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FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 16-56069
DC No. 3:15-cv-00540-JLS

[Filed August 13, 2018]

KARIM KHOJA, on behalf of himself and all others similarly situated, *Plaintiff-Appellant*,	)
v.	)
OREXIGEN THERAPEUTICS, INC.; JOSEPH P. HAGAN; MICHAEL A. NARACHI; PRESTON KLASSEN, *Defendants-Appellees.*	)

OPINION

Appeal from the United States District Court
for the Southern District of California
Janis L. Sammartino, District Judge, Presiding

Argued and Submitted November 6, 2017
Pasadena, California

Filed August 13, 2018

Before: A. Wallace Tashima, and Marsha S. Berzon, Circuit Judges, and Robert E. Payne,[*] District Judge

Opinion by Judge Tashima

SUMMARY[**]

Securities Fraud

The panel affirmed in part and reversed in part the district court's dismissal, for failure to state a claim, of a securities fraud action under the Securities Exchange Act of 1934.

Defendant Orexigen Therapeutics, Inc., a small biotechnology firm, developed Contrave, an obesity drug candidate. Count I alleged that Orexigen and its executives misrepresented and/or omitted material facts to conceal the truth and/or adverse material information about a drug trial called the Light Study, in violation of § 10(b) of the Act and SEC Rule 10b-5. Count II alleged a fraudulent scheme under SEC Rules 10b-5(a) and (c), and Count III alleged control person liability on the part of the executives under § 20(a) of the Act.

The district court relied, in part, on documents that it judicially noticed or incorporated into the complaint by reference. The panel held that under Federal Rule of Evidence 201, a court may take judicial notice of matters of public record without converting a motion to

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[*] The Honorable Robert E. Payne, United States District Judge for the Eastern District of Virginia, sitting by designation.

[**] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

dismiss into a motion for summary judgment, but a court cannot take judicial notice of disputed facts contained in such public records. The panel concluded that the district court abused its discretion in judicially noticing certain facts but properly took judicial notice of the date of Orexigen's international patent application for Contrave. The panel reversed and remanded for clarification on Exhibit D, reversed the district court's judicial notice of Exhibit E, and affirmed the judicial notice of Exhibit V.

The panel held that incorporation-by-reference is a judicially created doctrine that treats certain documents as though they are part of the complaint itself. The doctrine prevents plaintiffs from selecting only portions of documents that support their claims, while omitting portions of those very documents that weaken or doom their claims. The panel held that a defendant may seek to incorporate a document into the complaint if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim. But if a document merely creates a defense to the well-pled allegations in the complaint, then that document did not necessarily form the basis of the complaint. And it is improper to assume the truth of an incorporated document if such assumptions only serve to dispute facts stated in a well-pleaded complaint. The panel held that the district court abused its discretion by incorporating certain documents into the complaint and properly incorporated others. Specifically, the panel reversed the district court's incorporation-by-reference of Exhibits B, C, F, H, R, S, and U, and it affirmed the incorporation of Exhibits A, I K, L, N, O, P, and T.

The panel affirmed in part and reversed in part the district court's dismissal of Count I for failure sufficiently to allege falsity and materiality, and it affirmed the district court's dismissal of Count II on the basis that the substance of the claim could not be discerned. Where affirming, the panel granted leave to amend the complaint. As to Count III, the panel reversed so that the district court could reconsider those claims in light of the reversal of claims in Count I and any amendments to the complaint.

The panel specified that its disposition of the appeal pertained only to claims against the executive defendants. With respect to Orexigen, appellate proceedings remained stayed pending resolution of bankruptcy proceedings. The panel instructed the Clerk to administratively close the docket with respect to Orexigen, pending further order of the court.

COUNSEL

Ramzi Abadou (argued), Khan Swick & Foti, San Francisco, California; Lewis Khan, Alexander Burns, and Scott St. John, Khan Swick & Foti LLC, Madisonville, Louisiana; for Plaintiff-Appellant.

Jessica Valenzuela Santamaria (argued) and John C. Dwyer, Cooley LLP, Palo Alto, California; Mary Kathryn Kelley and Dane R. Voris, Cooley LLP, San Diego, California; for Defendants-Appellees.

OPINION

TASHIMA, Circuit Judge:

This is an appeal from the dismissal by the district court of an action under the Securities Exchange Act of

1934, 15 U.S.C. §§ 78a *et seq.* We must decide whether the district court erred in dismissing the action. We conclude that it did, in part. We also conclude that, in dismissing the action, the district court abused its discretion by improperly considering materials outside the Complaint. We also address and clarify when and how the district court should consider materials extraneous to the pleadings at the motion to dismiss stage via judicial notice and the incorporation-by-reference doctrine.

BACKGROUND

I. Facts Alleged in Complaint

Appellee Orexigen Therapeutics, Inc. ("Orexigen") is a small biotechnology firm that develops obesity drugs.[1] At all relevant times, Orexigen employed Michael Narachi (CEO and Director), Joseph Hagan (Chief Business Officer, Treasurer, and CFO), and Preston Klassen (Head of Global Development) (collectively, the "Executive Defendants").[2]

A. Contrave and the "Light Study"

Contrave is Orexigen's primary drug candidate. It was developed to treat obesity in patients. Obese

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[1] After oral argument in this appeal, Orexigen filed a voluntary petition for bankruptcy under Chapter 11, in the United States Bankruptcy Court for the District of Delaware, No. 18-10518-KG. Therefore, pursuant to the automatic stay, 11 U.S.C. § 362(a), this opinion does not address or decide Plaintiff's appeal as against defendant-appellee Orexigen.

[2] Unless necessary to distinguish them, we refer to the Executive Defendants and the company collectively as "Orexigen."

patients are at risk for major adverse cardiovascular events ("MACE"). To develop Contrave, Orexigen partnered with Takeda Pharmaceutical Co. Ltd. ("Takeda").

The Food and Drug Administration ("FDA") required Orexigen to conduct a trial of Contrave, called the "Light Study." Because obese persons are already at risk for MACE, the Light Study would assess if Contrave increased that risk. Once 25 percent of a predetermined amount of MACE occurred, an "interim analysis" would assess if patients on Contrave were more likely to suffer MACE than those on a placebo ("25 percent interim results"). As required by the FDA, an Executive Steering Committee ("ESC"), separate from Orexigen, oversaw the Light Study. Dr. Steven Nissen, from the Cleveland Clinic, headed the ESC. A Data Monitoring Committee ("DMC") was also created to monitor the trial and report its results.

FDA guidelines require that trial results remain confidential. Orexigen entered into a data access plan ("DAP") with the ESC and the DMC. Orexigen agreed that when it received the 25 percent interim results, only "those individuals at [Orexigen] who needed to facilitate its regulatory filings with the FDA" would have access to them.

Orexigen initiated the Light Study in June 2012.

B. Orexigen Leaks Positive 25 Percent Interim Results

In November 2013, subject to the DAP, the DMC shared the 25 percent interim results with Orexigen. The results were unexpectedly positive. Rather than increase the risk of MACE, "Contrave reduced

cardiovascular events by 41 [percent] compared with a placebo."

The Light Study administrators requested that Orexigen produce a list of individuals who knew of the 25 percent interim results. Orexigen revealed that over 100 people with a financial interest in the Light Study knew of the 25 percent interim results.

As a sanction for Orexigen's apparent leak, the FDA required that four Orexigen executives, including Klassen, sign an agreement forbidding Orexigen from disclosing the 25 percent interim results again. Another DAP further limited which Orexigen employees had access to interim results. Although the Light Study would continue, the FDA also required that Orexigen perform an entirely new trial to study Contrave's cardiovascular effects.

During a June 4, 2014, meeting about the leak, the FDA reminded Narachi and Klassen that the leaked results – representing only 25 percent of the pre-determined amount of MACE required for the study – have "a high degree of uncertainty and were likely to change with the accumulation of additional data."

C. Orexigen Files Patent Application Containing Interim Results Confidentially, Then Requests Publication.

Less than a month later, on July 2, 2014, Klassen submitted a provisional patent application ("2014 Patent Application") for Contrave to the United States Patent and Trademark Office ("USPTO"). The 2014 Patent Application contained the 25 percent interim results. Orexigen filed the 2014 Patent Application

pursuant to 35 U.S.C. § 122, which renders patent applications confidential.

In December 2014, the European Medicines Agency ("EMA") informed Orexigen that, in March 2015, the EMA would review a draft decision to grant marketing authorization for Contrave in Europe.[3] Orexigen then requested that the USPTO publish the 2014 Patent Application, thus rescinding its earlier request to keep it confidential. On February 11, 2015, the USPTO informed Orexigen that it would publish the 2014 Patent Application – which contained the confidential interim results – on March 3, 2015.

D. Orexigen Reveals Interim Results Again.

When the USPTO published the 2014 Patent Application, Orexigen filed a Form 8-K ("March 2015 Form 8-K") with the Securities and Exchange Commission ("SEC"). That filing described the 2014 Patent Application, including the Light Study and the 25 percent interim results.

Securities Analysts responded immediately and positively to the revelations about Contrave. One called the 25 percent interim results the "holy grail" for cardiometabolic disease treatment.

Orexigen's stocks surged. The day before the 25 percent interim results were revealed, Orexigen's stock closed at $5.79 per share. After the revelation, the stock peaked at $9.37 per share, and closed at $7.64 per share on an unusually high trading volume. Soon

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[3] In Europe, Contrave is marketed under a different name, "Mysimba."

after, on March 13, 2015, and pursuant to Orexigen's Incentive Award Plan, Narachi and Klassen registered six million Orexigen shares.

It was not all good news, though. A March 3, 2015, Forbes article reported that a senior FDA official stated that the FDA was "very disappointed by Orexigen's actions."[4] The FDA official further warned that the 25 percent interim results should not be misinterpreted. On March 5, 2015, another Forbes article quoted an FDA official "condemning Orexigen's SEC filing as 'unreliable,' 'misleading,' and 'likely false.'" Two days later, shares of Orexigen's common stock slid almost six percent to close at $8.01 and, the following day, slid 16 percent to as low as $6.76 in intraday trading.

Weeks later, on March 26, 2015, the ESC informed Orexigen that, as the Light Study reached 50 percent completion ("50 percent interim results"), the Light Study no longer indicated a heart benefit from Contrave, contrary to what the earlier 25 percent interim results suggested. Also, because Orexigen again disclosed the 25 percent interim results in the March 2015 Form 8-K, the ESC voted unanimously to halt the Light Study.

Dr. Nissen, the Chair of the ESC, worked with Takeda to draft a press release disclosing the new Light Study data and the termination of the Light Study. Takeda approved the press release, but Orexigen did not.

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[4] Unless otherwise noted, we omit the Complaint's emphasis of any quoted material.

E. Orexigen Does Not Reveal New Developments in SEC Filings or During Investor Call.

On May 8, 2015, Orexigen filed two forms with the SEC: a press release on a Form 8-K ("May 2015 Form 8-K"), and its Quarterly Report on Form 10-Q ("May 2015 Form 10-Q").

The May 2015 Form 8-K described the Light Study, stating, in part, "[t]he clinical trial program also includes a . . . trial known as the Light Study." The May 2015 Form 10-Q stated that "additional analysis of the interim results or new data from the continuing Light Study . . . may produce negative or inconclusive results, or may be inconsistent with the conclusion that the interim analysis was successful."

That same day, Orexigen hosted a conference call with investors and analysts. An analyst asked "what is the fate of the Light Study on this point. Has that been terminated?" Klassen said that the "Light Study is continuing and we are continuing to engage both Orexigen and Takeda with the FDA and with ESC and DMC regarding ultimately the status of the study, but it's an ongoing entity as of right now."

Regarding the 50 percent interim results, an analyst asked "I assume you're not going to be releasing that; are you going to be sending it to the FDA?" Klassen responded:

> [W]e're in ongoing discussions related to that and I don't think we're going to go into the details, because again that's a look that [the] DMC does. As a plan, they look at the 25% to 50% and 75%, but it's really on the 25% analysis

> that was used for regulatory purposes. So if any of that status changes, then we would of course announce that.

Narachi said, in part:

> So, *if the decision is made to terminate the trial early* and focus resources on the next [trial], which is what we have been advocating, then I think results would come out sooner . . . *if you decide to stop the study now* there will be additional events, so these details are being discussed and worked out and as we make formal decisions there, you'll learn more about the availability of data from the study.

(Emphasis in Comp.)

Again referencing the Light Study, an analyst asked "if you could provide an estimate of the time or the strategy for disclosure around the fate of the Light Study – is that something that you need to disclose . . . ?" Narachi said:

> *I think that that would be something we disclose*. As [Klassen] said, there are active discussions between FDA, the [ESC] and DMC . . . [and] Takeda and Orexigen. And as soon as we understand specifically what the status is, so for example, *if there was a decision to terminate the trial* and move on and focus resources on the new [trial], *that would be a disclosure that we would make.*

(Emphasis in Comp.)

F. Light Study's 50 Percent Interim Results and Status Revealed

Four days after that call, on May 12, 2015, Dr. Nissen issued a statement. He said, in part, "Following premature disclosure of interim study results, the 9,000-patient Light [Study] . . . has been halted by the [ESC]." He further revealed that the most recent results did not suggest a heart benefit from Contrave.

Orexigen learned that Dr. Nissen would issue such a statement, and then issued its own. Orexigen's statement said, "Today some of the 50% interim analysis of the Light Study was disclosed by a third party. Because most of our management team remains blinded to the 50% data, we are unable to comment."

II. Procedural History

Karim Khoja is an Orexigen investor who represents a class of similarly situated Orexigen investors. On August 20, 2015, after numerous related actions were consolidated, Khoja, acting on behalf of the putative investor class, filed the operative Complaint alleging three securities violations.

Counts I and II allege violations of §10(b) of the Securities Exchange Act, 15 U.S.C. § 78j(b), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5, against Orexigen (including the individually named Executive Defendants). Count I alleges that Orexigen and the executives misrepresented and/or omitted material facts "to conceal the truth and/or adverse material information" about the Light Study. Count II alleges a fraud scheme under SEC Rules 10b-5(a) and (c).

Count III is against only the Executive Defendants. Under § 20(a) of the Securities Exchange Act, 15 U.S.C. § 78t, Count III claims that, as "controlling" individuals, those executives are liable for the violations in Counts I and II.

Orexigen moved to dismiss the Complaint for failure to state a claim under §§ 10 and 20 of the Exchange Act. Concurrently, Orexigen requested judicial notice of 22 documents or, alternatively, that the district court treat those documents as incorporated into the Complaint itself. The district court granted this motion for all but one document.

The district court then dismissed the Complaint for failure to state a claim. It dismissed two claims under Count I with prejudice. It granted Khoja leave to amend the others.

Instead of amending the Complaint, Khoja requested entry of judgment in order to pursue the instant appeal. Judgment dismissing the action was entered on June 27, 2016. Khoja timely appealed.

JURISDICTION

We have jurisdiction to review final judgments of district courts. 28 U.S.C. § 1291. Khoja timely appealed the judgment. Fed. R. App. P. 4(b)(4). Accordingly, we have jurisdiction of this appeal.

STANDARD OF REVIEW

We review dismissal for failure to state a claim de novo. *Dougherty v. City of Covina*, 654 F.3d 892, 897 (9th Cir. 2011). The decision to take judicial notice and/or incorporate documents by reference is reviewed

for an abuse of discretion. *United States v. 14.02 Acres of Land More or Less in Fresno Cty.*, 547 F.3d 943, 955 (9th Cir. 2008) (judicial notice); *Davis v. HSBC Bank Nev., N.A.*, 691 F.3d 1152, 1160 (9th Cir. 2012) (incorporation by reference).

DISCUSSION

I. Judicial Notice and Incorporation-by-Reference Doctrine.

In dismissing the Complaint, the district court relied, in part, on 21 documents that it judicially noticed or incorporated into the Complaint by reference. To assess whether the district court erred in dismissing any claims, then, we must first determine whether the district court properly considered those documents at the motion to dismiss stage.

Generally, district courts may not consider material outside the pleadings when assessing the sufficiency of a complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure. *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001). When "matters outside the pleading are presented to and not excluded by the court," the 12(b)(6) motion converts into a motion for summary judgment under Rule 56. Fed. R. Civ. P. 12(d). Then, both parties must have the opportunity "to present all the material that is pertinent to the motion." *Id.*

There are two exceptions to this rule: the incorporation-by-reference doctrine, and judicial notice under Federal Rule of Evidence 201. Both of these procedures permit district courts to consider materials outside a complaint, but each does so for different

reasons and in different ways. We address each *seriatim*.

Before doing so, however, we note a concerning pattern in securities cases like this one: exploiting these procedures improperly to defeat what would otherwise constitute adequately stated claims at the pleading stage.

Properly used, this practice has support. The Supreme Court stated in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, that, in assessing securities fraud claims, "courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." 551 U.S. 308, 322 (2007).

Thus, judicial notice and incorporation-by-reference do have roles to play at the pleading stage. The overuse and improper application of judicial notice and the incorporation-by-reference doctrine, however, can lead to unintended and harmful results. Defendants face an alluring temptation to pile on numerous documents to their motions to dismiss to undermine the complaint, and hopefully dismiss the case at an early stage. Yet the unscrupulous use of extrinsic documents to resolve competing theories against the complaint risks premature dismissals of plausible claims that may turn out to be valid after discovery. This risk is especially significant in SEC fraud matters, where there is already a heightened pleading standard, and the defendants possess materials to which the plaintiffs do not yet have access. See *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 876 (9th Cir. 2012) (observing that

plaintiffs asserting "claims under section 10(b) and Rule 10b-5 must not only meet the requirements of Rule 8, but must satisfy the heightened pleading requirements of both Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act"); *see also Hsu v. Puma Biotechnology, Inc.*, 213 F. Supp. 3d 1275, 1281–82 (C.D. Cal. 2016) (describing "practical reality" of "inappropriate efforts by defendants" in SEC matters to "expand courts' consideration of extrinsic evidence at the motion to dismiss stage," which is "particularly troubling in the common situation of asymmetry, where a defendant starts off with sole possession of the information about the alleged wrongdoing"). If defendants are permitted to present their own version of the facts at the pleading stage – and district courts accept those facts as uncontroverted and true – it becomes near impossible for even the most aggrieved plaintiff to demonstrate a sufficiently "plausible" claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)) (articulating standard for "plausible" claim for relief at pleading stage). Such undermining of the usual pleading burdens is not the purpose of judicial notice or the incorporation-by-reference doctrine.

Accordingly, we aim here to clarify when it is proper to take judicial notice of facts in documents, or to incorporate by reference documents into a complaint, and when it is not.

A. Judicial Notice

Judicial notice under Rule 201 permits a court to notice an adjudicative fact if it is "not subject to reasonable dispute." Fed. R. Evid. 201(b). A fact is "not

subject to reasonable dispute" if it is "generally known," or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(1)–(2).

Accordingly, "[a] court may take judicial notice of matters of public record without converting a motion to dismiss into a motion for summary judgment." *Lee*, 250 F.3d at 689 (quotation marks and citation omitted). But a court cannot take judicial notice of disputed facts contained in such public records. *Id.*

The district court judicially noticed three exhibits attached to Orexigen's Motion to Dismiss. We address each, in turn.

1. September 11, 2014 Investors' Conference Call Transcript.

The district court judicially noticed a September 11, 2014, investors' conference call transcript (Ex. D) that was submitted with one of Orexigen's SEC filings.

An investor call transcript submitted to the SEC generally qualifies as a "source[] whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b); *see, e.g.*, *In re Wash. Mut., Inc. Sec., Derivative & ERISA Litig.*, 259 F.R.D. 490, 495 (W.D. Wash. 2009) (taking judicial notice of uncontested conference call transcripts in securities fraud action); *In re Pixar Sec. Litig.*, 450 F. Supp. 2d 1096, 1100 (N.D. Cal. 2006) (same).

But accuracy is only part of the inquiry under Rule 201(b). A court must also consider – and identify – which fact or facts it is noticing from such a transcript. Just because the document itself is susceptible to

judicial notice does not mean that every assertion of fact within that document is judicially noticeable for its truth.

Here, the district court did not clearly specify what fact or facts it judicially noticed from this transcript. The district court only indicated it would not "take notice of the truth of the facts cited" within the exhibit.

If the district court judicially noticed that there was an investors' conference call on September 11, 2014, that would, in theory, be permissible under Rule 201(b) because that fact "can be accurately and readily determined" from the transcript.[5]

Orexigen sought judicial notice of the transcript because it "reveals what investors already knew[] about the decision to conduct" another study besides the Light Study to assess Contrave's heart risks. Then, in its motion to dismiss the Complaint, Orexigen relied on the transcript to demonstrate that it "previously disclosed . . . that the FDA had determined that the Light Study would not serve as the" definitive trial for Contrave. Arguably, such a disclosure would be significant to Khoja's claim that Orexigen materially misrepresented the status of the Light Study in May 2015. If Orexigen already told investors that the Light Study would not serve as the definitive trial, then Orexigen could argue that it did not necessarily mislead investors when it failed to inform them about the Light Study's termination.

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[5] It is unclear, however, how this fact would be relevant. *See* 21B Charles Alan Wright & Kenneth W. Graham, Jr., *Federal Practice and Procedure* § 5104, at 156 (2d ed. 2005) ("An irrelevant fact could hardly be an 'adjudicative fact'. . . .").

Yet, from the transcript, it is unclear what exactly Orexigen "previously disclosed" about the Light Study. At one point, Klassen informed investors that, given recent "data confidentiality issues[,] . . . continuing doing the Light Study unchanged was not an option." At another point, though, Klassen said, "[i]n the meantime," while a new study began, "the Light Study is ongoing."

Reasonable people could debate what exactly this conference call disclosed about the Light Study. Klassen's statements are not entirely consistent; his former statement suggests the Light Study was no longer underway, but his latter statement suggests the opposite. It is improper to judicially notice a transcript when the substance of the transcript "is subject to varying interpretations, and there is a reasonable dispute as to what the [transcript] establishes." *Reina-Rodriguez v. United States*, 655 F.3d 1182, 1193 (9th Cir. 2011). In that scenario, there is no fact established by the transcript "not subject to reasonable dispute," and the fact identified does not qualify for judicial notice under Rule 201(b).

To the extent that the district court judicially noticed the September 11, 2014, investors' call transcript for the purpose for which was offered, *i.e.*, to determine what the investors knew about the status of the Light Study at that time, the district court abused its discretion.

2. December 18, 2014, EMA Report About Contrave.

The district court judicially noticed a December 18, 2014, EMA report ("2014 EMA report") (Ex. E) about

Contrave. Again, the district court did not expressly state what fact it noticed from that report. The rest of the district court's order, however, sheds some light on the district court's reasoning.

Based on the 2014 EMA Report, the district court concluded that the EMA already knew of the favorable, 25 percent interim results before Orexigen sought publication of the 2014 Patent Application, which contained the 25 percent interim results. Therefore, contrary to Khoja's theory, Orexigen could not hope to influence the EMA by improperly publishing the confidential, 25 percent interim results through the 2014 Patent Application.

It thus appears that the district court judicially noticed the fact that the 2014 EMA Report shows that the EMA learned of the 25 percent interim results from Orexiten by December 18, 2014. Judicially noticing that fact was improper.

To be sure, as an agency report, the 2014 EMA Report is generally susceptible to judicial notice. *See United States v. Ritchie*, 342 F.3d 903, 907–09 (9th Cir. 2003) (observing "[c]ourts may take judicial notice of some public records, including the records and reports of administrative bodies" (internal quotation marks and citation omitted)). But, again ascertaining this factor is only part of the inquiry under Rule 201(b). Here, like the September 2014 transcript, there is a reasonable dispute as to what the report establishes.

First, we look to what the 2014 EMA Report states. Regarding Contrave, the 2014 EMA Report states, "The Applicant has submitted the first interim report of the [Light Study]." and then summarizes te Light Study's

interim results. These statements indicate that, somehow, the EMA knew of the 25 percent interim results when the EMA published the instant report on December 18, 2014. Thus, the district court could have correctly noticed the fact that, based on the 2014 EMA Report, the EMA knew about the 25 percent interim results before Orexigen sought to publish its 2014 Patent Application.

Even so, the 2014 EMA report alone, does not establish who told the EMA about the 25 percent interim results. This gap is important. If Orexigen already provided the 25 percent interim results directly to the EMA, then, as the district court found, it would make little sense for Orexigen to go through the ruse of publishing the 2014 Patent Application. However, the report lists the "Applicant" only as "Orexigen Therapeutics Ireland Limited" ("Orexigen Ireland"). If Orexigen Ireland revealed the 25 percent interim results to the EMA without consulting the Orexigen defendants in this case, then Orexigen Ireland unwittingly foiled Orexigen's alleged scheme to reveal those results by publishing the 2014 Patent Application. Then, Orexigen's alleged scheme – although botched – could remain theoretically actionable under Rule 10b-5.

Of course, Orexigen Ireland may have obtained the 25 percent interim results from Orexigen, or Orexigen could have explicitly advised Orexigen Ireland to submit those results to the EMA, or Orexigen Ireland's actions could be imputed to Orexigen. The report does not particularly point to any of these inferences. Therefore, the district court could not reasonably conclude on a motion to dismiss what the 2014 EMA

Report revealed about Orexigen's alleged scheme to publish the 2014 Patent Application. The district court abused its discretion in judicially noticing that fact on the basis of the 2014 EMA Report.

3. International Patent Application.

The district court judicially noticed Orexigen's international patent application for Contrave to the World International Property Organization ("WIPO application") (Ex. V). Again, the district court did not explicitly state what it judicially noticed about the WIPO application. Based on the district court's order, however, it appears that the district court noticed only the filing date of the WIPO application.

To start, the date "can be accurately and readily determined from" the WIPO application, which was published by a foreign government agency. Fed. R. Evid. 201(b)(2). Neither party disputes the WIPO application's authenticity, or its accuracy. *Id.* The WIPO application is, thus, "verifiable with certainty, and of the same type as other governmental documents which courts have judicially noticed." *United States v. Camp*, 723 F.2d 741, 744 n.** (9th Cir. 1984); *see also GeoVector Corp. v. Samsung Elecs. Co.*, 234 F. Supp. 3d 1009, 1016 n.2 (N.D. Cal. 2017) (taking judicial notice of Korean patent application).

The district court did not abuse its discretion by judicially noticing when Orexigen filed the WIPO Application.

B. Incorporation-by-Reference.

Unlike rule-established judicial notice, incorporation-by-reference is a judicially created

doctrine that treats certain documents as though they are part of the complaint itself. The doctrine prevents plaintiffs from selecting only portions of documents that support their claims, while omitting portions of those very documents that weaken – or doom – their claims. *Parrino v. FHP, Inc.*, 146 F.3d 699, 706 (9th Cir. 1998), *superseded by statute on other grounds as recognized in Abrego Abrego v. Dow Chem. Co.*, 443 F.3d 676, 681–82 (9th Cir. 2006) (observing "the policy concern underlying the rule: Preventing plaintiffs from surviving a Rule 12(b)(6) motion by deliberately omitting references to documents upon which their claims are based").

Although the doctrine is straightforward in its purpose, it is not always easy to apply. In *Ritchie*, we said that a defendant may seek to incorporate a document into the complaint "if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *Ritchie*, 342 F.3d at 907. How "extensively" must the complaint refer to the document? This court has held that "the mere mention of the existence of a document is insufficient to incorporate the contents of a document" under *Ritchie*. *Coto Settlement v. Eisenberg*, 593 F.3d 1031, 1038 (9th Cir. 2010) (citing *Ritchie*, 342 F.3d at 908–09). A more difficult question is whether a document can ever "form[] the basis of the plaintiff's claim" if the complaint does not mention the document at all.

To be sure, there are those rare instances when assessing the sufficiency of a claim requires that the document at issue be reviewed, even at the pleading stage. For example, in *Knievel v. ESPN*, 393 F.3d 1068 (9th Cir. 2005), we affirmed the incorporation of

materials that the complaint did not reference at all. Evel Knievel alleged that ESPN defamed him and his wife on its website by posting a picture of them and another woman with an arguably suggestive caption. *Id.* at 1070. In the complaint, Knievel only referenced the allegedly defamatory photo and caption. *Id.* at 1076. ESPN then submitted the surrounding photos and captions to show a reasonable person would not view the caption at issue as defamatory. *Id.* A defamation claim requires showing that the statement at issue, given its context, "is capable of sustaining a defamatory meaning." *Id.* at 1073 (internal quotation maks omitted). Therefore, even though the complaint did not "allege or describe the contents of the surrounding pages," it was proper to incorporate them because the claim necessarily depended on them. *Id.* at 1076; *see also Parrino*, 146 F.3d at 706 (incorporating employee health plan where the claims were premised upon plaintiff's coverage under the plan).

However, if the document merely creates a defense to the well-pled allegations in the complaint, then that document did not necessarily form the basis of the complaint. Otherwise, defendants could use the doctrine to insert their own version of events into the complaint to defeat otherwise cognizable claims. *See In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 995–96 (S.D. Cal. 2005) (declining to incorporate numerous exhibits in SEC action where the complaint did not mention or rely on them, but the defendants instead "offer[ed] the documents as evidence that Defendants did not commit a securities violation"); *Glob. Network Commc'ns, Inc. v. City of New York*, 458 F.3d 150, 156–57 (2d Cir. 2006) (finding error where the court relied on documents the complaint did not

mention to resolve an issue in defendant's favor, even though the complaint had not raised the issue). Submitting documents not mentioned in the complaint to create a defense is nothing more than another way of disputing the factual allegations in the complaint, but with a perverse added benefit: unless the district court converts the defendant's motion to dismiss into a motion for summary judgment, the plaintiff receives no opportunity to respond to the defendant's new version of the facts. Without that opportunity to respond, the defendant's newly-expanded version of the complaint – accepted as true at the pleading stage – can easily topple otherwise cognizable claims. Although the incorporation-by-reference doctrine is designed to prevent artful pleading by plaintiffs, the doctrine is not a tool for defendants to short-circuit the resolution of a well-pleaded claim.

For this same reason, what inferences a court may draw from an incorporated document should also be approached with caution. We have stated that, unlike judicial notice, a court "may assume [an incorporated document's] contents are true for purposes of a motion to dismiss under Rule 12(b)(6)." *Marder v. Lopez*, 450 F.3d 445, 448 (9th Cir. 2006) (quoting *Ritchie*, 342 F.3d at 908). While this is generally true, it is improper to assume the truth of an incorporated document if such assumptions only serve to dispute facts stated in a well-pleaded complaint. This admonition is, of course, consistent with the prohibition against resolving factual disputes at the pleading stage. *See In re Tracht Gut, LLC*, 836 F.3d 1146, 1150 (9th Cir. 2016) ("At the motion to dismiss phase, the trial court must accept as true all facts alleged in the complaint and draw all reasonable inferences in favor of the plaintiff."); *see*

also Sgro v. Danone Waters of N. Am., Inc., 532 F.3d 940, 942, n.1 (9th Cir. 2008) (finding it proper to consider disability benefits plan referenced in complaint, but declining to accept truth of the plan's contents where the parties disputed whether defendant actually implemented the plan according to its terms).

With these principles in mind, we turn to the documents at issue here. The district court incorporated eighteen documents, fifteen of which Khoja objects to on appeal.

1. Analyst Reports and Blog Entries.

a. *March 6, 2015,* Wall Street Journal *blog post.*

The district court incorporated a March 6, 2015, *Wall Street Journal* blog post titled "Orexigen Data is 'Unreliable and Premature': FDA's Jenkins Explains." (Ex. C) The Complaint quotes this post once in a two-sentence footnote explaining the meaning and significance of a DAP. This footnote is the only reference to the blog post in the Complaint. For "extensively" to mean anything under *Ritchie*, it should, ordinarily at least, mean more than once. *See Coto*, 593 F.3d at 1038. Otherwise, the rule would simply require a complaint to "refer" to the document. In theory, a reference may be sufficiently "extensive" if a single reference is relatively lengthy. Here, the quotation comprises only a few lines in a footnote of a 67-page complaint. It conveys only basic historic facts about the DAP. It is not sufficiently extensive under *Ritchie*.

Nor did the blog post form the basis of any claim in the Complaint. Although the blog post shares a

discussion with Dr. Jenkins about the unreliability of the earlier 25 percent interim results, the claims do not rely on what exactly Dr. Jenkins said to this particular blogger. Rather, the claims concern whether Orexigen misled investors about the reliability of the interim results and the status of the Light Study. *Cf. Branch v Tunnell*, 14 F.3d 449, 453–54 (9th Cir. 1994), *overruled on other grounds by Galbraith v. County of Santa Clara*, 307 F.3d 1119 (9th Cir. 2002) (incorporating transcript of testimony plaintiff relied on to allege defendant submitted a false affidavit where the transcript actually proved defendant did not do so). Accordingly, the March 6, 2015, *Wall Street Journal* blog post (Ex. C) did not satisfy *Ritchie*. The district court abused its discretion by incorporating it.

b. *March 4, 2015, Blog Post, "Fat Chance: FDA Chastises Orexigen."*

The district court incorporated another blog post: a March 4, 2015 *Wall Street Journal* post titled "Fat Chance: FDA Chastises Orexigen for Disclosing Interim Trial Data." (Ex. I)

The Complaint only identifies and quotes this blog post once. The quotation – nearly a page and a half – is lengthy and conveys numerous facts: FDA officials were upset about the release of interim results; the FDA "considers the preliminary data 'far too unreliable to conclude anything further about cardiovascular safety'"; the Light Study may be at risk because of the disclosures; and Orexigen violated the Light Study's confidentiality once before.

Although the claims do not turn on the blog post itself, Khoja did more than merely mention it. *See Coto*,

593 F.3d at 1038. Per *Ritchie*, it was not an abuse of discretion to incorporate it.

c. *March 3, 2015, Market Reports.*

The Complaint quoted two reports (Ex. K & L) to demonstrate how analysts positively reacted to the interim results upon release of the allegedly misleading March 2015 Form 8-K: (1) a March 3, 2015, RBC Capital Markets report titled "Orexigen Therapeutics Inc. LIGHT interim data reveal Contrave positive CV effect; extend IP by 7 years"; and (2) a March 3, 2015, Leerink Partner report titled "OREXIGEN THERAPEUTICS, INC 25% Interim LIGHT Analysis Shows Stat. Sig. Contrave Benefit on CV Outcomes."

The quotes are not as extensive as the quotations of the March 4, 2015, blog post, discussed above. Nonetheless, the reports form the basis of Khoja's claim that the market relied on Orexigen's claims about the 25 percent interim results after "numerous securities analysts" followed and wrote reports about Orexigen. The district court did not abuse its discretion by incorporating these reports. *See, e.g.*, *Patel v. Parnes*, 253 F.R.D. 531, 546–50 (C.D. Cal. 2008) (incorporating analyst reports to show when the alleged misrepresentations were provided to the market and their materiality).

d. *March 3, 2015, Forbes Web Article – "The FDA Is Forcing Orexigen to Do a Second Safety Study Because of Contrave Disclosures."*

The Complaint quotes the article (Ex. N) to show that the FDA "warned patients and physicians that it was 'critical that the[] interim data [] not be

misinterpreted.'" (Alterations in original.) Then, "immediately after" this article, Orexigen submitted its own statement "to maintain the artificial price inflation in [Orexigen's] securities." Khoja thus claims that Orexigen's response to the article was truly part of its scheme to inflate its stock values. Because the article triggered the alleged scheme, the article formed the basis of the scheme. Accordingly, the district court did not abuse its discretion by incorporating the article.

e. *March 5, 2015 Forbes web article titled "Top FDA Official Says Orexigen Study Result 'Unreliable,' 'Misleading.'"*

The Complaint describes and quotes this article (Ex.O):

> After the close of trading on March 5, 2015, in a report entitled "Top FDA Official Says Orexigen Study Result 'Unreliable,' 'Misleading'" published on *Forbes.com*, top FDA official Dr. John Jenkins criticized Orexigen and its decision to release interim trial data. In the report, he criticized the released data as "unreliable," "misleading," and "likely false." Dr. Jenkins also said that the results must be kept confidential to avoid compromising the trial's integrity so researchers can get a clear sense of any cardiovascular risk that comes with the drug. The report also warned that if "Orexigen cannot find a way to set things right, it could face fines, civil penalties, or even the withdrawal of Contrave from the market.

The Complaint then alleges that, "[a]s a result of the FDA's" statements in the article, "the price of Orexigen stock plummeted."

These are more than passing reference to the article. *See Ritchie*, 342 F.3d at 908. The Complaint alleges the loss in Orexigen's stock price occurred because of this article's revelations. Put differently, the article revealed the materiality of Orexigen's alleged misrepresentations and omissions about the 25 percent interim results. Because such materiality forms the basis of Count I, the district court did not abuse its discretion by incorporating this article.

f. *April 6, 2015 Leerink Partner report – "OREXIGEN THERAPEUTICS, INC Meeting with Mgmt Highlights Partnering Goals, Next Steps for CV Studies."*

The Complaint does not name this report (Ex. P), but appears to quote from it. Per the Complaint, the article "relayed a highly positive report about the 25% interim results based [on] [Orexigen's] representations that '. . . Contrave is, at worst, CV safe or, at best, cardioprotective[.]'"

This single brief quotation is likely not extensive enough under *Ritchie*. Nonetheless, the Complaint uses the article to allege that Narachi and Hagan said that Contrave was "at best, cardioprotective" even though they allegedly knew by then that the data revealed no benefit. Count I is not based specifically on this alleged misrepresentation. The statement, however, represents another occasion when Narachi and Hagan may have misrepresented the benefits of Contrave, which evinces the same scheme alleged in Count I. Therefore, the

article – to the extent it contains an alleged misrepresentation – forms the basis of Count I. The district court did not abuse its discretion by incorporating this article.

2. SEC Filings and Attachments.

a. *February 27, 2015 Form 10-K*

The Complaint certainly quotes Orexigen's February 27, 2015, SEC filing. (Ex. B) But that is not the SEC filing that Orexigen submitted to the district court, and which the district court incorporated here. The date "February 27, 2015" does not even appear on the document that Orexigen submitted. Accordingly, the Complaint did not refer to this document, and the document did not form the basis of any claims. The district court abused its discretion by incorporating it.

This apparent misstep – although ostensibly inadvertent – highlights another risk in overuse of the incorporation-by-reference doctrine. When parties pile on volumes of exhibits to their motion to dismiss, hoping to squeeze some into the complaint, their submissions can become needlessly unwieldy. Simply reviewing these submissions demands precious time. It is the parties' duty to ensure their own accuracy. Otherwise, as here, materials may be inserted into pleadings when they should not be there.

b. *SEC filings regarding Orexigen executive compensation*

The Complaint alleges that Executive Defendants Narachi and Klassen financially benefitted from the "artificially inflated" Orexigen stock prices after leaking the 25 percent interim results. In particular,

Orexigen's "2007 Equity Incentive Plan" permitted Narachi, Klassen, and Hagan to register their inflated stocks. Also, Orexigen's corporate goals – and, by extension, these executives' compensation packages – depended on Contrave's success.

According to Orexigen, Khoja relied on three SEC filings (Exs. R, S & U) "to plead scienter against [the executive defendants] based on Orexigen's executive compensation and registration of stock during the class period."[6] Orexigen asked the district court to incorporate them "so that it may consider portions of those documents omitted from the [Complaint] which, among other things, show that such awards were routinely granted on an annual basis."

None of these documents qualified for incorporation. The Complaint did not refer to any of these documents extensively enough to warrant incorporation on that ground alone. Khoja's claims did not arise from these proxy statements and incentive plans. Rather, Khoja's references to these documents merely demonstrated that there was some financial incentive to misrepresent the success of Contrave to the investors.

Also, in seeking incorporation of these documents, Orexigen improperly asked the district court to engage in fact-finding in the course of deciding the sufficiency of the Complaint. It may be, as Orexigen argued, that those documents show that such financial incentives were routine. However, these nuances are irrelevant at

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[6] These filings include Orexigen's April 22, 2015 Schedule DEF-14A Proxy Statement (Ex. R), Orexigen's 2007 Equity Incentive Award Plan ("Award Plan") (Ex. U), and Orexigen's April 30, 2014 Schedule DEF-14A Proxy Statement (Ex. S).

the pleading stage.[7] Asking the district court to conclude that the alleged financial incentives were routine went beyond testing the sufficiency of the claims and into the realm of factual disputes. The district court abused its discretion by incorporating these documents for that improper purpose.

c. *March 13, 2015 Form S-8 Registration Statement*[8]

The Complaint references this Registration Statement twice to allege that "Narachi and Klassen . . . register[ed] six million Orexigen shares at an artificially inflated price of $7.08" pursuant to Orexigen's Award Plan. (Ex. T) The Complaint also alleges that the Registration Statement "incorporated by reference the Company's materially misleading March 3, 2015 Form 8-K."

The Complaint thus refers to the document to establish (1) the "artificially inflated price" of the shares, and (2) that the Registration Statement incorporated the "materially misleading" statements that allegedly caused the "artificially inflated price." These allegations form the basis of these claims. Therefore, the district court did not abuse its discretion by incorporating this document into the Complaint.

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[7] Orexigen's proposition is also illogical. Assuming such awards were "routinely granted," it is unclear why that necessarily means that executives would have no motive to commit securities fraud, especially if "such awards" are, as alleged, incentive-based.

[8] In its Request for Judicial Notice, Orexigen dated this Form S-8 Registration Statement as March 16, 2015. This was likely a mistake as the date appearing on the document is March 13, 2015.

3. Agency Reports

a. *September 10, 2014 FDA Report on Contrave.*

The Complaint references this report (Ex. A) several times.[9] The Complaint quotes it to show that, around November 2013, Light Study team members "requested that Orexigen produce a list of individuals who 'had knowledge of the interim results or access to unblended interim data.'" The Complaint quotes it again to describe Orexigen's violation of the DAP and the FDA's critical reaction to that violation.

Still, the claims do not rely on the report itself. They rely, to an extent, on the historical facts asserted therein. Even so, the numerous references were sufficiently extensive that incorporation was justified under *Ritchie*. The district court did not abuse its discretion by incorporating this report.

b. *EMA's December 19, 2014 Press Release – "[Contrave] recommended for approval in weight management in adults."*

Orexigen claimed that the Complaint "references" this press release. (Ex.F) In fact, the Complaint does not reference or identify this press release at all. The Complaint only alleges facts that the press release happens to report: Orexigen learned in December 2014 that the EMA adopted a "positive opinion" for Contrave

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[9] In its Request for Judicial Notice, Orexigen claimed that the Complaint referenced this report at ¶10. Although ¶10 references an "FDA Memorandum of Meeting," that memorandum does not appear to be the same report that Orexigen sought to incorporate here.

and recommended that the European Commission authorize marketing in Europe. Nothing in the Complaint connects this information with this press release. The facts alleged could have come from other sources. Therefore, the district court abused its discretion by incorporating the press release.

4. USPTO '371 Patent File History

According to Orexigen, Khoja "mischaracterize[d] the content, purpose, and effect of many portions of the '371 patent's file history" in the Complaint.[10] Orexigen asked the district court to incorporate that history (Ex. H) "to obtain an accurate understanding of" it.

Again, the Complaint does not refer to the particular "USPTO file history" that Orexigen presented to the court. Although the Complaint alleges facts that may appear there, those facts could have come from other sources.

At the same time, Count II claims that the Executive Defendants engaged in a scheme improperly to publish Light Study results through a patent application. To the extent the Complaint alleges that the timing of Orexigen's actions evinces a scheme, the USPTO file history is certainly relevant because it sets forth the timeline. However, the sufficiency of the alleged scheme itself does not depend on what the entire USPTO file history says. Whether Orexigen has other reasons or explanations for publishing the patent goes beyond the sufficiency of the alleged scheme at the pleading stage. It was, therefore, an abuse of discretion

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[10] The '371 Patent is the patent that was issued as a result of the 2014 Patent Application.

to incorporate the entire USPTO '371 patent file history.

To the extent the district court properly judicially noticed or incorporated by reference any of the above documents, the next issue is whether the district court properly considered those documents in dismissing Khoja's claims.

II. Dismissal for Failure to State a Claim Under The Securities Exchange Act.

A. Legal Standard

Dismissal "is appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory." *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1104 (9th Cir. 2008).

"'To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face;' that is, plaintiff must 'plead[ ] factual content that allows the court to draw the reasonable inference that the defendant is liable[.]'" *Telesaurus VPC, LLC v. Power*, 623 F.3d 998, 1003 (9th Cir. 2010) (quoting *Iqbal*, 556 U.S. at 678). "[T]he court [is not] required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008) (internal quotation marks and citation omitted).

If a claim includes an element of fraud, it must also "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). That is, the complaint must

allege the "who, what, when, where, and how" of the fraud. *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003).

If a claim alleges securities fraud, the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4, also applies. When the alleged fraud is a material misstatement or omission, "the complaint shall specify [1] each statement alleged to have been misleading, [2] the reason or reasons why the statement is misleading, and, [3] 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. § 78u-4(b)(1).

B. Count I - Material Misstatements and Omissions (Rule 10b-5)

To plead a primary violation of SEC Rule 10b-5, a complaint must allege "1) a material misrepresentation or omission by the defendant [falsity]; 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.

The district court's dismissal of Count I was based on the elements of falsity and materiality. Accordingly, the analysis here is limited to those issues. *In re Gilead Scis. Sec. Litig.*, 536 F.3d at 1055 (limiting consideration of Rule 10b-5 claim to sole issue the district court addressed because, generally, "a federal appellate court does not consider an issue not passed upon below").

Falsity is alleged when a plaintiff points to defendant's statements that directly contradict what the defendant knew at that time. *See In re Atossa Genetics Inc. Sec. Litig.*, 868 F.3d 784, 794–96 (9th Cir. 2017) (finding that plaintiff pled falsity where defendants said a drug had "gone through all of the FDA clearance process," but it had not received FDA clearance). Indeed, "[t]o be misleading, a statement must be capable of objective verification." *Retail Wholesale & Dep't Store Union Local 338 Ret. Fund v. Hewlett-Packard Co.*, 845 F.3d 1268, 1275 (9th Cir. 2017).

Even if a statement is not false, it may be misleading if it omits material information. *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1054 (9th Cir. 2014). "Disclosure is required . . . only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011) (quoting 17 C.F.R. § 240.10b-5(b)). As such, "companies can control what they have to disclose under these provisions by controlling what they say to the market." *Id.* at 45. "But once defendants [choose] to tout positive information to the market, they [are] bound to do so in a manner that wouldn't mislead investors, including disclosing adverse information that cuts against the positive information." *Schueneman v. Arena Pharm., Inc.*, 840 F.3d 698, 705–06 (9th Cir. 2016) (quotation marks and citation omitted).

Whether its allegations concern an omission or a misstatement, a plaintiff must allege materiality. "[A] misrepresentation or omission is material if there is a

substantial likelihood that a reasonable investor would have acted differently if the misrepresentation had not been made or the truth had been disclosed." *Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 946 (9th Cir. 2005).

The Supreme Court has eschewed brightline tests for materiality. *Matrixx Initiatives*, 563 U.S. at 398 (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 236 (1988)). At a minimum, "[p]laintiffs' allegations must suffice to raise a reasonable expectation that discovery will reveal evidence satisfying the materiality requirement, and to allow the court to draw the reasonable inference that the defendant is liable." *In re Atossa Genetics Inc. Sec. Litig.*, 868 F.3d at 794.

The district court identified five statements that arguably supported Khoja's claims in Count I. We address each in turn.

1. March 2015 Form 8-K.

The March 2015 Form 8-K announced the publication of the 2014 Patent Application, the Light Study, and 25 percent interim results. It stated:

> The 371 Patent and the Provisional Patent Applications contain claims related to a positive effect of Contrave on CV outcomes. The observed effects on CV outcomes were unexpected and appear to be unrelated to weight change. . . .
>
> The 25% Interim Analysis was prospectively designed to enable an early and preliminary assessment of safety to support regulatory approval. A larger number of MACE are

> required to precisely determine the effect of Contrave on CV outcomes.

The March 2015 Form 8-K also included a graph that showed a lower occurrence of MACE in patients on Contrave than in patients on placebos.

Khoja alleges that the chart and Orexigen's description in the March 2015 Form 8-K were false and misleading. First, Orexigen failed to disclose that the interim results "were 'unreliable,' 'likely false,' and 'misleading.'" Orexigen further failed to disclose that it violated the DAP by releasing the 25 percent interim results, and, as a result, could face penalties. Finally, Orexigen omitted the fact that it had, itself, requested the publication of the 2014 Patent Application so that investors would see the positive, yet unreliable interim results.

The district court dismissed these theories with prejudice. First, the district court found that Orexigen did not misrepresent the interim results. The district court reasoned that Orexigen "did not claim that the results were statistically significant." Also, the court noted that Orexigen cautioned that . . . "'[a] larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes.'" In other words, according to the district court, even though Orexigen did not outright say that the 25 percent interim results were unreliable, Orexigen sufficiently warned its investors by saying the results were preliminary.

But per the Complaint, the FDA previously had told Narachi and Klassen that "25 [percent] interim results have 'a high degree of uncertainty and were likely to

change with the accumulation of additional data.'" The question is whether Orexigen had a duty to reveal this when discussing the interim results in the 2015 Form 8-K.

Our decision in *Berson v. Applied Signal Technology, Inc.*, 527 F.3d 982 (9th Cir. 2008) is instructive. There, the defendant allegedly received several stop-work orders from its government clients. *Id.* at 983. Such orders typically signaled that the work would never be completed, thus leading to an immediate loss of revenue. *Id.* Yet, the defendants counted those orders in its "backlog report" of work to be completed. *Id.* at 985–86. The backlog report noted the "customers' rights to 'cancel' or 'modify' existing contracts," but said "nothing about the right to simply stop work and thus immediately interrupt the company's revenue stream." *Id.* at 986 (quotation marks omitted). Instead, the defendants spoke "entirely of as-yet-unrealized risks and contingencies," and failed to alert the investors that "some of these risks may already have come to fruition." *Id.* We concluded that "[h]ad defendants released no backlog reports, their failure to mention the stop-work orders might not have misled anyone. But once defendants chose to tout the company's backlog, they were bound to do so in a manner that wouldn't mislead investors as to what that backlog consisted of." *Id.* at 987.

Similarly here, once Orexigen chose to tout the apparently positive 25 percent interim results, Orexigen had the obligation also to disclose that they were likely unreliable. As the district court found, Orexigen claims it sufficiently warned its investors about the reliability of the 25 percent interim results.

Orexigen points to qualifiers in the March 2015 Form 8-K that label the 25 percent interim results as "early," and "preliminary"; that emphasize "the effect of Contrave . . . has not been established"; that "a larger number of [MACE] are required to precisely determine the effect of Contrave"; and that "[t]he interim analysis may not be predictive of future results." But telling investors that the data might change is different from saying the data already has "a high degree of uncertainty" and is likely to change. Without this information, the "surprising" 25 percent interim results appeared more promising than Orexigen allegedly knew they were. Consequently, the March 2015 Form 8-K is like the backlog report in *Berson*, which included work that the defendants knew would likely never be completed. *See Berson*, 527 F.3d at 987.

Khoja has thus pled a plausible claim that Orexigen had a duty to disclose that the 25 percent interim results in the March 2015 Form-8K were unreliable. *See In re NVIDIA Corp. Sec. Litig.*, 768 F.3d at 1052. It is possible that a jury might find that Orexigen's hedging about the preliminary nature of the results was enough to satisfy that duty. For pleading purposes, though, the Complaint sufficiently alleges that Orexigen's failure to disclose the unreliability of the 25 percent interim results in the March 2015 Form-8K was misleading. The district court erroneously dismissed this claim.

The district court also dismissed Khoja's theory that the March 2015 Form 8-K misled investors because Orexigen did not disclose that it had violated the DAP by releasing the 25 percent interim results. Although Orexigen touted the interim results and therefore

created a duty to disclose the corresponding adverse information, Orexigen never touted having permission to publish the results. Even though violating the DAP could have negative consequences for Orexigen (and its investors), Orexigen did not have a duty to share that information. The Complaint does not identify earlier statements by Orexigen that suggest a duty either. The district court properly dismissed this theory. *See Matrixx Initiatives*, 563 U.S. at 44–45.

However, the district court dismissed this theory with prejudice. Khoja has not yet amended the Complaint.[11] Given our policy favoring leave to amend, Khoja should have an opportunity to amend this claim on remand. Fed. R. Civ. P. 15; *see also Owens v. Kaiser Found. Health Plan, Inc.*, 244 F.3d 708, 712 (9th Cir. 2001) (observing this circuit views this rule with "extreme liberality" (internal quotation marks omitted)).

2. March 2015 Press Release.

The Complaint alleges that Orexigen's March 3, 2015, press release was misleading. The press release stated, in part, "[t]his morning the USPTO published the patent and supporting documentation."

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[11] We do not hold against Khoja the fact that he declined to amend the Complaint to correct claims that were dismissed without prejudice, and instead sought a final order expeditiously to appeal all claims. *See Edwards v. Marin Park, Inc.*, 356 F.3d 1058, 1064 (9th Cir. 2004) (observing that plaintiff "made a reasonable choice to expedite the rest of the case" by seeking a final order and declining to amend the complaint given the district court's order "dismissing most of her claims" and granting leave to amend only one).

Khoja claims that Orexigen failed to reveal the extent of its role in publishing the 2014 Patent Application. Khoja appears to have two theories. First, Orexigen failed to reveal that it supplied the 25 percent interim results in its 2014 Patent Application, thus violating the DAP. Khoja claims the investors had a right to know about that violation because of its possible negative consequences. Orexigen then submitted the 2014 Patent Application confidentially to hide the DAP violation from investors. Second, Orexigen failed to share that Orexigen requested that the USPTO publish the 2014 Patent Application, thus facilitating another leak of the interim results, and another violation of the DAP.

The district court rejected these theories. The district court was, in part, correct to do so, but it did so for incorrect reasons.

First, the district court held that Orexigen was required to submit the 25 percent interim results to the USPTO because of a patent theory called "enablement."[12] Without going into the nuances of patent law, "enablement" is sometimes a fact-driven inquiry. *See Dow Chems. Co. v. Nova Chems. Corp.*

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[12] "Enablement is the requirement that a patent teach a person skilled in the art (the field of the invention) how to make and use the invention without undue experimentation. In other words, a patent must describe the invention clearly enough so that a skilled person in the field can replicate the invention without having to perform experiments to determine how to make and use the invention." Audrey A. Millemann, *Enablement Is Key – Especially in Biotech Paatents*, IPL. Blog (Apr. 17, 2015), http://www.theiplawblog.com/2015/04/articles/patent-law/enablement-is-key-especially-in-biotechpatents/.

(Can.), 809 F.3d 1223, 1225 (Fed. Cir. 2015). On appeal, Khoja argues that a factual question existed below as to whether Orexigen needed to disclose data to demonstrate enablement. In fact, the Complaint never mentioned enablement, and neither did Orexigen. Khoja never had the opportunity to assert that factual dispute below. Because the district court imposed this fact-driven defense on Khoja, Khoja should have had the opportunity to develop the record and litigate the issue. *See* Fed. R. Civ. P. 12(b) (requiring that parties have "reasonable opportunity to present all material made pertinent to [the converted motion for summary judgment]"); *Bonilla v. Oakland Scavenger Co.*, 697 F.2d 1297, 1301 (9th Cir. 1982) (recognizing that it is reversible error when a court considers material outside the pleading on a Rule 12(b)(6) motion and yet fails to convert it into a motion for summary judgment); *In re Tracht Gut*, 836 F.3d at 1150 ("At the motion to dismiss phase, the trial court must accept as true all facts alleged in the complaint and draw all reasonable inferences in favor of the plaintiff.").

As for seeking the publication of the 2014 Patent Application, the district court held that Orexigen was obligated to do so because it filed the WIPO Application for Contrave on December 14, 2015. Once Orexigen filed the WIPO Application, Orexigen was required to notify the USPTO within forty-five days or the 2014 Patent Application would be deemed abandoned under 35 U.S.C. § 122(b)(2)(B)(iii).

Although possibly correct, this reasoning misses the point of the claim. Even if Orexigen was "obligated" to publish the 2014 Patent Application, the issue is whether Orexigen (1) misrepresented its role in the

publication process, (2) had a duty to disclose the fact that Orexigen first requested that the USPTO keep the 2014 Patent Application confidential, and (3) had a duty to disclose that Orexigen later rescinded that request, thus disclosing the positive, but unreliable 25 percent interim results.

As to the first issue, per the Complaint, the March 2015 press release did not directly state that the USPTO "independently published" the patent. Instead, the press release stated simply that, "the USPTO published the patent and supporting documentation." This statement is not false. Khoja does not contend, nor could he reasonably contend, that USPTO did not publish the patent.

Orexigen also did not have a duty, absent a statement suggesting otherwise, to tell its investors that it originally requested that the 2014 Patent Application remain confidential. Khoja does not allege that Orexigen ever suggested anything about the 2014 Patent Application's confidentiality.

Nonetheless, Orexigen's statement that "the USPTO published the patent," gives rise to a duty to elaborate. By itself, this statement only indicates who published the patent and nothing more. On the other hand, this statement plausibly gives the impression that the USPTO published the patent on its own. Ordinarily, this may be a fair impression to give. As alleged here, though, the patent had remained confidential until Orexigen sought its publication. And it was confidential because Orexigen asked the USPTO to make it confidential. Saying only that "the USPTO published the patent" may have mislead Orexigen's

investors about why the USPTO published the patent, and why it was not published sooner.

This omission was arguably material. If the investors knew that Orexigen had something to do with publishing the 2014 Patent Application, the investors would have known that Orexigen had a direct role in revealing the 25 percent interim results, thus violating the FDA's rules again and risking the integrity of the Light Study. Because such violations might – and allegedly did – impact the financial health of Orexigen, that information was likely material to reasonable investors. Ultimately, a jury should assess materiality as a question of fact. *Fecht v. Price Co.*, 70 F.3d 1078, 1080–81 (9th Cir. 1995).

At a minimum, accepting the allegations in the Complaint as true, and reading them in the light most favorable to Khoja, we conclude that the Complaint alleges a plausible claim that Orexigen materially misled its investors in the March 2015 press release. Specifically, by failing to inform investors about Orexigen's role in publishing the 2014 Patent Application, Orexigen arguably gave the false impression that it played no role in revealing the 25 percent interim results.

Therefore, because the district court relied, at least in part, on a fact-driven defense not raised by either party to dismiss Count I, we reverse. To the extent the district court dismissed Count I because the March 2015 Press Release did not affirmatively misrepresent that the USPTO "independently published" the 2014 Patent Application, we would ordinarily affirm. However, the district court dismissed this claim with prejudice. Khoja should have an opportunity to amend

this claim. *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003) (observing that the liberal application rule of Federal Rule of Civil Procedure 15 applies to claims subject to the PSLRA, where plaintiffs must plead "with an unprecedented degree of specificity" and "drafting of a cognizable complaint can be a matter of trial and error"). Accordingly, we also reverse the district court's dismissal of Count I on that basis.

3. May 2015 Form 8-K.

Khoja alleges that Orexigen's May 2015 Form 8-K included material misstatements, and omitted material information. The May 2015 Form 8-K describes the clinical trial program for Contrave and states, in pertinent part, "The clinical trial program also includes a . . . trial known as the Light Study."

Khoja appears to have three theories about why this statement is actionable. He alleges that the statement (1) misrepresented "that the Light Study was ongoing," (2) omitted that the ESC terminated the Light Study weeks earlier on March 26, 2015, and (3) omitted the 50 percent interim results, which "demonstrated that [Orexigen's] prior representations about Contrave's purported [heart] benefit were false."

As to the first and second theories, the district court found that the ESC did not terminate the Light Study on March 26, 2015. Therefore, Orexigen could not have misrepresented or omitted something that had not yet occurred. In reaching this conclusion, the district court agreed with Orexigen that "the ESC's vote [on March 26, 2015] was merely a recommendation." The district court relied on the Complaint's allegation that "[t]he

executive committee voted unanimously to recommend that the trial be stopped."

However, other portions of the Complaint indicate that ESC's vote was not merely a recommendation. The Complaint quotes from a May 12, 2015 press release, which stated "the 9,000-patient Light Trial – designed to study the cardiovascular safety of . . . Contrave . . . – *has been halted* by the trial's [ESC]." (Emphasis in Comp.) The phrase "has been halted by the trial's [ESC]" clearly implies that (1) the ESC has the authority to halt (or terminate) a study and (2) the ESC already did precisely that with the Light Study. Similarly, the Complaint alleges that, on March 26, 2015, the ESC informed Orexigen that "the ESC had voted unanimously to halt the Light Study as a result of [Orexigen's] improper March 3, 2015 disclosure breach." The Complaint's allegations are based, in part, on discussions that Khoja's counsel had with Dr. Nissen. As the chair of the ESC, Dr. Nissen likely would have had personal knowledge of the termination decision, and, more importantly, when it occurred.

At a minimum, then, these allegations support a plausible inference that the ESC terminated the Light Study before May 2015. By then stating that Contrave's "clinical trial program also includes . . . the Light Study," Orexigen gave the false impression that the Light Study was still underway.

The district court appears to have concluded that, even if the Light Study was terminated on March 26, 2015, "Orexigen had already reported to the press that it was recommending 'that [the Light Study] be stopped'" by the time Orexigen filed the May 2015 Form 8-K. The district court relied on a report that it

incorporated by reference: the April 6, 2015, Leerink Partner report. *See, supra* Part I.B.1.f. The district court properly incorporated that report, but the district court incorrectly inferred that the report amounted to a "prior disclosure that [Orexigen] was recommending termination of the Light Study."

The report was published on April 6, 2015. This was only days after "the ESC had voted unanimously to halt the Light Study as a result of [Orexigen's] improper March 3, 2015 disclosure breach." Per the report, Orexigen "ha[d] recommended" that the Light Study "be stopped" because it "is not a post-marketing requirement and has less utility over time[.]'" But, according to the Complaint, the Light Study ended because the ESC unanimously voted to terminate it. In other works, the Leerink report characterizes the Light Study termination as a practical, voluntary decision by Orexigen, but the Complaint portrays the termination as punishment by the ESC.

Thus, contrary to what the district court found, it was far from obvious that the April 6 report amounted to a prior, accurate disclosure about the fate of the Light Study. *See Fecht*, 70 F.3d at 1081 ("Only if the adequacy of the disclosure or the materiality of the statement is so obvious that reasonable minds could not differ are these issues appropriately resolved as a matter of law." (internal quotation marks and alterations omitted)). Therefore, the report could not plausibly rescue Orexigen from its alleged misrepresentations in the May 2015 Form 8-K.

The district court's reasoning here again demonstrates the danger in incorporating documents en masse into complaints. Once documents are

incorporated into a complaint, a district court faces competing, often inconsistent versions of the facts. Although plaintiffs are ordinarily afforded the benefit of every favorable inference, the incorporation-by-reference doctrine can allow defendants to exploit that benefit for themselves. Here, the district court accepted the statements in the Leerink report as true, and concluded that they absolved any earlier failure by Orexigen to make a more thorough disclosure about the Light Study's termination. Although incorporation by reference generally permits courts to accept the truth of matters asserted in incorporated documents, we reiterate that it is improper to do so only to resolve factual disputes against the plaintiff's well-pled allegations in the complaint. The incorporation-by-reference doctrine does not override the fundamental rule that courts must interpret the allegations and factual disputes in favor of the plaintiff at the pleading stage. *See Sgro*, 532 F.3d at 942, n.1 (finding it proper to consider a disability benefits plan referenced in complaint, but declining to accept the truth of the plan's contents where the parties disputed whether defendant actually implemented the plan according to its terms); *see also In re ECOtality, Inc. Sec. Litig.*, No. 13-03791, 2014 WL 4634280, at *3 (N.D. Cal. Sept. 16, 2014) (declining to assume the truth of incorporated documents where it "would mean assuming the truth of all of Defendants' allegedly false or misleading statements," which would make it "impossible ever to successfully plead a fraud claim"). For this additional reason, the district court erred in dismissing Khoja's claim that Orexigen misrepresented the status of the Light Study in its May 2015 Form 8-K.

The district court also concluded that the May 2015 Form 8-K did not misrepresent or omit the 50 percent interim results. Khoja does not clearly allege that the May 2015 Form 8-K misrepresented the 50 percent interim results,[13] but even if he intended to do so, the district court was correct. The May 2015 Form 8-K did not mention the 50 percent interim results, so it could not have made a misstatement about them. Therefore, to the extent Count I is based on alleged misstatements about the 50 percent interim results in the May 2015 Form 8-K, the district court properly dismissed that claim.

As for the omission of the 50 percent interim results, the district court was incorrect. The district court found that Orexigen did not materially omit those results because Orexigen had no duty to disclose them. The district court reasoned that Orexigen's earlier statements about the 25 percent interim results remained accurate because those results "still showed 'a positive effect of Contrave on CV outcomes.'"

This conclusion, however, reads the May 2015 Form 8-K – and Khoja's claim – too narrowly. Although the 25 percent interim results were still technically accurate, the issue is whether, having learned new information that diminished the weight of those results, Orexigen was obligated to share that information.

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[13] The confusion likely arose from Khoja's imprecise pleading of this claim. He listed numerous facts that were "materially false and misleading and/or [Orexigen] failed to disclose." The "and/or" obscured whether each following statement was supposedly omitted or misrepresented.

We conclude that Orexigen was so obligated. The 25 percent interim results were a boon to Orexigen. Upon their release, stocks traded in unusually high volumes and at higher prices. Analysts hailed Contrave as a potential miracle drug. The Complaint sufficiently pled that, even if investors understood that more results were necessary to confirm Contrave's potential heart benefit, the 25 percent interim results clearly suggested a promising venture. Naturally, if subsequent data indicated those earlier interim results were not so promising after all, their value diminished. Because the 50 percent interim results did precisely that, Orexigen had a duty to disclose them. *See Berson*, 527 F.3d at 987.

Therefore, we conclude that in relying on the alleged omissions from the May 2015 Form 8-K, Count I sufficiently pled a claim under SEC Rule 10b-5.

4. May 2015 Form 10-Q.

The Complaint asserts that, on the same day as the May 2015 Form 8-K, Orexigen also filed a misleading Form 10-Q. Similar to the May 2015 Form 8-K, the Form 10-Q allegedly failed to disclose the termination of the Light Study and the 50 percent interim results.

In dismissing this claim, the district court reasoned that Khoja's argument on this claim was "largely similar" to Khoja's argument for the May 2015 Form 8-K claim, described above. Accordingly, the district court adopted the same reasoning for dismissing both the May 2015 Form 8-K and 10-Q claims. However, these two claims are different. In fact, per the Complaint, the May 2015 Form 10-Q was even more misleading than the Form 8-K.

In the May 2015 Form 10-Q, Orexigen represented that its "share price *might* be impacted by announcements regarding our clinical trials, including [ ] the Light Study[.]" (Emphasis in Comp.) The Form 10-Q further indicated the possibility of "new data from the *continuing* Light Study[.]" (Emphasis in Comp.)

As discussed above, the Complaint sufficiently pled that Orexigen knew the Light Study was terminated by May 2015, when Orexigen submitted the instant Form 10-Q. If so, suggesting that the Light Study was "continuing" was an obvious, affirmative misrepresentation. *Retail Wholesale*, 845 F.3d at 1275–76.

Orexigen then went on to say that the "new data from the *continuing* Light Study . . . *may* be inconsistent with the conclusion that the interim analysis was successful." (Emphasis in Comp.) Yet, Orexigen allegedly knew already that the "new data" revealed exactly that. The Complaint therefore sufficiently pleads that Orexigen materially omitted the 50 percent interim results from the May 2015 Form 10-Q.

Accordingly, we reverse the district court's dismissal of Count I to the extent it is premised on alleged omissions from and misrepresentations in the May 2015 Form 10-Q.

5. May 2015 Earnings Conference Call.

The Complaint alleges that during the May 8, 2015, conference call, Klassen and Narachi (1) misrepresented the status of the Light Study and (2) omitted the 50 percent interim results. Again, the district court concluded that "the parties' arguments

. . . are largely repetitive of" those for the May 2015 Forms 8-K and 10-Q and, therefore, found no omissions or misstatements. And again, although these claims deal with similar alleged misconduct, they are distinct.

Posed with specific questions about the fate of the Light Study, Narachi said during the call that "*if there was a decision to terminate the trial* and move on and focus resources on the new [trial], *that would be a disclosure that we would make*."[14] (Emphasis in Comp.) By expressing the decision as a hypothetical, Narachi suggested that decision had not yet occurred. As alleged in the Complaint, however, Narachi knew the Light Study was already terminated.

Even accepting Orexigen's position that the ESC had only recommended terminating the Light Study, Orexigen was still obligated to share that development. Narachi and Klassen repeatedly discussed the status of the Light Study and the possible "decision to terminate" it. ESC's recommendation to terminate the Light Study would have pertained directly to the status of the Light Study. Without that information, termination seemed only a remote possibility. With that information, a reasonable investor would understand that termination may be imminent. The Complaint sufficiently alleged that Narachi and

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[14] Narachi said something similar twice more: "So, *if the decision is made to terminate the trial early* and focus resources on the next [trial], which is what we have been advocating, then I think results would come out sooner . . . , *if you decide to stop the study now* there will be additional events, so these details are being discussed . . . ." (Emphasis in Comp.)

Klassen either materially misrepresented or omitted that information.

Narachi's and Klassen's statements about the 50 percent interim results are a closer question. Klassen stated that "I don't think we're going to go into the details [about the 50 percent interim results], because again that's a look that DNC does." Klassen was apparently trying to control what he shared about the 50 percent interim results, and thereby avoid a duty to share more. But he then went on to say, that "it's really on the 25 percent analysis that was used for regulatory purposes. *So if any of that status changes, then we would of course announce that.*" One could reasonably interpret Klassen's statement to mean that if the value of the 25 percent interim analysis changed in light of new data, Orexigen would announce it. Yet Klassen allegedly knew the 50 percent interim results indicated that Contrave did not have a heart benefit. Regardless of what Klassen meant, the Complaint sufficiently alleged he had a duty to share the 50 percent interim results. As discussed above, by touting and publishing the "surprisingly" positive 25 percent interim results, Orexigen created its own obligation to report that those results did not pan out after all.

Admittedly, Orexigen put itself into a corner; either fulfill its duty to disclose by violating the DAP again, or risk misleading the investors. Orexigen created this dilemma by violating the DAP in the first place. Orexigen cannot ignore the DAP to its benefit, then use it to conceal its own misconduct. Orexigen cites no law to suggest that its obligations under the DAP overrode its obligations under §10 of the Securities Exchange Act and SEC Rule 10b-5. *See, e.g.*, *X Corp. v. Doe*, 805

F. Supp. 1298, 1310 n.24 (E.D. Va. 1992), (finding that, "[t]o the extent" a confidentiality agreement "prevented disclosure of evidence of fraud," the agreement "would be void as contrary to public policy" where the party "cannot rely on any contract to conceal illegal activity"), *aff'd sub nom. Under Seal v. Under Seal*, 17 F.3d 1435 (4th Cir. 1994).

For the reasons stated above, the Complaint sufficiently alleged that Narachi misrepresented the status of the Light Study and that Klassen omitted material information about the 50 percent interim results. We reverse the district court's decision to the contrary.

C. Count II - Scheme Liability (SEC Rules 10b-5(a) and (c))[15]

The Complaint alleges that Orexigen and the Executive Defendants violated § 10(b) of the Securities Exchange Act, and SEC Rules 10b-5(a) and (c). "Under Rule 10b-5(a) or (c), a defendant who uses a 'device, scheme, or artifice to defraud,' . . . may be liable for securities fraud." *WPP Lux. Gamma Three Sarl v. Spot Runner, Inc.*, 655 F.3d 1039, 1057 (9th Cir. 2011) (quoting 17 C.F.R. § 240, SEC Rules 10b-5(a) and (c)). The scheme must "encompass[] conduct beyond those misrepresentations or omissions." *Id.*

Count II alleges Orexigen and its executives "disseminated or approved the false statements specified" in the Complaint, and engaged in a fraudulent scheme "to conceal and then publish the

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[15] The district court dismissed Count II with prejudice against Hagan. Khoja does not challenge that ruling on appeal.

interim Light Study data via the 2014 Patent Application." Count II incorporates all of the allegations in the Complaint, but does not specify what steps, if any, Orexigen or the Executive Defendants took in furtherance of the alleged scheme. The Complaint concludes that their "misconduct is distinct from the materially misleading statements pertaining to Count I," but does not explain how. Arguably, a scheme "to conceal and then publish the interim Light Study data via the 2014 Patent Application" is distinct from the fraudulent misrepresentations therein. However, the Complaint does not articulate how such a scheme, by itself, is actionable under SEC Rules 10b-5(a) and (c).

The district court dismissed Count II without prejudice because it could not discern the substance of the claim. We affirm, but as above, instruct that Khoja should be granted leave to amend to cure that deficiency.

D. Count III - Controlling Individuals' Liability (§ 20(a) of the Securities Exchange Act)

The Complaint alleges that the Executive Defendants were "controlling" individuals under § 20(a) of the Securities Exchange Act. They could allegedly "influence and control and did influence and control . . . the decision-making of [Orexigen], including the content and dissemination of the" misleading statements alleged in the Complaint. Therefore, they might be liable under § 20(a).

The district court correctly noted that "'Section 20(a) claims may be dismissed summarily . . . if a

plaintiff fails to adequately plead a primary violation of section 10(b).'" (quoting *Zucco Partners, LLC v. Digimarc Corp*., 552 F.3d 981, 990 (9th Cir. 2009), as amended (Feb. 10, 2009).

Because the district court found that Khoja's claims under § 10(b) failed, the district court dismissed the claim under § 20(a). However, as set forth above, Khoja has sufficiently pled a number of primary violations of § 10(b). Further, he has been granted leave to amend as to others. On remand, the district court should reconsider the sufficiency of Count III in that light.

CONCLUSION

Accordingly, we affirm, in part, and reverse, in part, the district court's dismissal of Khoja's Complaint, and REMAND with instructions regarding the judicial notice and incorporation by reference of Orexigen's exhibits to its Motion to Dismiss. Specifically, we REVERSE and REMAND for clarification on Exhibit D consistent with this opinion, we REVERSE the district court's judicial notice of Exhibit E, and AFFIRM the judicial notice of Exhibit V. We REVERSE the district court's incorporation-by-reference of Exhibits B, C, F, H, R, S, and U. We AFFIRM the incorporation of Exhibits A, I, K, L, N, O, P, and T.

As to Count I, we AFFIRM, in part, and REVERSE, in part, the district court's dismissal. Where AFFIRMING, we GRANT LEAVE TO AMEND the Complaint.

As to Count II, we AFFIRM the district court's dismissal, but, again, with leave to amend the Complaint.

As to Count III, we REVERSE so the district court may reconsider those claims in light of our reversal of the district court's dismissal of claims in Count I and in light of any amendments to the Complaint.

Each party shall bear his own costs on appeal.

AFFIRMED in part, REVERSED in part, and REMANDED.

The foregoing disposition of this appeal pertains only to Plaintiff's claims against the Executive Defendants, Narachi, Hagan, and Klassen.

With respect Defendant-Appellee Orexigen, appellate proceedings remain stayed pending resolution of the bankruptcy proceedings. *See* footnote 1, *supra*. The Clerk shall administratively close this docket with respect to Orexigen pending further order of the Court, but the mandate shall not issue with respect to Orexigen. Within 28 days after resolution of the bankruptcy proceeding or the lifting of the automatic bankruptcy stay, which occurs earlier, Orexigen shall file a status report with the Clerk.

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Enablement is Key – Especially in Biotech Patents

By Audrey A Millemann on April 17th, 2015

Posted in Patent Law

Enablement is the requirement that a patent teach a person skilled in the art (the field of the invention) how to make and use the invention without undue experimentation. In other words, a patent must describe the invention clearly enough so that a skilled person in the field can replicate the invention without having to perform experiments to determine how to make and use the invention. The enablement requirement is set forth in 35 U.S.C. §112, first paragraph. If a patent is not enabled, it can be invalidated.

In the fields of biology and chemistry, referred to in the patent world as the "unpredictable" arts, enablement is particularly important. Thus, biotechnology patents must clearly satisfy the enablement requirement or they are at risk of being challenged and held invalid. That is what happened in Promega Corp. v. Life Technologies Corp. (Fed. Cir. 2014) 773 F.3d 1338.

Promega sued Life Technologies for infringement of five patents. The patents covered methods and test kits for analyzing DNA samples and were used in forensic science. Promega alleged that Life Technologies manufactured and sold genetic test kits that infringed Promega's patents.

Life Technologies moved for summary judgement of invalidity on four of the five Promega patents, arguing that the four patents were not enabled. The district court denied the motion. The court granted Promega's motion for summary judgment, holding that the patents were infringed. The jury then awarded $52 million in damages to Promega, but the district court granted Life Technologies' motion for judgment as a matter of law. The court then vacated its previous ruling of infringement.

Both parties appealed. In ruling on Life Technologies' motion for summary judgment for lack of enablement, the Federal Circuit Court of Appeals considered the prosecution file histories for Promega's patents. During prosecution, in order to overcome the patent examiner's prior art rejections, Promega had stated that the prior art was not sufficient to disclose or predict the invention. The court also noted that Promega had taken inconsistent positions in the litigation. In opposing Life Technologies' motion for invalidity, Promega had admitted that the field was unpredictable. In arguing for infringement, however, the court said "Promega sings a different tune" — Promega had asserted that its claims were broad enough to cover methods it had referred to as unpredictable.

The Federal Circuit explained that Promega cannot have it both ways. If Promega interpreted the language broadly enough to cover Life Technologies' products, then the claims, as interpreted broadly, had to be enabled for the full scope of that coverage.

The court found that Promega's patents covered "a virtually unlimited number" of DNA combinations. 773 F.3d at 1348. According to the court, the patents would not have enabled a person skilled in the field to develop Life Technologies' products without undue experimentation. The court stated: "the claims at issue here similarly cover potentially thousands of undisclosed embodiments in an unpredictable field." *Id*. at 1349. A person skilled in the field would have had to perform "laborious testing" (i.e., undue experimentation) to create Life Technologies' products. Thus, the court held that the patents were invalid for failure to satisfy the enablement requirement, concluding that "Promega's 'difficultly in enabling the asserted claims is a problem of its own making.'" *Id*.

APPENDIX B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

Case No.: 15-CV-540 JLS (JLB)

[Filed May 19, 2016]

KARIM KHOJA, on behalf of himself and all others similarly situated,
Plaintiff,

v.

OREXIGEN THERAPEUTICS, INC., JOSEPH P. HAGAN, MICHAEL A. NARACHI, and PRESTON KLASSEN,
Defendants.

AND ALL CONSOLIDATED CASES

ORDER: (1) GRANTING IN PART DEFENDANTS' REQUEST FOR JUDICIAL NOTICE, (2) GRANTING DEFENDANTS' MOTION TO DISMISS, AND (3) DISMISSING LEAD PLAINTIFF'S CONSOLIDATED COMPLAINT

(ECF No. 62)

Presently before the Court is Defendants Orexigen Therapeutics, Inc., Joseph P. Hagan, Michael A. Narachi, and Preston Klassen's Motion to Dismiss

Consolidated Complaint for Violation of the Federal Securities Laws. (MTD, ECF No. 62.) Also before the Court are Lead Plaintiff Karim Khoja's Opposition to (ECF No. 67) and Defendants' Reply in Support of (ECF No. 69) the MTD, as well as Defendants' Request for Judicial Notice (ECF No. 62-25) and Lead Plaintiff's Objections to (ECF No. 68) and Defendants' Reply in Support of (ECF No. 69-1) the RJN.[1] The Court vacated the hearing and took the matter under submission without oral argument pursuant to Civil Local Rule 7.1(d)(1). (ECF No. 70.) Having considered the parties' arguments and the law, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' RJN (ECF No. 62-25), **GRANTS** Defendants' MTD (ECF No. 62), and **DISMISSES** Lead Plaintiff's Consolidated Complaint (CC, ECF No. 55).

BACKGROUND

I. Factual Background

Defendant Orexigen is a developmental stage biotechnology firm focusing on the development of pharmaceutical product candidates for the treatment of obesity. (Consolidated Compl. (CC) ¶ 7, ECF No. 55.) Defendant Orexigen is a small company with approximately fifty employees. (*Id.* at ¶ 33.) Its common stock is traded on the NASDAQ. (*Id.* at ¶¶ 33, 131(a).) Defendant Narachi is Defendant Orexigen's CEO and a director. (*Id.* at ¶ 34.) Defendant Hagan is the Chief Business Officer and Acting CFO of

[1] Lead Plaintiff has also filed a number of notices of supplemental materials (*see* ECF Nos. 71, 72, 74), to which Defendants have responded (*see* ECF Nos. 73, 75).

Defendant Orexigen (*id.* at ¶ 36), while Defendant Klassen is its Head of Global Development (together with Defendant Narachi, the Insider Defendants) (*id.* at ¶ 38).

Defendant Orexigen's primary obesity treatment candidate is Contrave (*id.* at ¶ 7), which is designed to treat overweight and obese persons already at high risk for major adverse cardiovascular events (MACE), defined as myocardial infarction (heart attack), stroke, or cardiovascular death (*id.* at ¶¶ 8, 87). Contrave is made from two off-patent generic drugs, bupropion and naltrexone. (*Id.* at ¶ 66.) Defendant Orexigen has a collaboration agreement with Takeda Pharmaceutical Company Limited to develop and commercialize Contrave in the United States, Canada, and Mexico. (*Id.* at ¶ 7.)

Defendant Orexigen submitted a new drug application for Contrave to the United States Food and Drug Administration (FDA). (*Id.* at ¶ 49.) Concerned that Contrave may cause adverse cardiovascular events because of its effect on blood pressure and heart rate (*id.* at ¶ 127), in January 2011 the FDA mandated a randomized, double-blind, placebo-controlled clinical trial designed to assess the cardiovascular risks associated with Contrave (the Light Study) before the new drug application could be approved (*id.* at ¶¶ 8, 49). The Light Study's Executive Steering Committee was chaired by Dr. Steven Nissen, a Department Chair of Cardiovascular Medicine at the Cleveland Clinic. (*Id.* at 5 n.1.[2]) Defendant Orexigen initiated the Light

[2] Pin citations to docketed materials refer to the CM/ECF page number stamped at the top of the page.

Study in June 2012 and completed screening in December 2012, resulting in approximately 8,900 patients randomized for treatment. (*Id.* at ¶ 51.) The FDA agreed that if the Light Study's interim analysis revealed that Contrave did not increase the risk of a major cardiac event by 50% or more, Contrave could be approved. (*Id.* at ¶¶ 51, 96, 126.)

In November 2013, the Light Study's Data Monitoring Committee shared with Defendant Orexigen the completed interim results. (*Id.* at ¶ 52.) The results, based on ninety-four MACE, which was approximately 25% of the planned MACE for the Light Study, indicated that Contrave reduced cardiovascular events by 41% compared with a placebo. (*Id.* at ¶¶ 70, 87.) Specifically, thirty-five Contrave patients experienced MACE, while fifty-nine placebo patients did. (*Id.* at ¶ 88.)

The Light Study's steering committee, Data Monitoring Committee, and Defendant Orexigen entered into a data access plan, in which they agreed to limit the number of people within Defendant Orexigen who had access to the interim results to just those individuals who needed to facilitate submission of Defendant Orexigen's marketing application to the FDA. (*Id.* at ¶ 53 & n.10.) The Light Study's statistical review team, however, subsequently discovered that Defendant Orexigen had leaked the positive interim data to over 100 people. (*Id.* at ¶¶ 10, 53.) Included among those to whom the data was leaked was Defendant Narachi, who publicly pledged in a November 25, 2013 *Forbes* article, "We're going to honor the integrity of [the Light Study's] blind so we don't screw it up and get the final analysis." (*Id.* at

¶¶ 9, 52, 58.) Others who saw the data included investment bankers and several representatives from Takeda. (*Id.* at ¶ 58.) The FDA later confirmed in a September 10, 2014 report that Defendant Orexigen had improperly disseminated unblinded interim data "far beyond the intended core group." (*Id.* at ¶ 58 (emphasis omitted).) The Light Study's Data Monitoring Committee "found that it [was] particularly concerning that members of Orexigen's Board of Directors . . . , who have financial interest in the outcome of the trial, were also provided full access to the unblinded data." (*Id.* (emphasis omitted).) On February 3, 2014, Defendant Orexigen submitted a second data access plan to the FDA. (*Id.* at ¶¶ 11, 60; *see also* RJN Ex. A at 9, ECF No. 62-3.)

At a June 4, 2014 meeting, the FDA reminded Defendants Narachi and Klassen that the 25% interim results have "a high degree of uncertainty and were likely to change with the accumulation of additional data." (CC ¶ 59, ECF No. 55.) The FDA was also concerned that Defendant Orexigen's corporate leaders knew the 25% interim results. (*Id.* at ¶ 10.) The FDA also noted that the unblinding violated Defendant Orexigen's data access plan and that the extent of the confidentiality breach of interim results in the Light Study was unprecedented. (*Id.*)

On July 2, 2014, Defendant Orexigen filed patent application mi,ber 14/322,810 (the '810 Application) with the United States Patent and Trademark Office (USPTO), listing Defendant Klassen as the "patent applicant" and "inventor." (*Id.* at ¶¶ 12, 61.) The '810 Application covered a new indication—a cardiovascular benefit—for Contrave based on the 25% interim data.

(*Id.* at ¶ 66.) The '810 Application explicitly included the 25% interim Light Study data (*id.* at ¶¶ 12, 62), and noted:

> Surprisingly, rather than increasing the occurrence of MACE in this high risk patient population, the results indicate that treatment with [Contrave] decreases the occurrence of MACE in overweight and obese subjects with cardiovascular risk factors. Briefly stated, fewer subjects in the [Contrave] treatment group experienced a MACE even compared to placebo.

(*Id.* at ¶ 62 (alterations in original) (emphasis omitted).) Pursuant to 35 U.S.C. § 122, Defendant Orexigen requested that the USPTO keep the '810 Application confidential. (*Id.* at ¶¶ 12 & n.6, 61.) As part of that request, Defendant Orexigen had to "certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing." (RJN Ex. H at 3, ECF No. 62-10 (emphasis in original).) Defendant Orexigen also requested prioritized examination of the '810 Application pursuant to 37 C.F.R. § 1.102(e). (*Id.* at 9–10.)

On September 10, 2014, the FDA approved Contrave for commercial use (CC ¶¶ 14, 55, 126, ECF No. 55), and on November 26, 2014, the USPTO allowed the '810 Application for issuance as a patent (RJN Ex. H at 11–19, ECF No. 62-10). The USPTO's letter indicated that the issuance fee for the '810 Application had to be paid by February 26, 2015. (*Id.* at 11.)

In December 2014, the Committee for Medicinal Products for Human Use (CHMP), the centralized expert advisory committee of the European Medicines Agency, adopted a positive opinion for Contrave[3] and recommended that the European Commission grant a centralized marketing authorization. (CC ¶ 63, ECF No. 55.) The European Commission also informed Defendant Orexigen that it would review a draft decision granting marketing authorization for Contrave during a meeting of the Standing Committee scheduled for March 2015. (*Id.*)

On December 4, 2014, Defendant Orexigen filed patent application number PCT/US2014/068527 with the World Intellectual Property Organization (the WIPO Application). (RJN Ex. V, ECF No. 62-24.) The WIPO Application incorporated by reference the '810 Application. (*Id.* at 3.) On January 5, 2015, Defendant Orexigen sent the USPTO a Rescission of Previous Nonpublication Request, of which the USPTO acknowledged receipt on January 12, 2015. (CC ¶¶ 14, 64, ECF No. 55; *see also* RJN Ex. H at 20–21, 23, ECF No. 62-10.) The rescission noted that "[i]f a notice of foreign or international filing is or will be required by 35 U.S.C. 122(b)(2)(B)(iii) and 37 CFR 1.213(c), I hereby provide such notice." (RJN Ex. H at 20, ECF No. 62-10.) The USPTO informed Defendant Orexigen that "the earliest possible projected publication date" was June 11, 2015. (*Id.* at 23.) Defendant Orexigen paid the issue fee for the '810 Application on January 20, 2015. (*Id.* at 24.)

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[3] Contrave is marketed under the name Mysimba in Europe. (*Id.* at ¶ 63 n.16.)

On February 5, 2015, Defendants Hagan and Narachi were awarded a stock option grant on 202,605 and 635,150 shares, respectively, at an exercise price of $5.34 (CC ¶ 84, ECF No. 55), and on February 11, 2015, the USPTO advised Orexigen that the '810 Application would be issued as a patent on March 3, 2015 (*id.* at ¶ 67).

On February 25, 2015, Defendant Klassen informed investors on a conference call that "there won't be any release of the [Light Study] information unless pre-specified boundaries are hit." (*Id.* at ¶ 67 (emphasis omitted).) Defendant Orexigen's February 27, 2015 10-K noted that "[d]isclosure of interim results of ongoing clinical trials, including disclosure of interim results related to the protection of intellectual property . . . could significantly affect our product development costs or adversely impact our ability to maintain or receive additional regulatory approvals." (*Id.* at ¶ 68 (alteration in original) (emphasis omitted).)

On March 3, 2015, the USPTO issued U.S. Patent No. 8,969,371 (the '371 Patent) from the '810 Application. (RJN Ex. G, ECF No. 62-9; *see also* CC ¶¶ 15, 69, ECF No. 55.) Defendant Orexigen also filed an 8-K announcing the publication of '371 Patent and releasing the 25% interim Light Study Results. (CC ¶¶ 15, 69, 87, ECF No. 55.) The 8-K noted that the '371 Patent "incorporate[d] data from [the Light Study]," and that the '371 Patent "contain[s] claims related to a positive effect of Contrave on CV outcomes" based on an "analysis . . . conducted based on 94 observed an adjudicated [MACE], which was approximately 25% of the planned MACE for the Light Study." (*Id.* at ¶ 87.) The 8-K further explained that the interim analysis

"was prospectively designed to enable an early and preliminary assessment of safety to support regulatory approval" and that "[a] larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes." (*Id.*) It also stressed that, "**[i]mportantly, the U.S. package insert for Contrave states that the effect of Contrave on CV morbidity and mortality has not been established.**" (RJN Ex. J at 3 (emphasis in original), 5, ECF No. 52-12.) The 8-K also disclosed that "[a] second, large, randomized, placebo-controlled clinical trial evaluating the effect of Contrave on CV outcomes is planned to start later this year." (*Id.* at 5.) Defendant Orexigen did not consult the FDA, Dr. Nissen, or Takeda prior to filing the 8-K. (CC ¶ 15, ECF No. 55.)

Forbes reported that FDA senior official Dr. John Jenkins had stated that the FDA was unaware that Defendant Orexigen's '810 Application contained the 25% interim data and expressed "serious concerns" about Defendant Orexigen's disclosure of the interim data. (*Id.* at ¶¶ 93, 118.) The FDA reported that it was "very disappointed by Orexigen's actions" and warned patients and physicians that it was "critical that the[] interim data [] not be misinterpreted." (*Id.* at ¶ 93 (alterations in original).) The FDA noted that endpoints with less than 100 total events are statistically unreliable and were to be viewed with extreme caution. (*Id.* at ¶ 118.)

Defendant Orexigen then published a March 3, 2015 press release, explaining that it "filed patent applications based on the results in order to preserve the potential for additional intellectual property." (*Id.* at ¶¶ 94, 119.) It also explained that "[d]uring the

course of the study, the FDA informed [Defendant Orexigen] it had determined that the Light Study would not serve as the postmarketing requirement for Contrave; a new trial would be required." (*Id.* at ¶ 94) The new trial would start "later this year," and results "are anticipated by 2022." (*Id.*) "This morning the USPTO published the patent and supporting documentation, and [Defendant Orexigen] believed it was appropriate and necessary to make sure this information was equally available to all investors." (*Id.* at ¶¶ 94 (emphasis omitted), 119.) Although Defendant Orexigen's stock had closed at $5.79 per share on March 2, 2015, it closed on March 3, 2015 at $7.64 per share, trading as high as $9.37 per share. (*Id.* at ¶¶ 16, 89, 117.) More than 95.8 million of Defendant Orexigen's shares were traded on March 3, 2015, a "highly unusual trading volume" (*id.* at ¶¶ 89, 117), especially when compared to the average daily trading volume of approximately 3 million shares per day (*id.* at ¶ 16 n.7).

Analysts responded positively to the 8-K. (*Id.* at ¶¶ 90–91.) Analyst Simos Simeonidis from RBC Capital Markets noted that "[w]e view the news as very significant" and "[t]he newly revealed data demonstrated that not only is Contrave safe to use from a CV standpoint, but it actually appears to have a CV benefit." (*Id.* at ¶ 90 (emphasis omitted).) Consequently, he rated Defendant Orexigen's shares to "outperform." (*Id.*) Analysts at Piper Jaffray noted that the Light Study's interim results "[c]ould turn the obesity/metabolic syndrome market on its head. We see this CVOT effect as surprisingly positive and it has several implications, in our view for the potential of Contrave." (*Id.* at ¶¶ 17, 90.) Leerink analyst Paul

Matteis reported that "[t]he data this morning show a statistically significant Contrave benefit." (*Id.* at ¶ 91 (emphasis omitted).) Wells Fargo analyst Matthew J. Andrews, in analyzing the data, noted that "the 'holy grail' for treating cardiometabolic diseases is demonstration of a CV mortality benefit, which to date has not been demonstrated by an obesity therapeutic." (*Id.* at ¶¶ 17, 91 (emphasis omitted).)

On March 4, 2014, the *Wall Street Journal* published an article explaining that the FDA "considers the preliminary data 'far too unreliable to conclude anything further about cardiovascular safety.'" (*Id.* at ¶ 96 (emphasis omitted).) The article noted that "LIGHT study data was disclosed inappropriately" previously, and that the FDA had consequently decided that Defendant "Orexigen would have to launch a new study to satisfy the conditions of the approval of its Contrave drug." (*Id.*) The *Wall Street Journal* reported that Dr. Nissen, "the lead researcher for the study[,] is upset." (*Id.*) Dr. Nissen noted that "he was not aware of the interim study results until yesterday," "the disclosure was not approved by the data monitoring committee or the trial's executive committee," and Defendant Orexigen's business management was not included in the list of individuals with approved access to the data. (*Id.* (emphasis omitted).) On March 4, 2015, the price of Defendant Orexigen's stock closed at $8.49 per share (*id.* at ¶¶16, 97, 120), "again on unusually high trading volume of more than 40.5 million shares" (*id.* at ¶¶ 97, 120).

A March 5, 2015 *Forbes* article reported that "[t]here is widespread speculation that Orexigen used the excuse of the patent filing to publicly reveal the

interim results of the trial." (*Id.* at ¶ 70 (emphasis omitted).) The *Forbes* article further reported that critics believed that "[d]isclosing the results, through the medium of a patent filing and an SEC disclosure, is a deeply cynical and manipulative action." (*Id.* (emphasis omitted).) *Forbes* also speculated that Defendant Orexigen's repeated disclosure of the Light Study interim results could potentially threaten its relationship with the FDA and its ability to obtain further drug approvals. (*Id.* at ¶ 121.) On March 5, 2015, Defendant Orexigen's stock closed at $8.01 per share, down from its opening price of $8.50 per share. (*Id.* at ¶¶ 19, 121)

After the close of trading on March 5, 2015, *Forbes* published another report, which included criticisms of Defendant Orexigen and its decision to release the interim trial data by Dr. Jenkins, the FDA's director of the Office of New Drugs. (*Id.* at ¶¶ 18, 122.) Dr. Jenkins criticized the released data as "unreliable," "misleading," and "likely false," and warned that Defendant Orexigen "could face fines, civil penalties, or even the withdrawal of Contrave from the market" if it did not complete the new post-marketing study that the FDA would require. (*Id.*; *see also* RJN Ex. C at 4, ECF No. 62-5) On March 6, 2015, the price of Defendant Orexigen's stock dropped to $6.76 per share in intraday trading and closed at $7.10 per share, "again on unusually high trading volume." (CC ¶¶ 19, 123, 125, ECF No. 55.)

On March 13, 2015, Defendant Orexigen filed a Form S-8 Registration Statement, registering six million shares of common stock at a proposed maximum offering price of $7.08 per share. (*Id.* at

¶¶ 20, 85; *see also* RJN Ex. T at 3, ECF No. 62-22.) In its March 26, 2015 Form 8-K, Defendant Orexigen announced that Contrave had received marketing authorization in Europe. (CC ¶¶ 21, 72, 99, ECF No. 55.) Over nine million shares of Defendant Orexigen's stock traded on that day, with stock prices increasing from an opening price of $6.89 on March 26, 2015 to a closing price of $7.54 on March 27, 2015. (*Id.*)

Also on March 26, 2015, Light Study researchers discovered that Contrave's purported 25% interim heart benefit vanished once the additional 50% Light Study results were considered. (*Id.* at ¶¶ 21, 74.) The Light Study's Executive Steering Committee unanimously voted to recommend stopping the Light Study and to immediately release the 50% interim data. (*Id.* at ¶¶ 74, 127) Defendants were shown the 50% interim data demonstrating that the 25% interim cardiovascular benefit had disappeared. (*Id.* at ¶¶ 21, 74, 99, 127.) Dr. Nissen began to draft a press release disclosing the 50% Light Study data and termination of the Light Study, which Takeda approved but Defendant Orexigen refused to authorize. (*Id.* at ¶¶ 21, 75.)

On May 8, 2015, Defendant Orexigen filed an 8-K containing a press release announcing its business and financial results for the first quarter ended March 31, 2015. (*Id.* at ¶ 100.) The press release noted that Contrave's "clinical trial program also includes a double-blind, placebo-controlled cardiovascular outcomes trial known as the Light Study." (*Id.* (emphasis omitted).) Defendant Orexigen also filed a 10-Q (*id.* at ¶ 103), noting that Defendant Orexigen's share price might be impacted by "announcements

regarding [its] clinical trials, including [ ] the Light Study and the post-marketing required clinical trials, including the new CVOT, for Contrave" (*id.* at ¶ 104 (second alteration in original)). The 10-Q also represented that "additional analysis of the interim results or new data from the continuing Light Study, including safety-related data, and the additional cardiovascular outcomes trial, may produce negative or inconclusive results, or may be inconsistent with the conclusion that the interim analysis was successful." (*Id.* (emphasis omitted).) The 10-Q also noted that "[a]ny failure by [Defendant Orexigen] or delay in completing [its] clinical trials, including the Light Study, or in obtaining regulatory approvals, could cause a delay in the commencement of product revenues and cause [Defendant Orexigen's] research and development expenses to increase." (*Id.* at ¶ 105.)

Defendant also hosted an earnings conference call for analysts and investors on May 8, 2015. (*Id.* at ¶¶ 22, 107.) In response to a question about whether the Light Study had been terminated, Defendant Klassen represented that the "Light Study is continuing and we are continuing to engage both Orexigen and Takeda with the FDA and with [Executive Steering Committee] and [Data Monitoring Committee] regarding ultimately the status of the study, but it's an ongoing entity as of right now." (*Id.* at ¶ 108 (emphasis omitted).) In response to a query about the 50% interim data, Defendant Klassen responded:

> We have passed the 50% time point and as we've stated before, those results are viewed by the Data Monitoring Committee and it wasn't a planned look by the sponsors, like the 25% was.

> The 25% was special because it was for regulatory purposes and so we have had 50% time point.

(*Id.* at ¶ 109 (alteration in original).) Defendant Narachi added:

> The results from the 50% analysis . . . only come out in the context of wrapping up the trial or as a final analysis. So, if the decision is made to terminate the trial early and focus resources on the next CVOT, which is what we have been advocating, then I think results would come out sooner.

(*Id.* (emphasis omitted).) Defendant Narachi also noted that "if there was a decision to terminate the [Light Study] . . . , that would be a disclosure that we would make." (*Id.* at ¶ 111 (emphasis omitted).)

On May 12, 2015, Defendant Orexigen and Takeda announced discontinuation of the Light Study (*id.* at ¶¶ 24, 126), but did not reveal the 50% data (*id.* at ¶¶ 24, 127). They noted that they were "pleased that the Light Study is now being terminated and want[ed] to thank the patients and all those involved in the study." (*Id.* at ¶ 27 (alteration in original) (emphasis omitted).) Minutes later, Dr. Nissen and the Cleveland Clinic issued a press release announcing both the termination of the Light Study and the 50% interim data. (*Id.* at ¶¶ 24, 75, 126, 127.) The 50% Light Study data revealed that at 192 MACE, the difference between the Contrave and placebo groups shrank to 12% and was no longer statistically significant. (*Id.* at ¶ 127.) Dr. Nissen noted:

> These results do not confirm the cardiovascular benefits of Contrave claimed by [Defendant] Orexigen in the patent application based on the data obtained at the 25 percent time point in the trial . . . . These results show neither benefit nor harm for patients taking the drug, but are consistent with the requirement by the FDA that the Light Trial demonstrate an absence of a doubling of cardiovascular risk for patients taking the drug . . . . The inconsistency of effects on cardiovascular outcomes between the first 25 percent and the second 25 percent of the Light Study clearly illustrates the risks inherent in pre-judgment of clinical trial results based upon an interim analysis and demonstrate why interim results should remain confidential during any ongoing trial.

(*Id.* at ¶ 126 (emphasis omitted).)

In an article appearing on *Forbes.com*, Dr. Nissen claimed that "[p]atients were misled, investors were misled." (*Id.* at ¶ 127 (emphasis omitted); *see also id.* at ¶ 25.) Dr. Nissen also noted that Defendant Orexigen had refused to approve a press release publicizing the 50% Light Study data for six weeks. (*Id.* at ¶¶ 25, 127.) An article published in *Medscape* on that same day quoted Dr. Nissen as saying:

> Essentially, when they [Orexigen] filed the patent the company chose what they were going to put in there and what they were going to leave out . . . . We felt it was in the public interest to take an unprecedented step and release the 50% data because we couldn't allow unreliable data to be used in clinical decision

> making. We had a duty to the public and also to the investment community, to tell the truth.

(*Id.* at ¶ 128 (alteration in original); *see also id.* at ¶ 26.) The price of Defendant Orexigen's common stock fell from an opening price of $6.75 on May 11, 2015, to $5.02 per share at the close of May 13, 2015. (*Id.* at ¶¶ 26, 130.)

II. Procedural Background

On March 10, 2015, Plaintiff Lisa Colley filed a class action complaint against Defendants, alleging (1) violation of § 10(b) of the 1934 Act and Rule 10b-5, and (2) violation of § 20(a) of the 1934 Act. (ECF No. 1.) The case was originally assigned to Judge M. James Lorenz. (*See id.*) Two related actions—*Stefanko v. Orexigen Therapeutics, Inc.*, No. 3:15-cv-00549-JAH-JLB, and *Yantz v. Orexigen Therapeutics, Inc.*, No. 3:15-cv-557-CAB-MDD—were filed on March 11, 2015. (ECF No. 4.)

On May 12 and 13, 2015, a number of competing motions for consolidation, appointment of lead plaintiff, and approval of lead counsel were filed. (*See* ECF Nos. 26, 27, 28, 29, 32, 33, 34, 35, 37, 38.) On June 15, 2015, Lead Plaintiff informed Judge Lorenz that his motions were unopposed. (ECF No. 42.) Consequently, Judge Lorenz granted Lead Plaintiff's motions on June 22, 2015. (ECF No. 43.)

On June 26, 2015, Judge Lorenz recused himself from this action, which was reassigned to this Court. (ECF No. 46.) Lead Plaintiff filed its CC on August 20, 2015, and Defendants filed the instant MTD on October 5, 2015 (ECF No. 62).

DEFENDANTS' RJN

I. Legal Standard

Federal Rule of Evidence 201(b) provides that "[t]he court may judicially notice 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." "Judicially noticed facts often consist of matters of public record." *Botelho v. U.S. Bank, N.A.*, 692 F. Supp. 2d 1174, 1178 (N.D. Cal. 2010) (citation omitted); *see also Reyn's Pasta Bella, LLC v. Visa USA, Inc.*, 442 F.3d 741, 746 n.6 (9th Cir. 2006) (The court "may take judicial notice of court filings and other matters of public record."). While "[a] court may take judicial notice of the existence of matters of public record, such as a prior order or decision," it should not take notice of "the truth of the facts cited therein." *Marsh v. San Diego Cnty.*, 432 F. Supp. 2d 1035, 1043 (S.D. Cal. 2006).

"When ruling on a Rule 12(b)(6) motion to dismiss, if a district court considers evidence outside the pleadings, it must normally convert the 12(b)(6) motion into a Rule 56 motion for summary judgment, and it must give the nonmoving party an opportunity to respond." *United States v. Ritchie*, 342 F.3d 903, 907–08 (9th Cir. 2003) (citing Fed. R. Civ. P. 12(b); *Parrino v. FHP, Inc.*, 146 F.3d 699, 706 n.4 (9th Cir. 1998)). "A court may, however, consider certain materials—documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice—without converting the motion to dismiss into a motion for summary

judgment." *Id.* at 908 (citing *Van Buskirk v. CNN*, 284 F.3d 977, 980 (9th Cir. 2002); *Barron v. Reich*, 13 F.3d 1370, 1377 (9th Cir. 1994); 2 James Wm. Moore et al., *Moore's Federal Practice* § 12.34[2] (3d ed. 1999)). "Even if a document is not attached to a complaint, it may be incorporated by reference into a complaint if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *Id.* (citing *Van Buskirk*, 284 F.3d at 980; *Branch v. Tunnell*, 14 F.3d 449, 453–54 (9th Cir. 1994), *overruled on other grounds by Galbraith v. Cnty. of Santa Clara*, 307 F.3d 1119 (9th Cir. 2002); *Venture Assoc. Corp. v. Zenith Data Sys. Corp.*, 987 F.2d 429, 431(7th Cir. 1993)). "The defendant may offer such a document, and the district court may treat such a document as part of the complaint, and thus may assume that its contents are true for purposes of a motion to dismiss under Rule 12(b)(6)." *Id.*; *see also Marder v. Lopez*, 450 F.3d 445, 448 (9th Cir. 2006) ("The court may treat . . . a document [incorporated by reference] as 'part of the complaint, and thus may assume that its contents are true for purposes of a motion to dismiss under Rule 12(b)(6).'") (citing *Ritchie*, 342 F.3d at 908).

II. Analysis

Defendants ask the Court to take judicial notice of pursuant to Federal Rule of Evidence 201 and/or consider pursuant to the incorporation by reference doctrine twenty-two documents:

(1) Center for Drug Evaluation & Research, U.S. Food & Drug Admin., Summary Review for Regulatory Action for Application No. 200063Orig1s000 (Sept. 10, 2014), *available at* http://www.accessdata.fda.gov/

drugsatfda_docs/nda/2014/200063Orig1s000SumR.pdf (RJN Ex. A, ECF No. 62-3);

(2) Orexigen Therapeutics, Inc., Annual Report (Form 10-K) (Feb. 27, 2015) (RJN Ex. B, ECF No. 62-4);

(3) Ed Silverman, *Orexigen Data is 'Unreliable and Premature:' FDA's Jenkins Explains*, Wall St. J. (Mar. 6, 2015, 9:39 AM), http://blogs.wsj.com/pharmalot/2015/03/06/orexigen-data-is-unreliable-and-premature-fdas-jenkins-explains/ (RJN Ex. C, ECF No. 62-5);

(4) Orexigen Therapeutics, Inc., Current Report (Form 8-K) Ex. 99.1 (Sept. 11, 2014) (RJN Ex. D, ECF No. 62-6);

(5) Comm. for Medicinal Prods. for Human Use, European Med. Agency, Assessment Report for an Initial Marketing Authorisation Application for Mysimba (Dec. 18, 2014), *available at* http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/003687/WC500185582.pdf (RJN Ex. E, ECF No. 62-7);

(6) Press Release, Comm. for Medicinal Prods. for Human Use, European Med. Agency, Mysimba Recommended for Approval in Weight Management in Adults (Dec. 19, 2014), *available at* http://ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/12/news_detail_002240.jsp&m

id=WC0b01ac058004d5c1 (RJN Ex. F, ECF No. 62-8);

(7) U.S. Patent No. 8,969,371 (filed July 2, 2014) (RJN Ex. G, ECF No. 62-9);

(8) Excerpts from the USPTO's file history of the '371 Patent, including:

(a) U.S. Patent No. 8,969,371 Application Data Sheet (July 2, 2014) (RJN Ex. H at 2–8, ECF No. 62-10),

(b) Certification and Request for Prioritized Examination under 37 CFR 1.102(e) (July 2, 2014) (RJN Ex. H at 9–10, ECF No. 62-10),

(c) Notice of Allowance and Fee(s) Due (Nov. 26, 2014) (RJN Ex. H at 11–19, ECF No. 62-10),

(d) Rescission of Previous Nonpublication Request (Jan. 5, 2015) (RJN Ex. H at 20–21, ECF No. 62-10),

(e) Notice of New or Revised Projected Publication Date (Jan. 8, 2015) (RJN Ex. H at 22, ECF No. 62-10),

(f) Communication Regarding Rescission of Nonpublication Request and/or Notice of Foreign Filing (Jan. 12, 2015) (RJN Ex. H at 23, ECF No. 62-10), and

(g) Fee(s) Transmittal (Jan. 20, 2015) (RJN Ex. H at 24, ECF No. 62-10);

(9) Ed Silverman, *Fat Chance: FDA Chastises Orexigen for Disclosing Interim Trial Data*, Wall St. J. (Mar. 4, 2015, 10:57 AM), http://blogs.wsj.com/pharmalot/2015/ 03/04/ fat-chance-fda-chastises-orexigen-for-disclosing-interim-trial-data/ (RJN Ex. I, ECF No. 62-11);

(10) Orexigen Therapeutics, Inc., Current Report (Form 8-K) (Mar. 3, 2015) (RJN Ex. J, ECF No. 62-12);

(11) Simos Simeonidis, RBC Capital Markets, *Orexigen Therapeutics Inc: LIGHT Interim Data Reveal Contrave Positive CV Effect; Extend IP by 7 Years*, Equity Research: First Glance (Mar. 3, 2015) (RJN Ex. K, ECF No. 62-13);

(12) Paul Matteis & Jason M. Gerberry, Leerink Partners LLC, *Orexigen Therapeutics, Inc.: 25% Interim LIGHT Analysis Shows Stat. Sig Contrave Benefit on CV Outcomes* (Mar. 3, 2015) (RJN Ex. L, ECF No. 62-14);

(13) Adam Feuerstein, *Orexigen Weight-Loss Pill Shows Surprise Heart-Safety Benefit*, www.thestreet.com (Mar. 3, 2015, 11:51 AM), *available at* http://www.thestreet.com/story/ 13065624/1/orexigen-weight-loss-pill-shows-surprise-heart-safety-benefit.html (RJN Ex. M, ECF No. 62-15);

(14) Matt Herper, *The FDA Is Forcing Orexigen to Do a Second Safety Study Because of Contrave Disclosures*, www.forbes.com (Mar. 3, 2015, 3:33 PM), *available at*

http://www.forbes.com/sites/matthewherper/2015/03/03/the-fda-will- force-orexigen-to-do-a-second-safety-study-because-of-contrave-disclosures/ (RJN Ex. N, ECF No. 62-16);

(15) Matt Herper, *Top FDA Official Says Orexigen Study Result 'Unreliable,' 'Misleading,'* www.forbes.com (Mar. 5, 2015, 5:28 PM), *available at* http://www.forbes.com/sites/matthewherper/2015/03/05/top-fda-official-says-orexigen-data-unreliable-likely-false/ (RJN Ex. O, ECF No. 62-17);

(16) Paul Matteis & Jason M. Gerberry, Leerink Partners LLC, *Orexigen Therapeutics, Inc.: Meeting with Mgmt Highlights Partnering Goals, Next Steps for CV Studies* (Apr. 6, 2015) (RJN Ex. P, ECF No. 62-18);

(17) Press Release, Orexigen Therapeutics, Inc., Takeda Pharmaceuticals and Orexigen Therapeutics Announce Termination of the Cardiovascular Outcomes Study (Light Study) of the Obesity Drug Contrave (naltrexone HCl and bupropion HCl) (May 12, 2015), *available at* http://ir.orexigen.com/phoenix.zhtml?c=207034&p=irol-newsArticle&ID=2046959 (RJN Ex. Q, ECF No. 62-19);

(18) Orexigen Therapeutics, Inc., Proxy Statement (Schedule DEF-14A) (Apr. 30, 2014) (RJN Ex. R, ECF No. 62-20);

(19) Orexigen Therapeutics, Inc., Proxy Statement (Schedule DEF-14A) (Apr. 30, 2014) (RJN Ex. S, ECF No. 62-21);

(20) Orexigen Therapeutics, Inc., Registration Statement (Form S-8) (Mar. 16, 2015) (RJN Ex. T, ECF No. 62-22);

(21) Orexigen Therapeutics, Inc., Proxy Statement (Schedule DEF-14A) App. A (RJN Ex. U, ECF No. 62-23); and

(22) World Intellectual Property Organization Patent Application No. WO/2015/085044 (filed Dec. 4, 2014) (RJN Ex. V, ECF No. 62-24).

Defendants argue that "[a]ll of these documents are appropriate for judicial notice under Federal Rule of Evidence 201 or consideration by the Court under the incorporation-by-reference doctrine." (RJN 9, ECF No. 62-25.) Specifically, Defendants argue that the Court should take judicial notice of Exhibits A through V and consider Exhibits A through C and F through U under the incorporation-by-reference doctrine. (*See generally id.* at 11–19.)

Lead Plaintiff counters that Defendants' RJN of Exhibits A, E through H, and J—files of the FDA, USPTO, and EMA—should be denied because "[c]ourts are consistently unwilling to allow judicial notice to be used as a tool to create and support an alternate universe of facts even where such information may be contained in public records and internet websites, or constitute governmental documents available on a government website." (RJN Opp'n 9–10, ECF No. 68 (citing *Michajlun v. Bausch & Lomb, Inc.*, No. 14-cv-1365 JM (JMA), 2015 WL 1119733, at *3 (S.D. Cal. Mar. 11, 2015)).) Similarly, documents filed with the SEC—Exhibits B, D, J, and R through U—"may not be

judicially noticed for the truth of the matters stated therein." (*Id.* at 10–11.) Lead Plaintiff challenges Exhibits C, F, I, K through N, and Q on the grounds that "press releases, news articles, and analyst opinions cannot be embraced to support any factual scenario advanced by Defendants except that which is alleged in the Complaint itself." (*Id.* at 12.) Lead Plaintiff adds that "Ex. M cannot be noticed for any reason as it is not cited or referenced to or relied upon in the Complaint." (*Id.*) Lead Plaintiff objects to the Court taking judicial notice or incorporating by reference Exhibits D, E, M, and V on the grounds that "they are superfluous, irrelevant and do not meet the 'indisputability' requirements of Rule 201 with respect to the 'facts' contained therein" and, "[w]here a document is not cited or referenced in the Complaint, the incorporation by reference doctrine does not apply." (*Id.* at 12–13 (citing *Pearce v. Bank of Am. Home Loans*, No. C 09-3988 JF, 2010 WL 689798, at *3 (N.D. Cal. Feb. 23, 2010); *Witriol v. LexisNexis Grp.*, No. C05-02392 MJJ, 2006 WL 4725713, at *2–3 (N.D. Cal. Feb. 10, 2006)).) Lead Plaintiff also argues that "[a]ll of the 'factual' contentions Defendants proffer in order to contradict the well-pleaded factual allegations of the Complaint should be disregarded." (*Id.* at 14–21.)

The Court concludes that Exhibits A through C, F through L, and N through U are incorporated by reference because they are "explicitly referenced and relied on in the [Consolidated] Complaint . . . and Plaintiff[] do[es] not contest the[ir] authenticity." *See City of Royal Oak Ret. Sys. v. Juniper Networks, Inc.*, 880 F. Supp. 2d 1045, 1059 (N.D. Cal. 2012); *see also Interstate Nat. Gas Co. v. S. Cal. Gas Co.*, 209 F.2d 380, 384 (9th Cir. 1953) (considering on appeal contract

referenced in amended complaint, on file with Federal Power Commission, and introduced in support of Rule 12(b)(6) motion to dismiss). Consequently, the Court may "treat such . . . document[s] as part of the complaint, and thus may assume that [their] contents are true for purposes of a motion to dismiss under Rule 12(b)(6)." *See Marder*, 450 F.3d at 448; *Ritchie*, 342 F.3d at 908. Despite Lead Plaintiff's arguments to the contrary (*see* RJN Opp'n 14–21, ECF No. 68), "[t]he district court obviously is not bound to accept the pleader's allegations as to the effect of the exhibit, but can independently examine the document and form its own conclusions as to the proper construction and meaning to be given the attached material." Charles Alan Wright et al., 5A Fed. Prac. & Proc. Civ. § 1327 (3d ed. 2016) (citing *Ott v. Home Sav. & Loan Ass'n*, 265 F.2d 643, 646–48 (9th Cir. 1958)).

Furthermore, the Court concludes that it may properly take judicial notice of Exhibits D (exhibit to Orexigen's September 11, 2014 Form 8-K), E (CHMP's December 18, 2014 report on Mysimba), and V (the WIPO Application), *see, e.g.*, *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1064 n.7 (9th Cir. 2008) (judicially noticing SEC filings); *Jasin v. Vivus, Inc.*, No. 14-CV-03263-BLF, 2016 WL 1570164, at *22 (N.D. Cal. Apr. 19, 2016) (judicially noticing CHMP reports); *Anderson v. Kimberly-Clark Corp.*, No. C12-1979RAJ, 2013 WL 9760040, at *2 (W.D. Wash. Sept. 25, 2013) (judicially noticing WIPO patent), *aff'd* 570 F. App'x 927 (Fed. Cir. 2014), although the Court cannot take notice of "the truth of the facts cited" in these Exhibits, *see Marsh*, 432 F. Supp. 2d at 1043. The Court declines, however, to judicially notice Exhibit M,

the March 3, 2015 article authored by Adam Feuerstein and appearing on www.thestreet.com.

Accordingly, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' RJN (ECF No. 62-25), as outlined above.

DEFENDANTS' MTD

I. Legal Standard

Rule 12(b)(6) permits a party to raise by motion the defense that the complaint "fail[s] to state a claim upon which relief can be granted," generally referred to as a motion to dismiss. The Court evaluates whether a complaint states a cognizable legal theory and sufficient facts in light of Federal Rule of Civil Procedure 8(a), which requires a "short and plain statement of the claim showing that the pleader is entitled to relief." Although Rule 8 "does not require 'detailed factual allegations,' . . . it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). In other words, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do." *Twombly*, 550 U.S. at 555 (alteration in original). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (alteration in original) (quoting *Twombly*, 550 U.S. at 557).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.*

(quoting *Twombly*, 550 U.S. at 570); *see also* Fed. R. Civ. P. 12(b)(6). A claim is facially plausible when the facts pled "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). That is not to say that the claim must be probable, but there must be "more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citing *Twombly*, 550 U.S. at 556). "[F]acts that are 'merely consistent with' a defendant's liability" fall short of a plausible entitlement to relief. *Id.* (quoting *Twombly*, 550 U.S. at 557). Further, the Court need not accept as true "legal conclusions" contained in the complaint. *Id.* at 678–79 (citing *Twombly*, 550 U.S. at 555). This review requires "context-specific" analysis involving the Court's "judicial experience and common sense." *Id.* at 679. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* (quoting Fed. R. Civ. P. 8(a)(2)). The Court will grant leave to amend unless it determines that no modified contention "consistent with the challenged pleading . . . [will] cure the deficiency." *DeSoto v. Yellow Freight Sys., Inc.*, 957 F.2d 655, 658 (9th Cir. 1992) (quoting *Schriber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986)).

"Claims brought under Rule 10b-5 . . . must meet Federal Rule of Civil Procedure 9(b)'s particularity requirement that '[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.'" *In re Dura Pharm., Inc. Sec. Litig.*, 452 F. Supp. 2d 1005, 1016 (S.D. Cal. 2006) (alteration in original) (quoting Fed. R.

Civ. P. 9(b)) (citing *In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1014 (9th Cir. 2005), *cert. denied* 546 U.S. 1172 (2006); *Yourish v. Cal. Amplifier*, 191 F.3d 983, 993 (9th Cir. 1999)). "In addition, in 1995, Congress enacted the Private Securities Litigation Record Act of 1995 (PSLRA) and altered the pleading requirements in private securities fraud litigation by requiring a complaint plead with particularity both falsity and scienter." *Id.* at 1016–17 (quoting *Daou Sys.*, 411 F.3d at 1014) (internal quotation marks omitted).

II. Analysis

Lead Plaintiff alleges three causes of action: (1) violations of § 10(b) of the Exchange Act and Rule 10b-5(b) against all Defendants, (2) violations of § 10(b) of the Exchange Act and Rules 10b-5(a) & (c) against all Defendants, and (3) violations of § 20(a) of the Exchange Act against the Insider Defendants. (CC ¶¶ 142–55, ECF No. 55.) Defendants move to dismiss Lead Plaintiff's CC for failure to state a claim. (MTD 2, ECF No. 62.) The Court addresses each of Lead Plaintiff's causes of action in turn.

A. First Cause of Action: Violations of § 10(b) of the Exchange Act and Rule 10b-5(b) Against Defendants

"Section 10(b) of the Securities Exchange Act of 1934 forbids (1) the 'use or employ[ment] . . . of any . . . deceptive device,' (2) 'in connection with the purchase or sale of any security,' and (3) 'in contravention of' Securities and Exchange Commission 'rules and regulations.'" *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341 (2005) (quoting 15 U.S.C. § 78j(b)). "Commission Rule 10b-5 forbids, among other things,

the making of any 'untrue statement of a material fact' or the omission of any material fact 'necessary in order to make the statements made . . . not misleading.'" *Id.* (quoting 17 CFR § 240.10b-5 (2004)). "The basic elements of a Rule 10b-5 claim, therefore, are: (1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss." *Daou Sys.*, 411 F.3d at 1014 (citing *Dura Pharms.*, 544 U.S. at 341–42). Because the Court concludes that Lead Plaintiff has failed to plead a material misrepresentation or omission of fact, the Court need not address the remaining elements of Plaintiff's Rule 10b-5(b) cause of action.

A statement or omission is misleading "if it would give a reasonable investor the 'impression of a state of affairs that differs in a material way from the one that actually exists.'" *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008) (quoting *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)). "[A]n omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important." *Basic Inc. v. Levinson*, 485 U.S. 224, 231 (1988) (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976). "[T]here must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Id.* at 231–32 (quoting *TSC Indus.*, 426 U.S. at 449). "[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*, 563 U.S. 27, 44 (2011). "Disclosure is required under these provisions

only when necessary 'to make . . . statements made, in light of the circumstances under which they were made, not misleading.'" *Id.* (quoting 17 C.F.R. § 240.10b-5(b)).

1. Orexigen's Current Report on Form 8-K (March 3, 2015)

Lead Plaintiff alleges that Defendant Orexigen's March 3, 2015 Form 8-K, in which it announced the issuance of the '371 Patent and the 25% interim Light Study data, was "materially false and misleading" for a number of reasons, including:

> (i) the 25% study results Defendants improperly released on March 3, 2015 showing that Contrave reduced the risk of heart attacks and cardiovascular death were "unreliable," "likely false," and "misleading;" (ii) Orexigen violated the FDA Agreement forbidding the Company from releasing Light Study interim results; (iii) Orexigen knew, no later than July 2, 2014, that Defendant Klassen had included specific interim Light Study data in the 2014 Patent Application; (iv) Orexigen had made a request with the USPTO in January 2015 to have the patent publicly disseminated; (v) Orexigen faced potential fines, civil penalties, and the possible removal of Contrave from the market by the FDA; and (vi) as a result of the above, the Company's Class Period filings with the SEC were materially false and misleading at all relevant times.

(CC ¶ 92, ECF No. 55.)

Defendants argue that, "to this day, no one has identified any false information disclosed in the graph or in any other aspect of the 25% analysis." (MTD Mem. 18, ECF No. 62-1.) Moreover, "the 8-K could not have been clearer that the data was 'interim' and that a 'larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes.'" (*Id.* (quoting CC ¶ 87, ECF No. 55).) Consequently, "[t]here simply was no fraud." (*Id.* at 19.) Lead Plaintiff counters that "the Company misrepresented that Contrave reduced cardiovascular events by 41% compared with a placebo without disclosing that the FDA had previously told defendants Klassen and Narachi that the 25% data was 'far too unreliable to conclude ***anything***.'" (MTD Opp'n 18, ECF No. 67 (emphasis in original) (citing CC ¶¶ 18, 47, 96, 126, ECF No. 55).) "While Orexigen may have accurately reported what the 25% interim data ***appeared*** to show, . . . Defendants do not credibly dispute that they exaggerated the 25% data's statistical significance and failed to disclose that it was unreliable." (*Id.* (emphasis in original).) "Moreover, nowhere in the 8-K did Orexigen disclose that the Company had signed the FDA Agreement prohibiting it from releasing the 25% data." (*Id.*) Had investors known this information, they "could have stayed on the sidelines until the statistically relevant 50% data became available." (*Id.* at 19.)

The Court concludes that there were no material misrepresentations or omissions of fact in Defendant Orexigen's March 3, 2015 8-K. First, although dissemination of the 25% interim results further violated Defendant Orexigen's data access plan, Defendant Orexigen nowhere claimed that it had the

FDA's approval to publish the data. Consequently, there was no affirmative duty to disclose the violation of the data access plan. *See Matrixx Initiatives*, 563 U.S. at 44 ("Disclosure is required under these provisions only when necessary 'to make . . . statements made, in light of the circumstances under which they were made, not misleading.'") (quoting 17 C.F.R. § 240.10b-5(b)).

Moreover, and more importantly, Defendants did not misrepresent the 25% interim data. The 8-K made clear that "[t]he 371 Patent . . . incorporate[s] data from a pre-planned interim analysis of the large, randomized, placebo-controlled, cardiovascular . . . outcomes trial of Contrave®" and that "[t]he 371 Patent . . . contain[s] claims related to a positive effect of Contrave on CV outcomes." (CC ¶ 87, ECF No. 55.) The 8-K further disclosed:

> This analysis was conducted based on 94 observed and adjudicated major adverse cardiovascular events . . . , which was approximately 25% of the planned MACE for the Light Study . . . . The 25% Interim Analysis was prospectively designed to enable an early and preliminary assessment of safety to support regulatory approval. A larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes.

(*Id.*) Defendants themselves did not claim that the results were statistically significant, even if analysts later jumped to that conclusion. (*See, e.g.*, *id.* at ¶ 91 ("On March 3, 2015 Leerink analyst Paul Matteis . . . not[ed] that . . . '. . . The data this morning show a statistically significant Contrave benefit . . . .'")

(emphasis omitted).) Rather, Defendants twice cautioned that "[t]he 25% Interim Analysis was prospectively designed to enable an early and preliminary assessment of safety to support regulatory approval. A larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes." (*See* RJN Ex. J at 3, 5, ECF No. 62-12.)

Consequently, Defendants are correct that "the 8-K could not have been clearer that the data was 'interim' and that a 'larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes.'" (*See* MTD Mem. 18, ECF No. 62-1 (quoting CC ¶ 87, ECF No. 55).) Accordingly, the Court **DISMISSES WITH PREJUDICE** Plaintiff's first cause of action to the extent it is predicated upon material misstatements or omissions of fact in Defendant Orexigen's March 3, 2015 8-K.

2. Orexigen's Press Release (March 3, 2015)

On March 3, 2015, Defendant Orexigen issued a press release noting that "[t]his morning the USPTO published the ['371 P]atent and supporting documentation." (CC ¶ 94, ECF No. 55.) Lead Plaintiff asserts that Defendant Orexigen's "representation that the USPTO had independently published the patent without the Company's input was highly misleading" because Defendant Orexigen "failed to disclose that the USPTO only published what Orexigen itself needlessly put into the 2014 Patent Application." (*Id.* at ¶ 95.) Lead Plaintiff further alleges that "Defendants also failed to disclose that [Defendant Orexigen] had rescinded its earlier request that the 2014 Patent Application remain unpublished. In truth, [Defendant Orexigen] even paid the USPTO an extra fee to

expedite publication of the 25% interim Light Study data." (*Id.*)

Defendants argue that these allegations are "based on a misunderstanding of the patent process." (MTD Mem. 18–19, ECF No. 62-1.) Defendants explain that, "[i]n general, patent applications must be 'kept in confidence' by the PTO for at least 18 months, at which time the application is published." (*Id.* at 10–11 (citing 35 U.S.C. §§ 122(a), (b)(1)(A)).) "An applicant may request that an application remain unpublished even after 18 months *if* the invention is not subject to a patent application in another country that requires publication within 18 months." (*Id.* at 11 (emphasis in original) (citing 35 U.S.C. § 122(b)(2)(B)(i)).) "Orexigen . . . sought prioritized *examination* of the Application, but did not request (much less pay for) expedited *publication*." (*Id.* (emphasis in original) (citing RJN Ex. H at 3, 9, ECF No. 62-10).) "Because the [WIPO A]pplication would also be published 18 months after its priority date, Orexigen was obligated by law to rescind its request that the Application not be published." (*Id.* (footnote omitted) (citing 35 U.S.C. § 122(b)(2)(B)(iii)).) "Orexigen did so on January 5, 2014, and the PTO set the Application to be published on June 11, 2015." (*Id.* (citing RJN Ex. H at 20, ECF No. 62-10).) When the USPTO published the '371 Patent of March 3, 2015, "the June 2015 publication date for the Application no longer mattered." (*Id.*)

The Court agrees with Defendants that Lead Plaintiff's allegations are based on a misunderstanding of the patent process. Defendants were required to notify the USPTO of the filing of the WIPO Application within forty-five days or the '810 Application would be

"regarded as abandoned." 35 U.S.C. § 122(b)(2)(B)(iii). Although it is true that Defendants requested prioritized examination pursuant to 37 C.F.R. § 1.102(e) (*see* RJN Ex. H at 9–10, ECF No. 62-10), it is the USPTO that ultimately determines the timetable for issuance of the patent and publication of the application. Consequently, the USPTO did not publish the '371 Patent "with[] the Company's input." (CC ¶ 95, ECF No. 55.)

Lead Plaintiff's allegation that Defendant Orexigen "needlessly put [the 25% interim data] into the ['810] Application" is equally misguided. (*See id.* at ¶ 95.) Lead Plaintiff acknowledges that the '810 Application disclosed that "***[s]urprisingly***, rather than increasing the occurrence of MACE in this high risk patient population, the results indicate that treatment with [Contrave] ***decreases*** the occurrence of MACE in overweight and obese subjects with cardiovascular risk factors." (*Id.* at ¶ 62 (emphasis in original).) The Federal Circuit has explained that, under such circumstances, supporting data may be required to demonstrate enablement during patent prosecution:

> where there is "no indication that one skilled in [the] art would accept without question statements [as to the effects of the claimed drug products] and no evidence has been presented to demonstrate that the claimed products do have those effects," an applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement [pursuant to 35 U.S.C. § 112].

Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1323 (Fed. Cir. 2005) (first and second alterations

in original) (quoting *Application of Novak*, 306 F.2d 924, 928 (C.C.P.A. 1962)). In light of these authorities and the parties' recognition that the '810 Patent explicitly conceded the "[s]urprising[]" nature of the 25% interim results, Lead Plaintiff's allegations that Defendant Orexigen "needlessly put [the 25% interim data] into the ['810] Application" (*see* CC ¶ 95, ECF No. 55) is not based on a "cognizable legal theory" and must be dismissed. *See, e.g.*, *Taylor v. Yee*, 780 F.3d 928, 935 (9th Cir. 2015) ("Dismissal [under Rule 12(b)(6)] is proper only where there is no cognizable legal theory or an absence of sufficient facts alleged to support a cognizable legal theory.") (quoting *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001)), *cert. denied* 136 S. Ct. 929 (2016).

Accordingly, the Court **DISMISSES WITH PREJUDICE** Plaintiff's first cause of action to the extent it is predicated upon material misstatements or omissions of fact appearing in Defendant Orexigen's March 3, 2015 press release.

3. Orexigen's Current Report on Form 8-K (May 8, 2015)

On May 8, 2015, Defendant Orexigen filed an 8-K announcing that "[t]he clinical trial program also includes a double-blind, placebo-controlled cardiovascular outcomes trial known as the Light Study." (CC ¶ 100, ECF No. 55 (emphasis omitted).) Lead Plaintiff alleges that "the Form 8-K failed to disclose that the Light Study had been terminated weeks earlier on March 26, 2015 and that the 50% interim data demonstrated that the Company's prior representations about Contrave's purported cardiovascular benefit were false." (*Id.* at ¶ 101.)

Consequently, the statements and material omissions in the 8-K "were materially false and misleading and/or failed to disclose that: . . . all of the Defendants knew or were deliberately reckless in not knowing no later than March 26, 2015 that the Light Study had been terminated and that the 50% interim data showed no heart benefit." (*Id.* at ¶ 102.)

With respect to Lead Plaintiff's allegations concerning the termination of the Light Study, Defendants argue that "the CC does not plead facts supporting its allegation that the ESC vote in March 2015 terminated the Light Study at that time" and, "because trial sponsors, not ESCs, decide whether and when to terminate clinical trials, any ESC vote to halt a trial is a *recommendation*, not a termination." (MTD Mem. 20–21, ECF No. 62-1.) Moreover, "[i]nvestors were aware that Orexigen and Takeda had been evaluating the fate of the Light Study for some time" and, "given that Orexigen and Takeda publicly disclosed just four days later that they had accepted the recommendation of the ESC and terminated the trial . . . , it makes no sense to allege that Defendants hid this fact." (*Id.* at 21 (citation omitted).) With regard to the 50% data, Defendants argue that "[o]n May 8, Orexigen said *nothing* about the CV effect demonstrated by the 50% data." (*Id.*) "Further, Orexigen had no independent duty to disclose the 50% results on May 8, even if it knew what the analysis revealed." (*Id.* at 22 (citing *Matrixx Initiatives*, 563 U.S. at 44; *WPP Lux. Gamma Three Sarl v. Spot Runner, Inc.*, 655 F.3d 1039, 1048 (9th Cir. 2011)).) "Before May 8, Orexigen had only disclosed the 25% data, which had not changed. Orexigen had no duty to update this accurate statement of historical fact." (*Id.* (citing *In re*

Foxhollow Techs., Inc. Sec. Litig., 359 Fed. App'x 802, 804–05 (9th Cir. 2009)).)

Lead Plaintiff counters that "[o]n March 26, 2015, defendants were specifically told that the Light Study had been terminated and that the 25% data they touted on March 3, 2015 had been deemed invalid at the 50% mark." (MTD Opp'n 20, ECF No. 67.) Consequently, "even if the ESC's vote could be denigrated as [a recommendation], defendants ***still*** failed to disclose that the ESC had unanimously voted to end the Light Study due to defendants' improper disclosure of 25% interim data." (*Id.* at 23 (emphasis in original).) Moreover, "[Defendants'] failure to disclose the truth they then knew about the 50% data . . . is black-letter securities fraud." (*Id.* at 21 (citing *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 987 (9th Cir. 2008); *Reese v. Malone*, 747 F.3d 557, 574 (9th Cir. 2014)).) In short, "defendants made public statements while in the possession of information that contradicted those statements." (*Id.* at 22 (citing *Nursing Home Pension Fund, Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1230 (9th Cir. 2004)).)

The Court concludes that Lead Plaintiff has failed sufficiently to allege any material misstatements or omissions of fact appearing in Defendant Orexigen's May 8, 2015 Form 8-K. Regarding the termination of the Light Study, despite Lead Plaintiff's conclusory allegations that the Light Study had terminated on March 26, 2015 (*see, e.g.*, CC ¶ 101, ECF No. 55), Lead Plaintiff's other allegations and the evidence the Court may properly consider instead compel the conclusion that the ESC's vote was merely a recommendation (*see, e.g.*, *id.* at ¶ 127 ("The executive committee voted

unanimously to recommend that the trial be stopped . . . ."); *see also* RJN Ex. Q at 2, ECF No. 62-19 ("Takeda . . . and Orexigen . . . have accepted the recommendation of the [ESC] . . . for early termination of the Light Study . . . .")), as Defendants argue (*see* MTD Mem. 20, ECF No. 62-1). Neither of the May 12, 2015 press releases indicates that the study was terminated prior to that date. (*See* CC ¶ 126, ECF No. 55 ("Following premature disclosure of interim results, the 9,000-patient Light Trial . . . has been halted by the trial's executive steering committee . . . .") (emphasis omitted); *see also* RJN Ex. Q at 2, ECF No. 62-19.) Moreover, Defendant Orexigen had already reported to the press that it was recommending "that LIGHT be stopped as it is not a post-marketing requirement and has less utility over time as more and more cardiovascular events happen off therapy." (*See* RJN Ex. P at 2, ECF No. 62-18.) In light of the evidence contradicting Lead Plaintiff's conclusory allegations that the Light Study terminated prior to May 12, 2015 and Defendant Orexigen's prior disclosure that it was recommending termination of the Light Study, the Court concludes that Defendant Orexigen's May 8, 2015 8-K did not contain material omissions of fact concerning the termination of the Light Study.

Additionally, the May 8, 2015 8-K did not contain material misstatements or omissions of fact regarding the 50% interim data. The May 8, 2015 8-K did not mention the 50% interim results, and so did not contain any material misstatements. Moreover, the failure of the 8-K to include the 50% interim data did not constitute an "omi[ssion] to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were

made, not misleading," *see United States v. Laurienti*, 611 F.3d 530, 539 (9th Cir. 2010) (quoting 17 C.F.R. § 240.10b-5(b)), because the statements made about the interim 25% results on March 3, 2015 were not rendered misleading. The interim 25% results still showed "a positive effect of Contrave on CV outcomes" and it was still true that "[a] larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes." (CC ¶ 87, ECF No. 55.) For the same reason, Defendant Orexigen was also under no affirmative duty to disclose the 50% interim results. *See Matrixx Initiatives*, 563 U.S. at 44. Rather, as Defendant Orexigen later explained on its earnings conference call that same day, Defendant Orexigen was unable to publicize the results of the 50% interim data pursuant to the data access plan. (*See, e.g.*, CC ¶¶ 109–10, ECF No. 55.) Lead Plaintiff's allegations leave Lead Plaintiff in the awkward position of faulting Defendant Orexigen for disclosing the 25% interim results in contravention of the data access plan, but then criticizing Defendant Orexigen for *not* doing the same with the 50% interim data.

Although the Court harbors doubts that Lead Plaintiff can cure the deficiencies outlined above, in an abundance of caution, the Court **DISMISSES WITHOUT PREJUDICE** Lead Plaintiff's first cause of action to the extent it is predicated upon material misstatements or omissions of fact appearing in Defendant Orexigen's May 8, 2015 8-K. *See, e.g.*, *Hague v. Wells Fargo Bank, N.A.*, No. C11-02366 TEH, 2011 WL 3360026, at *4 (N.D. Cal. Aug. 2, 2011).

4. Orexigen's Quarterly Report on Form 10-Q (May 8, 2015)

On May 8, 2015, Defendant Orexigen also filed a 10-Q, which "failed to disclose that the Light Study had been terminated and that the 50% interim data demonstrate that the 25% data Defendants had released on March 3, 2015 was false." (CC ¶ 103, ECF No. 55.) Specifically, the 10-Q noted that "additional analysis of the interim results or new data from the continuing Light Study, including safety-related data, and the additional cardiovascular outcomes trial, may produce negative or inconclusive results, or may be inconsistent with the conclusion that the interim analysis was successful." (*Id.* at ¶ 104 (emphasis omitted).)

The parties' arguments for and against dismissal of the May 8, 2015 10-Q allegations are largely similar to those for and against dismissal of the May 8, 2015 8-K allegations. (*See* MTD Mem. 19–21, ECF No. 62-1 (arguing for dismissal of "challenge[d] statements made by the Company on May 8, 2015"); MTD Opp'n 20–23, ECF No. 67 (arguing that "Defendants' materially false and misleading May 8, 2015 statements and omissions are actionable") (emphasis omitted).) Accordingly, for the reasons discussed above, *see supra* Part II.A.3, the Court **DISMISSES WITHOUT PREJUDICE** Lead Plaintiff's first cause of action to the extent it is predicated upon material misstatements or omissions of fact appearing in Defendant Orexigen's May 8, 2015 10-Q.

5. Orexigen's 1Q 2015 Earnings Conference Call (May 8, 2015)

Lead Plaintiff alleges that "[o]n May 8, 2015, the Company hosted its 1Q 2015 earnings conference call for analysts and investors." (CC ¶ 107, ECF No. 55.) During that call, "Defendant Klassen knowingly and/or with deliberate indifference represented that the 'Light Study is continuing and we are continuing to engage both Orexigen and Takeda with the FDA and with ESC and DMC regarding ultimately the status of the study, but it's an ongoing entity as of right now." (*Id.* at ¶ 108 (emphasis omitted).) Defendant Klassen also "failed to disclose that the 50% interim data he had seen weeks earlier showed that the 25% data was false" when he reported that "[w]e have passed the 50% time point and as we've stated before, those results are viewed by the Data Monitoring Committee and it wasn't a planned look by the sponsors, like the 25% was. The 25% was special because it was for regulatory purposes and so we have had 50% time point." (*Id.* at ¶ 109 (alteration in original).) Defendant Narachi added:

> [t]he results from the 50% analysis, I think the way to think about it is, those only come out in the context of wrapping up the trial or as a final analysis. So, if the decision is made to terminate the trial early and focus resources on the next CVOT, which is what we have been advocating, then I think results would come out sooner . . . .

(*Id.* at ¶ 110 (emphasis omitted).) Defendant Narachi also noted that "I think that [the fate of the Light Study] would be something we disclose. . . . [I]f there was a decision to terminate the trial and move on and focus resources on the new CVOT, that would be a

disclosure that we would make." (*Id.* at 111 (emphasis omitted).)

Again, the parties' arguments for and against dismissal are largely repetitive of those made above. (*See* MTD Mem. 19–21, ECF No. 62-1; MTD Opp'n 20–23, ECF No. 67.) Accordingly, for the reasons discussed above, *see supra* Parts II.A.3, 4, the Court **DISMISSES WITHOUT PREJUDICE** Lead Plaintiff's first cause of action to the extent it is predicated upon material misstatements or omissions of fact made in Defendant Orexigen's May 8, 2015 earnings conference call.

B. Second Cause of Action: Violations of § 10(b) of the Exchange Act and Rules 10b-5(a) & (c) Against Defendants

"Under Rule 10b-5(a) or (c), a defendant who uses a 'device, scheme, or artifice to defraud,' or who engages in 'any act, practice, or course of business which operates or would operate as a fraud or deceit,' may be liable for securities fraud." *WPP Lux.*, 655 F.3d at 1057 (quoting 17 C.F.R. § 240.10b-5(a), (c)) (citing *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta*, 552 U.S. 148, 158 (2008)), *cert. denied* 132 S. Ct. 2713 (2012). This is often referred to as "scheme liability." *See Stoneridge*, 552 U.S. at 149. "A defendant may only be liable as part of a fraudulent scheme based upon misrepresentations and omissions under Rules 10b-5(a) or (c) when the scheme also encompasses conduct beyond those misrepresentations or omissions." *WPP Lux.*, 655 F.3d at 1057–58 (citing *SEC v. Lucent Techs., Inc.*, 610 F. Supp. 2d 342, 359 (D.N.J. 2009); *SEC v. Patel*, No. 07-cv-39-SM, 2009 WL 3151143, at *6–7 (D.N.H. Sept. 30, 2009); *In re Nat'l Century Fin.*

Enters., Inc. Inv. Litig., No. 2:03-MD-1565, 2006 WL 469468, at *21 (S.D. Ohio Feb. 27, 2006); *In re Alstom SA Sec. Litig.*, 406 F. Supp. 2d 433, 475 (S.D.N.Y. 2005)). "Manipulative conduct . . . is actionable under Rule 10b-5(a) or (c) and includes activities designed to affect the price of a security artificially by simulating market activity that does not reflect genuine investor demand." *Desai v. Deutsche Bank Sec. Ltd.*, 573 F.3d 931, 940-41 (9th Cir. 2009) (citing *Santa Fe Indus., Inc. v. Green*, 430 U.S. 462, 476–77 (1977); *Ernst & Ernst v. Hochfelder,* 425 U.S. 185, 199 (1976) ("[Manipulation] connotes intentional or willful conduct designed to deceive or defraud investors by controlling or artificially affecting the price of securities.")). "To state a primary liability claim under Rules 10b-5(a) or (c), a plaintiff must allege a device, scheme or artifice to defraud, or an act, practice or course of business which would operate as a fraud, in addition to alleging the standard elements of a § 10(b) and Rule 10b-5 violation." *N.Y. City Emps.' Ret. Sys. v. Berry*, 616 F. Supp. 2d 987, 996 (N.D. Cal. 2009) (citing *Stoneridge*, 552 U.S. at 158).

Defendants argue that Lead Plaintiff's "scheme claim must be dismissed because it is nothing more than a repackaging of the Rule 10b-5(b) claims discussed above." (MTD Mem. 27, ECF No. 62-1 (citing CC ¶¶ 142–52, ECF No. 55).) Moreover, "even if the CC's farfetched 'patent scheme' theory was actionable under the securities laws, the judicially-noticeable documents make clear that no such scheme existed (or makes any sense)" because Defendant "Orexigen did not request non-publication of the patent Application to keep the FDA in the dark," Defendant "Orexigen's rescinding of [the non-publication] request [did not]

have anything to do with the timing of the '371 [P]atent issuance on March 3, 2015," "[a]nd finally, Orexigen had no need to engage in a patent charade to get the 25% data to European regulators; they already had it." (*Id.* at 28.) Defendant also argues that Lead Plaintiff cannot show reliance because "[Defendant Orexigen]'s prosecution of the patent . . . had no effect on its stock price." (MTD Reply 14, ECF No. 69.)

Lead Plaintiff counters that "Plaintiff alleges that Orexigen had no credible reason to even file its formal patent application on July 2, 2014 because its intellectual property rights were ***already*** protected by the Company's previously-filed December 2013 provisional patent application," meaning that "defendants engaged in a scheme to use a patent application that included statistically insignificant data to publicize the 25% interim Light Study data." (MTD Opp'n 27, ECF No. 67 (emphasis in original).) Moreover, "Plaintiff alleges that Orexigen then requested prioritized examination of its formal patent application" to "advance[] the publication date well in advance of the eighteen-month nonpublication period it now points to," an "action[] . . . designed to release the 25% data, not to protect [Defendant Orexigen's] intellectual property." (*Id.* at 28–29.)

The crux of Lead Plaintiff's scheme liability cause of action is that "Defendants Narachi and Klassen engaged in an undisclosed reckless scheme to leak the positive 25% interim data they knew they were prohibited from revealing *via* the ['810] Application." (CC ¶ 61, ECF No. 55; *see also id.* at ¶ 12; MTD Opp'n 27, ECF No. 67.) Lead Plaintiff's first cause of action,

however, is also premised upon statements that "were materially false and misleading" because:

> Orexigen violated the [data access plan] forbidding the Company from releasing Light Study interim results; . . . Orexigen knew, no later than July 2, 2014, that Defendant Klassen had included specific interim Light Study data in the ['810] Application; [and] Orexigen had made a request with the USPTO in January 2015 to have the patent publicly disseminated . . . .

(CC ¶ 92, ECF No. 55.) Both Lead Plaintiff's Rule 10b-5(b) and scheme liability causes of action hinge upon the wrongful dissemination of the 25% interim data through the filing of the '810 Application. Although it is a close question, the Court is inclined to conclude that Lead Plaintiff's scheme liability cause of action does not allege conduct beyond that underlying the alleged misrepresentations and omissions of fact. Consequently, "the scheme [does not] encompass[] conduct beyond those misrepresentations or omissions" and must be dismissed. *See WPP Lux.*, 655 F.3d at 1057.

Even if the Court were to find that Lead Plaintiff's scheme liability cause of action alleged conduct beyond the misrepresentations and omissions, however, "there is no indication that Defendants' action . . . would constitute a deceptive act." *See Abbate v. Wells Fargo Bank, N.A.*, No. CV 10-6561 DOC RNBX, 2011 WL 9698215, at *3 (C.D. Cal. Nov. 17, 2011); *see also Veltex Corp. v. Matin*, No. CV 10-1746 ABC PJWX, 2010 WL 3834045, at *6 n.9 (C.D. Cal. Sept. 27, 2010) (dismissing scheme liability claim where "[p]laintiff has

failed to allege with specificity an actionable deceptive act purportedly engaged in by [defendant]"). In the Ninth Circuit, "engaging in a transaction, the principal purpose and effect of which is to create the false appearance of fact, constitutes a 'deceptive act.'" *Simpson v. AOL Time Warner Inc.*, 452 F.3d 1040, 1048 (9th Cir. 2006), *vacated on other grounds*, 552 U.S. 1162; 519 F.3d 1041 (9th Cir. 2008); *Burnett v. Rowzee*, No. SA CV 07-641DOCANX, 2007 WL 4754539, at *5 (C.D. Cal. Oct. 18, 2007) ("[T]he defendant's act must, standing alone, be manipulative or deceptive and must further the fraudulent scheme."). The Court agrees with Defendants that the filing of the '810 Application was "not inherently deceptive or manipulative." (*See* MTD Reply 13–14, ECF No. 69.)

As the Court explained previously, *see supra* Part II.A.2, Lead Plaintiff's allegations concerning the patent scheme are based upon a misunderstanding of the patent process. Defendants filed a provisional patent application on December 6, 2013. (*See* RJN Ex. G at 2, ECF No. 62-9.) They were required to file a non-provisional patent application claiming the benefit of the provisional application within twelve months. 35 U.S.C. § 111(b)(5). Patent applications are not published for eighteen months "from the earliest filing date for which a benefit is sought," 35 U.S.C. § 122(b)(1)(A), meaning that Defendants' provisional patent application would generally have been published in early June 2014. As Lead Plaintiff acknowledges, however, Defendants originally requested that the USPTO *not* publish the '810 Application at that time. (CC ¶ 61, ECF No. 55; *see also* RJN Ex. H at 3, ECF No. 62-10.) Defendants only rescinded this request on January 5, 2015 (RJN Ex. H

at 20–21, ECF No. 62-10), within forty-five days of filing the WIPO Application on December 4, 2014 (RJN Ex. V at 2, ECF No. 62-24), as required under 35 U.S.C. § 122(b)(2)(B)(iii). Although the USPTO projected a new publication date for the '810 Application of June 11, 2015 (RJN Ex. H at 23, ECF No. 62-10), the USPTO ultimately issued the '371 Patent before that date on March 3, 2015 (RJN Ex. G, ECF No. 62-9).

The evidence also contradicts Lead Plaintiff's allegations that the patent scheme was intended to publicize the 25% interim results to European regulators by March 2015, as Defendants had already provided that data to CHMP by December 18, 2014. (*See* RJN Ex. E at 11–12, ECF No. 62-7 ("The Application has submitted the first interim report of the NB-CVOT study. . . ."); RJN Ex. F at 1, ECF No. 62-8 ("Interim results from an ongoing cardiovascular outcome trial were reassuring in terms of risk of serious cardiovascular disease related to treatment with Mysimba.").) Consequently, while it is true that Defendants violated their own data access plan and disregarded the FDA's "significant concerns" regarding breaches of that confidentiality (*see, e.g.*, CC ¶¶ 10–11, 59–60, ECF No. 55), Lead Plaintiff's allegations that the primary purpose and effect of the filings of the '810 Application was to wrongfully publicize the 25% interim results are not borne out by the evidence the Court may properly consider on Defendants' MTD. Consequently, Lead Plaintiff fails plausibly to plead the requisite deceptive act. *See Simpson*, 452 F.3d at

1048. Accordingly, the Court **DISMISSES WITHOUT PREJUDICE** Plaintiff's second cause of action.[4]

C. Third Cause of Action: Violations of § 20(a) of the Exchange Act Against the Insider Defendants

"Section 20(a) of the Act makes certain 'controlling' individuals also liable for violations of section 10(b) and its underlying regulations." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009), *as amended* (Feb. 10, 2009). Specifically, Section 20(a) provides:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable (including to the Commission in any action brought under paragraph (1) or (3) of section

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[4] The Court **DISMISSES WITH PREJUDICE**, however, Lead Plaintiff's second cause of action against Defendant Hagan on the ground of abandonment. Although the CC alleges that *all* defendants violated § 10(b) and Rules 10b-5(a) and (c) (CC ¶¶ 147–52, ECF No. 55), Lead Plaintiff's Opposition argues only that "Plaintiff adequately pleads scheme liability against Defendants Orexigen, Narachi and Klassen" (MTD Opp'n 27, ECF No. 67). Lead Plaintiff has therefore abandoned his second cause of action against Defendant Hagan, which the Court may dismiss with prejudice. *See, e.g.*, *Qureshi v. Countrywide Home Loans, Inc.,* No. 09–4198, 2010 WL 841669, at *6 n.2 (N.D. Cal. Mar. 10, 2010) (citing *See Jenkins v. Cnty. of Riverside*, 398 F.3d 1093, 1095 n.4 (9th Cir. 2005)); *In re TFT-LCD (Flat Panel) Antitrust Litig.,* 586 F. Supp. 2d 1109, 1131 (N.D. Cal. 2008).

> 78u(d) of this title), unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a). "Thus, a defendant employee of a corporation who has violated the securities laws will be jointly and severally liable to the plaintiff, as long as the plaintiff demonstrates 'a primary violation of federal securities law' and that 'the defendant exercised actual power or control over the primary violator.'" *Zucco Partners*, 552 F.3d at 990 (quoting *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 945 (9th Cir. 2003)) (citing *Paracor Fin., Inc. v. Gen. Elec. Capital Corp.*, 96 F.3d 1151, 1161 (9th Cir. 1996)). "Section 20(a) claims may be dismissed summarily . . . if a plaintiff fails to adequately plead a primary violation of section 10(b)." *Id.* (citing *In re VeriFone Sec. Litig.*, 11 F.3d 865, 872 (9th Cir. 1993); *In re Metawave Commc'ns Corp. Sec. Litig.*, 298 F. Supp. 2d 1056, 1087 (W.D. Wash. 2003)).

Because the Court has dismissed Lead Plaintiff's causes of action predicated upon violations of Section 10(b), *see supra* Parts II.A, B, the Court **GRANTS** Defendants' MTD and **DISMISSES WITHOUT PREJUDICE** Lead Plaintiff's third cause of action against the Individual Defendants for violations of Section 20(a).

CONCLUSION

In light of the foregoing, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' RJN (ECF No. 62-25), **GRANTS** Defendants' MTD (ECF

No. 62), and **DISMISSES** Lead Plaintiff's CC (ECF No. 55). Specifically, the Court **DISMISSES WITH PREJUDICE** Lead Plaintiff's first cause of action for violations of Section 10(b) and Rule 10b-5(b) to the extent it is predicated upon material misstatements or omissions of fact made in Defendants' March 3, 2015 statements and second cause of action for violations of Section 10(b) and Rules 10b-5(a) and (c) against Defendant Hagan. The Court **DISMISSES WITHOUT PREJUDICE** Lead Plaintiff's remaining causes of action. Lead Plaintiff **MAY FILE** an amended consolidated complaint (ACC) within thirty (30) days of the date on which this Order is electronically docketed. *Failure to file an ACC by this date may result in dismissal of this action with prejudice*.

IT IS SO ORDERED.

Dated: May 19, 2016 /s/ Janis L. Sammartino
Hon. Janis L. Sammartino
United States District Judge

APPENDIX C

United States District Court
SOUTHERN DISTRICT OF CALIFORNIA

Civil Action No. 15CV0540-JLS(JLB)

[Filed June 27, 2016]

KARIM KHOJA, on behalf of himself and all others similarly situated; KURT R. YANTZ; GERALD J. STEFANKO
Plaintiff,

V.

OREXIGEN THERAPEUTICS, INC., JOSEPH P. HAGAN, MICHAEL A. NARACHI, and PRESTON KLASSEN,
Defendant.

JUDGMENT IN A CIVIL CASE

Decision by Court. This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

IT IS HEREBY ORDERED AND ADJUDGED:

The Court grants in part and denies in part Defendants' Request for Judicial Notice (ECF No. 62-25), grants Defendants' MTD (ECF No. 62), and dismisses Lead Plaintiff's Consolidated Complaint (ECF No. 55). Specifically, the Court dismisses with

prejudice Lead Plaintiff's first cause of action for violations of Section 10(b) and Rule 10b-5(b) to the extent it is predicated upon material misstatements or omissions of fact made in Defendants' March 3, 2015 statements and second cause of action for violations of Section 10(b) and Rules 10b-5(a) and (c) against Defendant Hagan. The Court dismisses without prejudice Lead Plaintiff's remaining causes of action.

CLERK OF COURT
JOHN MORRILL, Clerk of Court
By: s/ K. Martin-Brown
K. Martin-Brown, Deputy

Date: 6/27/16

APPENDIX D

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 16-56069
DC No. CV 15-0540 JLS

[Filed November 2, 2018]

KARIM KHOJA, on behalf of himself and all others similarly situated,
Plaintiff - Appellant,

v.

OREXIGEN THERAPEUTICS, INC.; JOSEPH P. HAGAN; MICHAEL A. NARACHI; PRESTON KLASSEN,
Defendants - Appellees.

O R D E R

Before: TASHIMA and BERZON, Circuit Judges, and PAYNE,[*] District Judge

The panel has voted to deny the petition for panel rehearing. Judge Berzon votes to deny the petition for rehearing en banc and Judges Tashima and Payne so

[*] The Honorable Robert E. Payne, United States District Judge for the Eastern District of Virginia, sitting by designation.

recommend. The full court has been advised of the petition for rehearing en banc and no judge of the court has requested a vote on en banc rehearing. *See* Fed. R. App. P. 35(f). The petition for panel rehearing and the petition for rehearing en banc are denied.

APPENDIX E

* * *

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

No. 3:15-cv-00540 JLS (KSC)

[Filed August 20, 2015]

KARIM KHOJA; on behalf of himself and all others similarly situated,

Plaintiffs,

VS.

OREXIGEN THERAPEUTICS, INC., JOSEPH P. HAGAN, MICHAEL A. NARACHI, and PRESTON KLASSEN

Defendants.

AND ALL CONSOLIDATED CASES

CLASS ACTION

CONSOLIDATED COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

* * *

17. In addition to artificially inflating the price of Orexigen's securities, Defendants' publication of the misleading 25% interim Light Study results also had the intended effect of deceiving analysts and investors. On March 3, 2015, Piper Jaffray issued a report remarking that the 25% interim results were "***surprisingly positive***" and could "turn the obesity/metabolic syndrome market ***on its head***." On March 4, 2015 Wells Fargo analyst Matthew J. Andrews similarly characterized the interim Light Study data as "the '***holy grail***' for treating cardiometabolic diseases [which] is demonstration of a CV mortality benefit, which to date has not been demonstrated by an obesity therapeutic…." If the 25% Interim Light Study results the Company improperly released on March 3, 2015 were confirmed, the reduction in major adverse cardiovascular events would place Contrave among the most effective cardiovascular drugs of all time.

* * *

B. Defendants' Materially False and Misleading Class Period Statements and Omissions

1. *Orexigen's Current Report on Form 8-K* (March 3, 2015)

87. The Class Period commences on March 3, 2015 with Orexigen's wrongful release of 25% interim results for the then ongoing Light Study. The 25% interim results indicated that Contrave reduced cardiovascular events by 41% compared with a placebo. According to the Company's Form 8-K:

The 371 Patent and the Provisional Patent Applications incorporate data from a pre-planned interim analysis of the large, randomized, placebo-controlled, cardiovascular ("CV") outcomes trial of Contrave® . . . , or the Light Study. The 371 Patent, which expires in 2034, is the first in the Light Study family of patent applications Orexigen has prosecuted and covers two subgroups of the larger Light Study patient population. The Provisional Patent Applications are part of the same family of patent applications that were first filed in December 2013.

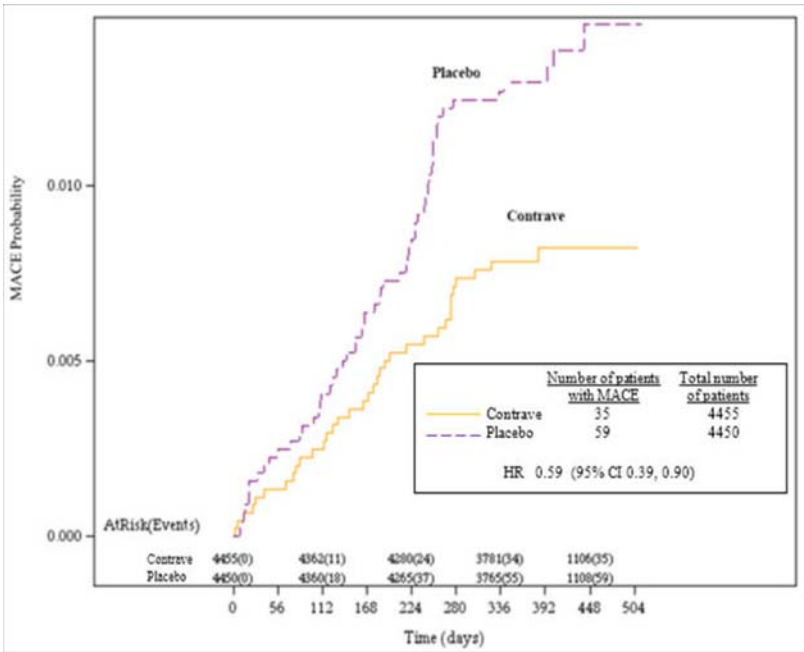
The 371 Patent and the Provisional Patent Applications contain claims related to a positive effect of Contrave on CV outcomes. The observed effects on CV outcomes were unexpected and appear to be unrelated to weight change.

* * *

The Light Study randomized 8,910 obese patients with a primary endpoint of evaluating the impact of treatment on the combined incidence of myocardial infarction (heart attack), stroke and CV death in patients taking Contrave versus placebo. For regulatory approval purposes, the Light Study, included a pre-planned interim analysis designed to exclude a doubling of CV risk compared to placebo (i.e., to rule out a hazard ratio of 2.0 using the upper bound of the 95% confidence interval). This analysis was conducted based on 94 observed and adjudicated major adverse cardiovascular events ("MACE"), which was

approximately 25% of the planned MACE for the Light Study (the "25% Interim Analysis"). The 25% Interim Analysis was prospectively designed to enable an early and preliminary assessment of safety to support regulatory approval. A larger number of MACE are required to precisely determine the effect of Contrave on CV outcomes.

88. After misleadingly describing specific 25% interim Light Study data, the 8-K displayed a deceptive graph indicating a much lower incidence of cardiac events for participants receiving Contrave in the study than for those receiving the placebo:



89. The Company's statements and other representations had their intended effect as the price

of Orexigen common stock soared from a March 2, 2015 close of $5.79 per share to trade as high as $9.37 per share in intraday trading on March 3, 2015, closing that day at $7.64 per share, on highly unusual trading volume of more than 95.8 million shares.

90. In a research note dated March 3, 2015, RBC Capital Markets analyst Simos Simeonidis responded to Defendants' disclosure, stating that "[w]e view the news as very significant.… The ***newly*** revealed data demonstrated that not only is Contrave safe to use from a CV standpoint, but it ***actually appears to have a CV benefit***." He rated the Company's shares to "outperform." Analysts at Piper Jaffray also issued a Company note on March 3, 2015 saying that the Light Study interim results that Orexigen disclosed in the 8-K "[c]ould turn the obesity/metabolic syndrome market ***on its head***. We see this CVOT effect as ***surprisingly positive*** and it has several implications, in our view for the potential of Contrave."

91. On March 3, 2015 Leerink analyst Paul Matteis similarly relayed Defendants' materially misleading representations noting that "25% Interim Light Analysis Shows Stat. Sig [statistical significant] Contrave Benefit on CV Outcomes." His note added that, after meeting with Orexigen management, "the company unexpectedly disclosed the data from the 25% interim analysis of the Light Contrave cardiovascular study.… The data this morning show a ***statistically significant*** Contrave benefit.…" On March 4, 2015, Wells Fargo analyst Matthew J. Andrews characterized the data as "the '***holy grail***' for treating cardiometabolic diseases is demonstration of a CV

mortality benefit, which ***to date*** has not been demonstrated by an obesity therapeutic.…"

92. The statements in ¶¶87-88, *supra*, were materially false and misleading and/or failed to disclose that: (i) the 25% study results Defendants improperly released on March 3, 2015 showing that Contrave reduced the risk of heart attacks and cardiovascular death were "unreliable," "likely false," and "misleading;" (ii) Orexigen violated the FDA Agreement forbidding the Company from releasing Light Study interim results; (iii) Orexigen knew, no later than July 2, 2014, that Defendant Klassen had included specific interim Light Study data in the 2014 Patent Application; (iv) Orexigen had made a request with the USPTO in January 2015 to have the patent publicly disseminated; (v) Orexigen faced potential fines, civil penalties, and the possible removal of Contrave from the market by the FDA; and (vi) as a result of the above, the Company's Class Period filings with the SEC were materially false and misleading at all relevant times.

2. *Orexigen's Press Release* (March 3, 2015)

93. On March 3, 2015, *Forbes* reported that FDA senior official Dr. John Jenkins had stated, in pertinent part, that the FDA was unaware that Orexigen's 2014 Patent Application contained specific interim study data and expressed "serious concerns" about Orexigen's disclosure of the interim data. The FDA also stated that day that it had already "strongly urged Orexigen to protect the interim data from public disclosure and [that the agency was] very disappointed by Orexigen's actions." Stunned by the Company's intentional leak of interim Light Study data, the FDA warned patients

and physicians that it was "critical that the[] interim data [] not be misinterpreted."

94. In an effort to maintain the artificial price inflation in the Company's securities, immediately after Dr. Jenkins' quote was carried on *Forbes* on March 3, 2015, Orexigen publicly responded to the *Forbes* report (which had first reported on the FDA's comments on the disclosure of the interim trial data on March 3, 2015) stating, in pertinent part:

> Orexigen conducted a large cardiovascular outcomes trial in order to file for approval, with the study planned to continue after approval to serve a postmarketing regulatory requirement for additional risk exclusion. We observed an unexpected result in the interim analysis. We filed patent applications based on the results in order to preserve the potential for additional intellectual property. During the course of the study, the FDA informed us it had determined that the Light Study would not serve as the postmarketing requirement for Contrave; a new trial would be required. At this point, the company decided to continue with the patent prosecution. The second cardiovascular outcomes trial is expected to start later this year, and we look forward to the results of that study which are anticipated by 2022.
>
> This morning ***the USPTO published the patent and supporting documentation***, and we believed it was appropriate and necessary to make sure this information was equally available to all investors.

> Orexigen has been working closely with, and is committed to continuing to work with FDA and others to support its regulatory obligations to thoroughly explore Contrave's therapeutic profile. Just as important, Orexigen is committed to its obligation to patients to fully explore the drug's profile.

95. The Company's representation that the USPTO had independently published the patent without the Company's input was highly misleading. In making the statement, Defendants failed to disclose that the USPTO only published what Orexigen itself needlessly put into the 2014 Patent Application. Defendants also failed to disclose that the Company had rescinded its earlier request that the 2014 Patent Application remain unpublished. In truth, the Company even paid the USPTO an extra fee to expedite publication of the 25% interim Light Study data.

96. As reported by the *Wall Street Journal*, in an article published at approximately 11 a.m. on March 4, 2015:

> For the FDA, a basic principle is in play. The agency considers the preliminary data "***far too unreliable*** to conclude anything further about cardiovascular safety" and is concerned that premature disclosure of positive results can undermine the LIGHT study. Why? Participants may want to drop out of the trial if they believe they are taking a placebo. And the FDA believes Orexigen should know this.

"In order to protect the integrity of an ongoing trial, preserving confidentiality of the interim results is essential,[“] the agency says in its statement. "The importance of maintaining confidentiality is well-articulated in International Conferences on Harmonization guidelines, FDA guidance, and the scientific literature."

But why had the agency already conveyed concerns about disclosure to the drug maker? This was not the first time that LIGHT study data was disclosed ***inappropriately***, according to the FDA. Prior to the Contrave approval last fall [2014], the agency learned that Orexigen had shared interim study results with "more individuals than FDA considered necessary to prepare a regulatory submission."

For this reason, the FDA last year decided that the LIGHT study should continue, but that Orexigen would have to launch a new study to satisfy the conditions of the approval of its Contrave drug. The LIGHT trial was designed to assess the extent to which the diet drug may increase the risk of a major cardiac event by 40% or more. Orexigen says this newly required trial will begin later this year.

Not surprisingly, the lead researcher for the study is upset. Steve Nissen, a cardiologist at the Cleveland Clinic, writes us that Orexigen had agreed to a "data access plan" with the trial's data monitoring committee that "strictly limited use of the data for a regulatory filing to FDA. ***Public disclosure*** of these incomplete

> data or use of data for business purposes was ***strictly forbidden*** by the [A]greement."
>
> [Dr.] Nissen says he was not aware of the interim study results until yesterday, says the disclosure was ***not approved*** by the data monitoring committee or the trial's executive committee. And he notes that Orexigen "business management" was not included in the list of individuals with approved access to the data.

97. As a result of the Company's materially misleading response to the FDA's March 3, 2015 admonition emphasizing that the interim data disclosure, while not expressly condoned by the FDA, was important and material information that the investment community should recognize, the price of Orexigen stock closed up further on March 4, 2015 at $8.49 per share, again on unusually high trading volume of more than 40.5 million shares, as the market continued to digest the positive news about the interim results.

98. The statements in ¶¶94-95, *supra* were materially false and misleading and were known or deliberately disregarded as such for the same reasons set forth in ¶92, *supra*.

99. On March 26, 2015, the Company announced in a Form 8-K that Contrave had received marketing authorization in Europe which maintained the artificial inflation in the Company's stock price as alleged in ¶72, *supra*. The same day, and unbeknownst to investors, Defendants were specifically told that the Light Study had been halted and that the 50% interim

Light Study results showed no heart benefit. Nevertheless, on April 6, 2015, after personally meeting with Defendants Narachi and Hagan, Leerink analyst Paul Matteis relayed a highly positive report about the 25% interim results based Defendants' representations that "interim Light data could meaningfully increase Contrave prescribing as they provided most survey respondents comfort that the ***Contrave is, at worst, CV safe or, at best, cardioprotective***…."

3. *Orexigen's Current Report on Form 8-K* (May 8, 2015)

100. On May 8, 2015, Orexigen filed its press release on Form 8-K with the SEC announcing its business and financial results for the first quarter ended March 31, 2015. The press release stated, *inter alia*, that:

> Four 56-week multicenter, double-blind, placebo-controlled Phase 3 clinical trials were conducted to evaluate the effect of Contrave in conjunction with lifestyle modification in 4,536 subjects randomized to Contrave or placebo. In these studies, the most common adverse reactions (>5 percent) seen in patients taking Contrave included nausea, constipation, headache, vomiting, dizziness, insomnia, dry mouth, and diarrhea.
>
> ***The clinical trial program also includes a double-blind, placebo-controlled cardiovascular outcomes trial known as the Light Study***.

101. While discussing Contrave's business and financial results, prospects and suggesting that the Light Study was ongoing in this manner, the Form 8-K failed to disclose that the Light Study had been terminated weeks earlier on March 26, 2015 and that the 50% interim data demonstrated that the Company's prior representations about Contrave's purported cardiovascular benefit were false.

102. The statements and material omissions in ¶¶100-101, *supra* were materially false and misleading and/or failed to disclose that: (i) the 25% study results Defendants improperly released on March 3, 2015 showing that Contrave reduced the risk of heart attacks and cardiovascular death, were "unreliable," "likely false" and "misleading;" (ii) Orexigen violated the FDA Agreement forbidding it from releasing Light Study interim results; (iii) Orexigen knew no later than July 2, 2014 that it had relied on specific interim Light Study data in the 2014 Patent Application; (iv) Orexigen had made a request with the USPTO in January 2015 to have the patent publicly disseminated; (v) all of the Defendants knew or were deliberately reckless in not knowing no later than March 26, 2015 that the Light Study had been terminated and that the 50% interim data showed no heart benefit; (vi) Orexigen faced potential fines, civil penalties, and the possible removal of Contrave from the market by the FDA; and (vii) as a result of the above, the Company's filings with the SEC were materially false and misleading at all relevant times.

4. *Orexigen's Quarterly Report on Form 10-Q* (May 8, 2015)

103. On May 8, 2015, the Company filed its Quarterly Report for 1Q 2015 with the SEC on Form 10-Q. The 1Q 2015 10-Q failed to disclose that the Light Study had been terminated and that the 50% interim data demonstrated that the 25% data Defendants had released on March 3, 2015 was false.

104. Specifically, the Company represented that the Company's share price ***might*** be impacted by "announcements regarding our clinical trials, including [ ] the Light Study and the post-marketing required clinical trials, including the new CVOT, for Contrave" without disclosing that the Light Study had already been terminated on March 26, 2015. The Company also misleadingly represented that "additional analysis of the interim results or new data from the ***continuing*** Light Study, including safety-related data, and the additional cardiovascular outcomes trial, ***may*** produce negative or inconclusive results, or ***may*** be inconsistent with the conclusion that the interim analysis was successful," without disclosing that the Company knew that more mature 50% interim data had already demonstrated that Contrave did not produce any heart benefit as the Company had earlier represented.

105. In addition, the Company's 1Q 2015 10-Q misrepresented that:

> Future development expenses will depend on the ***timing of the Light Study***, the new CV outcomes trial and any other additional clinical trials for Contrave, ***if any***, our financial resources and ongoing assessments as to

> Contrave's commercial potential. Clinical development timelines, the probability of success and development costs can differ materially from expectations. The lengthy process of completing our clinical trials, ***including the Light Study***, and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. ***Any failure by us*** or delay in completing our clinical trials, ***including the Light Study***, or in obtaining regulatory approvals, ***could*** cause a delay in the commencement of product revenues and cause our research and development expenses to increase and, in turn, have a material adverse effect on our results of operations.

106. The statements in ¶¶103-105, *supra* were materially false and misleading and were known or deliberately disregarded as such for the same reasons set forth in ¶102, *supra*.

5. *Orexigen's 1Q 2015 Earnings Conference Call* (May 8, 2015)

107. On May 8, 2015, the Company hosted its 1Q 2015 earnings conference call for analysts and investors. At the beginning of the call, Defendant Narachi revealed that the Company's Chief Commercial Officer, Mark Booth, was "leaving Orexigen." RBC Capital Markets analyst Simos Simeonidis asked why "one of the key players" on commercializing Contrave after its FDA approval in fall 2014 was "leaving." Defendant Narachi responded that Mr. Booth purportedly wanted to "focus on

opportunities closer to home."[19] Mr. Booth's role, prior to his departure, was to "[a]chieve or exceed Contrave commercial launch goals consistent with the expectations of Orexigen and Takeda," and to "[d]rive progress on the Contrave Life Cycle Management Plan with Takeda. Further, Mr. Booth was to develop and communicate both "the commercial investor relations story pre/post launch" and "the commercial plan to drive progress on ROW partnership." The timing of Mr. Booth's departure, particularly given his function at the Company so soon after Contrave was approved in the U.S. and Europe, was suspicious.

108. During the same call, Merrill Lynch analyst Steve Byrne then specifically asked: "what is the fate of the Light Study at this point. Has that been terminated?" In response, Defendant Klassen knowingly and/or with deliberate recklessness represented that the "***Light Study is continuing*** and we are continuing to engage both Orexigen and Takeda with the FDA and with ESC and DMC regarding ultimately the status of the study, but ***it's an ongoing entity as of right now***."

109. RBC Capital Markets analyst Simos Simeonidis then asked a targeted question about the Company's quantitative Light Study interim data

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[19] As an executive member of the Company's Senior Management team, Orexigen was required to file a Form 8-K disclosing Mr. Booth's departure under Item 5.02 of Form 8-K. Instead, on March 30, 2015, the Company issued a press release announcing that it had hired Tom Cannell as Chief Commercial Officer. Buried at the very bottom of that press release, Orexigen noted that "Mark Booth, who has served as Chief Commercial Officer since 2009, will leave Orexigen later this year."

results, asking whether: "the 50% interim look happened? Have events occurred yet?" Unwilling to answer the questions himself, Defendant Narachi punted, asking whether "[Defendant] Preston …want[ed] to take that?" Defendant Klassen of course was then forced to try to respond that: "[w]e have passed the 50% time point and as we've stated before, those results are viewed by the Data Monitoring Committee and it wasn't a planned look by the sponsors, like the 25% was. The 25% was special because it was for regulatory purposes and so we have had 50% time point." Defendant Klassen failed to disclose that the 50% interim data he had seen weeks earlier showed that the 25% data was false.

110. Analyst Simeonidis then pressed the 50% data issue, asking: "I assume you're not going to be releasing that; are you going to be sending it to the FDA?" Defendant Klassen responded that: "[s]o we're in ongoing discussions related to that and I don't think ***we're going to go into the details***, because again that's a look that DNC does. As a plan, they look at the 25% to 50% and 75%, but it's really on the 25% analysis that was used for regulatory purposes. So ***if*** any of that status changes, then we would of course announce that." Defendant Narachi then interrupted, saying:

> Yes. Steve, I think that 50% interim was always designed as an administrative look only unless of course the trial stuff for either superiority or harm, then results would come out. The results from the 50% analysis, I think the way to think about it is, those only come out in the context of wrapping up the trial or as a final analysis. So, ***if the decision is made to***

> ***terminate the trial early*** and focus resources on the next CVOT, which is what we have been advocating, then I think results would come out sooner perhaps that would either be the 50% of the final results in that, there's quite a few events between the 50% analysis, for example, ***if you decide to stop the study now*** there will be additional events, so these details are being discussed and worked out and as we make formal decisions there, you'll learn more about the availability of data from the study.

111. Still honing in on the Light Study data issue, analyst Charles Duncan of Piper Jaffray insisted on asking:

> [O]ne final obligatory Light Study question … I'm wondering if you could provide an estimate of the time or the strategy for disclosure around the fate of the Light Study – ***is that something that you need to disclose*** or is there a timing that you would estimate when you would disclose what's going on with the Light Study or would that just be seen on some public website like I think it's clinic trials?

Defendant Narachi, who had been informed weeks earlier by Dr. Nissen that the Light Study had been halted, misleadingly responded that:

> ***I think that that would be something we disclose***. As [Defendant] Preston said, there are active discussions between FDA, the executive steering committee and DMC as a study Takeda and Orexigen. And as soon as we understand specifically what the status is, so for example, ***if***

> ***there was a decision to terminate the trial*** and move on and focus resources on the new CVOT, ***that would be a disclosure that we would make***.

112. The statements in ¶¶108-111, *supra* were materially false and misleading and were known or deliberately disregarded as such for the same reasons set forth in ¶102, *supra*.

* * *

APPENDIX F

* * *

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

Case No. 15-cv-0540 JLS KSC

[Filed October 5, 2015]

KARIM KHOJA; on behalf of himself and all others similarly situated,

Plaintiffs,

v.

OREXIGEN THERAPEUTICS, INC., JOSEPH P. HAGAN, MICHAEL A. NARACHI, and PRESTON KLASSEN,

Defendants.

AND ALL CONSOLIDATED CASES

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS CONSOLIDATED COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

Date: December 17, 2015
Time: 1:30 p.m.
Judge: Hon. Janis L. Sammartino

* * *

[p.17]

* * *

information.'") (citation omitted). Before May 8, Orexigen had only disclosed the 25% data, which had not changed. Orexigen had no duty to update this accurate statement of historical fact. *In re Foxhollow Techs., Inc. Sec. Litig.*, 359 Fed. App'x 802, 804–05 (9th Cir. 2009) (In those circuits that have recognized a duty to update, "a duty to update true statements . . . applies only to statements that are clear, factual, and *forward-looking* . . . .") (emphasis added).

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