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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

CITY OF BIRMINGHAM RELIEF AND RETIREMENT SYSTEM AND OHIO CARPENTERS' PENSION FUND, Individually and On Behalf of All Others Similarly Situated,

Plaintiffs,

v.

ACADIA PHARMACEUTICALS INC., STEPHEN R. DAVIS, and SRDJAN (SERGE) R. STANKOVIC,

Defendants.

Case No. 3:21-CV-00762-WQH-NLS

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR RECONSIDERATION OF THE ORDER DENYING DEFENDANTS' MOTION TO DISMISS THE AMENDED CLASS ACTION COMPLAINT

Judge: Hon. William Q. Hayes
Hearing Date: December 5, 2022

NO ORAL ARGUMENT UNLESS REQUESTED BY THE COURT

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I. INTRODUCTION

Private securities fraud class actions can be hugely expensive if "courts do not filter out the unfounded ones early enough." *Ronconi v. Larkin*, 253 F.3d 423, 428 (9th Cir. 2001). To prevent plaintiffs from leveraging the threat of discovery into undeserved settlements, Congress passed the Private Securities Litigation Reform Act of 1995 (the "PSLRA"), which created one the highest pleading standards in the law. The PSLRA requires plaintiffs to provide an unprecedented degree of detail to survive a motion to dismiss. A complaint must plead concrete facts that defendants made materially false or misleading statements with the intent to deceive investors or with an extreme reckless disregard of the truth. And courts must consider all inferences—those favoring defendants as well as plaintiffs—in evaluating scienter allegations. In its order denying Defendants' Motion to Dismiss ("Order"), the Court quoted those pleading standards. But, instead of strictly applying them, the Court examined Plaintiffs' allegations as though they were subject to the more lenient requirements of Rules 8 and 9(b). In so doing, the Order sidestepped the requirements of the PSLRA and binding Ninth Circuit law. This was clear error and, as a result, Defendants respectfully ask the Court to reconsider its Order.

II. LEGAL STANDARD

District courts can reconsider their orders at any time before final judgment, for any reason they deem sufficient. *See City of Los Angeles v. Santa Monica Baykeeper*, 254 F.3d 882, 885–87 (9th Cir. 2001); *Abada v. Charles Schwab & Co.*, 127 F. Supp. 2d 1101, 1102 (S.D. Cal. 2000) ("A district court may reconsider and reverse a previous interlocutory decision for any reason it deems sufficient, even in the absence of new evidence or an intervening change in or clarification of controlling law."); *see also* Fed. R. Civ. P. 54(b). When ruling on such motions, courts in this district refer to the standards for reconsideration under Rule 59(e). *See Victorino v. FCA US LLC*, 2018 WL 2149223, at *2 (S.D. Cal. May 10, 2018). Reconsideration is appropriate under Rule 59(e) to correct clear error. *See Allstate Ins. Co. v. Herron*, 634 F.3d 1101, 1111

(9th Cir. 2011). Misapplication of the PSLRA's exacting pleading requirements merits reconsideration. *Hamano v. Activision Blizzard, Inc.*, 2019 WL 7882076, at *1 (C.D. Cal. Oct. 17, 2019). Defendants do not request reconsideration lightly, but it is warranted here.

III. ARGUMENT

A. The Order Departs from Controlling Law on Scienter.

Pleading scienter in a securities fraud case is no small feat. The PSLRA imposes exacting pleading requirements that require far more than the typical fraud case subject only to Rule 9(b). Conclusory allegations about Defendants' state of mind are inadequate. Instead, "the complaint ***must*** contain allegations of ***specific contemporaneous*** statements or conditions that demonstrate the intentional or the deliberately reckless false or misleading nature of the statements ***when made.***" *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1066 (9th Cir. 2008).[1] Additionally, the Court "***must consider plausible, nonculpable explanations***" for Defendants' conduct. *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 324 (2007). In other words, unlike a traditional 12(b)(6) analysis, the Court does ***not*** draw all inferences in favor of Plaintiffs when assessing scienter under the PSLRA.

The Order's scienter analysis departs from the requisite application of these pleading standard in three ways, each of which warrants reconsideration for clear error.

1. Plaintiffs' conclusory allegations of "access to information" do not meet the pleading requirements of the PSLRA.

The Order improperly credits Plaintiffs' conclusory allegations of Defendants' "access" to unspecified information. (Order at 22 (finding it "plausible" that Defendants "would have been aware of the terms of any agreement with the FDA and the alleged shortcomings with the design and results of the Harmony and -019 Studies" because Defendants supposedly had "access to material information").) The Ninth Circuit has

[1] Unless otherwise noted, all emphasis is added, internal quotation marks and citations are removed, and alterations are omitted.

repeatedly held that such allegations—which do not link any specific reports and their contents to executives—do not satisfy the PSLRA. *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1063 (9th Cir. 2014) ("Negative characterizations of reports relied on by insiders, without specific reference to the contents of those reports, are insufficient to meet the heightened pleading requirements of the PSLRA."); *In re Silicon Graphics, Inc. Sec. Litig.*, 183 F.3d 970, 985 (9th Cir. 1999) ("We would expect that a proper complaint which purports to rely on the existence of internal reports would contain at least some specifics from those reports as well as such facts as may indicate their reliability."); *see also Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1036 (9th Cir. 2002); *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 417 (9th Cir. 2020).

It may be reasonable to infer that Defendants had access to the FDA minutes where the agreement was documented. But Plaintiffs allege no facts about what those minutes contained.[2] And without such facts, the Court cannot possibly (much less strongly) infer that Defendants intentionally or recklessly misrepresented the existence or terms of that agreement. *See Nguyen*, 962 F.3d at 417 (finding allegations regarding internal reports inadequate to support scienter because "the complaint does not plead any details about these reports that would demonstrate a strong inference of scienter in Endologix's later statements about FDA approval").

Finally, even if it was "plausible" that Defendants "would have been aware of the terms of any agreement with the FDA," as the Court suggests, plausibility is not the

[2] The fact that Acadia did not publicly release the confidential FDA minutes does not give Plaintiffs free reign to speculate about what they may or may not contain. *See Immanuel Lake v. Zogenix, Inc.*, 2020 WL 3820424, at *8 n.5 (N.D. Cal. Jan. 27, 2020) ("The fact that the NDA is confidential and the RTF letter has not been made public, however, does not relieve Plaintiffs of their obligation to meet the exacting pleading standards of the PSLRA."); *Bauer v. Eagle Pharms., Inc.*, 2017 WL 2213147, at *7 (D.N.J. May 19, 2017) ("While the Court acknowledges that Plaintiffs may lack information due to the confidentiality of the [FDA's critical response letter], this fact does not give Plaintiffs the authority to speculate. That is, speculation and conjecture will not support a claim under the PSLRA's heightened pleading standard.").

standard. Under the PSLRA, "an inference of scienter must be ***more than merely plausible or reasonable***—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314; *see also Nguyen*, 962 F.3d at 414; *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 882–83 (9th Cir. 2012).

2. Stock sales are insufficient to support a "strong" inference of scienter under the PSLRA.

Other than Plaintiffs' conclusory "access to information" allegations, all that remains to support the Order's scienter holding are the individual defendants' stock sales. (Order at 23–24.) Those allegations cannot support a strong inference of scienter, however, because stock sales suggest only "a motive to commit fraud and opportunity to do so." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009). And in the Ninth Circuit, allegations of motive and opportunity are "not sufficient to establish a *strong* inference" of scienter. *Id.* (emphasis in original); *see also In re Silicon Graphics*, 183 F.3d at 988 (finding allegations of stock sales inadequate "[i]n the absence of greater particularity and more incriminating facts" because the court has no way of distinguishing such allegations "from the countless 'fishing expeditions' which the PSLRA was designed to deter").[3] !

3. The Order errs in discounting the competing inference arising from Defendants' disclosure of the HARMONY results.

Finally, the Order does not appropriately weigh all nonculpable inferences against those favoring Plaintiffs. *See Tellabs*, 551 U.S. at 324. Instead, the Order improperly discounts any nonculpable inference arising from Defendants' December 4, 2019, release of the HARMONY trial results because "this disclosure occurred almost three months after the initial actionable omission." (Order at 24.) However, all but three of the statements challenged in the FAC were made after this disclosure. (¶¶ 113, 115,

[3] Additionally, because such sales were pursuant to pre-determined 10b5-1 plans and sell-to-cover arrangements—and there are no allegations undermining the legitimacy of those plans—they "rebut an inference of scienter." *Metzler*, 540 F.3d at 1067 n.11.

117, 119, 121, 123, 125, 127, 128, 130, 132, 134, 135, 137, 138, 140, 141.)[4] One of those three statements relates solely to the -019 study, the details of which were publicly disclosed years before the proposed class period. (¶ 109.) As for the other two statements, there are no facts pled to suggest that any Defendant had access to the full HARMONY dataset or knew the allegedly negative subgroup results in September and October 2019, when those statements were made. (¶¶ 107, 111). *See Metzler*, 540 F.3d at 1066 (requiring "allegations of ***specific contemporaneous*** statements or conditions that demonstrate the intentional or the deliberately reckless false or misleading nature of the statements ***when made***"). Nor is such an inference reasonable. How would the full results from the ***double-blinded*** HARMONY study be immediately known and available to Defendants at the same time a ***third-party independent data monitoring committee*** unexpectedly halts the ongoing trial following an interim analysis? (*See* ECF 53-4 (Ex. M) at 61.) They would not, and Plaintiffs plead no facts to suggest otherwise, much less that three months—to collect, clean, unblind, analyze, and present clinical trial results—is unusual or excessive.

The Order also finds "an inference that Defendants intended that their earlier statements be understood by investors as suggesting that Acadia and the FDA had reached agreements concerning test design and analysis that were ultimately not consistent with the FDA's rationale for denying approval." (Order at 22–23.) But that inference is not one of fraud. Nothing about it suggests an intent to "***deceive, manipulate, or defraud,***" as required under the PSLRA to survive dismissal. *Tellabs*, 551 U.S. at 313. Instead, the Order's stated inference is entirely consistent with what Defendants genuinely believed and publicly said all along, including at the time the FDA denied approval.

Moreover, the Court is required to consider the nonculpable inference: that, as disclosed in the April 5, 2021 press release, the FDA's basis for denying approval ***was***

[4] References to "FAC" and "¶ " refer to Plaintiffs' Amended Class Action Complaint for Violations of the Federal Securities Laws. (ECF 45.)

not consistent with the terms of its agreement with Acadia. *See Tellabs*, 551 U.S. at 324. There is not a single contemporaneous fact suggesting otherwise. And when factoring in Defendants' December 4th disclosure of the HARMONY trial results, the far more cogent and compelling inference is that Defendants accurately represented the terms of the agreement with the FDA and were just as surprised as investors when the FDA denied approval of the sNDA on bases inconsistent with that agreement.

B. The Order Departs from Controlling Law on Falsity

The Order's falsity analysis also departs from controlling law in two ways, each of which warrants reconsideration for clear error.

1. The Order improperly relies on disputes about trial design to support falsity.

The Order holds that Defendants' alleged "failure to disclose that the studies were not properly designed . . . rendered Defendants' positive statements regarding the results of the studies materially misleading." (Order at 19.) This is clear error because, under binding Ninth Circuit authority, "***disagreements over statistical methodology and study design are insufficient to allege a materially false statement***." *Rigel*, 697 F.3d at 877.

In *Rigel*, the plaintiff claimed that the defendants' statements about the efficacy results of Rigel's Phase 2 study were false and misleading because the design for the study employed a statistical methodology to determine efficacy that plaintiff contended gave a false impression of statistical significance. 697 F.3d at 877–78. According to the plaintiff, if the trial design had used the proper statistical methodology to evaluate the results, the study would have failed. *Id.* at 877. The Ninth Circuit rejected this theory: "Because Plaintiff does not allege that Defendants misrepresented their own statistical methodology, analysis, and conclusions, but instead criticizes only the statistical methodology employed by Defendants, Plaintiff did not adequately plead falsity with respect to statistic results." *Id*. at 879.[5] In reaching that holding, the Ninth Circuit relied

[5] District courts in this circuit and elsewhere are in near-perfect accord. *See, e.g.*, *Philco Invs. Ltd. v. Martin*, 2011 WL 500694, at *8 (N.D. Cal. Feb. 9, 2011); *Abely v. Aeterna*

heavily on *Padnes v. Scios Nova Inc.*, 1996 WL 539711 (N.D. Cal. Sept. 18, 1996). In that case, the plaintiffs alleged that a clinical trial was flawed as it was not double-blinded or randomized, and that these design defects were "so serious that the study had no predictive value for the efficacy of" the drug. *Id.* at *5. The district court rejected that theory:

> [W]here a company accurately reports the results of a scientific study, it is under no obligation to second-guess the methodology of that study. Medical researchers may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols. The securities laws do not impose a requirement that companies report only information from optimal studies, even if scientists could agree on what is optimal. Nor do they require that companies who report information from imperfect studies include exhaustive disclosures of procedures used, including alternatives that were not utilized and various opinions with respect to the effects of these choices on the interpretation of the outcome data.

Id.; *see also Rigel*, 697 F.3d at 869.

Here, as in *Rigel* and *Padnes*, Plaintiffs do not allege that Defendants failed to disclose or misrepresented the design of the -019 or HARMONY trials. (*See* ¶¶ 62, 87.) Rather, they allege—with the benefit of hindsight—that Defendants should have somehow known and disclosed that the FDA would later criticize those trials as poorly designed and insufficient to support FDA approval. (¶¶ 73–91) This theory is simply not cognizable under *Rigel* and the Court erred in crediting Plaintiffs' *post-hoc* critique of the trial designs following the FDA's denial of the sNDA.

Zentaris, Inc., 2013 WL 2399869, at *10 (S.D.N.Y. May 29, 2013) (holding that "plaintiff's critiques all go toward the design of the study . . . [and] merely amount to a competing view of how the trial should have been designed" and therefore do not raise an actionable claim); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1232 (S.D. Cal. 2001) ("Plaintiffs' theory of fraud rests on hindsight-driven criticism prompted by [the Advisory Committee's] ultimate refusal to recommend approval of [the drug to the FDA]."); *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 568, n. 15 (E.D. Pa. 2009) (holding that purported problems with the statistical analysis of a clinical trial were disagreements over how to analyze the study not false statements).

2. The Order disregards Defendants' disclosures of the very facts Plaintiffs allege were misleadingly omitted.

The Order found that Plaintiffs plausibly alleged that Defendants "misled investors by omitting the adverse information the FDA later cited in denying approval of the sNDA." (Order at 21.) However, under binding Ninth Circuit authority, "***an omission is actionable under section 10(b) and Rule 10b-5 only if the allegedly undisclosed information has not already entered the market***." *Heliotrope Gen., Inc. v. Ford Motor Co.*, 189 F.3d 971, 975–76 (9th Cir. 1999); *see also Tadros v. Celladon Corp.*, 738 F. App'x 448, 448–49 (9th Cir. 2018) (affirming dismissal under *Heliotrope*). Here, there is no dispute that all of the allegedly omitted "adverse information"—*i.e.*, the designs and results of the -019 and HARMONY studies—was disclosed by Acadia on or before December 4, 2019. (¶ 49 ("In December 2016, the Company announced positive top-line results from the -019 study"); ¶ 62 ("On December 4, 2019, Acadia presented the Harmony Study's top-line results . . . [and] released the full data set of the Harmony Study.").)[6] As such, it is clear error to find any actionable omission based on information that had already entered the market.

The Order, however, disregarded the December 4 disclosure because it accepted Plaintiffs' argument that it was a truth-on-the-market defense. (Order at 20–21.) Respectfully, that is incorrect. A truth-on-the-market defense asserts that a "defendant's failure to disclose material information may be excused where the information was made credibly available to the market by other sources." *In re Obalon Therapeutics, Inc.*, 2019 WL 4729461, at *6 (S.D. Cal. Sept. 25, 2019). Here, Defendants made a different argument—*i.e.*, that ***there was no omission because Defendants had already disclosed the allegedly omitted information***. And Plaintiffs allege that Acadia's stock traded in an efficient market, which rapidly incorporates "all publicly available information[.]" *Heliotrope*, 189 F.3d at 975–76.

[6] Although not addressed in the Order, the HARMONY study design was also publicly available since October 30, 2017 at clinicaltrials.gov. (*See also* ¶¶ 52–55.)

Moreover, the Order accepted Plaintiffs' ***argument***—unsupported by any allegations in the FAC—that the December 4 presentation was "not sufficient to counterbalance the misleading impression created by Defendants' statements" because it was made only to "medical professionals." (Order at 18, 20–21.) This argument is relevant only to rebut a truth-on-the-market defense, which, as noted above, Defendants did not raise. In any event, the law is well settled that, on a Rule 12(b)(6) motion, "a court ***may not*** look beyond the complaint to a plaintiff's moving papers, such as a memorandum in opposition to a defendant's motion to dismiss." *Schneider v. California Dep't of Corr.*, 151 F.3d 1194, 1197 n.1 (9th Cir. 1998) (emphasis in original); *see also Broam v. Bogan*, 320 F.3d 1023, 1026 (9th Cir. 2003) (same); *Morgan v. Aurora Loan Servs., LLC*, 646 F. App'x 546, 549 n.2 (9th Cir. 2016) (same); *Ajaelo v. Carrillo*, 2022 WL 35659, at *3 (S.D. Cal. Jan. 3, 2022) (Hayes, J.) (same). Accordingly, it was clear error for the Court to consider this argument, which was made ***only*** in Plaintiffs' Opposition and not alleged in the FAC.

But, even if Plaintiffs ***had*** alleged that the December 4 presentation was made only to medical professionals at a healthcare conference, it would still be clear error to disregard the disclosure on that basis. Plaintiffs challenge multiple statements made at healthcare conferences, including all three of the statements the Order addresses regarding the FDA agreement. (¶¶ 117, 128, 132, 134–35; Order at 15–16.) If Plaintiffs can rely on the efficient market hypothesis to plead that the ***allegedly misleading statements*** made at healthcare conferences were rapidly digested by the market and incorporated into Acadia's stock price (¶ 154), then that same principle must hold true for ***all statements*** made at healthcare conferences.[7] *See Sprewell v. Golden State*

[7] In pleading reliance, Plaintiffs allege that Acadia's stock traded in an efficient market where those challenged statements were rapidly incorporated into Acadia's stock price. (¶ 154.) Additionally, Defendants submitted two analyst reports and a stock price chart with their Reply in response to Plaintiffs' illogical argument (in their Opposition brief) that disclosure at a healthcare conference is insufficient to inform the market. The Court, however, declined to take judicial notice of these materials because Plaintiffs had no "opportunity to respond to the request." (Order at 2 n.1.) Plaintiffs, however, could have

Warriors, 266 F.3d 979, 988 (9th Cir.) (the court need not accept "unreasonable inferences").

IV. CONCLUSION

For the foregoing reasons, Defendants respectfully ask the Court to reconsider the Order and, in accord with the PSLRA and binding Ninth Circuit law, dismiss the FAC in its entirety.

Dated: October 25, 2022

Respectfully submitted,

/s/ Peter M. Adams
Peter M. Adams

Attorneys for Defendants Acadia Pharmaceuticals Inc., Stephen Davis, and Srdjan (Serge) R. Stankovic

raised an objection with Court during oral argument, but did not. Regardless, Rule 201(c)(2) of the Federal Rules of Evidence is mandatory: courts "***must*** take judicial notice if a party requests it and the court is supplied with the necessary information." Here, the analyst reports reproduced the subgroup data from Acadia's December 4 presentation of the HARMONY trial results and the stock chart shows that, on December 5, Acadia's stock price increased 14%. This belies Plaintiffs' argument that the December 4 disclosure was insufficient to inform the market. To the contrary, the market reaction to this disclosure "provides a singularly appropriate context for assessing the adequacy of Plaintiffs' theory of loss causation" as it disclosed the very facts that Plaintiffs allege were omitted. *See Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1198 (9th Cir. 2021) (finding a "quick and sustained price recovery after the modest October 9 drop refutes the inference that the alleged concealment of this particular fact caused any material drop in the stock price").