UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

HSINGCHING HSU,

Plaintiffs,

v.

PUMA BIOTECHNOLOGY, INC. ET AL.

Defendants.

CASE NO. SACV 15-0865 AG (JCGx)

ORDER DENYING MOTION TO DISMISS

Lead Plaintiff Norfolk County Council, as administering authority of the Norfolk Pension Fund, and others filed this lawsuit under the Securities Exchange Act of 1934 ("Exchange Act") and Securities and Exchange Commission Rule 10b-5. Defendants Puma Biotechnology, Inc., Alan H. Auerbach, and Charles R. Eyler (collectively, "Puma") filed a motion to dismiss the case ("Motion to Dismiss") under Federal Rule of Civil Procedure 9(b) ("Rule 9(b)"), Federal Rule of Civil Procedure 12(b)(6) ("Rule 12(b)(6)"), and the Private Securities Litigation Reform Act ("PSLRA").

The Court DENIES the Motion to Dismiss.

1. BACKGROUND

In 2013—the most recent year numbers are available—232,924 people in the United States were diagnosed with breast cancer. Breast Cancer Statistics, Centers for Disease Control and Prevention, http://www.cdc.gov/cancer/breast/statistics/index.htm (last visited September 30, 2016). That year, 41,324 people in the United States died from breast cancer. *Id.* The disease is the most common cancer among women in our country. *See id.* And as they often do, statistics fail to give us the right measure of heartbreak. Breast cancer radically reshapes the lives of our mothers and daughters, sons and fathers, brothers and sisters, husbands and wives, friends and family, every day of every year, in every corner of every country. The disease's impact far too often includes (but never ends with) the loss of those who we love most.

Some of the science behind this sickness is relevant here. In particular, this case revolves around statements about a potential treatment for a subset of breast cancers that are called HER2-positive breast cancers. A fourth or fifth of breast cancer patients are HER2-positive: they have cells that make too many copies of a cell surface receptor called human epidermal growth factor receptor 2, or HER2 for short. These HER2 receptors promote cell

division and proliferation, which results in HER2-positive breast cancer spreading more aggressively than other types of breast cancer. There are drugs that combat overexpression of the HER2 gene, but most patients develop resistance to them after a year. So up until now, there generally haven't been any drugs that patients with HER2-positive breast cancer can use after a year on the existing drugs.

Puma hoped to change this. It's a pharmaceutical company that acquires and develops new drugs. Puma has focused its efforts almost entirely on drug PB272, also called neratinib. Neratinib is an "extended adjuvant treatment." "Extended" refers to neratinib's viability as a long-term treatment beyond the year window that existing drugs cover. "Adjuvant therapy" means that neratinib is a therapy given after an initial treatment (such as surgery) to help suppress further formation of cancerous tumors. Neratinib is supposed to irreversibly bind to the HER2 receptor, and eventually slow down or stop out-of-control cell growth.

There was a clinical trial of neratinib called the ExteNET trial. This case concerns Puma's statements about the results of that trial. In short, Norfolk County Council and other investors accuse Puma and its executives of making false or misleading statements about the ExteNET trial results, and accordingly filed this putative class action.

The alleged misstatements are basically about two things. First, there's the DFS rate. The success of the ExteNET neratinib trial was primarily measured by the percentage of disease free survival ("DFS") among patients taking neratinib versus those taking a placebo. Norfolk County Council says Puma lied to or misled investors and others about the absolute DFS rates coming out of the ExteNET trial and the improvement in DFS between the neratinib group and the placebo group. Second, there are the Kaplan-Meier curves. These are used to identify trends in DFS rates over time—here, for example, between the neratinib group and the placebo group. What's the DFS difference between the two groups after two years? Four years? Eight years? The Kaplan-Meier curves would tell you. A widening

difference between the neratinib group and the placebo group over time could suggest that the drug is effective. Norfolk County Council says Puma lied to or misled investors and others about whether that the gap was widening over time, when it was really narrowing.

Finally, there's a money side to medicine too, of course. A few figures are relevant here. During a public offering, Puma sold $218.5 million in Puma stock. Defendants Auerbach and Eyler—both Puma executives—earned more than $23 million in performance-based compensation. If neratinib makes it to the market, it's expected to cost $6,500 a month, or $78,000 a year.

2. LEGAL STANDARD

A court will grant a motion to dismiss if the complaint does not allege claims upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A claim to relief must be plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that 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).

Securities fraud claims like the ones in this case require more. Specifically, they "must satisfy the heightened pleading requirements of both Federal Rule of Civil Procedure 9(b) and the [PSLRA]." *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 876 (9th Cir. 2012). Rule 9(b) "requires particularized allegations of the circumstances constituting fraud, including identifying the statements at issue and setting forth what is false or misleading . . . about the statement and why the statements were false or misleading at the time they were made." *Id.* The PSLRA requires "plaintiffs to state with particularity both the facts constituting the alleged violation and the facts evidencing" that the defendants had the required state of

mind. *Id.*

In analyzing the complaint's sufficiency, a court must "accept[] all factual allegations in the complaint as true and construe[] them in the light most favorable to the nonmoving party." *Skilstaf, Inc. v. CVS Caremark Corp.*, 669 F.3d 1005, 1014 (9th Cir. 2012).

3. WHAT (ELSE) SHOULD THE COURT CONSIDER?

The Court has accordingly accepted all the facts alleged in the complaint as true. But there are remaining questions about what else the Court can consider in its analysis of the Motion to Dismiss.

Typically, a court can only consider what's in the complaint when it is deciding a Rule 12(b)(6) motion to dismiss a complaint. *See Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001). And typically, if a court considers more than what's in the complaint, the motion gets converted into a Federal Rule of Civil Procedure 56 ("Rule 56") motion for summary judgment. *See* Fed. R. Civ. P. 12(d). This conversion can muddy the analysis for clients, counsel, and courts alike, by implicating rules and requirements that don't otherwise apply to motions to dismiss. *See, e.g.*, L.R. 56-1 (requiring that a party moving for summary judgment file a separate "Statement of Uncontroverted Facts and Conclusions of Law"); *see also Kramer v. Time Warner Inc.*, 937 F.2d 767, 773 (2d Cir. 1991) ("If a district court wishes to consider additional material, Rule 12(b) requires it to treat the motion as one for summary judgment under Rule 56, giving the party opposing the motion notice and an opportunity to conduct necessary discovery and to submit pertinent material.").

But there are a couple of doctrines that allow a court to consider material outside of the complaint without turning a Rule 12(b)(6) motion to dismiss into a Rule 56 motion for summary judgment: judicial notice and incorporation by reference. *United States v. Ritchie*, 342

F.3d 903, 908 (9th Cir. 2003); *see also In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d at 876 (holding that a court deciding a motion to dismiss for failure to state a claim is "generally limited to the face of the complaint, materials incorporated into the complaint by reference, and matters of which [the court] may take judicial notice").

3.1 Judicial Notice

First, judicial notice. Judicial notice is an explicitly limited doctrine that's supposed to be used to allow a court to consider "a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201. For example, a court might take judicial notice that January 4, 1986, was a Saturday, or that a party filed a brief opposing a motion in a state court case, or that a particular document was recorded with the county recorder's office. *See Lee*, 250 F.3d at 690 (discussing judicial notice of undisputed matters of public record); *see also Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 n.11 (1993) (discussing judicial notice of "firmly established" scientific laws); *Barnes v. Indep. Auto. Dealers Ass'n of Cal. Health & Welfare Benefit Plan*, 64 F.3d 1389, 1395 (9th Cir. 1995) (discussing judicial notice of "[w]ell-known medical facts").

Judicial notice functions like an evidentiary exception in two different ways. First, judicial notice can be a substitute for the presentation of evidence. As a general rule, a party asserting a fact bears the burden of proving that fact with evidence. But judicial notice lets a party skip this production (and the accompanying authentication) for certain facts. *See Castillo-Villagra v. INS*, 972 F.2d 1017, 1026 (9th Cir. 1992) ("Notice is a way to establish the existence of facts without evidence."). Second, as noted, judicial notice can be a workaround for the exclusion of evidence. As a general rule, parties can't present (and courts can't consider) evidence outside of the complaint when deciding a Rule 12(b)(6) motion to

dismiss. *See Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555 n.19 (9th Cir. 1989). But "[f]acts subject to judicial notice may be considered on a motion to dismiss." *Maiman v. Talbott*, No. SACV 09-0012 AG (ANx), 2011 WL 13065750, at *2 (C.D. Cal. Aug. 29, 2011) (citing *Mullis v. U.S. Bankr. Ct.*, 828 F.2d 1385 (9th Cir. 1987)).

Unfortunately, too many attorneys don't understand judicial notice. Some take judicial notice literally, as a command. "Hey! Judge! Look!" They use judicial notice to get a court's attention like a businessman who's running late and trying to whistle down a taxi on a crowded downtown street. But courts aren't cabbies, and judicial notice isn't appropriately used this way. Other attorneys ask courts to judicially notice things that don't need to be judicially noticed, like a controlling piece of law. Or attorneys ask courts to judicially notice things that aren't appropriate for judicial notice, like emails between the parties' counsel. All of these misuses misconstrue the narrow doctrine.

3.2 Incorporation by Reference

There's also the doctrine of incorporation by reference. As this Court has previously noted, "[a]lthough often conflated, the doctrine of incorporation by reference is distinct from judicial notice." *Gammel v. Hewlett Packard Co.*, 905 F. Supp. 2d 1052, 1061 (C.D. Cal. 2012). Further confusing things, different courts and counsel use "incorporation by reference" to encompass at least three different approaches to extrinsic evidence.

In its most limited and literal form, incorporation by reference allows a court deciding a Rule 12(b)(6) motion to dismiss to consider materials attached to the complaint that are referenced in the complaint. *Hal Roach Studios*, 896 F.2d at 1555 n.19. This application of the doctrine echoes Federal Rule of Civil Procedure 10, which states in relevant part that "[a] copy of a written instrument that is an exhibit to a pleading is a part of the pleading for all purposes." Fed. R. Civ. P. 10(c).

Incorporation by reference has also been used to allow a court deciding a Rule 12(b)(6) motion to dismiss to consider a document that isn't attached to the complaint if the complaint "necessarily relies" on it and "(1) the complaint refers to the document; (2) the document is central to the plaintiff's claim; and (3) no party questions the authenticity of the copy attached to the 12(b)(6) motion." *Marder v. Lopez*, 450 F.3d 445, 448 (9th Cir. 2006). The Ninth Circuit has suggested the complaint must refer to the document "extensively." *Ritchie*, 342 F.3d at 908.

In its most expansive form, incorporation by reference has been used to get a court considering a Rule 12(b)(6) motion to dismiss to consider materials that are neither attached to nor mentioned in the complaint. Specifically, the Ninth Circuit has

> extended the "incorporation by reference" doctrine to situations in which the plaintiff's claim depends on the contents of a document, the defendant attaches the document to its motion to dismiss, and the parties do not dispute the authenticity of the document, even though the plaintiff does not explicitly allege the contents of that document in the complaint.

Knievel v. ESPN, 393 F.3d 1068, 1076 (9th Cir. 2005). In this way, the incorporation by reference doctrine has become the incorporation without reference doctrine.

3.3 The Impact on Access to Justice

This last interpretation of the incorporation by reference doctrine and the incorrect use of judicial notice merit more discussion. Although these are two distinct doctrines with different legal requirements, they both can be used to get a court to consider extrinsic evidence on a Rule 12(b)(6) motion to dismiss. For a plaintiff, this consideration can mean having the courthouse doors slammed shut, such that there's no discovery, no further

motion practice, no cross-examination, and no jury trial. For a defendant, this consideration can mean avoiding lengthy litigation, arduous motion practice, and expensive, expansive discovery battles.

This practical reality has led to inappropriate efforts by defendants to expand the two doctrines. These efforts are distinct from the other inappropriate misuses of the doctrines already identified. Nowadays, it seems more and more common to come across Rule 12(b)(6) motions to dismiss filed with hundreds of pages of attachments, authenticated through attorney declarations. These declarations will be coupled with a request for judicial notice. That judicial notice will often conflate judicial notice and incorporation by reference. Too often, these mountainous motions make arguments more appropriate for a motion for summary judgment or some other later stage of the case. Nonetheless, with little to lose, too many defense attorneys are tempted by the puncher's chance offered by such a motion. At worst, they lose a generally inexpensive motion. But at best, they can knock their opponent out cold, right at the beginning of round one. In this way, efforts to expand courts' consideration of extrinsic evidence at the motion to dismiss stage are consistent with other developments in the law that diminish the ability of wronged plaintiffs to get their constitutionally-protected day in court. *See Iqbal*, 556 U.S. 662; *Twombly*, 550 U.S. 544. Such trends are particularly troubling in the common situation of asymmetry, where a defendant starts off with sole possession of the information about the alleged wrongdoing.

3.4 The Doctrines Applied Here

So how do these two doctrines apply here? Puma filed two supporting requests for judicial notice—one with its Motion to Dismiss, and one with its reply. Norfolk County Council opposed the request for judicial notice filed with the Motion to Dismiss, and tried unsuccessfully to get permission to file a surreply opposing the request for judicial notice filed with the reply. There are also incorporation by reference arguments in some of the

requests for judicial notice, reflecting the common conflation of the two doctrines by counsel (and sometimes courts). The parties largely seem to agree that any documents the Court considers under either doctrine should only be considered for their existence, and not for the truth of their contents. *See Gammel*, 905 F. Supp. 2d at 1061.

There are fourteen or fifteen disputed exhibits. Puma asks the Court to consider (one way or another) twenty-eight exhibits as part of its analysis of the Motion to Dismiss. These exhibits consist of SEC filings, transcripts of conference calls, a press release, and a set of slides from a presentation. To its credit, Norfolk County Council only disputes some of the exhibits—specifically, exhibits 14 and 16 through 28. Norfolk County Council also objects to the incompleteness of exhibit 15, but not in any meaningful way. Accordingly, the Court will now consider documents 1 through 13 and 15, without determining whether these documents are appropriate for judicial notice or whether they fall within the doctrine of incorporation by reference.

3.4.1 Should the Court Consider Exhibit 14? Yes, Sort Of.

Exhibit 14 is a set of slides. Puma asks the Court to consider these under the incorporation by reference doctrine, and in the alternative, through judicial notice. Puma says the complaint "references certain materials available on the American Society of Clinical Oncology's ("ASCO") website," including these slides. Norfolk County Council argues that Puma included the wrong set of slides, and attaches what it sees as the right set of slides.

The Court will consider Norfolk County Council's version of Exhibit 14, as Puma asks the Court to do, without determining whether these slides fall within the doctrine of incorporation by reference or whether they are appropriate for judicial notice.

3.4.2 Should the Court Consider Exhibits 16, 17, and 19 through 26? No.

Exhibits 16, 17, and 19 through 26 are market analyst reports. Puma wants the Court to consider these documents through judicial notice "to demonstrate the information publicly available and known to the market." Norfolk County Council argues that Puma hasn't shown that these reports were publically available and that the reports reflect an inherent bias favoring Puma.

The Court agrees with Norfolk County Council that Puma hasn't adequately shown that Exhibits 16, 17, and 19 through 26 should be judicially noticed here. Puma argues that the complaint itself refers to analyst reports, but it doesn't show that the complaint refers to the same reports Puma wants the Court to consider. Puma also cites several cases supporting its proposition that "[m]arket analyst reports . . . are frequently subject to judicial notice" and that judicial notice is appropriate here. But some of these cases don't clarify the types of documents they address. *See, e.g.*, *In re Impact Mortgage Holdings, Inc. Sec. Litig.*, 554 F. Supp. 2d 1083, 1088 (C.D. Cal. 2008) ("The Court takes judicial notice of the 22 documents submitted as exhibits to Defendants' Request for Judicial Notice ('RJN').") Some of these cases discuss different sorts of documents. *See, e.g.*, *In re Nuvelo, Inc. Sec. Litig.*, 668 F. Supp. 2d 1217, 1219 (N.D. Cal. 2009) (discussing a journal article and FDA documents); *Constr. Laborers Pension Trust of Greater St. Louis v. Neurocrine Biosciences, Inc.*, No. 07-CV-1111 IEG RBB, 2008 WL 2053733, at *6 (S.D. Cal. May 13, 2008) ("[D]efendants request judicial notice of several FDA documents."). Some of these cases involve undisputed requests for judicial notice. *See, e.g.*, *Primo v. Pac. Biosciences of Cal., Inc.*, 940 F. Supp. 2d 1105, 1115 n.1 (N.D. Cal. 2013) ("Plaintiffs do not oppose Defendants' requests. Accordingly, the Court GRANTS Defendants' request for judicial notice."). Some of these cases discuss analyst reports objected to on different grounds. *See, e.g.*, *In re Century Aluminum Co. Sec. Litig.*, 749 F. Supp. 2d 964, 980 (N.D. Cal. 2010) ("Plaintiffs object that the . . . analyst reports . . . are hearsay.") All of these cases are meaningfully distinguishable.

3.4.3 Should the Court Consider Exhibit 18? Yes, Sort Of.

Exhibit 18 is a transcript of a conference call. Like the market analyst reports, Puma wants the Court to consider this transcript through judicial notice. Puma offers the transcript "to demonstrate the information publicly available and known to the market." Perhaps conflating judicial notice with the doctrine of incorporation by reference, Norfolk County Council argues that the transcript wasn't referenced in the complaint. And perhaps questioning the accuracy of the transcript, Norfolk County Council argues that the transcript lacks authentication. It compares the transcript to other transcripts that it didn't object to. Puma responded by providing a more properly authenticated transcript.

The Court will consider the more properly authenticated version of Exhibit 18 only because the parties appear to agree that the Court should consider this version of the transcript. This is not a determination that this transcript is appropriate for judicial notice. Puma appears to have addressed most, and maybe all, of Norfolk County Council's concerns. It is unclear why Puma couldn't have done this from the get-go.

3.4.4 Should the Court Consider Exhibit 27? No.

Exhibit 27 is a printout from the website of Herceptin, the name-brand version of another drug called trastuzumab that's used to treat HER2-positive cancer in the first year after the initial treatment. Puma again asks the Court to consider this document through judicial notice. Puma argues that Norfolk County Council "relies on data from four clinical trials for the breast cancer treatment Herceptin, but does not provide full context for those data." Accordingly, Puma argues, the Court should take judicial notice of some "publicly available figures" from the Herceptin website. Norfolk County Council argues (and Puma doesn't seem to dispute) that the webpages Puma provided were captured in November 2015, while the relevant time period for the claims here is from roughly July 2014 through

May 2015. Norfolk County Council also argues that being publicly available online doesn't mean a document is a "source . . . whose accuracy cannot be reasonably questioned," as Puma argues this document is.

The Court agrees with Norfolk County Council that Puma hasn't adequately shown that Exhibit 27 should be judicially noticed here. There are a few problems with Puma's arguments to the contrary. First, Puma appears to improperly push the burden on a request for judicial notice onto the party opposing the request. Specifically, Puma notes that "Plaintiff cites no authority for the argument that the accuracy of the Herceptin website is questionable just because Genentech uses the website to sell Herceptin." Second, Puma argues that the Herceptin website has a link to FDA archives, and that those FDA archives have been up since at least 2010 and can't be reasonably questioned. Maybe. But Puma isn't asking the Court to take judicial notice of the FDA archives.

Or is it? Puma says, "[s]hould Plaintiff continue to dispute the accuracy of Exhibit 27 because its source (the Herceptin website) is questionable, Defendants submit the identical information reflected in the FDA archive as Exhibit 29 to this Reply." This raises a fundamental question of fairness. Moving parties typically get the last written word on motions, through a reply brief. To make things fair then, moving parties can't save arguments or requests to spring on an opponent for the first time in a reply brief, where the opponent has no chance to reply in writing (and given the frequency with which courts allow oral argument these days, often no chance period). Puma's request for the Court to take judicial notice of the FDA archives, presented for the first time in its reply brief, is inappropriate, and accordingly the Court won't address the merits of the issue. That's particularly true because, again, it's not clear why Puma couldn't have included this request in its initial motion. *See* Fed. R. Evid. 201(c)(2) (emphasis added) ("The court . . . must take judicial notice if a party requests it *and the court is supplied with the necessary information*.")

3.4.5 Should the Court Consider Exhibit 28? No.

Exhibit 28 is the "Policies and Exceptions" page from a website maintained by ASCO. Puma again asks the Court to consider this document through judicial notice. But Puma seems to conflate that legal principle with the doctrine of incorporation by reference. Puma says Norfolk County Council "relies on materials submitted to ASCO, but omits the policies governing the submission of such documents." So, Puma says, the Court should take judicial notice of the ASCO Confidentiality Policy, which it pulled in November 2015. As with the Herceptin webpage, Norfolk County Council argues (and Puma doesn't seem to dispute) that the webpages Puma provided were captured in November 2015, while the relevant time period for the claims here is from roughly July 2014 through May 2015. Norfolk County Council also has some objections about how Puma uses this document in its Motion to Dismiss.

The Court agrees with Norfolk County Council that Puma hasn't adequately shown that Exhibit 28 should be judicially noticed here. Puma responds to Norfolk County Council's arguments by providing information from the Internet Archive's Wayback Machine, an online internet page archive, showing the November 2015 page and the relevant page are "substantively identical." But even if the Court accepted this as a sufficient showing to take judicial notice, Puma is again providing this extrinsic evidence to support its extrinsic evidence for the first time in a reply brief.

3.4.6 The Requests for Judicial Notice Generally

Applying the law and the Court's best judgment, the Court has tried to justly resolve the disputes over the requests for judicial notice. But the Court can't help but note that the disputes largely reflect lots of effort with little effect. The Court's ultimate ruling on the Motion to Dismiss wouldn't change if its rulings on these requests for judicial notice were

different, given that it generally had to take all well-plead factual allegations in the complaint as true.

The requests to consider extrinsic evidence weren't inherently inappropriate, as extrinsic evidence does sometimes come in on securities fraud cases like this one. But a dispute over fourteen or fifteen of twenty-eight exhibits may have been unnecessary. A reply brief supporting a request for judicial notice may be unnecessary. An emergency application to file a surreply to that reply brief may be unnecessary. And it's not clear what happened during the meet-and-confer process required under Local Rule 7-3. Puma should have been able to avoid filing a reply laden with new material, and Norfolk County Council should have been able to avoid filing an emergency application to file a surreply responding to that reply, if the parties had meaningfully discussed these requests. It's not clear who's at fault—it's possible Puma didn't adequately describe its planned requests, it's possible Norfolk County Council held back its objections, and it's possible neither side wanted to focus on requests for judicial notice instead of the Motion to Dismiss itself. It's also not particularly important now. The inefficiencies created by whatever happened here are small in the scope of civil litigation. But the Court notes them to encourage counsel to try to avoid them moving forward.

4. ANALYSIS

Finally, at last, to the merits of the Motion to Dismiss. Norfolk County Council asserts two claims: (1) violation of § 10(b) of the Exchange Act and Rule 10b-5 and (2) violation of § 20(a) of the Exchange Act. Both parties appear to agree that the second claim's fate at this point in the case is tied to the fate of the first claim. Accordingly, the Court only discusses the first claim.

To adequately plead a violation of Rule 10b-5 based on misstatements, a plaintiff must adequately allege: "1) a material misrepresentation or omission by the defendant; 2) scienter; 3) a connection between the misrepresentation or omission and the purchase or sale of a security; 4) reliance upon the misrepresentation or omission; 5) economic loss; and 6) loss causation." *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d at 876.

Puma points to three reasons why the Court should shut the courthouse doors on Norfolk County Council's complaint. First, Puma says Norfolk County Council hasn't adequately pled falsity, which is part of the first element. Second, Puma says Norfolk County Council hasn't adequately pled scienter. Third, Puma says Norfolk County Council hasn't adequately tailored its allegations so that each Defendant knows what it supposedly did wrong. Rule 9(b), Rule 12(b)(6), the PSLRA, and the cases interpreting each of these laws provide the relevant pleading standards. For example, there are particular pleading standards applicable to the falsity and scienter elements.

4.1 More Pleading Standards

The PSLRA has exacting requirements for pleading "falsity." *Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1070 (9th Cir. 2008). A complaint has to "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C.A. § 78u-4.

Similarly, to adequately plead scienter under the PSLRA, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(a). Courts have described the required state of mind as one that intends to deceive, manipulate, or defraud. *See Metzler*, 540 F.3d at 1070.

Courts have also said a complaint "must allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness." *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1180 (9th Cir. 2009) (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009), *aff'd sub nom. Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27 (2011) (quotation marks omitted)). But in any case, "[t]he inferences that the defendant acted with scienter need not be . . . of the 'smoking-gun' genre." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007).

"[F]alsity and scienter in private securities fraud cases are generally strongly inferred from the same set of facts, and the two requirements may be combined into a unitary inquiry under the PSLRA." *In re Daou Sys., Inc.*, 411 F.3d 1006, 1015 (9th Cir. 2005) (quotation marks omitted) (quoting *In re Vantive Corp. Sec. Litig.*, 283 F.3d 1079, 1091 (9th Cir. 2002)). The Court does just that here.

4.2 Falsity, Scienter, and the Adequacy of the Allegations

Norfolk County Council has pled both falsity and scienter well enough to allow this case to get out of the starting gate. Many of Puma's arguments to the contrary are really a better measure of whether Norfolk County Council's case will be victorious past the eighth pole and down to the finish line. The Court has considered all of those arguments, and summarizes and addresses some of them here.

Puma argues that the alleged DFS misrepresentations don't satisfy the falsity pleading requirement because Norfolk County Council is confusing the absolute difference between two DFS rates with another way DFS rates can be evaluated, the hazard ratio. Using the hazard ratio, Puma argues, the disputed representations are true.

But there's enough here to force Puma to pony up and present that theory another day. For example, Puma issued a press release and held a conference call with analysts in July 2014. The press release stated that the ExteNET trial had "demonstrated that treatment with neratinib resulted in a 33% improvement in disease free survival versus placebo." On the call, an analyst asked Defendant Auerbach if the DFS for the placebo group is "probably around mid to high 80s, around 86% or so?" Auerbach says he's "comfortable with that number." The DFS rate for the placebo group was 91.6%. On the call, the analyst then asked Auerbach if he and Puma "probably had to show around 90% or 91% [in the neratinib group]? Is that reasonable?" Auerbach said "yes" and then stated "I think you can do a 33% improvement in DFS and come up with that calculation, given the numbers we gave." The DFS rate for the neratinib group was 93.9%. Norfolk County Council has adequately and specifically alleged why each of these statements and several others could be false or at least misleading. Puma's hazard ratio explanation doesn't so obviously control here as to stop Norfolk County Council's complaint in its tracks.

This is true for Puma's arguments about the Kaplan-Meier curves too. During the same conference call, another analyst said to Auerbach, "I assume you have seen the curves for the two arms," and then asked whether the curves separated over time. Auerbach replied with a "yes," describes some of the data, and then states "it looks like the curves are continuing to separate." He went on. Puma noted that in several of these statements, the analyst, and not Auerbach, offered the DFS rate or other applicable measure. But Auerbach didn't appear to correct or disagree with the analysts. In any case, Puma's innocuous explanations for these statements might be right, but they're not right for right now. Puma underscores that with its repeated reference to statements taken "out of context." Perhaps Norfolk County Council is taking statements out of context. But a motion to dismiss isn't typically where that context is fully fleshed out.

Puma places great weight on *Kleinman v. Elan Corp.*, a case from the Second Circuit. *See Kleinman v. Elan Corp.*, 706 F.3d 145 (2d Cir. 2013). It's understandable why, but *Kleinman* is meaningfully distinguishable. The facts there and here are different enough to merit different outcomes. In *Kleinman*, "[m]ost if not all of [the plaintiff's] argument centers on omissions—statements he believe[d] were necessary to make [a press release] not misleading." *Id.* at 152. In *Kleinman*, the complaint "does not allege that anything in the [press release] was literally false." *Id.* at 153. In *Kleinman*, the disputed representations involve relatively clear-cut, inactionable puffery—for example, a statement that some preliminary findings were "encouraging." *Id.* These and other facts distinguish that case from this one.

Like Puma's arguments about falsity, Puma's arguments about scienter aren't persuasive at this point. Norfolk County Council points to another part of the conference call to show that Auerbach knew about the allegedly real trial results when he made the alleged misrepresentations. That and the other allegations in the complaint are enough to adequately plead the required state of mind. After all, "[t]he most direct way to show both that a statement was false when made and that the party making the statement knew it was false is via contemporaneous reports or data, available to the party, which contradict the statement." *Nursing Home Pension Fund v. Oracle Corp.*, 380 F.3d 1226, 1230 (9th Cir. 2004). That seems to be exactly what Norfolk County Council's alleged here.

It's a close call deciding whether there's enough in the complaint to support a strong inference as to motive to commit the fraud, particularly under the heightened pleading standard. But taken together and examined alongside the other allegations in this case, Norfolk County Council's allegations about the timing of Puma's alleged misrepresentations and the public offering, as well as the allegations about Auerbach and Eyler's individual performance-based compensation, are enough, even if barely so. "[A] reasonable person would deem the inference of scienter cogent and at least as compelling as" Puma's arguments to the contrary. *Tellabs*, 551 U.S. at 324.

Puma makes other arguments—for example, about whether allegations are sufficiently specific as to each Defendant. As noted, the Court has considered and rejected these arguments.

For all of these reasons and others, the Court DENIES the Motion to Dismiss. So, we're out of the starting gate, off and running. Looming ahead, just around the turn, may be a summary judgment motion.

5. DISPOSITION

The Court DENIES the Motion to Dismiss.

DATED: September 30, 2016

Andrew J. Guilford
United States District Judge