *Id.* at 548. Finally, the court denied Plaintiffs' motion for leave to amend the complaint, noting that the deficiencies in the complaints were substantive and would not likely be cured upon amendment. *Id.* at 548–49. Judgment was entered against Plaintiffs on January 30, 2015. This appeal followed.

DISCUSSION

We review a district court's dismissal of a complaint under Fed. R. Civ. P. 12(b)(6) de novo, "accepting all factual allegations in

[11] The court also discussed materiality with regard to Defendants' statements about the Lemtrada clinical trials, holding that the omissions were not material because there was no credible allegation that disclosure of the FDA's interim, nondispositive feedback would have "significantly altered the total mix of information made available" to investors. *Sanofi*, 87 F. Supp. 3d at 540–41 (internal quotation marks omitted) (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1318 (2011)). Because we affirm on the grounds that Plaintiffs failed to allege materially misleading omissions, we need not confront Plaintiffs' concern that the district court endorsed a bright-line test absolving issuers from any duty to disclose interim FDA feedback.

the complaint as true and drawing all reasonable inferences in the plaintiff's favor." *Fait*, 655 F.3d at 109. The Court must examine the complaint for "facial plausibility," considering whether the "factual content" "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). The Court may also "consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff upon which it relied in bringing the suit." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007).

Plaintiffs' claims under § 10(b) of the Exchange Act (and Rule 10b-5 promulgated thereunder) require a showing of scienter. *Kleinman v. Elan Corp.*, 706 F.3d 145, 152 (2d Cir. 2013).[12] By contrast, Plaintiffs' claims under §§ 11 and 12(a)(2) of the Securities Act do not require a showing of scienter, reliance, or loss causation, and require Plaintiffs to show only that Defendants issued or signed a registration statement containing "an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k(a); *see also Fait*, 655 F.3d at 109. Claims under § 18 of the Exchange Act likewise need not allege scienter. *Ross v. A. H. Robins Co.*, 607 F.2d 545, 556 (2d Cir. 1979).

We see no reason to disturb the conclusions of the district court. However, after the district court's opinion, the Supreme Court decided *Omnicare*, which refined the standard for analyzing whether a statement of opinion is materially misleading. Plaintiffs have urged us to reconsider the district court's ruling in light of *Omnicare*. We do so here, but conclude that even under *Omnicare*'s

[12] Because § 20(a) of the Exchange Act imposes derivative liability on parties controlling persons who commit Exchange Act violations, scienter is also required for Plaintiffs' § 20(a) claim to succeed. *See SEC v. First Jersey Sec., Inc.*, 101 F.3d 1450, 1472 (2d Cir. 1996).

standard, Plaintiffs have failed to allege that Defendants made materially misleading statements of opinion.

A. *Omnicare*

In *Omnicare*, the Supreme Court held that where an investor has alleged that an issuer omitted stating material information and thereby rendered a statement of opinion misleading,

> [t]he 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.

135 S. Ct. at 1332. This holding altered the standard announced by this Court in *Fait*, where we held that "when a plaintiff asserts a claim . . . based upon a belief or opinion alleged to have been communicated by a defendant, liability lies only to the extent the statement was both objectively false and disbelieved by the defendant at the time it was expressed." 655 F.3d at 110 (citing *Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1095–96 (1991)). *Omnicare* affirmed that liability for making a false statement of opinion may lie if either "the speaker did not hold the belief she professed" or "the supporting fact she supplied were untrue." 135 S. Ct. at 1327. But *Omnicare* went on to hold that opinions, though sincerely held and otherwise true as a matter of fact, may nonetheless be actionable if the speaker omits information whose omission makes the statement misleading to a reasonable investor. *Id.* at 1332.

The Supreme Court emphasized that meeting the standard under *Omnicare* "is no small task for an investor," *id.*, and also provided guidance for applying its ruling. The Court noted that a reasonable investor, upon hearing a statement of opinion from an issuer, "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 a time." *Id.* at 1329. The Court provided an example: if an issuer tells investors that "We believe our conduct is lawful," an investor in such a situation "likely expects such an assertion to rest on some meaningful inquiry—rather than, say, on mere intuition." *Id.* at 1328. The core inquiry is whether the omitted facts would "conflict with what a reasonable investor would take from the statement itself." *Id.* at 1329.

The Court, however, cautioned against an overly expansive reading of this standard, noting that "[r]easonable investors understand that opinions sometimes rest on a weighing of competing facts," and adding that "[a] reasonable investor does not expect that *every* fact known to an issuer supports its opinion statement." *Id.* The Court went on to say that a statement of opinion "is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way." *Id.*

The Court also recognized the unique context in which securities claims arise. Acknowledging the formality and legal weight of documents filed with the SEC, the Court noted that "[i]nvestors do not, and are right not to, expect opinions contained in those statements to reflect baseless, off-the-cuff judgments"; "[a]t the same time, an investor reads each statement within such a document . . . in light of all its surrounding text, including hedges, disclaimers, and apparently conflicting information." *Id.* at 1330. The Court further stated that "the investor takes into account the customs and practices of the relevant industry," and instructed that "an omission that renders misleading a statement of opinion when viewed in a vacuum may not do so once that statement is considered, as is appropriate, in a broader frame." *Id.*

B. Allegedly Materially Misleading Statements of Opinion

As the district court recognized, some of the statements at issue are not ones of opinion, and thus *Omnicare* does not impact the

court's analysis with regard to those statements.[13] The district court analyzed three groups of statements of opinion:

(1) Six statements in the Offering Materials related to Sanofi's expectation that the FDA would approve Lemtrada prior to March 31, 2014, the cutoff date for the Approval Milestone;

(2) A subset of statements made after the tender offer regarding the launch of Lemtrada, such as that Defendants were "very satisfied with where the progress is going," they "expect[ed] a decision on Lemtrada by the end of the year," and they were "feeling pretty, pretty relaxed"; and

(3) A subset of statements regarding Lemtrada's clinical trial results, such as that Lemtrada demonstrated "strong and robust treatment effect," the test results "underscore[d] the tremendous promise that Lemtrada holds," and "[w]e are very pleased with the results of the [Phase III] study."

We analyze each group of statements in turn.

1. Expected Timing of FDA Approval

The first set of statements is found exclusively in the Offering Materials. Plaintiffs argue that by failing to disclose the FDA's repeated statements of concern about the use of single-blind studies, statements from Defendants estimating a 90% likelihood of achieving the Approval Milestone and projecting FDA approval in late 2012 were materially misleading.

Two points from *Omnicare* are important here. First, the omitted facts must "conflict with what a reasonable investor would take from the statement itself." 135 S. Ct. at 1329. There is no

[13] Plaintiffs do not argue that the district court incorrectly categorized any statements as opinions.

plausible allegation that the FDA's interim feedback conflicted with any reasonable interpretation of Defendants' statements about FDA approval. Though the FDA had expressed concern about Defendants' testing methodology, it had also stated that any deficiency could be overcome if the results showed an "extremely large effect." The record reflects, and the parties do not dispute, that Lemtrada's treatment effect was, in fact, large. There can be no conflict inferred from a statement of optimism consistent with the FDA's instructions as to the treatment results necessary for approval.

Moreover, the Supreme Court emphasized the need to examine the context of an allegedly misleading opinion, *id.* at 1330, and context is instructive here. Plaintiffs are sophisticated investors, 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. These investors are similarly aware, as the district court recognized, that "[c]ontinuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process." *Sanofi*, 87 F. Supp. 3d at 542 (internal quotation marks omitted) (quoting *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995)). These sophisticated investors, well accustomed to the "customs and practices of the relevant industry," would fully expect that Defendants and the FDA were engaged in a dialogue, as they were here, about the sufficiency of various aspects of the clinical trials and that inherent in the nature of a dialogue are differing views.

That such a dialogue was ongoing did not prevent Defendants from expressing optimism, even exceptional optimism, about the likelihood of drug approval. Furthermore, the Offering Materials themselves made numerous caveats to the reliability of the projections, and a reasonable investor, especially one dealing in a complex financial instrument like the CVRs here, would have considered the statements "in light of all [the] surrounding text, including hedges, disclaimers, and apparently conflicting

information." *Omnicare*, 135 S. Ct. at 1330. While 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.

Thus, fatal to Plaintiffs' case is the absence of any serious conflict between the FDA's interim, albeit repeated, concerns about methodology and Defendants' optimism about FDA approval. As the Supreme Court noted, "a statement of opinion is not misleading just because external facts show the opinion to be incorrect." *Id.* at 1328.

Second, the Supreme Court noted that "[a]n opinion statement, however, is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way." *Id.* at 1329. Plaintiffs' case essentially boils down to an allegation that the statements were misleading for failure to include a fact that would have potentially undermined Defendants' optimistic projections. But *Omnicare* imposes no such disclosure requirements on issuers. Defendants were only tasked with making statements that "fairly align[ed] with the information in the issuer's possession at the time." *Id.* Defendants need not have disclosed the FDA feedback merely because it tended to cut against their projections—Plaintiffs were not entitled to so much information as might have been desired to make their own determination about the likelihood of FDA approval by a particular date. Certainly, Plaintiffs would have been interested in knowing about the FDA feedback, 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.

Counsel for Plaintiffs urged at oral argument that the test is whether Defendants failed to disclose a risk above and beyond the normal risks associated with drug approval. No plain reading of

Omnicare supports this interpretation. Such a test eschews the more taxing question of whether an issuer's statement is misleading, and instead seeks to impose a bright-line disclosure rule, regardless of the nature of the statements actually made by the issuer. But even if *Omnicare* did impose such a standard, Plaintiffs' case would still falter. As counsel acknowledged at oral argument, nowhere in the complaints do Plaintiffs allege that the risks arising out of the FDA feedback were out of the ordinary, or presented a special challenge not of the kind normally confronted by pharmaceutical companies seeking FDA approval for their drugs.

Plaintiffs' argument here is further belied by the fact that the FDA has long made public its preference for double-blind trials, telling pharmaceutical companies that "[t]he double-blind trial is the optimal approach." Guidance on Statistical Principles for Clinical Trials, 63 Fed. Reg. 49583, 49587 (Dep't of Health & Human Servs. Sept. 16, 1998).[14] Defendants admitted they were relying on single-blind trials, and even alluded at times to the desirability of double-blind trials.[15] Sophisticated investors, aware of the FDA's strong preference for double-blind trials, cannot claim surprise when it is revealed that the FDA meant what it said. 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.

Thus, even with the benefit of *Omnicare*'s expanded standard for liability, Plaintiffs have not stated a claim with regard to the statements regarding the likelihood of FDA approval.

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[14] *See also Sanofi*, 87 F. Supp. 3d at 539–40 (citing 21 C.F.R. §§ 314.126(b)(2)(iv), 314.126(b)(5), 352.72(e), 514.117(b)(7), 860.7(f)).

[15] *See* Joint App'x at 685 ("The infusion-related syndrome associated with alemtuzumab precluded double-blinding."); *id.* at 801 ("[M]asking of patients and treating clinicians to treatment assignment was not feasible. Several steps were undertaken to lessen the risk of bias."); *id.* at 807 ("Because both study drugs had adverse effects that precluded double-blinding, . . . clinical data integrity was secured by stringent rater-masking and independent adjudication of relapses.").

2. Timing of Launch of Lemtrada

Plaintiffs' next challenge is to statements made by Defendants relating to the anticipated launch date of Lemtrada. As the district court recognized, these statements fail to support a claim for many of the same reasons as the statements pertaining to FDA approval in the Offering Materials.

First, it can hardly be said that the FDA's critique of Sanofi's testing methodology conflicted with Defendants' statements that they were feeling "relaxed" or "satisfied." Such a generalized statement of subjective optimism arguably does not even "convey facts about how the speaker has formed the opinion." *Omnicare*, 135 S. Ct. at 1328. But whatever the implication of such a statement, 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.

Second, Defendants' statement that they "expect[ed] a decision on Lemtrada by the end of the year" did not conflict with the information available to them at the time. On the contrary, Defendants were correct about the proposed timing—Defendants announced on December 30, 2013 that the FDA had rejected Lemtrada. Defendants' statement is about timing, not about the likelihood of approval. Further, as set forth above, Defendants' optimism about the approval of Lemtrada was not in conflict with the FDA's comments, which had indicated that Lemtrada could be approved if it demonstrated an "extremely large effect."

For these reasons, Plaintiffs' allegations with regard to statements made about the prospective launch of Lemtrada fail to support a claim.

3. Lemtrada's Trial Results

The final set of opinion statements identified by Plaintiffs as misleading are Defendants' statements that Lemtrada demonstrated

a "strong and robust treatment effect," and that "the data are nothing short of stunning."

Plaintiffs fail, in the first instance, to show a relationship between the FDA's critical feedback and Defendants' statements touting the results of the Lemtrada trials. Sanofi is a global pharmaceutical company operating in a $14 billion market—by early 2014, Lemtrada had already been approved for distribution in the European Union, Canada, Australia, Mexico, and Brazil, totaling at least 30 countries, based on Lemtrada's exceptional clinical results. Plaintiffs' argument that Sanofi had no reason to comment on Lemtrada's Phase III success except to build investor anticipation about FDA approval has no merit—Sanofi had an interest in building global interest in Lemtrada. Statements 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.

In addition to the lack of any rational connection between Defendants' statements about the general effectiveness of Lemtrada and the FDA's methodological feedback, Plaintiffs fail to demonstrate any conflict between the two. The Supreme Court's example of an issuer stating a belief that its conduct is lawful is particularly instructive. Such a statement does not imply that the issuer's conduct is, in fact, lawful, but only that the issuer has conducted a meaningful inquiry and has a reasonable basis upon which to make such an assertion. Here, too, 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 held that view, the statements did not mislead in a manner that is actionable.

At bottom, Plaintiffs' allegations regarding Defendants' stated opinion about the Lemtrada trial results are little more than a dispute about the proper interpretation of data, a dispute this Court rejected as a basis for liability in *Kleinman*. 706 F.3d at 154.

Defendants' statements were not misleading simply because the FDA disagreed with Defendants' interpretation of the data; an issuer is not liable merely because it "knows, but fails to disclose, some fact cutting the other way." *Omnicare*, 135 S. Ct. at 1329.

Nowhere in the complaints do Plaintiffs even allege that Defendants' interpretation of the data was irrational or unreasonable, and such an allegation would have little merit anyway, as the FDA eventually accepted Lemtrada without further clinical trials. Again, as *Omnicare* counsels, investors account for the "customs and practices of the relevant industry," and statements must be considered "as is appropriate, in a broader frame." *Id.* at 1330. Reasonable investors understand that dialogue with the FDA is an integral part of the drug approval process, and no sophisticated investor familiar with standard FDA practice would expect that every view of the data taken by Defendants was shared by the FDA. In the absence of plausible allegations showing a conflict between Defendants' statements and the FDA feedback, Plaintiffs' claims here fail as well.

CONCLUSION

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. As *Omnicare* instructs, issuers need not disclose a piece of information merely because it cuts against their projections. Given the sophistication of the investors here, the FDA's public preference for double-blind studies, and the absence of a conflict between Defendants' statements and the FDA's comments, we conclude that no reasonable investor would have been misled by Defendants' optimistic statements regarding the approval and launch of Lemtrada. The judgment of the District Court is affirmed.