11-3706-cv
Kleinman v. Elan Corp., plc

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2011

(Argued: April 19, 2012 Decided: February 1, 2013)

Docket No. 11-3706-cv

GARY W. KLEINMAN, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED,

Plaintiff-Appellant,

v.

ELAN CORPORATION, PLC, PFIZER, INC., AS SUCCESSOR-IN-INTEREST TO WYETH, INC., G. KELLY MARTIN, LARS EKMAN,

Defendants-Appellees.[1]

Before: JACOBS, *Chief Judge*, KEARSE and HALL, *Circuit Judges*.

Plaintiff appeals from a judgment of the district court (Hellerstein, *J.*) dismissing his amended complaint in this putative class action securities litigation. Defendants, including two pharmaceutical companies jointly developing an Alzheimer's drug called bapineuzumab, are

[1] The Clerk of Court is directed to amend the official caption in this case to conform to the listing of the parties above.

alleged to have issued a misleading press release describing the preliminary clinical trial results for bapineuzumab, which omitted several facts that rendered the press release false and misleading in contravention of Section 10(b) of the Securities Exchange Act of 1934. The facts omitted were disclosed six weeks later by the companies when they released the full results of the clinical trial. The United States District Court for the Southern District of New York dismissed the amended complaint on the ground that it failed to allege a false or misleading statement. We agree with the district court and hold that nothing omitted from the press release rendered it false or misleading to a reasonable investor.

AFFIRMED.

BRIAN C. KERR (David A.P. Brower, *on the brief*), Brower Piven, New York, New York, *for Plaintiff-Appellant Gary W. Kleinman*.

JACULIN AARON (Stuart J. Baskin, *on the brief*), Shearman & Sterling LLP, New York, New York, *for Defendants-Appellees Elan Corporation, plc, G. Kelly Martin, and Lars Ekman*.

JOHN K. VILLA (George A. Borden, David R. Riskin, *on the brief*), Williams & Connolly LLP, Washington, D.C., *for Defendant-Appellee Pfizer, Inc.*

HALL, Circuit Judge:

Plaintiff-Appellant Gary Kleinman ("Kleinman") appeals from the judgment of the district court (Hellerstein, *J.*) dismissing Kleinman's amended complaint with prejudice for failure to state a cause of action under Fed. R. Civ. P. 12(b)(6) and denying leave to amend.

Kleinman alleges that Defendants-Appellees Elan Corporation, plc ("Elan"), Pfizer, Inc. ("Pfizer") (as successor-in-interest to Wyeth, Inc. ("Wyeth")), G. Kelly Martin, and Lars Ekman (collectively, the "Defendants") violated Section 10(b) and Section 20(a) of the Securities Exchange Act of 1934 by issuing a misleading press release on June 17, 2008 (the "June press release") concerning the results of a clinical trial for a drug called bapineuzumab (then under joint development by Elan and Wyeth). Kleinman brought this putative class action on behalf of all those who purchased Elan's call options during the Class Period—June 17, 2008, to July 29, 2008. He alleges the press release omitted several facts that, in his view, were necessary to prevent the press release from being misleadingly optimistic. We write to explain how, in the context of the full presentation of the details surrounding the study of the drug, nothing omitted from the June press release rendered it false or misleading to a reasonable investor. Moreover, we hold that Kleinman offered insufficient additional allegations to cure this deficiency. For the reasons that follow, we affirm the judgment of the district court.

Background

We draw the following facts from Kleinman's amended complaint, written instruments attached to it, and statements or documents incorporated by reference. *See Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152 (2d Cir. 2002).

Elan is a neuroscience-based biotech company with operations in New York, California, and Pennsylvania. Elan's American Depositary Receipts ("ADRs") are traded on the New York Stock Exchange and its publicly traded call options are derivative of, and trade in tandem with, Elan's ADRs. Wyeth was a Delaware Corporation before its acquisition by Pfizer in October

2009. During the relevant timeframe, Wyeth and Elan had a joint project aimed at researching, developing, and eventually marketing drugs designed to treat mild to moderate Alzheimer's.

Estimates show that more than five million Americans currently suffer from Alzheimer's, and that count is expected to grow as the population ages. The current panoply of drugs on the market treat only the symptoms of Alzheimer's—loss of cognition and function—and for only a short time. Elan and Wyeth developed bapineuzumab, which was designed to clear and prevent the toxic beta-amyloid plaques that build up in the brain. Some scientists believe these plaques are the main cause of the symptoms of the disease.

Before presentation of a new drug to the FDA, pharmaceutical companies are required to engage in three phases of clinical trials, with each phase growing in complexity and size, before ultimate presentation to the FDA.[2] Phase 1 consists of a closely monitored, relatively small study (twenty to eighty volunteers) to determine the safety of the drug and, if possible, early evidence of effectiveness. *See* 21 C.F.R. § 312.21(a). Phase 2 involves further clinical research and study to determine the drug's efficacy and any "common short-term side effects and risks associated with the drug." *Id.* § 312.21(b). Finally, Phase 3 clinical trials "are performed after preliminary evidence suggesting effectiveness of the drug has been obtained" and usually include "several hundred to several thousand subjects." *Id.* § 312.21(c).

[2] According to the FDA's web site, sponsors "must show the FDA results of preclinical testing in laboratory animals and what they propose to do for human testing." These results, along with the proposed protocols for testing on humans, are "reviewed by the FDA and a local institutional review board" that decide if human testing, beginning with Phase 1, may proceed. *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm (last visited on January 29, 2013).

After completing a successful Phase 1 trial for bapineuzumab, Wyeth and Elan designed the Phase 2 study to measure bapineuzumab's overall effectiveness and safety. That study consisted of a 240-patient, randomized, double-blind, placebo-controlled study.[3] Patients enrolled in Phase 2 on a rolling basis, so although the trial began in April 2005, it was not complete until April 2008. Bapineuzumab's effectiveness was measured by common diagnostics that test cognition and dementia. The two primary tests were the ADAS-Cog[4] and the Disability Assessment Scale for Dementia ("DAD"). The Phase 2 trial, as planned, used a standard model with certain assumptions. Phase 2 also predesignated certain goals—endpoints—by which success would be measured based on how patients performed at the end of the study using the ADAS-Cog and DAD tests. Phase 2 included, as additional tests, changes in spinal fluid and brain volume. Patients' progress was also examined using the Neuropsychological Test Battery, the Clinical Dementia Rating Sum of Boxes, and the Mini-Mental State Examination ("MMSE").

Having taken an interim look at the Phase 2 data in May 2007, Elan and Wyeth announced that they would commence Phase 3 for bapineuzumab later that year. The Phase 3 trials involve approximately 4,000 patients and include four randomized, double-blind studies across two subgroup populations.

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[3] About ninety-five percent of patients also took (in addition to either bapineuzumab or the placebo) certain "background therapies" representing the best standard of care currently available for Alzheimer's disease. Under the randomization technique employed, for every eight patients taking bapineuzumab, seven took the placebo.

[4] The ADAS-Cog test "is the most widely recognized and utilized measure of cognition in Alzheimer's drug trials." Am. Compl. ¶ 32 n.3 (internal quotation marks omitted).

In April 2008, Elan announced that while Phase 2 remained ongoing, it (along with Wyeth) expected to present a "top line finding some time around mid-year [2008]" and a "full data review" of Phase 2 at the International Conference on Alzheimer's Disease ("ICAD") in Chicago on July 29, 2008. In line with that plan, Wyeth and Elan jointly issued the June press release, informing the public of the top-line results for Phase 2 in advance of the ICAD. That press release forms the basis of this litigation.

The June press release stated that although "[t]he study did not attain statistical significance on the primary efficacy endpoints in the overall study population[, p]ost-hoc analyses did show statistically significant and clinically meaningful benefits in important subgroups." J.A. 237. The main headline of the June press release stated that Phase 2 resulted in "Encouraging Top-line Results." *Id.* A subheadline also announced that "Primary Efficacy Endpoints In Overall Study Population [Were] Not Statistically Significant." The positive results, the June press release stated, were seen in a subgroup of the Alzheimer's population: non-carriers of the Apolipoprotein ("ApoE4") gene. *Id.* Specifically, with regard to

> non-carriers of the [ApoE4] allele, estimated in the literature to be from 40 to 70 percent of the Alzheimer's disease population, posthoc analyses showed statistically significant and clinically meaningful benefits associated with bapineuzumab treatment on several key efficacy endpoints, including the Alzheimer's Disease Assessment Scale (ADAS-cog), the Neuropsychological Test Battery (NTB), the [MMSE] and the Clinical Dementia Rating - Sum of Boxes (CDR-SB). A favorable directional change was seen on the [DAD], although this was not statistically significant.

Id. Regarding ApoE4 carriers, the June press release noted that a post-hoc analysis similar to the one used for the non-carrier group yielded "no clinical benefits or statistically significant effects"; however, "favorable directional changes were observed on a number of endpoints." *Id.*

With respect to the safety findings, the June press release stated that "adverse events were very common in both placebo and bapineuzumab-treated patients[,]" with ApoE4 carriers experiencing more frequent adverse effects when taking bapineuzumab as compared to those taking the placebo. J.A. 237-38. "In addition, vasogenic edema[5] was reported in the treated population with an increased frequency in carriers and at higher doses." J.A. 238. However, Wyeth and Elan "believe[d] that the overall safety findings from this Phase 2 trial support their prior decision to move to Phase 3 studies." *Id.*

Commenting on the overall results, Defendant Kelly Martin, Elan's CEO, remarked in the press release that Elan and Wyeth were encouraged by the findings and that "[t]hese results clinically support [their] decision to move into Phase 3." *Id.* The press release noted that the "findings reflect preliminary analyses of the Phase 2 data," and also that the Phase 2 trial had "imbalances in patient numbers and characteristics at baseline between subgroups studied that may or may not have affected" the results. *Id.* "Further analysis" was contemplated "in advance of a planned scientific presentation of detailed results of this study at the [ICAD] in Chicago, July 29, 2008." *Id.* A disclaimer read that "these statements are subject to the risk that further analyses of the Phase 2 data may lead to different (including less favorable) interpretations of the data than the preliminary analyses conducted to date and/or may identify important implications of the Phase 2 data that are not reflected in these statements." J.A. 239.

According to Kleinman's amended complaint, on the heels of the June press release, the price of Elan's ADRs rose from $27.11 to $30.00 in a single day. "By July 10, 2008, Elan ADRs

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[5] Vasogenic edema is a buildup of extracellular fluid in the brain due to increased permeability of the capillaries.

were trading at over $36," which was a nearly $9 increase in the price the ADRs traded at before the Class Period began on June 17, 2008. Am. Compl. ¶ 39.

Six weeks later, Elan and Wyeth presented the entire Phase 2 results at the ICAD as planned. In addition to making a full presentation of the findings, Defendants issued another press release that included the detailed results to which the June (and April) press release had alluded. Kleinman contends that the complete detailed results presented at the ICAD demonstrated that the June press release was false and misleading due to a number of omissions in that release. The alleged omissions can be summarized as follows: higher doses did not correlate with better results; the control group was losing cognitive function at a greater rate than normal, thus exaggerating any evidence of effectiveness in the group taking bapineuzumab; the positive results were the result of backward-looking, post-hoc analysis that identified trends not in the original modeling; there was no short-term effect for those taking bapineuzumab; one test used by Defendants showed no significant difference between the bapineuzumab group and the placebo group; there were a host of serious adverse consequences and three deaths; and the trial

failed by a "large margin."[6] On July 30, 2008, the day after the full release, the price of Elan's

[6] Specifically, Kleinman's amended complaint alleges that the July release and presentation disclosed the following information (which was omitted from the June press release):

- The Phase 2 Trial showed no dose response, *i.e.*, taking higher doses of bapineuzumab did not correlate with greater improvement in symptoms;

- Among ApoE4 non-carriers in the Phase 2 Trial, the group in which some evidence of bapineuzumab's efficacy was purportedly found, the patients taking [the] placebo showed a larger than expected cognitive decline. Specifically, the ADAS-Cog scores of this group of patients (21 in all) dropped 11 points over the 78-week period of the trial, compared with a 7 point loss of cognition by placebo patients in a much larger trial recorded publicly, and lower rates in other 18-month trials, which suggests that the condition of the placebo patients may have been more severe than the norm in such trials;

- The post hoc analysis reported in the June press release was done by changing the statistical modeling from linear to curvilinear;

- There was little or no short-term effect on patients taking bapineuzumab. Patients that showed improvement generally did not do so until well into the study period;

- Using the MMSE, which was not a primary test but one which Defendants characterized as a "key measure of cognitive function," there was no significant signal that bapineuzumab worked better than the placebo in Phase 2;

- Nearly 10 percent of patients taking bapineuzumab in Phase 2 developed vasogenic edema, while zero patients developed it in the placebo group. Additionally, three of the bapineuzumab patients developed micro bleeds in the their brains;

- Three deaths were reported in the group taking bapineuzumab compared to none in the placebo group;

- There were nine additional adverse effects that occurred two or more times as often in patients taking bapineuzumab and in more than 5% of such patients, including back pain, anxiety, vomiting, hypertension, weight loss, paranoia, skin laceration, gait disturbance, and muscle

ADRs dropped by forty-two percent.

Kleinman commenced this action on behalf of all purchasers of Elan call options between June 17, 2008, and July 29, 2008, the Class Period.[7] Kleinman alleges the Defendants' misrepresentations and omissions in the June press release violated Section 10(b) and Rule 10b-5 of the Exchange Act. Defendants Kelly Martin and Lars Ekman allegedly violated Section 20(a) of the Exchange Act because they had direct and supervisory involvement in the day-to-day operations of Elan, and, therefore, are liable as controlling persons.

In an oral ruling, during oral argument, the district court granted a motion to dismiss this case and related ones.[8] Other courts in the Northern District of California and the District of New Jersey have also dismissed similar securities actions arising from the June press release.[9]

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spasms; and

- Bapineuzumab not only failed to show a statistically significant benefit compared to placebo per the original trial protocol, but failed to do so by a large margin.

Am. Compl. ¶ 54.

[7] After the Supreme Court decided *Morrison v. National Australia Bank, Ltd.*, 130 S. Ct. 2869 (2010), the district court requested that Kleinman amend his complaint to ensure that only claims based on call options traded on American exchanges were being pursued.

[8] The related cases, which involved the same allegations as Kleinman's, were consolidated in *In re Elan Corporation Securities Litigation*, No.1:08-cv-8761-AKH. Kleinman's action was kept separate because he traded in call options instead of common shares. The district court dismissed the consolidated case for the same reason it dismissed this case: failure to plausibly allege false or misleading statements.

[9] *See Philco Invs., Ltd. v. Martin*, No. C 10-2785, 2011 WL 500694 (N.D. Cal. Feb. 9, 2011); *Sec. Police & Fire Prof'ls of Am. Ret. Fund v. Pfizer, Inc.*, No. 10-cv-3105, 2012 WL 458431 (D.N.J. Feb. 10, 2012).

Both of those courts have determined that the June press release was not misleading. *See Sec. Police & Fire*, 2012 WL 458431, at *7; *Philco*, 2011 WL 500694, at *7-9. We join them.

The district court invited Kleinman to submit supplementary papers, offering any new allegations that could cure the deficiencies identified by the district court. In response, Kleinman submitted that if leave to amend were granted, he would add the following allegations to the complaint:

- Because the Phase 2 study was not designed to test the effects of Bapineuzumab in the subgroup of patients who do not carry the ApoE4 allele ("non-carriers"), the small number and composition of Phase 2 patients in that subgroup did not generate meaningful data from which to draw conclusions about the efficacy of Bapineuzumab;

- More specifically, at the time the Phase 2 study began, the non-carriers receiving a placebo, on average, had Alzheimer's for six months longer than the non-carriers receiving Bapineuzumab; and

- Further, at the time the Phase 2 study began, the non-carriers receiving a placebo, on average, had a much lower rate of functionality than the non-carriers receiving Bapineuzumab.

In re Elan Corp., No. 1:08-cv-8761-AKH, Doc. No. 102. The district court issued a summary order denying leave to amend, stating that the new allegations "do nothing to disturb the decision" it reached at oral argument. *Kleinman v. Elan Corp.*, No. 1:10-cv-5630-AKH, Dist. Ct. Doc. No. 33. Kleinman appealed.

Discussion

We review *de novo* a district court's dismissal of a complaint pursuant to Fed. R. Civ. P. 12(b)(6), "accepting all factual allegations in the complaint and drawing all reasonable inferences in the plaintiff's favor." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98

(2d Cir. 2007). We 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 and upon which it relied in bringing the suit." *Id.* "To survive dismissal, the plaintiff must provide the grounds upon which his claim rests through factual allegations sufficient 'to raise a right to relief above the speculative level.'" *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

For a violation of Section 10(b) and Rule 10b-5, a plaintiff must plead a plausible claim, *Ashcroft v. Iqbal*, 556 U.S. 662, 680 (2009), that includes the action's basic elements: "(1) a material misrepresentation (or omission); (2) scienter, *i.e.*, a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance . . . ; (5) economic loss; and (6) loss causation[.]" *Dura Pharm., Inc v. Broudo*, 544 U.S. 336, 341-42 (2005) (citations and quotation marks omitted). A securities fraud complaint must also meet the heightened pleading standards of Fed. R. Civ. P. 9(b) and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Pub. L. No. 104-67, 109 Stat. 737 (codified as amended in scattered sections of Title 15 U.S.C.). The "circumstances constituting fraud" must be "state[d] with particularity." Fed. R. Civ. P. 9(b). Under the PSLRA, the pleaded facts must give "rise to a strong inference" of fraudulent intent. 15 U.S.C. § 78u-4(b)(2)(A). Untrue statements must be identified and, if applicable, so must the omitted facts that are "necessary in order to make the statements made, in the light of the circumstances in which they were made, not misleading." *Id.* § 78u-4(b)(1)(B). "[T]he reason or reasons why the statement is misleading" must also be pleaded. *Id.* We focus

our analysis here on the first element: whether Kleinman has alleged an untrue statement or a cognizable omission.[10]

Kleinman's amended complaint alleges that Defendants knowingly failed to disclose the full magnitude of overall negative Phase 2 trial results and duped him and other investors with the overly optimistic June press release. Most if not all of his argument centers on omissions—statements he believes were necessary to make the June release not misleading. Yet even when viewed in the light most favorable to him, Kleinman's allegations do not survive scrutiny and fail as a matter of law.

"[I]t bears emphasis that § 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1321 (2011). "Disclosure of an item of information is not required . . . simply because it may be relevant or of interest to a reasonable investor." *Resnik v. Swartz*, 303 F.3d 147, 154 (2d Cir. 2002). "Disclosure is required . . . only when necessary 'to make statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx*, 131 S. Ct. at 1321 (ellipsis omitted) (quoting 17 C.F.R. § 240.10b-5(b)); *see also In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 267 (2d Cir. 1993) (discussing how omissions may be actionable if the corporation has a duty to disclose, which depends on the context).

With regard to the statements that are actually made, "veracity of a statement or omission is measured not by its literal truth, but by its ability to accurately inform rather than mislead prospective buyers." *Operating Local 649 Annuity Trust Fund v. Smith Barney Fund Mgmt.*

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[10] Because we agree with the district court that none of the omissions alleged makes the June press release misleading, we do not reach Defendants' argument that the amended complaint fails to allege facts supporting a strong inference of scienter.

LLC, 595 F.3d 86, 92 (2d Cir. 2010). Statements of literal truth "can become, through their context and manner of presentation, devices which mislead investors." *McMahan & Co. v. Wherehouse Entm't, Inc.*, 900 F.2d 576, 579 (2d Cir. 1990). "Even a statement which is literally true, if susceptible to quite another interpretation by the reasonable investor[,] may properly be considered a material misrepresentation." *Id.* (internal citations, ellipses, and quotation marks omitted).

Kleinman's amended complaint does not allege that anything in the June press release was literally false. On appeal, he argues that the headline "Encouraging Top-line Results" was itself an affirmative misstatement because top-line results, by definition, equate to the entire study population, which failed to achieve efficacy endpoints. But Kleinman does not identify the headline in his Amended Complaint as misleading; this alone falls short of the heightened pleading standard of the PSLRA. *See* 15 U.S.C. § 78u-4(b)(1); *Wright v. Ernst & Young LLP*, 152 F.3d 169, 178 (2d Cir. 1998) (explaining that a party may not amend pleadings through a brief). In any event, there was no actionable misstatement. The June press release, while referring to top-line results, also refers to "encouraging preliminary findings" including that statistically significant results were found in a subgroup that may represent forty to seventy percent of the Alzheimer's population. It also disclosed that the "overall study population" did not attain statistically significant results based on the primary endpoints. Thus, even if Kleinman's definition of "top-line results" is correct, given the context of the statements, no reasonable investor could have understood the headline to mean anything other than the positive subgroup results.

We have also held that words like "encouraging" are the type of "expressions of puffery and corporate optimism" that do not generally "give rise to securities violations." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004). Subjective statements can be actionable only if the "defendant's opinions were both false and not honestly believed when they were made." *Fait v. Regions Fin. Corp.*, 655 F.3d 105, 113 (2d Cir. 2011). At the time the statement was made, Elan and Wyeth had moved on to Phase 3 of the clinical trials—a step that can only be taken after there have been positive Phase 2 results sufficient to satisfy both business and regulatory interests. *See* 21 C.F.R. § 312.21(c). We thus have no reason to think (nor is one is alleged) that Defendants' statements were not honestly believed.

As for the allegations found in Kleinman's Amended Complaint, none of what was omitted was necessary to make the June press release not misleading. Kleinman alleges that the June press release omitted the fact that those taking higher doses of bapineuzumab did not show a "dose response." Nothing in that June press release, however, discussed whether there was a dose response or whether one was expected. The absence of a dose response "may be relevant or of interest to a reasonable investor," but that circumstance alone does not necessitate its disclosure. *Resnik*, 303 F.3d at 154. We also observe that the Credit Suisse report, relied upon by Kleinman in his amended complaint to demonstrate how researchers normally measure a dose response, states that the Phase 2 trial contained "too few patients . . . to make meaningful comparisons between individual doses." Credit Suisse, *Bapineuzumab data asks questions - we still see an opportunity*, at 2 (July 31, 2008). Thus, even some of Kleinman's allegations contradict his argument that a dose response would be of import here.

Kleinman also complains that the June press release omitted that the control group for the non-carriers of ApoE4 showed a larger than expected cognitive decline, which exaggerated any efficacy results. This characterization of the control group, however, is only Kleinman's view and is not alleged to be a mischaracterization corrected by the July presentation and press release. The July press release and presentation also did not disclose that the decline in that particular subgroup was larger than expected. Researchers at the July presentation, in fact, stated that they disagreed with the proposition that the decline in the control group was atypical. Defendants are not required to adopt Kleinman's view regarding the degree of difference or its effect on the results. *See DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1225 (S.D. Cal. 2001). Kleinman (and others) may take issue with Defendants' researchers and scientists, but where a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement. *See In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966-67 (D. Md. 1995) (discussing that a reasonably held opinion that is later proven wrong is, nevertheless, not actionable). Kleinman does not challenge the statements made at the July presentation regarding the control group differences. Thus we have no basis to believe that the researchers and scientists' statements regarding the control group were unreasonable. We also observe that the June press release disclosed that there were "imbalances in . . . characteristics at baseline between subgroups" in Phase 2. To the extent Defendants chose to speak about subgroup characteristics, they spoke reasonably.

Kleinman argues that the June press release did not disclose that the post-hoc analysis was curvilinear. The press release simply stated that a post-hoc analysis was used without specifying the methodology; nothing about this is misleading. Kleinman's real complaint is that

Defendants were able to tout positive results only because they deviated from the established protocol (which called for a linear analysis) and changed the metrics by which data was analyzed. At bottom, Kleinman simply has a problem with using post-hoc analysis as a methodology in pharmaceutical studies. Kleinman cites commentators who liken post-hoc analysis to moving the goalposts or shooting an arrow into the wall and then drawing a target around it. Nonetheless, when it is clear that a post-hoc analysis is being used, it is understood that those results are less significant and should therefore have less impact on investors. Our job is not to evaluate the use of post-hoc analysis generally in the scientific community; the FDA has already done so.[11] Instead, we look to see whether the statements made were misleading or rendered misleading due to an omission. The June press release accurately disclosed that the only positive results from the entirety of the Phase 2 study stemmed from the use of post-hoc analysis.

Kleinman's remaining allegations warrant little discussion. Defendants were not obligated to disclose that bapineuzumab patients showed little or no improvement in the short term because nothing in the June press release suggested that bapineuzumab had a short-term effect (nor was there a previously identified corporate statement to the contrary that created a duty to correct it). *See SEC v. Manor Nursing Ctrs., Inc.*, 458 F.2d 1082, 1095 (2d Cir. 1972). Regarding the incidence rates of vasogenic edema, side effects, and three reported deaths, the June press release disclosed that ApoE4 carriers were more frequently treated for vasogenic edema, that the same group treated with bapineuzumab experienced more "serious adverse

[11] Referring to post-hoc analysis as "exploratory," the FDA has cautioned that "[a]ny conclusion of treatment efficacy (or lack thereof) or safety based solely on exploratory subgroup analyses is unlikely to be accepted." FDA Center for Drug Evaluation and Research, E9 Statistical Principles for Clinical Trials, 63 Fed. Reg. 49583, 49595 (Sept. 16, 1998).

events" than those taking the placebo, and the July presentation disclosed that none of the deaths that occurred in the bapineuzumab group have ever been linked to the drug. None of these purported omissions, therefore, renders the June press release false or misleading. The July statement that, based on the MMSE, the *total population* failed to show statistical significant differences between those taking bapineuzumab and those taking the placebo is not at odds with the statement in the June press release that there were statistically significant differences *for a subgroup* of those taking bapineuzumab (when measured using post-hoc analysis and the MMSE). Nor are Defendants required to adopt (and disclose) Kleinman's view that Phase 2 failed by a "large margin"; Defendants disclosed in the June press release that the Phase 2 results "did not attain statistical significance." J.A. 237.

Kleinman points to the forty-two percent drop in the price of Elan ADRs on July 30, 2008, as evidence of falsity. Presumably he is arguing that had the June press release been more candid, the price would not have dropped so precipitously. Kleinman cites no authority for the proposition that market reaction is a gauge for falsity—and we have found none. There are a host of problems with Kleinman's argument. A drop in stock price, if relevant, tends to establish materiality, *i.e.*, whether reasonable investors would consider the information "to be significant or to have altered the total mix of information affecting their investment decisions." *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 166 (2d Cir. 2000). The lack of a drop in stock prices on the heels of the June press release could be attributable to other positive news about Elan that circulated at that time.[12] Or it could be that investors were awaiting the full test results before

[12] Elan experienced favorable results (and made several public statements regarding those results) related to its then best-selling drug Tysabri during the same time Elan's ADRs are alleged to have spiked based on the June press release. *See* Credit Suisse, *Bapineuzumab data asks questions - we still see an opportunity*, at 6 (July 31, 2008) (quoted in amended complaint ¶

deciding whether or not to invest in Elan.[13] In addition, the vast potential upside for a successful Alzheimer's drug could well cause an outsized upward spike in stock price even on guarded and hedged Phase II results. In the absence of a single misleading statement to which Kleinman can point, we decline to venture further into this argument. *See Silver v. H&R Block, Inc.*, 105 F.3d 394, 397 (8th Cir. 1997) (declining to infer that allegedly material statements were false "from the movement of the stock price alone . . . given the abundance of market variables").

None of the cases relied upon by Kleinman assist his argument. This is not an example of positive predictions made without qualification when the company withheld material information, as in *Goldman v. Belden*, 754 F.2d 1059, 1069 (2d Cir. 1985). Defendants' positive statements came with the very "note of caution" that did not accompany the misstatements in *Goldman*. *Id.* at 1068. Nor is this situation as in *Caiola v. Citibank, N.A.*, 295 F.3d 312, 330 (2d Cir. 2002), where the defendant was not under an obligation to disclose its hedging practices, but it nevertheless offered affirmative "false assurances" regarding the same. There are no actionable affirmative false statements in this case.

Defendants in this action issued a press release in June that stated in general terms what eventually came out at the ICAD in July. The June press release told investors like Kleinman that Phase 2 for bapineuzumab failed to achieve its primary endpoints. It also disclosed the

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61); *Philco*, 2011 WL 500694, at *3-4.

[13] In fact, Kleinman and other plaintiffs' allegations support this conclusion. *See* Cowen & Co., *Bapineuzumab Could Be a Breakthrough . . . But Several Hurdles Remain* (July 8, 2008) (analyst report cited in Kleinman's Amended Complaint ¶ 45 stating that "Phase II Data Presentation Will Be A Stock-Moving Event"); Natixis Bleichroeder Inc., *ELN: Crohn's Is Nice, But Focus on Bapineuzumab* (July 31, 2007) (analyst report cited in consolidated action stating that "[m]any investors have stated that they will need to wait until the data [are available] to make a decision on whether to be involved in Elan").

positive subgroup results that were discovered as a result of post-hoc analysis. These results, according to the June press release, supported the decision to forge ahead into Phase 3 clinical trials. It cautioned that "imbalances in patient numbers and characteristics at baseline between subgroups studied that may or may not have affected" the results. "Further analysis" was contemplated "in advance of a planned scientific presentation of the detailed results of this study at" the ICAD in Chicago approximately six weeks later. J.A. 238 The June press release disclaimed that the results were final; instead it stated that the statements in the press release were "subject to the risk that further analyses of the Phase 2 data may lead to different (including less favorable) interpretations of the data than the preliminary analyses conducted to date." J.A. 239. Defendants revealed nothing in the July press release or presentation at ICAD that rendered the June press release false or misleading to a reasonable investor. For these reasons, we affirm the district court's dismissal of the amended complaint with prejudice.[14]

We also agree with the district court's decision not to grant leave to amend. Kleinman is correct that district courts should generally give a plaintiff an opportunity to amend. *Luce v. Edelstein*, 802 F.2d 49, 56 (2d Cir. 1986). The district court allowed Kleinman to set forth in a memorandum what new allegations he would add. The new allegations proffered by Kleinman tend to show that the control group of ApoE4 non-carriers was too small and worse off than those treated with bapineuzumab. Kleinman's amended complaint, however, already made substantially the same allegations, which we and the district court have rejected. We therefore affirm the district court's denial of leave to amend.

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[14] Because Kleinman's Section 20(a) claims require a predicate violation of the Exchange Act and we have concluded there was none, the district court was correct to dismiss Kleinman's Section 20(a) claims. *See ATSI Commc'ns, Inc.*, 493 F.3d at 108.

Conclusion

We have examined Kleinman's remaining arguments and find them to be without merit. For the foregoing reasons, the judgment of the district court dismissing Kleinman's amended complaint with prejudice and denying leave to amend is affirmed.