UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	SACV 15-00865 AG (JCGx)	Date	October 5, 2018
Title	HSINGCHING HSU v. PUMA BIOTECHNOLOGY, INC. ET AL.		

Present: The Honorable	ANDREW J. GUILFORD	
Lisa Bredahl	Not Present	
Deputy Clerk	Court Reporter / Recorder	Tape No.
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:	

Proceedings: [IN CHAMBERS] ORDER RE MOTIONS FOR SUMMARY JUDGMENT

This is a securities class action. A certified class of plaintiffs, led by Norfolk County Council, assert claims against Defendant Puma Biotechnology for misleading investors about the effectiveness of a breast cancer treatment drug developed by Puma. Plaintiffs also sued Defendant Alan H. Auerbach (Puma's CEO) and Defendant Charles R. Eyler (Puma's senior vice president of finance and administration). Norfolk County Council now moves for partial summary judgment on some aspects of its class claims. (Dkt. No. 367.) Because Norfolk represents a class, the Court will refer to "Plaintiffs" throughout this order. Defendants also move for summary judgment. (Dkt. No. 372.)

The Court GRANTS in part Plaintiffs' motion for partial summary judgment. (Dkt. No. 367.) The Court GRANTS in part Defendants' motion for summary judgment. (Dkt. No. 372.)

1. BRIEF BACKGROUND

Puma owns the rights to a breast cancer treatment drug, neratinib (also called Nerlynx). At bottom, this case is about whether Defendants misrepresented neratinib's safety and effectiveness in a July 2014 investor call. The main subject of the investor call was neratinib's ExteNET trial—a large-scale human trial of the drug's ability to prevent a certain type of

breast cancer from coming back after surgery.

In a press release issued the same day as the investor call, Puma announced the results of the trial. (Dkt. No. 369-5.) The press release explained that the "primary endpoint of the trial was disease free survival (DFS)." (*Id.* at 2.) According to the release, "The results of the trial demonstrated that treatment with neratinib resulted in a 33% improvement in disease free survival versus placebo." (*Id.*) Puma explained that, based on the trial's results, it "plan[ned] to file for regulatory approval of neratinib . . . in the first half of 2015." (*Id.*) The company announced that it would present the full results of the trial at "a future scientific meeting," but would host an investor conference call concerning the trial the same day as the press release. (*Id.*)

On the investor call, Plaintiffs contend Puma's CEO, Alan Auerbach, made various misrepresentations about the ExteNET trial. Specifically, Plaintiffs' securities fraud claims rely on the following four statements:

> *DFS Absolute Rates*. An investment analyst on the call asked Auerbach if "the DFS is probably around mid to high 80s, around 86% or so in" those members of the ExteNET trial taking a placebo rather than neratinib. (Dkt. No. 369-6 at 6.) Auerbach said he "would be comfortable with that number." (*Id.*) The same investor asked Auerbach if it was reasonable that "one would imagine" that the neratinib patients' DFS was "around 90% or 91%." (*Id.*) Auerbach confirmed that statement, reiterating that the study had revealed "a 33% improvement in DFS." (*Id.*) Plaintiffs contend these statements were at least misleading because the actual DFS numbers were 91.6% in the placebo patients and 93.9% in the neratinib patients, a closer spread than the 86% to 90-91% revealed on the call.
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> *Kaplan-Meier Curves*. Another investment analyst asked Auerbach about certain graphical depictions of neratinib's effectiveness, known as Kaplan-Meier Curves. The analyst said, "I assume you have seen the curves for the two arms. Can you give us a sense as to whether the separation is widening over time? Or how would you describe the curve separation?" (*Id.* at 8.) Auerbach explained that the trial included "a lot of patients who have been in for much more than [the trial's] 2-year cutoff." (*Id.*) He

then said, "If we look at the curves going out beyond that, it looks like the curves are continuing to separate" and that "the curves appear to be continuing to separate as you go out year over year." (*Id.*) Plaintiffs contend that Auerbach hadn't actually seen Kaplan-Meier data beyond two years and, more importantly, that the data showed the curves narrowing at the end of the two-year trial—meaning neratinib was growing less effective over that period.

Grade 3 Diarrhea Rates. An apparently common side effect for cancer treatment drugs like neratinib is diarrhea. On the investment call, an analyst asked Auerbach what he knew "about the safety profile" based on the ExteNET results. (*Id.* at 6.) Auerbach responded that the company hadn't "yet fully validated the database" of ExteNet trial information, but that the company "would anticipate that the diarrhea rate, the grade 3 diarrhea rate, would be in line with the 29% to 30% that's been seen in prior studies of neratinib." (*Id.*) Plaintiffs say that Auerbach had the results of the ExteNET showing that the actual rate of grade 3 diarrhea (a categorization diarrhea frequency) was actually 39.9%.

Dropout Rates. Another investor asked Auerbach about the "dropout rate" from the trial, meaning the number of patients who stopped using neratinib due to side effects. (*Id.* at 10.) Auerbach explained that he didn't have the dropout rates, but that Puma "anticipate[d]" that the dropout rates would be "in the same vein" as previous studies, which "was usually in the 5% to 10% range." (*Id.* at 11.) Plaintiffs say this statement, too, was false, because Auerbach knew that 16.8% of neratinib users dropped out of the trial due to diarrhea alone, with the total dropout rate at 27.6% across all kinds of side effects or "adverse events."

Plaintiffs say Auerbach's misstatements were uncovered in late May and early June 2015 during a medical conference put on by the American Society of Clinical Oncology (ASCO). The ASCO had selected the ExteNET trial results for presentation at the conference. After the stock market closed on May 13, ASCO released Abstract #508, a summary of the ExteNET clinical data that would be presented at the conference. (Dkt. No. 376-2 at 76.) The abstract included the 91.6% (placebo) and 93.9% (neratinib) DFS rates. (*Id.* at 77.) It also included a statement that 40% of neratinib patients reported grade 3 diarrhea. (*Id.*) The next

day, Puma's stock closed almost $40 a share lower than the day before—down to $170.67 from $209.72

On June 1, an independent oncologist, Dr. Arlene Chan, presented the ExteNET trial data at the ASCO conference. (*See* Dkt. No. 376-41 at 2.) Dr. Chan's presentation included information showing that 16.8% of naratinib trial patients discontinued the trial due to diarrhea. (*Id.* at 18.) Dr. Chan's presentation also included the actual Kaplan-Meier curves, which Plaintiffs contend show that neratinib's effectiveness decreased (the curves narrowed) over certain time periods. (*Id.* at 14–16.) After Dr. Chan's presentation, several oncologists expressed concerns about neratinib's potential for FDA approval and its effectiveness over time.

During the last few hours of the June 1 trading day after the ASCO presentation, Puma's stock dropped from $195.45 to $169.97. On June 2, the stock dropped even more, from $169.97 to $146.65.

Plaintiffs assert two claims against Defendants: (1) securities fraud violations of § 10(b) Exchange Act of 1934 and SEC Rule 10b-5, and (2) control person liability under § 20(a) of the Exchange Act. (First Amended Complaint, Dkt. No. 138.)

2. PRELIMINARY ISSUES

Before diving into the merits of the parties' motions, the Court must first clear up a few ancillary matters.

2.1 Evidentiary Objections

Along with their mountainous filings, the parties filed hundreds of pages' worth of evidentiary objections. (*See* Dkt. Nos. 422, 475.) This along with five motions to exclude set for hearing a week after the parties' summary judgment hearing. (*See* Dkt. Nos. 398, 401, 404, 407, 409, 416, 423.)

On a motion for summary judgment, parties must cite specific evidence to assert that a fact

cannot be or is genuinely disputed. Fed. R. Civ. P. 56(c)(1). Federal Rule of Civil Procedure 56(c)(4) requires that an "affidavit or declaration used to support or oppose a motion must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated." Parties "may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence." Fed. R. Civ. P. 56(c)(2). But when the parties file numerous objections on a summary judgment motion, it's "often unnecessary and impractical for a court to methodically scrutinize each objection and give a full analysis of each argument raised." *See Doe v. Starbucks, Inc.*, No. SACV 08-00582 AG (CWx), 2009 WL 5183773, at *1 (C.D. Cal. Dec 18, 2009). Here, both sides' objections are often formulaic, including many objections on relevance grounds. These objections are a waste.

At bottom, the Court doesn't rely on any inappropriate evidence, and addresses specific objections in its analysis as necessary.

2.2 Requests for Judicial Notice

Defendants request that the Court take judicial notice of (1) Puma's stock price on certain dates and at certain times, and (2) various press releases issued by public biotechnology companies announcing clinical trial results and stock offerings. (Dkt. No. 373, 432, 474.) Plaintiffs don't object to the Court taking judicial notice of the opening and closing price of Puma's stock on certain dates, but do object to the Court taking judicial notice of the price of Puma's stock on a minute-by-minute basis. (Dkt. No. 417.) Plaintiffs also object to the Court taking judicial notice of the press releases. (Dkt. No. 417.)

Under Federal Rule of Evidence 201(b), a court may "judicially notice a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Courts may take judicial notice of "undisputed matters of public record." *See Lee v. L.A.*, 250 F.3d 668, 690 (9th Cir. 2001). The Court concludes that taking judicial notice of the opening and closing price of Puma's stock on the relevant dates is appropriate, particularly since Plaintiffs don't object. Setting aside whether the other documents are appropriate for judicial notice, the Court considered them in reviewing the evidence available for Defendants. For what it's worth, these documents

don't conclusively prove any material aspect of either side's case.

3. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate where the record, read in the light most favorable to the non-moving party, shows that "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(a); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). Material facts are those necessary to the proof or defense of a claim, as determined by reference to substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A factual issue is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party," based on the issue. *See id.* In deciding a motion for summary judgment, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255. But if the evidence of the nonmoving party "is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249–50.

The burden is first on the moving party to show an absence of a genuine issue of material fact. *Celotex*, 477 U.S. at 323. The moving party satisfies this burden either by showing an absence of evidence to support the nonmoving party's case when the nonmoving party bears the burden of proof at trial, or by introducing enough evidence to entitle the moving party to a directed verdict when the moving party bears the burden of proof at trial. *See Celotex*, 477 U.S. at 325; *C.A.R. Transp. Brokerage Co. v. Darden Rests., Inc.*, 213 F.3d 474, 480 (9th Cir. 2000). If the moving party satisfies this initial requirement, the burden then shifts to the nonmoving party to designate specific facts, supported by evidence, showing that there is a genuine issue for trial. *Celotex*, 477 U.S. at 324.

4. PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Plaintiffs move for partial summary judgment on aspects of their securities fraud claim, as well as on several of Defendants' affirmative defenses.

4.1 Reliance

The Exchange Act of 1934, through SEC Rule 10b-5, prohibits securities fraud. 17 C.F.R. § 240.10b-5(b). To prevail on a securities fraud claim under Rule 10b-5, a plaintiff must prove, among other things, that they relied on the purportedly fraudulent statements in deciding whether to buy or sell a particular security. *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37–38 (2011) (quoting *Stoneridge Inv. Partners v. Scientific–Atlanta, Inc.*, 522 U.S. 148, 157 (2008)). Plaintiffs contend that they're entitled to summary judgment on this reliance element.

One tool available to Plaintiffs in proving reliance is the so-called "fraud-on-the-market" presumption. *See Basic Inc. v. Levinson*, 485 U.S. 224, 250 (1988). The fraud-on-the-market presumption allows an injured investor to prove reliance without showing that the defendant's misstatements inspired the investor's decision to buy a particular security. Instead, as the name implies, the fraud-on-the-market presumption acknowledges that fraudulent misstatements distort the market for the lied-about security. In other words, an "investor who buys or sells stock at the price set by the market does so in reliance on the integrity of that price. Because most publicly available information is reflected in market price, an investor's reliance on any public material misrepresentations, therefore, may be presumed for purposes of a Rule 10b-5 action." *Id.* at 247.

The fraud-on-the-market presumption applies where "(1) the alleged misrepresentations were publicly known, (2) they were material, (3) the stock traded in an efficient market, and (4) the plaintiff traded the stock between when the misrepresentations were made and when the truth was revealed." *Halliburton Co. v. Erica P. John Fund, Inc.*, 134 S. Ct. 2398, 2413 (2014) ("*Halliburton II*") (citing *Basic*, 485 U.S. at 248, n.27). But even if a plaintiff establishes these elements, a defendant can rebut the presumption of reliance through any "showing that severs the link between the alleged misrepresentation and either the price received (or paid) by the plaintiff, or his decision to trade at a fair market price" because such showings would erase any "basis for finding that the fraud had been transmitted through the market." *Basic*, 485 F.3d at 248.

4.1.1 Public Knowledge, Market Efficiency, and Trading Period

The parties agree that the statements at the heart of Plaintiffs' complaint—Auerbach's July 22 conference call statements—were publicly known. Similarly, the parties agree that Puma's stock trades on an efficient market. Lastly, the parties agree that Plaintiff (and, by definition, the class members) traded after Puma made the alleged misrepresentations but before the alleged truth came out. (*See* Mot., Dkt. No. 368 at 8–11; Opp'n, Dkt. No. 441 at 10.)

Federal Rule of Civil Procedure 56 permits the Court to enter partial summary judgment on individual issues that need not be submitted to a jury for resolution. "If the court does not grant all relief requested by [a] motion [for summary judgment], it may enter an order stating any material fact . . . that is not genuinely in dispute and treating the fact as established in dispute and treating that fact as established in the case." Fed. R. Civ. P. 56(f)(3). By the parties' agreement that there is no material dispute on the issues of public knowledge, market efficiency, and Plaintiffs' trading during the relevant period, the Court treats those issues as established in Plaintiffs' favor for the fraud-on-the-market presumption.

4.1.2 Materiality

That takes care of 3 out of the 4 elements of the fraud-on-the-market presumption, but what about materiality? The parties agree that materiality remains in dispute, with evidence supporting both sides. (*See* Mot., Dkt. No. 368 at 7 ("With respect to the materiality of Defendants' misrepresentations, that issue will be decided separately by the jury, as it is an independent element of the § 10(b) claim.").) This dispute prevents the Court from entering summary judgment on the fraud-on-the-market presumption and, thus, the element of reliance for Plaintiffs' 10b-5 claim.

The Court isn't persuaded by Plaintiffs' arguments that summary judgment on the reliance element is appropriate despite the parties' materiality dispute. Plaintiffs rely on the notion that the test for fraud-on-the-market and the test for securities fraud under Rule 10b-5 overlap. Plaintiffs argue, "[I]f the jury finds in Defendants' favor on materiality, reliance is moot" but if "the jury finds that Defendants' statements and omissions were material, there will be no need to revisit the issue of materiality to make a finding in reliance." (Reply, Dkt.

No. 464 at 1.) This argument, though creative, doesn't address Rule 56's clear parameters for summary judgment. If there's a genuine dispute of material fact—as there is here on materiality—the Court can't enter summary judgment. Fed. R. Civ. P. 56(a). Although the Ninth Circuit's model jury instruction on the fraud-on-the-market presumption doesn't include materiality, *see* Ninth Circuit Model Jury Instruction 18.7, the Supreme Court has clearly included it in the presumption's enumerated elements. *See Halliburton II*, 134 S. Ct. at 2408 (detailing the elements of the fraud-on-the-market theory as "(1) the alleged misrepresentations were publicly known, (2) they were *material*, (3) the stock traded in an efficient market, and (4) the plaintiff traded the stock between when the misrepresentations were made and when the truth was revealed.").

Because of the parties' genuine dispute about whether Auerbach's misstatements were material, the Court declines to enter summary judgment on the fraud-on-the-market presumption or the broader issue of Plaintiffs' reliance.

4.1.3 Rebuttal

Plaintiffs haven't established beyond dispute all elements of the fraud-on-the-market presumption, so the Court need not address whether Defendants have sufficient evidence to rebut that presumption at this time.

4.2 "Affirmative Defenses": Mitigation, Offset, Assumption of Risk, and Allocation

Plaintiffs also ask for summary judgment on Defendants' affirmative defenses of mitigation, offset, assumption of risk, and allocation. Defendants explicitly acknowledge that both its assumption of risk and allocation defenses are not affirmative defenses at all. They contend "both are simply ways of contesting elements of liability as to which *Plaintiff* bears the burden of proof." (Opp'n, Dkt. No. 441 at 2.) After reviewing Defendants' explanation for their other challenged "affirmative defenses", the Court concludes they suffer from the same defect. Defendants don't argue that they maintain any burden of proof on the issues raised by the defenses. Nor do they put forward evidence to support them. Instead, all these defenses rest on the same premise: Plaintiffs can't prove they're entitled to some types of

damages. But Plaintiffs' recovery, if any, is appropriately limited by Plaintiffs' evidence and the relevant law. Moreover, it's unclear how these doctrines—particularly mitigation, offset, and assumption of risk—would even apply in the securities fraud context.

"A defense which demonstrates that plaintiff has not met its burden of proof is not an affirmative defense." *Zivkovic v. S. Cal. Edison Co.*, 302 F.3d 1080, 1088 (9th Cir. 2002). Under Federal Rule of Civil Procedure 12(f), the Court, on its own, "may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." The Court concludes that this is the best course here. Because they're unnecessary in this case, the Court STRIKES Defendants' "affirmative defenses" for mitigation, offset, assumption of risk, and allocation (Defendants' Fifth, Eighth, Seventh, and Ninth affirmative defenses). The Court does so without prejudice to Defendants' ability to present evidence, where appropriate, to show that Plaintiffs haven't met their burden to prove their claims, particularly on issues concerning damages and causation.

5. DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Defendants contend that they're entitled to summary judgment on Plaintiffs' claims. The Court addresses each of Defendants' arguments in turn.

5.1 False or Misleading Statements

Defendants argue that Auerbach's July 22 conference call statements about the ExteNET trial weren't false or misleading. To win on their securities fraud claims, it's Plaintiffs' burden to prove that the statements were misleading or untrue, not simply incomplete. *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). Defendants contend none of the statements Plaintiffs rely on was sufficiently misleading to warrant securities fraud liability. "Generally, whether a public statement is misleading, or whether adverse facts were adequately disclosed is a mixed question to be decided by the trier of fact"—here, the jury. *SEC v. Todd*, 642 F.3d 1207, 1220 (9th Cir. 2011) (internal citations and quotation marks omitted).

5.1.1 33% Improvement Statement and DFS Rates

Plaintiffs contend that information about the ExteNET trial's DFS rates was presented in a misleading way during Auerbach's investor call. During the call, Auerbach (responding to an investor's question) confirmed that the DFS rates were "around 86% or so" for the placebo group and "around 90 to 91%" in the neratinib group. (Dkt. No. 369-6 at 6.) If those numbers were true, the absolute difference between the groups would've been about 4–5%. Auerbach went on to say that the trial's results were consistent with "a 33% improvement in DFS" when comparing the two groups. (*Id.* at 7.)

As for whether all this was false, there's evidence going both ways. On the one hand, the percentages Auerbach confirmed on the investor call weren't accurate. The ExteNET results showed that the DFS rate was 91.6% for placebo participants while it was 93.9% for neratinib participants, an absolute difference of only 2.3%. That means Auerbach's confirmation of different numbers—numbers hinting at a 4–5% absolute difference—was actually false. On the other hand, Defendants argue that a 2.3% absolute difference in DFS rates is consistent with the 33% improvement in comparing the DFS rates of placebo and neratinib users over the life of the trial. (*See* Mot., Dkt. No. 372-1 at 13–15.) But even assuming that's true, Plaintiffs submit evidence that, after the call, investment analysts estimated that the absolute difference in the DFS rates in the ExteNET trial was roughly 4-6%. (Plaintiff's Statement of Uncontroverted Fact No. 13, Dkt. No. 420.) This shows that at least some analysts focused on the inaccurate DFS rates without considering whether they was consistent with the 33% statistic.

Put simply, Auerbach's confirmation of the 86% and 90–91% DFS numbers even though those numbers weren't accurate creates a genuine dispute of material fact on whether Auerbach's DFS rate statements were misleading to investors. Because the parties agree that the 33% improvement statement was true, the Court enters partial summary judgment as to that statement.

5.1.2 Kaplan-Meier Curve Statements

Defendants contend that Auerbach's statements about the Kaplan-Meier curves—a graphical

depiction of the effectiveness of a drug compared to a placebo—also weren't misleading. On the investor call, an analyst asked Auerbach, "Can you give us a sense as to whether the separation is widening over time? Or how would you describe the curve separation?" (Dkt. No. 369-6 at 8.) Auerbach replied, "So from those numbers [we have from the ExteNET trial], you can see we have a lot of patients who have been in for much more than the 2-year cutoff. If we look at the curves going out beyond that, it looks like the curves are continuing to separate." (*Id.*) He also said that "the curves appear to be continuing to separate as you go out year over year, and the absolute DFS difference is increasing year over year as well." (*Id.*)

Viewed in a light most favorable to Plaintiffs, the evidence creates a reasonable basis to conclude that Auerbach's statements about the Kaplan-Meier curves were misleading. Plaintiffs produce evidence that, less than a week before the call, Auerbach had received Kaplan-Meier curves that were narrowing at the end of the second year of treatment, meaning neratinib became less effective as time went on. (*See* Dkt. No. 424-37 at ¶ 10–12.) His investor call statement that the curves were "continuing" to separate suggested that the curves had been separating all along, which is inconsistent with the data he received. Further, there's a dispute about what information Auerbach did and didn't have before the investor call. There's some evidence that Auerbach didn't have Kaplan-Meier curves extending beyond two years at that time, which calls into question whether he could comment on what happened to the curves beyond two years at all. These material factual disputes are best left for a jury to decide.

In reaching this conclusion, the Court must explicitly overrule Defendants' objection to Plaintiffs' expert Dr. Philip Lavin. (Dkt. No. 407.) Oddly, Defendants moved the hearing for their motion to exclude Dr. Lavin's testimony to a week after the hearing on its motion for summary judgment. (*See* Dkt. Nos. 416, 423.) At any rate, the Court has reviewed the briefing on the motion to exclude and concludes that it may appropriately rely on Dr. Lavin's testimony in reaching this order's conclusions. Dr. Lavin's testimony largely addresses whether the data available to Puma before Auerbach's investor called supported his statements about widening Kaplan-Meier curves. Specifically, Dr. Lavin intends to testify that (1) the Kaplan-Meier curves narrowed toward the end of the two-year ExteNET trial data, and (2) that there is no record that Puma ever assessed the Kaplan-Meier curves beyond two years before the investor call. The Court concludes that this opinion evidence is

largely appropriate, and cannot categorically exclude Mr. Lavin's testimony at this time.

Defendants' contention that Dr. Lavin's testimony is irrelevant isn't persuasive. Defendants argue that Dr. Lavin's testimony about what the curves were doing before the two-year mark isn't relevant since Auerbach's investor call statements focused on what happened after the two-year mark. But Auerbach stated that the curves were "continuing to separate" after two years, which leads to a reasonable inference that the curves had been separating all along—a point Dr. Lavin's testimony explicitly contradicts. Further, Dr. Lavin's testimony doesn't appear to rely on "cherry-picked" data to reach a predetermined conclusion, as Defendants argue. (Mot. to Exclude, Dkt. No. 407-1 at 2.) Instead, Dr. Lavin explains that he relied on the exact ExteNET data that Puma had before the investor call, and occasionally limited his analysis to neratinib's effects between years one and two. These limitations don't render Dr. Lavin's conclusions scientifically dubious, and Defendants are free to attempt to discredit his testimony by explaining these limitations (among others like statistical significance) to the jury. Further, Dr. Lavin's opinion that biostatisticians typically keep "audit trails" of reports they run would be helpful to the jury, assuming it's appropriately limited to his industry-related knowledge. (*See* Dkt. No. 408-1 at ¶ 35.) Defendants may disagree with Dr. Lavin's conclusions, but that's not a good enough reason to exclude his testimony. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 594–95 (1993). This limited ruling is without prejudice to Defendants' raising more specific challenges to Dr. Lavin's testimony later.

5.1.3 Grade 3 Diarrhea Rates and Dropout Rates

Defendants contend that Auerbach's statements about the safety results of the ExteNET trial weren't false or misleading. On the investor call, Auerbach explained that Puma "anticipate[d] that the grade 3 diarrhea rates in the ExteNET trial [were] likely to be in line with what was previously published in the prior Phase II trials." (Dkt. No. 369-6 at 6.) Auerbach explained that those previous trials had seen grade 3 or higher diarrhea rates of 29–30%. (*Id.*) Auerbach also said that Puma anticipated that the dropout rate would be "in [the] same vein" as the dropout rate of previous studies, which was about 5-10%. (Dkt. No. 369-6 at 10–11.) As it turns out, the ExteNET data Auerbach reviewed several days before the investor call showed that 39.9% of the neratinib patients suffered from grade 3 or higher diarrhea and that 16.8% of the neratinib patients dropped out of the study due to diarrhea.

Consequently, comparing Auerbach's statements to the data he received, his statements were false.

Defendants argue that the statements weren't misleading because they were appropriately qualified. After all, Auerbach basically said that the "data were still being validated, and that once validated he expected the data to be in line with the ranges observed in past studies." (Mot., Dkt. No. 372-1 at 17.) So, Defendants argue, "Puma had no obligation to disclose unvalidated data." (*Id.*) But this argument misses the point. Auerbach had information, even if not-yet-totally-final, showing that the ExteNET safety results were worse than previous studies—there were higher rates of diarrhea and diarrhea-related dropouts among neratinib users. Defendants provide no persuasive evidence to show that Auerbach expected those numbers to change dramatically (and indeed they didn't) after validation, giving him some basis to tell investors that the numbers would be lower. Even assuming Auerbach had no duty to disclose the information pending validation, he chose to make statements directly inconsistent with the information he did have. Consequently, at the very least, there's a triable issue of fact on whether Auerbach's safety statements were false.

5.2 Scienter

Another part of Plaintiffs' securities fraud case is that they must prove Defendants acted with "scienter"—a lawyer's way of saying Defendants acted with an "intent to deceive, manipulate, or defraud." *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 (1976). Plaintiffs may meet this burden by showing that Defendants made the statements knowing they were false or with reckless disregard for whether the statements were false. *Provenz v. Miller*, 102 F.3d 1478, 1490 (9th Cir. 1996).

Plaintiffs contend that summary judgment on scienter is inappropriate because Auerbach knew "of the very ExteNET trial results he lied about." (Opp'n, Dkt. No. 426-1 at 11.) That's true. As discussed, some of Auerbach's statements, especially when viewed in a light most favorably to Plaintiffs, were directly inconsistent with the ExteNET data he admits he received and reviewed several days before the investor call. Defendants argue that Puma didn't fully disclose the ExteNET results because they feared that would mean "forfeiting the chance at a coveted presentation" at the ASCO conference, which required that

companies keep their trial results secret before the conference. (Mot., Dkt. No. 372-1 at 18.) Fair enough. But Puma's desire to keep information secret doesn't erase it's duty not to make false or misleading statements about the data it's purportedly keeping secret. When Auerbach chose to speak about DFS rates, Kaplan-Meier curves, diarrhea rates, and dropout rates, he did so under a duty not to say anything false or misleading, imposed upon him by federal securities laws. But there's evidence Auerbach did just that, even though he knew the information he was conveying wasn't consistent with the ExteNET data. That's enough to show scienter. *See Gebhart v. SEC*, 595 F.3d 1034, 1042 (9th Cir. 2010) ("[T]he ultimate [scienter] question is whether defendant knew his or her statements were false, or was consciously reckless as to their truth or falsity.").

Defendants do make one convincing argument on the scienter front. They argue that Plaintiffs don't have evidence showing Defendant Eyler acted with scienter. Plaintiffs contend that Eyler's first false statement came on January 20, 2015—when Eyler signed off on a securities regulation disclosure that cited the "33% improvement" in DFS rates vs. the placebo. As discussed previously, it appears that statement—especially when made by itself without reference to the underlying DFS rates—was true. Further, Eyler testified that he didn't know about the ExteNet data until May 2015. Plaintiffs' minimal evidence to the contrary isn't convincing, because none of it shows that Eyler specifically reviewed the ExteNET results at issue here. At most, Eyler possibly had access to the ExteNET data. That's not enough to show he knew or should've known that the four specific technical statements Auerbach made during the investor call were false or misleading, such that Eyler acted with any intent to deceive, manipulate, or defraud.

As to Eyler, summary judgment on Plaintiffs' 10b-5 claim is appropriate because Plaintiffs can't show that he acted with scienter.

5.3 Loss Causation

Defendants argue that the alleged misrepresentations weren't a "substantial factor" in Puma's stock price changes. To survive summary judgment on their securities fraud claims, Plaintiffs must provide some evidence showing that the alleged corrective disclosures before and during the ASCO conference played a "substantial factor" in causing their economic loss.

McCabe v. Ernst & Young, LLP, 494 F.3d 418, 436 (9th Cir. 2007). Issues relevant to this inquiry are "materiality, directness, foreseeability, and intervening causes." *Id.* (internal citations omitted). "Because there are a tangle of factors that affect" the price of a security, "evidence that certain misrepresent[ations] are responsible for a loss must reasonably distinguish the impact of [the misrepresentations] from other economic factors." *Nuveen Mun. High Income Opportunity Fund v. City of Alameda*, 730 F.3d 111, 1123 (9th Cir. 2013). Plaintiffs focus on three dates when Puma's stock price dropped: May 14, June 1, and June 2, 2015.

5.3.1 May 14

Defendants make no argument about the stock price drop on May 14, which Plaintiffs say was caused by the release of absolute DFS rates and grade 3 diarrhea rates in Abstract #508 on May 13. Consequently, the Court doesn't address whether Abstract #508 caused Plaintiffs' May 14 losses.

5.3.2 June 1

Defendants contend that the June 1 corrective disclosures—the release of the Kaplan-Meier curves and the 16.8% diarrhea discontinuation rate at the ASCO conference—didn't actually affect Puma's stock price that same day.

Isolating the stock-price effect of somewhat technical corrective disclosures seems difficult to do. Both sides agree that the ASCO presentation wasn't short, and it included a lot of information about ExteNET and neratinib. (*See* Dkt. No. 376-41.) As such, Defendants contend that there was "a host of confounding information" released in the ASCO presentation that's inextricably intertwined with any price effect from the alleged corrective disclosures. (Mot., Dkt. No. 372-1 at 23.) The Court is nonetheless mindful that this is *Defendants'* summary judgment motion. In this context, it's first Defendants' burden to show an absence of material fact. *Celotex*, 477 U.S. at 323. If they do that, only then does the burden shift to Plaintiffs to show that they have evidence to support their claims. *Id.* at 323–25.

Defendants have failed to show that factors other than the June 1 corrective disclosures caused the stock's decline. Sure, Defendants have some strong evidence supporting their position. As they point out, the "vast majority of analysts commenting on Dr. Chan's ASCO presentation did not even mention the two-year KM curves or the 16.8% discontinuation rate; the four analysts that mentioned these facts referred to them briefly as neutral or positive." (Mot., Dkt. No. 372-1 at 22.) But this isn't conclusive proof that the June 1 Kaplan-Meier curve and discontinuation rate disclosures didn't contribute to the drop in price.

Moreover, Plaintiffs provide contrary evidence. Particularly helpful to Plaintiffs' position is the report of their expert, Dr. Steven P. Feinstein. Dr. Feinstein explains that, "Other than the disclosures regarding the ExteNET trial efficacy and safety results" revealed at the ASCO conference, he "identified no other Company-specific news that could have been a substantial cause" of the Puma stock drop on June 1 and 2. (Dkt. No. 424-110 at ¶ 67.) Dr. Feinstein identified several analyst reports covering the ASCO conference that expressed concerns with, among other things, "underwhelming *efficacy* and high rate of *side effects* seen with [Puma's] breast cancer drug neratinib." (*Id.* at ¶ 37 (emphasis added).) The disclosures that Plaintiffs rely on are important features of those two areas: the Kaplan-Meier curves concern *efficacy* and the diarrhea rates concern *side effects*. Dr. Feinstein also importantly explained why he excluded other pieces of information (like the efficacy of neratinib on node-negative groups and concerns about the ExteNET trial's time limitations) that were discussed at the ASCO conference. (Dkt. No. 424-129 at pp. 8–16.) He also excluded industry-wide and macro-economic factors as potential causes of the stock's decline. Put simply, Plaintiffs have provided enough evidence to survive summary judgment on the issue of loss causation. Dr. Feinstein's report is reasonable evidence that the corrective disclosures and price drop are related.

These conclusions again require the Court to decide a lingering evidentiary issue. Defendants contend that Dr. Feinstein's testimony should be excluded. (Dkt. No. 409.) Again, they did so in a motion to exclude set for hearing on October 1, a week after the hearing on these motions to dismiss. Nonetheless, the Court has considered the briefing on Defendants' motion to exclude and concludes that Dr. Feinstein's testimony, at least as much as the Court relies on it in this order, need not be excluded. Defendants don't truly challenge

whether Dr. Feinstein used reliable scientific methods, they just challenge the scope of his report. But Dr. Feinstein provided detailed reasons for why he excluded certain evidence from his report. He chose to focus on only *new* negative information released at the ASCO conference to account for the sudden stock drop. That's reasonable. Defendants are free to later challenge the scope of the information Dr. Feinstein considered. These arguments go more toward the weight of Dr. Feinstein's testimony, not whether Dr. Feinstein's methods were appropriate. This ruling is without prejudice to Defendants' raising more focused challenges to Dr. Feinstein's testimony later.

5.3.3 June 2

Even if the corrective disclosures affected Puma's stock price on June 1, Defendants argue that the Court shouldn't allow Plaintiffs to recover for any drop on June 2. Defendants' theory goes that Puma's stock trades on an efficient market, meaning the price would absorb important information in mere hours, not days. Defendants contend that, after the ASCO presentation on June 1, the market had over 3 hours before closing to respond to the corrective disclosures, making the drop on the next day irrelevant.

Defendants don't cite anything—legal or evidentiary—that convincingly shows a two-day loss causation window is inappropriate under the circumstances. To the contrary, the Ninth Circuit has explained that "adoption of a bright-line rule assuming that [a] stock price will instantly react [to negative information] would fail to address the realities of the market." *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 934 (9th Cir. 2003). Setting aside Defendants' invitation to adopt a bright-line one-day loss causation rule, there's a dispute of fact about whether the June 1 disclosures had some effect on Puma's stock on June 2. Dr. Feinstein concluded that the June 1 corrective disclosures did affect the June 2 stock price. Part of this conclusion relied on the notion that no new Puma-specific news came out after the ASCO conference that would lead to such a drop. This, among other things, prevents summary judgment in Defendants' favor on loss causation for June 2.

5.4 Joint and Several Liability (Control Person Liability)

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

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Defendants say that Plaintiffs' control person liability claim fails because their underlying 10b-5 claim fails. As discussed, Plaintiffs haven't produced evidence sufficient to show that Defendant Eyler acted with scienter, meaning any 10b-5 claim against him fails. So, too, does any control person liability claim. *See* 15 U.S.C. § 78t(a). Other than that, Plaintiffs' 10b-5 claims remain alive and well, so the Court will not enter summary judgment on their control person liability claim.

6. PLAINTIFFS' MOTION TO UNSEAL

In the many of the documents filed with the Court, the parties included numerous redactions. Relatedly, Plaintiffs ask the Court to unseal 21 of Defendants' summary judgment exhibits, along with various references to those exhibits. (Mot., Dkt. No. 412.) Defendants oppose this motion, saying that Puma's proprietary and competitively sensitive information, along with certain bank documents, should remain under seal. (Opp'n, Dkt. No. 459.) Several non-party investment banks also oppose the request. (Opp'n, Dkt. No. 454.)

Considering the parties' arguments and their good faith effort to reduce the number of filings under seal, the Court DENIES Plaintiffs' motion to unseal exhibits 4, 26, 43, 44, 45, 46, 51, 69, 96, and 97 to Defendants' motion for summary judgment. (Dkt. No. 412.) As to the other challenged exhibits, the Court DENIES Plaintiffs' request as moot, since Defendants have agreed to unseal those exhibits.

7. DISPOSITION

The Court GRANTS in part Plaintiffs' motion for partial summary judgment. (Dkt. No. 367.) The Court GRANTS in part Defendants' motion for summary judgment. (Dkt. No. 372.)

The Court enters partial summary judgment on the following three elements of the fraud-on-the-market presumption: the alleged misrepresentations were publicly known, Puma's stock traded in an efficient market, and Plaintiffs traded Puma's stock between the alleged misrepresentations and corrective disclosures. The issue of materiality remains.

UNITED STATES DISTRICT COURT
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The Court also enters partial summary judgment on the 33% DFS improvement statement. That statement was true.

The Court also enters partial summary judgment in Defendant Eyler's favor on all Plaintiffs' claims.

The Court has thoroughly reviewed the parties' voluminous filings. Any arguments not specifically addressed in this order either weren't convincing or didn't need to be addressed.

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