FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

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

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 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

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

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 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,

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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."

the Light Study would assess if Contrave increased that risk. Once 25 percent of a pre-determined 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 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

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

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.

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").

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

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.

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."

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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'. . . .").

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

[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).

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 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."

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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.

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.

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.

[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.

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 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

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

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 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)).

[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).

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."

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

[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),

the nuances of patent law, "enablement" is sometimes a fact-driven inquiry. *See Dow Chems. Co. v. Nova Chems. Corp. (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).

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http://www.theiplawblog.com/2015/04/articles/patent-law/enablement-is-key-especially-in-biotechpatents/.

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.

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

[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.

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 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

[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.)

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 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

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

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.

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.*

TAGS: biotech, infringement, Intellectual Property, invention, patent, Technology

United States Court of Appeals for the Ninth Circuit

Office of the Clerk
95 Seventh Street
San Francisco, CA 94103

Information Regarding Judgment and Post-Judgment Proceedings

Judgment

- This Court has filed and entered the attached judgment in your case. Fed. R. App. P. 36. Please note the filed date on the attached decision because all of the dates described below run from that date, not from the date you receive this notice.

Mandate (Fed. R. App. P. 41; 9th Cir. R. 41-1 & -2)

- The mandate will issue 7 days after the expiration of the time for filing a petition for rehearing or 7 days from the denial of a petition for rehearing, unless the Court directs otherwise. To file a motion to stay the mandate, file it electronically via the appellate ECF system or, if you are a pro se litigant or an attorney with an exemption from using appellate ECF, file one original motion on paper.

Petition for Panel Rehearing (Fed. R. App. P. 40; 9th Cir. R. 40-1)
Petition for Rehearing En Banc (Fed. R. App. P. 35; 9th Cir. R. 35-1 to -3)

(1) A. Purpose (Panel Rehearing):

- A party should seek panel rehearing only if one or more of the following grounds exist:
  - A material point of fact or law was overlooked in the decision;
  - A change in the law occurred after the case was submitted which appears to have been overlooked by the panel; or
  - An apparent conflict with another decision of the Court was not addressed in the opinion.
- Do not file a petition for panel rehearing merely to reargue the case.

B. Purpose (Rehearing En Banc)

- A party should seek en banc rehearing only if one or more of the following grounds exist:

- ▶ Consideration by the full Court is necessary to secure or maintain uniformity of the Court's decisions; or
- ▶ The proceeding involves a question of exceptional importance; or
- ▶ The opinion directly conflicts with an existing opinion by another court of appeals or the Supreme Court and substantially affects a rule of national application in which there is an overriding need for national uniformity.

(2) Deadlines for Filing:

- A petition for rehearing may be filed within 14 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the United States or an agency or officer thereof is a party in a civil case, the time for filing a petition for rehearing is 45 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the mandate has issued, the petition for rehearing should be accompanied by a motion to recall the mandate.
- *See* Advisory Note to 9th Cir. R. 40-1 (petitions must be received on the due date).
- An order to publish a previously unpublished memorandum disposition extends the time to file a petition for rehearing to 14 days after the date of the order of publication or, in all civil cases in which the United States or an agency or officer thereof is a party, 45 days after the date of the order of publication. 9th Cir. R. 40-2.

(3) Statement of Counsel

- A petition should contain an introduction stating that, in counsel's judgment, one or more of the situations described in the "purpose" section above exist. The points to be raised must be stated clearly.

(4) Form & Number of Copies (9th Cir. R. 40-1; Fed. R. App. P. 32(c)(2))

- The petition shall not exceed 15 pages unless it complies with the alternative length limitations of 4,200 words or 390 lines of text.
- The petition must be accompanied by a copy of the panel's decision being challenged.
- An answer, when ordered by the Court, shall comply with the same length limitations as the petition.
- If a pro se litigant elects to file a form brief pursuant to Circuit Rule 28-1, a petition for panel rehearing or for rehearing en banc need not comply with Fed. R. App. P. 32.

- The petition or answer must be accompanied by a Certificate of Compliance found at Form 11, available on our website at www.ca9.uscourts.gov under *Forms*.
- You may file a petition electronically via the appellate ECF system. No paper copies are required unless the Court orders otherwise. If you are a pro se litigant or an attorney exempted from using the appellate ECF system, file one original petition on paper. No additional paper copies are required unless the Court orders otherwise.

Bill of Costs (Fed. R. App. P. 39, 9th Cir. R. 39-1)

- The Bill of Costs must be filed within 14 days after entry of judgment.
- See Form 10 for additional information, available on our website at www.ca9.uscourts.gov under *Forms*.

Attorneys Fees

- Ninth Circuit Rule 39-1 describes the content and due dates for attorneys fees applications.
- All relevant forms are available on our website at www.ca9.uscourts.gov under *Forms* or by telephoning (415) 355-7806.

Petition for a Writ of Certiorari

- Please refer to the Rules of the United States Supreme Court at www.supremecourt.gov

Counsel Listing in Published Opinions

- Please check counsel listing on the attached decision.
- If there are any errors in a published opinion, please send a letter **in writing within 10 days** to:
  - ► Thomson Reuters; 610 Opperman Drive; PO Box 64526; Eagan, MN 55123 (Attn: Jean Green, Senior Publications Coordinator);
  - ► and electronically file a copy of the letter via the appellate ECF system by using "File Correspondence to Court," or if you are an attorney exempted from using the appellate ECF system, mail the Court one copy of the letter.

Form 10. Bill of Costs .....*(Rev. 12-1-09)*

United States Court of Appeals for the Ninth Circuit

BILL OF COSTS

This form is available as a fillable version at:
http://cdn.ca9.uscourts.gov/datastore/uploads/forms/Form%2010%20-%20Bill%20of%20Costs.pdf.

Note: If you wish to file a bill of costs, it MUST be submitted on this form and filed, with the clerk, with proof of service, within 14 days of the date of entry of judgment, and in accordance with 9th Circuit Rule 39-1. A late bill of costs must be accompanied by a motion showing good cause. Please refer to FRAP 39, 28 U.S.C. § 1920, and 9th Circuit Rule 39-1 when preparing your bill of costs.

_____ v. _____ 9th Cir. No. _____

The Clerk is requested to tax the following costs against: _____

Cost Taxable under FRAP 39, 28 U.S.C. § 1920, 9th Cir. R. 39-1	**REQUESTED** *(Each Column Must Be Completed)*				**ALLOWED** *(To Be Completed by the Clerk)*			
	No. of Docs.	Pages per Doc.	Cost per Page*	TOTAL COST	No. of Docs.	Pages per Doc.	Cost per Page*	TOTAL COST
Excerpt of Record			$	$			$	$
Opening Brief			$	$			$	$
Answering Brief			$	$			$	$
Reply Brief			$	$			$	$
Other**			$	$			$	$
			TOTAL:	$			**TOTAL:**	$

* *Costs per page*: May not exceed .10 or actual cost, whichever is less. 9th Circuit Rule 39-1.

** *Other*: Any other requests must be accompanied by a statement explaining why the item(s) should be taxed pursuant to 9th Circuit Rule 39-1. Additional items without such supporting statements will not be considered.

Attorneys' fees **cannot** be requested on this form.

Continue to next page

Form 10. Bill of Costs - *Continued*

I, _____ , swear under penalty of perjury that the services for which costs are taxed were actually and necessarily performed, and that the requested costs were actually expended as listed.

Signature _____

("s/" plus attorney's name if submitted electronically)

Date _____

Name of Counsel: _____

Attorney for: _____

(To Be Completed by the Clerk)

Date _____ Costs are taxed in the amount of $ _____

Clerk of Court

By: _____ , Deputy Clerk