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28IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA

PHILCO INVESTMENTS, LTD ET AL.,

No. C 10-02785 CRB

Plaintiff,

**ORDER GRANTING MOTION TO  
DISMISS WITH PREJUDICE**

v.

MARTIN ET AL.,

Defendants.  

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This is a securities fraud suit about allegedly false and misleading statements made by a pharmaceutical company about the safety and efficacy of two of its drugs. Defendants Elan Corporation (the pharmaceutical company) and three of its officers and directors moved to dismiss the original Complaint, and this Court granted their motion with leave to amend on February 9, 2011. Plaintiff filed their First Amended Complaint (“FAC”) on March 25, 2011 and Defendants again move to dismiss. The Court GRANTS their Motion.

**I. BACKGROUND**

Plaintiffs Philco Investments, David Mauer, and David and Maria Rosenbaum are investors who, in June and July 2008 (the “Relevant Period”), purchased August 2008 strike price call contracts for ADRs (negotiable certificates issued by a U.S. bank representing a specified number of shares in a foreign stock that is traded on a U.S. exchange) of Elan Corporation. Compl. (dkt. 1) ¶ 1; FAC (dkt. 37) ¶ 1. Plaintiffs allege that Defendants made

1 misleading statements in June and July 2008 about two of Elan’s drugs: (1) a drug it was  
2 developing to treat Alzheimer’s disease, called Bapineuzumab, and (2) a drug then marketed  
3 to treat multiple sclerosis, called Tysabri. Id. ¶ 2. Following Defendants’ revelations at the  
4 end of July 2008 that the drugs were not as effective (in the case of Bapineuzumab) or safe  
5 (in the case of Tysabri) as previously understood, the market price for Elan’s ADRs dropped  
6 from a high of \$36 during the Relevant Period to a low of \$9.93. Id. The drop rendered  
7 Plaintiffs’ call options, which had a \$30 or higher strike price, worthless. Id.

8 This Court’s February 9, 2011 Order granting Defendants’ motion to dismiss with  
9 leave to amend (“Dismissal Order”) describes in detail the relevant facts contained in the  
10 original Complaint about Bapineuzumab and Tysabri. See Dismissal Order (dkt. 31) at 2-6.  
11 The Discussion section of this Order summarizes the most relevant facts from the original  
12 Complaint, this Court’s reasons for dismissing the original Complaint, and the changes  
13 Plaintiffs have made in their FAC, before analyzing the sufficiency of the Plaintiffs’  
14 amended claims.

15 **II. LEGAL STANDARD**

16 Pursuant to Federal Rule of Civil Procedure 12(b)(6), a complaint may be dismissed  
17 for failure to state a claim upon which relief may be granted. Dismissal may be based on  
18 either “the lack of a cognizable legal theory or the absence of sufficient facts alleged under a  
19 cognizable legal theory.” Balistreri v. Pacifica Police Dep’t, 901 F.2d 696, 699 (9th Cir.  
20 1990). For purposes of evaluating a motion to dismiss, a Court “must presume all factual  
21 allegations of the complaint to be true and draw all reasonable inferences in favor of the  
22 nonmoving party.” Usher v. City of Los Angeles, 828 F.2d 556, 561 (9th Cir. 1987). A  
23 complaint must plead “enough facts to state a claim to relief that is plausible on its face.”  
24 Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (citing Bell Atlantic Corp. v. Twombly, 550  
25 U.S. 544, 570 (2007)). A claim is plausible “when the plaintiff pleads factual content that  
26 allows the court to draw the reasonable inference that the defendant is liable for the  
27 misconduct alleged.” Id.

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1           Claims for fraud must meet the pleading standard of Federal Rule of Civil Procedure  
2 9(b), which requires a party “alleging fraud or mistake [to] state with particularity the  
3 circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). Rule 9(b) “requires an  
4 account of the time, place, and specific content of the false representations as well as the  
5 identities of the parties to the misrepresentations.” Swartz v. KPMG LLP, 476 F.3d 756, 764  
6 (9th Cir. 2007) (internal quotation marks omitted). Security fraud claims must also meet the  
7 heightened pleading requirements of the Private Securities Litigation Reform Act (PSLRA):  
8 “the complaint shall specify each statement alleged to have been misleading, the reason or  
9 reasons why the statement is misleading, and, if an allegation regarding the statement or  
10 omission is made on information and belief, the complaint shall state with particularity all  
11 facts on which that belief is formed.” 15 U.S.C.A. § 78u-4(b)(1).

12           The PSLRA also requires Plaintiffs to state with particularity facts giving rise to a  
13 strong inference of Defendants’ scienter. See 15 U.S.C. § 78u-4(b)(2). “The inference of  
14 scienter must be more than merely ‘reasonable’ or ‘permissible’” – “it must be cogent and at  
15 least as compelling as any opposing inference one could draw from the facts alleged.”  
16 See Tellabs v. Makor Issues & Rights, Ltd., 551 U.S. 308, 324 (2007). Therefore, a court  
17 “must consider plausible nonculpable explanations for the defendant’s conduct.” Id.

18           If a court does dismiss a complaint for failure to state a claim, the Federal Rules of  
19 Civil Procedure state that the court should freely give leave to amend “when justice so  
20 requires.” Fed. R. Civ. P. 15(a)(2). A court nevertheless has discretion to deny leave to  
21 amend due to “undue delay, bad faith or dilatory motive on the part of the movant, repeated  
22 failure to cure deficiencies by amendments previously allowed, undue prejudice to the  
23 opposing party by virtue of allowance of the amendment, [and] futility of amendment.”  
24 Leadsinger, Inc. v. BMG Music Pub., 512 F.3d 522, 532 (9th Cir. 2008) (citing Foman v.  
25 Davis, 371 U.S. 178, 182 (1962)).

26 **III. DISCUSSION**

27           To state a claim for securities fraud under Section 10(b) of the Securities Exchange  
28 Act of 1934, a plaintiff must plead: (1) a misrepresentation or the use or employment of any

1 manipulative or deceptive device or contrivance; (2) scienter; (3) a connection with the  
2 purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation.

3 Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc., 552 U.S. 148, 157 (2008).

4 Defendants here move to dismiss, arguing that Plaintiffs' FAC inadequately pleads false and  
5 misleading statements, and scienter.

6 **A. Bapineuzumab**

7 Elan developed Bapineuzumab in association with Wyeth, another pharmaceutical  
8 company, for the treatment of Alzheimer's disease. FAC ¶ 7. To win FDA approval for  
9 Bapineuzumab, Elan planned to conduct both Phase 2 and Phase 3 trials. Id. ¶ 9. Phase 2  
10 trials are designed to assess dosing requirements, efficacy at particular doses, and safety on a  
11 medium-sized group of patients. Id. Phase 3 trials expand the safety and efficacy assessment  
12 to a larger group of patients. Id. Plaintiffs make two sets of allegations about Bapineuzumab  
13 in their FAC: (1) that Defendants misled investors into believing that Defendants would  
14 proceed to Phase 3 only if the interim Phase 2 results from two particular tests were  
15 "spectacular," and (2) that Defendants misled investors by failing to disclose certain material  
16 information about the results of Phase 2. Both claims fail to adequately allege falsity, and  
17 therefore the Court does not reach the issue of scienter.<sup>1</sup>

18 **1. Statements About Commencing Phase 3**

19 As alleged in the original Complaint, before Defendants began conducting Phase 2  
20 trials of Bapineuzumab in April 2005, they decided that they would conduct an interim  
21 review of the Phase 2 results to determine whether to launch Phase 3 trials before completion  
22 of Phase 2. Compl ¶ 10. Defendants privately agreed with Wyeth that they would assess the  
23 interim Phase 2 results using the ADAS-cog and DAD tests. Id. ¶ 11. They then told  
24 investors that the company would commence Phase 3 trials only if the interim results of  
25 Phase 2 met "certain very specific criteria." Id. Defendants also publicly stated that the  
26 interim results from the Phase 2 trials would have to be "spectacular," "strong," and "very  
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28 <sup>1</sup> See In re Thornburg Mortg., Inc. Sec. Litig., 695 F. Supp. 2d 1165, 1208 (D.N.M. 2010)  
("Statements Not False When Made Do Not, Standing Alone, Support a Strong Inference of Scienter").

1 meaningful” to justify an early launch of Phase 3. Id. Plaintiffs claim that by issuing a press  
2 release on May 21, 2007 announcing that Elan was commencing Phase 3 trials of  
3 Bapineuzumab before completion of Phase 2, Defendants led them to believe that the interim  
4 Phase 2 results under the two tests had been spectacular. Id. ¶¶ 12-15. This impression was  
5 misleading in light of Defendants’ previous statements, Plaintiffs claim, because the drug had  
6 failed to outperform the placebo in the ADAS-cog and DAD tests. Id.

7 In dismissing the original Complaint, this Court noted that terms like “strong” and  
8 “spectacular” are not actionable under the securities laws. Dismissal Order at 11 (citing Glen  
9 Holly Entm’t Inc. v. Tektronix Inc., 352 F.3d 367, 379 (9th Cir. 2003) (stating that  
10 “reasonable consumer cannot rely on “generalized, vague and unspecific assertions,  
11 constituting mere ‘puffery’”). This Court also explained that Plaintiffs had failed to identify  
12 a statement made by Defendants to investors setting out the ADAS-cog and DAD tests as the  
13 “certain very specific criteria” by which they would evaluate the interim results of Phase 2.  
14 Id. at 11-12. This Court stated: “If, in fact, investors understood that ‘strong’ and  
15 ‘spectacular’ were proxies for a ‘very specific criteria’ of which the investors were aware –  
16 i.e., success using the ADAS-cog and DAD tests – then these allegations might have merit.”  
17 Id. (internal citations omitted).

18 To address the Court’s concerns, Plaintiffs added new allegations to their FAC in an  
19 attempt to show that investors understood that “certain very specific criteria” referred to the  
20 ADAS-cog and DAD tests. See FAC ¶¶ 75-76. First, Plaintiffs cite to a 2002 article in the  
21 British Journal of Psychiatry that describes the two tests and sets them out as standard tests  
22 used to evaluate the effectiveness of Alzheimer’s drugs. Id. ¶ 75. Second, Plaintiffs cite a  
23 July 3, 2007 article in Neurology Today reporting that at a July 2006 10th International  
24 Conference on Alzheimer’s Disease and Related Disorders, researchers said they had used  
25 the ADAS-cog and DAD tests, as well as one other test, to evaluate the efficacy of  
26 Bapineuzumab during its Phase 1 and 2 trials to that date. Id. ¶ 76.

27 Plaintiffs’ new allegations do not go far enough to establish falsity. Viewed in the  
28 light most favorable to Plaintiffs, the two new factual allegations do support a reasonable

1 inference that Plaintiffs believed Defendants would likely use the ADAS-cog and DAD tests  
2 to evaluate the interim Phase 2 results. They do not, however, support a “reasonable  
3 inference” that Defendants’ statements themselves were false or misleading. The Court  
4 cannot reasonably infer that just because Defendants once reported using those tests (along  
5 with one other test) to evaluate Bapineuzumab before July 2006, they would also use those  
6 two tests to evaluate the interim Phase 2 results in May 2007.

7         Second, even if Defendants had implied that “very specific criteria” referred to the  
8 ADAS-cog and DAD tests, the FAC still fails to adequately allege that the drug did not  
9 perform as well during the interim review as Defendants implied. In a June 17, 2008 press  
10 release, Defendants announced that although primary efficacy endpoints in the overall study  
11 population were not statistically significant in the final Phase 2 results, in non-carriers of the  
12 ApoE4 allele (estimated to constitute 40-70% of the Alzheimer’s disease population), post-  
13 hac analysis did show statistically significant and clinically meaningful benefits. Hibbard  
14 Decl. Ex. R.<sup>2</sup> This press release suggests that the final Phase 2 results show the drug  
15 outperforming the placebo in non-carriers, which seemingly contradicts Plaintiffs’  
16 conclusory allegation that “Bapineuzumab did not outperform the placebo” and thus “failed  
17 the interim review.” FAC ¶ 12. Plaintiffs have also failed to allege any additional facts that  
18 suggest that Defendants’ use of the terms “spectacular,” “strong,” and “meaningful”  
19 amounted to more than mere puffery. Therefore, Plaintiffs have provided insufficient facts to  
20 support a “reasonable inference” that Defendants’ statements were misleading.

21         Plaintiffs have already had an opportunity to amend the original Complaint to bolster  
22 their allegations that Defendants’ statements about commencing Phase 3 were misleading.  
23 They have alleged no facts that allow the Court to reasonably infer that “very specific  
24 criteria” referred to the ADAS-cog and DAD tests and that the drug failed those tests. When  
25 asked at the motion hearing what Plaintiffs’ factual basis was for asserting that the drug  
26 failed the tests, Plaintiffs’ counsel had no answer. Finally and most significantly, Plaintiffs

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28         <sup>2</sup> The Court may take judicial notice of this document as it was cited in the FAC. See In re Silicon Graphics, Inc. Sec. Litig., 183 F.3d 970, 986 (9th Cir. 1999).

1 cannot establish that Defendants' statements were more than puffery and thus actionable  
2 under securities laws. Because Plaintiffs cannot cure their pleading by alleging additional  
3 facts, the Court grants Defendants' Motion with prejudice. See Lory v. Federal Ins. Co., 122  
4 Fed. Appx. 314, 319 (9th Cir. 2005) (denying leave to amend where the plaintiff had "not  
5 asserted, either before the district court or [the Ninth Circuit], any additional facts that could  
6 overcome" the deficiencies in the complaint); Cook, Perkiss and Liehe, Inc. v. N. Cal.  
7 Collection Serv. Inc., 911 F.2d 242, 243, 246-47 (9th Cir. 1990) (upholding a denial of leave  
8 to amend a claim under section 43(a) of the Lanham Act where the alleged  
9 misrepresentations were mere puffery, and therefore no factual allegation could support the  
10 cause of action).

## 11 2. Statements About Results of Phase 2

12 Plaintiffs' second set of allegations about Bapineuzumab in the original Complaint  
13 related to Defendants' June 17, 2008 press release announcing top-line interim results for the  
14 Phase 2 trials. The press release in question announced that Defendants would proceed with  
15 Phase 3 trials:

16 based on the seriousness of the disease and the totality of what the  
17 companies have learned from their immunotherapy programs,  
18 including a scheduled Interim look at data from an ongoing Phase 2  
19 study, which remains blinded. No conclusion about the Phase 2 study  
20 can be drawn until the study is completed and the final data are  
21 analyzed and released in 2008.

22 Hibbard Decl. Ex. K.<sup>3</sup> Plaintiffs, in both their original Complaint and FAC, allege that the  
23 press release was "materially false and misleading because it failed to disclose [certain]  
24 known, materially adverse results of the Phase 2 Alzheimer Study." Compl. ¶ 83; FAC ¶ 86.  
25 This Court disagreed, finding that omitting some adverse results did not render the press  
26 release misleading. Dismissal Order at 13. The press release reported discouraging news<sup>4</sup>

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27 <sup>3</sup> The Court may take judicial notice of this document as it was cited in the FAC. See In re  
28 Silicon Graphics, Inc. Sec. Litig., 183 F.3d at 986.

<sup>4</sup> For example, the press release also stated: "Primary Efficacy Endpoints in Overall Study Population Not Statistically Significant"; "In carriers [of the ApoE4 allele], serious adverse events were more frequently observed in bapineuzumab-treated patients"; and "vasogenic edema was reported in the treated population with an increased frequency in carriers and at higher doses." See Dismissal Order

1 along with the encouraging news, and therefore did not “affirmatively create an impression  
2 of a state of affairs that differ[ed] in a material way from the one that actually exist[ed].” Id.  
3 at 13 (quoting Brody v. Transitional Hospitals Corp., 280 F.3d 997, 1006 (9th Cir. 2002)).

4 Plaintiffs’ allegations relating to Defendants’ June 17 press release are largely the  
5 same in the FAC as in the original Complaint. See FAC ¶ 86. Therefore, for the same  
6 reasons this Court previously dismissed this claim, see Dismissal Order at 14-15, the Court  
7 also dismisses it here. Because Plaintiffs did not take advantage of their opportunity to  
8 address the Court’s concerns by amending this claim in their FAC, the Court denies leave to  
9 amend. See Rutman Wine Co. v. E. & J. Gallo Winery, 829 F.2d 729, 738 (9th Cir. 1987)  
10 (finding that a district court could reasonably conclude that allowing further leave to amend  
11 would be futile where the plaintiffs failed to cure deficiencies identified by the court in its  
12 previous order dismissing the complaint).

### 13 3. Bapineuzumab Class Action

14 Plaintiffs asserted in their Opposition that they “recently learned that Judge  
15 Hellerstein in the Southern District of New York” dismissed a class’s complaint in a related  
16 Bapineuzumab class action “with an opportunity to seek leave to amend.” See Opp’n (dkt.  
17 42) at 12. They therefore requested leave to amend “to the extent the class amends their  
18 Bapineuzumab allegations.” Id. As Defendants point out, however, Judge Hellerstein  
19 actually dismissed the class action on August 10, 2011, denying leave to amend. See Reply  
20 (dkt. 46) at Ex. C.<sup>5</sup> Therefore, the New York case does not serve as a basis for allowing  
21 Plaintiffs to amend.

22 Although counsel for Plaintiffs acknowledged at the motion hearing that Judge  
23 Hellerstein had dismissed the class’s complaint with prejudice, he asked for permission to  
24 amend the FAC to include the allegations that the class would have added to their complaint.  
25 He did not, however, explain what those allegations were or why they would alter the

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27 at 13.

28 <sup>5</sup> Plaintiffs filed their Opposition on July 8 before learning of the August 10 decision. See  
Opp’n.

1 analysis. Instead, after the hearing, Plaintiffs submitted a copy of the class’s supplemental  
2 brief filed with Judge Hellerstein, which lists several proposed amendments.<sup>6</sup> See Supp.  
3 Opp’n (dkt. 47) at 2-4. The Court concludes that the proposed amendments do not change  
4 the analysis set forth in this Order, and that allowing leave to amend would be futile.

5 **B. Tysabri**

6 During the Relevant Period, Elan’s best-selling drug was Tysabri, which was used to  
7 treat autoimmune diseases such as multiple sclerosis. FAC ¶ 3. Tysabri had been removed  
8 from the market in 2005 after two patients taking it died from a rare neurological disorder  
9 called progressive multifocal leukoencephalopathy (“PML”). Id. ¶ 3. Elan then “collaborated  
10 with leading experts in MS and progressive PML to complete a safety evaluation” and  
11 established an Independent Adjudication Committee (“IAC”) to review suspected cases of  
12 PML. Id. ¶ 4. The IAC determined that patients who met all three of the following criteria  
13 would be diagnosed as having confirmed PML: (1) progressive clinical disease; (2) MRI  
14 findings typical of PML; and (3) detectable virus DNA in the cerebrospinal fluid. Id. ¶ 5. In  
15 2006, the FDA approved Tysabri’s reintroduction to the market. Id. ¶ 6.

16 **1. The Original Complaint and This Court’s Order**

17 Plaintiffs alleged in their original Complaint that in June and July 2008, (1)  
18 Defendants’ enthusiastic reports of “no new confirmed PML cases” were misleading because  
19 Defendants were aware of 12 suspected cases of PML, and (2) Defendants’ public statements  
20 in July 2008 forecasting large revenues based on future Tysabri sales were also misleading  
21 because Defendants were aware of 12 suspected cases. Compl. ¶¶ 22, 24-25, 80-81, 90-93.  
22 Plaintiffs also alleged that Defendants acted with scienter in making the misleading  
23 statements; the original Complaint stated that Defendants “were motivated to conceal 12  
24 suspected PML cases because the prior suspension of the drug in 2005 had cast doubts over

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26 <sup>6</sup> Judge Hellerstein allowed the class action plaintiffs to submit supplemental briefing “setting  
27 forth grounds for allowing them to amend their Complaints.” Summary Order Denying Leave to Amend  
28 and Closing Cases, 08 Civ. 8761; 10 Civ. 5630 (AKH). After considering the supplemental brief, Judge  
Hellerstein denied leave to amend, stating: “These new allegations may offer additional details regarding  
Plaintiffs’ theory of their cases, but they do nothing to disturb the decision I reached at oral argument.  
Accordingly, I find there is no basis to permit Plaintiffs to amend their Complaints.” Id.

1 the future of the predicted blockbuster and because the news would be a huge blow to  
2 Tysabri and the company’s financials.” Id. ¶ 139.

3 In its Dismissal Order, this Court explained that the original Complaint failed to  
4 identify a false or misleading statement made by Defendants about Tysabri. Dismissal Order  
5 at 8. In response to Plaintiffs’ first allegation (that the reporting of “no new confirmed  
6 cases” was misleading), this Court emphasized that a suspected case is “not the equivalent of  
7 a confirmed case,” and therefore such statements were not false. Id. In response to  
8 Plaintiffs’ second allegation (that Defendants’ positive financial forecasts were misleading in  
9 light of the 12 suspected cases), this Court found that the Complaint did not state with  
10 particularity why the reporting of suspected cases would “mean that there is likely to be a  
11 confirmed case of PML.” Id. at 8-9. Additionally, the Court noted that the Complaint failed  
12 to state whether the two cases confirmed at the end of July had been among the 12 suspected  
13 cases. Id. at 9.

14 This Court also found Plaintiffs’ allegations of scienter insufficient under Rule 9(b)’s  
15 strict pleading standard. Id. at 9. In particular, this Court noted that a more plausible motive  
16 for not publicizing the suspected cases was “a desire to avoid creating an unfounded panic  
17 among patients, doctors, and the market” by announcing PML cases before any patients had  
18 been diagnosed under the IAC’s criteria. Id. Also weighing against an inference that  
19 Defendants acted with scienter in “concealing” the suspected PML cases was the listing of  
20 the suspected cases in the AERS database “to which the public presumably had access.” Id.

## 21 2. Amendments to the Original Complaint

22 Plaintiffs added no new allegations to their FAC to support their claim that  
23 announcing “no new confirmed PML cases” was false. However, the FAC does contain new  
24 allegations to support a claim that Defendants’ public statements forecasting large revenues  
25 were misleading and that Defendants acted with scienter in making those statements. The  
26 following new allegations aim to address the Court’s concerns and support the argument that  
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1 Defendants might have known that PML would likely be confirmed in some of the suspected  
2 cases<sup>7</sup> (an event that inevitably would have a negative impact on Tysabri sales):

3 (1) Defendants knew that a patient’s likelihood of becoming infected with  
4 PML increases over time as the patient continues taking Tysabri, FAC ¶ 98;

5 (2) the AERS database contained no suspected PML cases before February  
6 2008, approximately a year and half after Tysabri’s reintroduction to the  
7 market, id.;

8 (3) within the six months leading up to Defendants’ reporting of two  
9 confirmed cases (February through July 2008), between 10 and 12 suspected  
10 cases<sup>8</sup> suddenly appeared in the AERS database, id.;

11 (4) the two PML cases confirmed on July 31 had been among the 10 to 12  
12 suspected cases in the AERS database, id. ¶¶ 22, 98;

13 (5) the AERS database, according to the FDA, contains “only raw data and  
14 ‘[a] simple search . . . cannot be performed . . . by persons who are not  
15 familiar with creation of relational databases,’” id. ¶ 22, n.4;

16 (6) at least one of the patients later diagnosed with PML had been receiving  
17 plasma exchanges before Defendants disclosed the two confirmed cases, id. ¶  
18 104; and

19 (7) receipt of plasma exchanges is a “strong indicator that a patient [is]  
20 infected with PML,” id.

21 On the sixth point, the FAC and a document to which it cites contain inconsistent  
22 information about (a) which patients suspected of having PML received plasma exchanges  
23 and (b) when those patients began plasma exchange treatment. Plaintiffs state in their FAC,  
24 at ¶ 104, that “many of th[e] suspected cases of PML were receiving plasma exchanges,” and  
25 at ¶ 128, that both patients diagnosed with PML in late July 2008 had been receiving plasma  
26 exchanges for at least two and a half months before Defendants announced them as  
27 confirmed on July 31. Yet the August 1, 2008 Biogen and Elan conference call transcript, to  
28 which Plaintiffs cite in support of their allegations, states that at the time the July 31 press  
release announced the two confirmed cases, only one of those two patients had received

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<sup>7</sup> The FAC does not actually state that Defendants knew of a high likelihood that a PML case would soon be confirmed. However, Plaintiffs’ new allegations appear to support such a claim.

<sup>8</sup> Plaintiffs have not explained why they have changed all references to “12 suspected cases” in the original Complaint to “between 10 and 12 suspected cases” in the FAC.

1 plasma exchanges (over a ten-day period in July), and that the other had not yet begun  
2 plasma exchange.<sup>9</sup> See Hibbard Decl. Ex. BB at 4, 6, 14.<sup>10</sup>

### 3 3. Analysis of Tysabri Claims: Falsity

4 Because Plaintiffs have not made any new allegations to support their claim that  
5 Defendants' reports of "no new confirmed PML cases" were false, this claim is dismissed  
6 with prejudice. See Rutman Wine Co., 829 F.2d at 738. As to the second claim (that  
7 Defendants' public statements forecasting large revenues based on future Tysabri sales were  
8 misleading), however, the FAC does provide stronger support for the allegations of falsity<sup>11</sup>  
9 than does the original Complaint. If, as the FAC implies, Defendants believed that there was  
10 a high likelihood that a suspected case would soon be confirmed, then they also should have  
11 anticipated a corresponding drop in revenue from Tysabri sales. Thus taking the FAC's  
12 allegations as true, and assuming that Defendants acted with the requisite state of mind, "the  
13 Court [could] draw a reasonable inference" that Defendants' public statements conveying

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17 <sup>9</sup> A court "need not accept as true allegations in the Complaint that are contradicted by exhibits  
18 attached to the Complaint." Alvarez v. Yates, No. 1:09 Civ. 02148, 2011 WL 3319718, at \*4 n.2 (E.D.  
19 Cal. July 29, 2011) (citing Crenshaw v. Lister, 556 F.3d 1283, 1292 (11th Cir. 2009); United States ex  
20 rel. Riley v. St. Luke's Episcopal Hosp., 355 F.3d 750, 754 (5th Cir. 2004); Thompson v. Ill. Dep't of  
21 Prof'l Regulation, 300 F.3d 750, 754 (7th Cir. 2002); KKE Architects, Inc. v. Diamond Ridge Dev.  
22 LLC, No. CV 07-06866, 2008 WL 637603, at \*3 (C.D. Cal. Mar. 3, 2008)). If a complaint cites to a  
document not actually attached as an exhibit, the court may still treat that document as part of the  
pleading for purposes of evaluating a motion to dismiss." Branch v. Tunnell, 14 F.3d 449, 453-54 (9th  
Cir. 1994) (overruled on other grounds). Therefore, this Court need not accept as true Plaintiffs'  
allegations in the FAC that are contradicted by the conference call transcript.

23 <sup>10</sup> The Court may take judicial notice of this document as it was cited in the Complaint. See In  
re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970 at 986.

24 <sup>11</sup> Plaintiffs rely heavily on Siracusano v. Matrixx Initiatives, Inc., 131 S. Ct. 1309 (2011) in  
25 opposing Defendants' Motion, arguing that information about the 10-12 suspected cases was "material"  
26 to investors. See Opp'n at 5-9. Their reliance on Matrixx is misplaced because materiality is not at  
27 issue here; Defendants moved to dismiss for failure to allege a false or misleading statement and  
28 scienter. See generally Mot. Because this claim involves an omission, the issue is whether Defendants  
owed Plaintiffs a duty to disclose information about the suspected cases. As the Supreme Court  
recognized in Matrixx, whether a defendant owed a duty to disclose depends on whether the omission  
rendered his or her statement false or misleading, not whether the omitted information was material.  
See Matrixx, 131 S. Ct. at 1321-22 (citing 17 CFR § 240.10b-5(b); Basic Inc. v. Levinson, 485 U.S.  
224, 239 n.17 (1988)).

1 confidence that Tysabri revenues would increase were false and misleading when made.<sup>12</sup>  
2 See Iqbal, 129 S. Ct. at 1949 (citing Twombly, 550 U.S. at 570); Usher, 828 F.2d at 561.  
3 The main question, then, is whether the FAC adequately pleads scienter: i.e., that Defendants  
4 were aware of a high likelihood that a PML case would soon be confirmed, and therefore  
5 either knew that their statements were false, or were reckless as to the truth or falsity of their  
6 statements. See Gebhart v. S.E.C., 595 F.3d 1034, 1040 (9th Cir. 2010).

#### 7 4. Analysis of Tysabri Claims: Scienter

8 Plaintiffs' allegations of scienter in the FAC are also stronger than their allegations in  
9 the original Complaint, but still do not meet the strict pleading requirements of the PSLRA.  
10 The allegations of scienter are stronger for several reasons. As acknowledged by  
11 Defendants, that Tysabri had been pulled off the market in 2005 due to concerns that it had  
12 caused three patients to contract PML was public knowledge. Reply (dkt. 46) at 3. Thus  
13 Defendants knew of a potential causal link between Tysabri and PML before the drug's  
14 reintroduction to the market. See FAC ¶ 107. Plaintiffs now allege that within the first year  
15 and a half following the drug's reintroduction to the market, no new suspected cases  
16 appeared in the AERS database. Id. ¶ 98. If Defendants knew, as Plaintiffs now allege, that  
17 the likelihood of contracting PML increases over time, see id., then the sudden appearance of  
18 10 to 12 suspected cases between February and July should have at least raised a red flag.  
19 And if, as alleged, some of those suspected cases were receiving plasma exchanges, see id. ¶  
20 104, and such treatment is a strong indicator that a patient is infected with PML, see id., then  
21 knowledge of that treatment might have put Defendants on further notice that the cases  
22 would likely be confirmed. The chain of inferences would be as follows: (1) Defendants  
23 knew that the sudden appearance of suspected cases a year and a half after reintroduction of

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25 <sup>12</sup> Note that 15 U.S.C. § 78u-5 creates a safe harbor for a forward-looking statement that meets  
26 any one of three requirements: (1) the statement was "accompanied by meaningful cautionary  
27 statements"; (2) the statement was immaterial; or (3) the plaintiff fails to demonstrate that the statement  
28 was made with knowledge of falsity. Here, the statements apparently were not accompanied by  
cautionary statements, and Defendants do not contend that they were immaterial. The question,  
therefore, is whether Plaintiffs have alleged facts to support a reasonable inference that Defendants  
made the statements with knowledge that they were false or misleading. The Court addresses this  
question in the next section.

1 the drug to the market and the plasma exchanges made it more likely that there would soon<sup>13</sup>  
2 be a confirmed case; (2) Defendants therefore also knew that Tysabri sales would soon drop;  
3 and finally (3) Defendants thus either knew that their public statements conveying  
4 confidence in future Tysabri sales were false when made, or were reckless as to whether their  
5 statements were true or false.

6 Nevertheless, the FAC does not state with particularity facts giving rise to a strong  
7 inference of scienter, as required by the PSLRA. See 15 U.S.C. § 78u-4(b)(2). Conclusory  
8 allegations about a defendant’s state of mind, without specific facts, are not enough. See 15  
9 U.S.C. § 78u-4(b)(3); Tellabs, 551 U.S. at 324. Here, the FAC asserts, without alleging any  
10 supporting facts, that Defendants knew that a patient’s likelihood of contracting PML  
11 increases over time while taking Tysabri. FAC ¶ 98. This allegation is crucial to Plaintiffs’  
12 theory of liability because, as described above, the Court might reasonably infer that because  
13 Defendants had such knowledge, they acted with scienter when conveying their confidence  
14 in future Tysabri sales. Because the FAC contains no facts to support this conclusory  
15 allegation, however, it fails to satisfy the PSLRA’s pleading requirements.

16 Similarly, Plaintiffs’ allegations that at least one suspected PML patient was receiving  
17 plasma exchanges and that receipt of plasma exchanges is a “strong indicator that a patient  
18 [is] infected with PML,” Id. ¶ 104, also fail to support a strong inference of scienter.  
19 Nowhere in the FAC do Plaintiffs allege (or state facts supporting an inference) that  
20 Defendants knew that receipt of plasma exchanges is a strong indicator of PML. Neither do  
21 Plaintiffs allege (or state facts supporting an inference) that Defendants knew that at least one  
22 suspected PML patient was receiving plasma exchanges before making their allegedly  
23 misleading statements. Therefore, even assuming, as the Court must, that Plaintiffs’ factual  
24 allegations are true, inferring that Defendants acted with the requisite state of mind would be

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26 <sup>13</sup> Defendants’ allegedly misleading statements forecasted increased Tysabri revenues only  
27 through the year 2010; for example, Defendants stated that the increase in Tysabri patients in the first  
28 quarter of 2008 “underscores the confidence that Elan’s total revenue for this year will approach the  
\$1bn mark and we will achieve our target of having 100,000 patients on Tysabri by the end of 2010.”  
See FAC ¶ 93. Therefore, to give rise to a strong inference of scienter, Plaintiffs would have had to  
allege facts suggesting that Defendants knew in mid-2008 of a strong likelihood that a case would be  
confirmed within less than two years. They have not done so.

1 unreasonable. Because Plaintiffs have not stated with particularity facts giving rise to a  
2 strong inference of scienter, the PSLRA requires the Court to dismiss the FAC. See 15  
3 U.S.C. § 78u-4(b)(3).

4 Plaintiffs have also failed to fully address the Court’s concern that the suspected cases  
5 appeared in a database to which the investors presumably had access. See Dismissal Order at  
6 9. Although Plaintiffs now allege that the AERS database contains “only raw data and ‘[a]  
7 simple search . . . cannot be performed . . . by persons who are not familiar with creation of  
8 relational databases,’” FAC ¶ 22, n.4, they do not allege that they themselves, as  
9 sophisticated investors in the pharmaceutical industry, were unable to search the database.<sup>14</sup>  
10 Plaintiffs also admit that Defendants made general, public references to suspected cases of  
11 PML, see, e.g., id. ¶ 96, which further undermines any inference that Defendants acted with  
12 scienter in “concealing” the suspected cases.

13 Because Plaintiffs’ allegations of scienter do not meet the heightened pleading  
14 standards of the PSLRA, the Court dismisses the claim. This Court already gave Plaintiffs  
15 an opportunity to amend their Complaint to explain why the reporting of suspected cases  
16 would “mean that there is more likely to be a confirmed case of PML.” See Dismissal Order  
17 at 8-9. They did not cure this deficiency, and therefore the Court denies further leave to  
18 amend. See Rutman Wine Co., 829 F.2d at 738.

19 **C. Section 20(a)**

20 Because Plaintiffs have not adequately alleged a 10(b)-5 securities law violation, the  
21 Court also dismisses the section 20(a) “control person” claim. See Howard v. Everex Sys.,  
22 Inc., 228 F.3d 1057, 1065 (9th Cir 2000).

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28 <sup>14</sup> When asked at the hearing whether Plaintiffs themselves could search the database, Plaintiffs’  
counsel professed not to know.

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**IV. CONCLUSION**

For the foregoing reasons, the Court GRANTS the Motion with prejudice.

**IT IS SO ORDERED.**

Dated: October 4, 2011



CHARLES R. BREYER  
UNITED STATES DISTRICT JUDGE