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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

REPLY IN FURTHER 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

TABLE OF CONTENTS

I. INTRODUCTION

Allegations of securities fraud "inescapably carry a degree of moral turpitude," and thus require "***a greater degree of pre-discovery investigation by the plaintiff***" and ***"particular allegations***" to protect defendants from unfounded allegations. *Irving Firemen's Relief & Ret. Fund v. Uber Techs., Inc.*, 998 F.3d 397, 403–04 (9th Cir. 2021).[1] This is why Rule 9(b), the PSLRA, and binding Supreme Court and Ninth Circuit law impose heightened pleading standards—under which allegations based on hindsight speculation simply do not suffice. *See Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 320 (2007); *see also United States v. Students Challenging Regul. Agency Procs. (SCRAP)*, 412 U.S. 669, 688 (1973) ("[P]leadings must be something more than an ingenious academic exercise in the conceivable.").

Reconsideration is the proper mechanism for the Court to correct clear errors in its application of these stringent pleading standards. Indeed, the Opposition confirms that Plaintiffs failed to meet their pleading burden because their allegations are based on nothing but hindsight. They admit that the only "fact" alleged in the FAC supporting their theory of fraud—that Defendants deliberately lied about the existence of an agreement with the FDA—is the FDA's later denial of the sNDA. (*See* Opp. at 5 (quoting Order at 23).) This is not enough. Plaintiffs must allege specific ***contemporaneous*** facts demonstrating that Defendants knowingly lied about the agreement with the FDA. *See Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1066 (9th Cir. 2008).

Because no such facts are alleged, it was clear error for the Court to find that Plaintiffs pled a strong inference of scienter. And this pleading failure infects the whole

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[1] Unless otherwise noted, all emphasis is added, internal quotation marks and citations are removed, and alterations are omitted. Citations to "Order" are to the Court's Order Denying Defendants' Motion to Dismiss as ECF No. 65; citations to "Mot." are to Defendants' Memorandum of Points and Authorities in Support of Motion for Reconsideration at ECF No. 75-1; and citations to "Opp." are to Plaintiffs' Opposition to Defendants' Motion for Reconsideration at ECF No. 78.

complaint because the alleged non-existence of an agreement with the FDA is the sole basis for Plaintiffs' entire case, including Defendants' statements about positive trial results. For this reason, as well as additional errors in the application of binding Ninth Circuit case law regarding disputes about trial design and a prohibition against relying on facts not alleged in the complaint, Defendants respectfully request that the Court reconsider its Order Denying Defendants' Motion to Dismiss.[2]

II. THE ORDER DEPARTS FROM CONTROLLING LAW ON SCIENTER

To plead a strong inference of scienter under the PSLRA, "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*, 540 F.3d at 1066.

The only "contemporaneous" allegation supporting the Court's scienter finding is Defendants' purported "access to material information available to them but not to the public." (Order at 19, 22 (quoting ¶ 26).) This conclusory allegation falls well short of demonstrating "the ***intentional or the deliberately reckless false or misleading nature*** of the statements when made." *Metzler*, 540 F.3d at 1066.

Indeed, Plaintiffs' allegations do not show that the unspecified non-public "material information" to which Defendants' purportedly had access was inconsistent in any way with their public statements. And it does not suffice to assert, as Plaintiffs do, that Defendants' own public statements qualified as "specific" allegations supporting scienter. (*See* Opp. at 4–5 (citing Order at 23–25).) Rather, the Ninth Circuit

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[2] Defendants complied with Local Rule 7.1(i)(1). (*Cf.* Opp. at 3 n.2.) The Declaration filed in support of Defendants' Motion ("Adams Declaration") details when and to what judge the initial application was made, what decision was made, and the basis upon which Defendants' seek reconsideration. (Adams Decl., ¶ 6). Plaintiffs' cited authority is inapposite. In *FTC v. Neovi, Inc.*, 2009 WL 56130, at *2 (S.D. Cal. Jan. 7, 2009), defendants failed to attach ***any*** declaration to their motion for reconsideration. And in *Strobel v. Morgan Stanley Dean Witter*, 2007 WL 1053454, at *2 (S.D. Cal. Apr. 10, 2007), the declaration failed to identify ***any*** proper basis for reconsideration, claiming instead that the parties were not given an opportunity to brief the court's *sua sponte* decision to remand. *Strobel*, No. 3:04-cv-01069-BEN-BLM, at ECF No. 33, ¶ 9.

demands "***specific reference to the contents***" of any alleged material inside information to support an inference of scienter. (*See* Mot. at 2–3 (citing cases).) To be sure, Plaintiffs need not "plead the ***exact*** contents of confidential, non-public FDA minutes." (Opp. at 4.) But they must plead ***some specific contemporaneous facts*** to support their "belief" that Defendants fabricated an agreement with the FDA—thereby risking their careers, reputation, and rebuke from the FDA—all for a short-term boost in Acadia's stock price.[3] There are none. For example, there is no allegation from a confidential witness who attended the FDA meetings and reported that no such agreement was reached. There is no allegation that Defendants privately admitted that the FDA had not actually "agreed" to the HARMONY trial design or analysis plan. There is no allegation that the FDA minutes were inconsistent with Defendants' representations about the agreement documented therein. Plaintiffs must plead something to show that, ***at the time the challenged statements were made***, Defendants knew, or were reckless in not knowing, that their statements were materially false or misleading. Plaintiffs concede that they allege no such facts. (*See* Opp. at 4–6.)

All that exists to support Plaintiffs' claim of fraud is Acadia's April 5, 2021, press release, which was issued ***after*** the FDA denied approval of the sNDA. (Opp. at 5.) Based on this, the Court found that the FDA's justification for denial was inconsistent with Defendants' representations about the agreement. (Order at 17, 23.) But Plaintiffs allege no ***contemporaneous facts*** to explain this purported inconsistency, only hindsight speculation. This is not enough to plead a strong inference of scienter under the PSLRA. *See Tellabs*, 551 U.S. at 320 (there is no "fraud by hindsight").

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[3] Plaintiffs continue to malign Defendants for not disclosing the confidential FDA minutes as if it is Defendants' burden to disprove Plaintiffs' unsupported belief. (*See* Opp. at 5 ("[I]t is Defendants who are relying on terms of a purported agreement that ***Plaintiffs believe do not exist*** (and which Defendants continue to conceal).").) But it is Plaintiffs' burden—not Defendants'—to allege contemporaneous facts to support their "belief" that no agreement existed. *See* 15 U.S.C. § 78u–4(b)(1) (requiring allegations based on "information and belief" to be accompanied by ***particularized facts*** "on which that belief is formed").

The Court also relied on the same April 5 press release to conclude that Defendants "intended that their . . . statements be understood by investors as suggesting Acadia and the FDA had reached agreements concerning test design and analysis." (Order at 23.) This, however, is ***not*** a finding of scienter. (*Cf.* Opp. at 5.) If Defendants honestly and reasonably believed such agreements existed—because, for example, they were documented in the FDA meeting minutes—then Defendants would naturally intend their statements to communicate their belief to investors. Nothing about that intent suggests fraud.

Finally, contrary to Plaintiffs' contention, Defendants never suggested that the Court erred by applying a holistic analysis. (*See* Opp. at 3.) Rather, even when viewed holistically, all that remains to support the Court's scienter finding—after properly disregarding conclusory allegations and discounting hindsight speculation—are Defendants' stock sales. (Mot. at 4; Order at 23–24.) And there is no dispute that under binding Ninth Circuit authority, such allegations, on their own, are insufficient to support a strong inference of scienter. (*See* Opp. at 6; Mot. at 4.)

Accordingly, Defendants respectfully ask the Court to reconsider its Order. The PSLRA and binding Ninth Circuit law require ***specific contemporaneous*** facts to support a strong inference of scienter, and Plaintiffs pled no such facts here.

III. THE ORDER DEPARTS FROM CONTROLLING LAW ON FALSITY

As to falsity, the Order misapplied binding Ninth Circuit law in two ways, both of which warrant reconsideration for clear error.

A. The Order Clearly Erred in Finding that Plaintiffs' Allegations About Acadia's Trial Design Are Actionable.

Defendants' Motion does not argue what the Court "should have found" (*see* Opp. at 8), but rather, identifies clear error in what the Court ***did*** find: that Defendants "failure to disclose that the studies were not properly designed . . . rendered Defendants' positive statements regarding the results of the studies materially misleading" (Mot. at 6 (quoting Order at 19)).

This finding is clear error because, under binding Ninth Circuit authority, "***disagreements over statistical methodology and study design are insufficient to allege a materially false statement***." *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 877 (9th Cir. 2012). Plaintiffs do not dispute this legal standard; rather, they argue it is inapplicable because their allegations do not concern a dispute about proper trial design or analysis. (Opp. at 8–9.) This is nonsense. The FAC includes an entire section titled, "***The Design of the Harmony Study was Patently Flawed.***" (FAC at 17, Section A.) It also specifically alleges that some of Defendants' statements were misleading because "Defendants failed to disclose that the Harmony Study ***was not properly designed*** to evaluate the efficacy of pimvanserin." (*See, e.g.*, ¶¶ 133, 136, 142.) And the Order expressly relied on these allegations in finding Plaintiffs had adequately pled falsity. (*See* Order at 18 ("The FAC alleges that Defendants made a series of at least fifteen statements during the class period that were misleading because they failed to disclose that the Harmony Study was not properly designed and had disappointing data . . ."); *id.* ("The FAC alleges that '-019 Study's poorly analyzed data and poor design … rendered that dataset far from 'supportive.'"); *id.* at 19 (Defendants "failure to disclose that the studies were not properly designed . . . rendered Defendants' positive statements regarding the results of the studies materially misleading.").)

In a transparent attempt to shift the focus away from inactionable disputes about trial design and analysis, Plaintiffs argue that the Ninth Circuit "has taken a broader view of a drug company's duty to disclose adverse information about clinical trials." (Opp. at 9.) This is a straw man. Neither of the cases Plaintiffs cite concern disputes about trial design. *Cf. Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1010 (9th Cir. 2018); *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 709 (9th Cir. 2016). And both are readily distinguishable, as the "adverse information" that allegedly rendered the statements misleading in those cases had not previously been disclosed. *Cf. Khoja*, 899 F.3d at 1010; *Schueneman*, 840 F.3d at 709. Here, conversely, there is no dispute

that the trial design and subgroup results were publicly disclosed on or before December 4, 2019. (*See* Mot. at 8–9; *infra* Section III.B)

B. The Order Clearly Erred in Finding that the Market Was Not Aware of the Allegedly Omitted Information.

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* Mot. at 8; Order at 20; Opp. at 10–11.)

Here, there is no dispute that Acadia disclosed the allegedly "disappointing" subgroup data on December 4, 2019, and the trial design well before the alleged class period even began. (Mot. at 8 n.6; Opp. at 11; Order at 7, 20–21.) The Order, however, disregarded the December 4 disclosure because it accepted Plaintiffs' ***argument***—untethered to 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.)

Recognizing that it would be clear error for the Court to rely on argument rather than factual allegations, Plaintiffs now insist that they did plead the requisite facts. (Opp. at 11 (quoting ¶¶ 61–62).) But the FAC alleges ***only*** that the Harmony Study results were presented at a healthcare conference. (*See* ¶¶ 61–62.) Plaintiffs' argument that the healthcare conference was ***attended only by "medical professionals"***—as opposed to analysts, investors, and market participants generally—is made up and appears nowhere in the FAC. Put simply, there is ***no allegation*** that the December 4 presentation was disclosed only to medical professionals. Thus, it was clear error for the Court to rely on Plaintiffs' argument. (*See* Order at 20 ("The allegation that the data set of the Harmony Study was released in connection with ***a presentation to medical professionals*** is not sufficient at the pleading stage to establish that this disclosure was sufficient to counterbalance any misleading impression generated by Defendants' omissions."); *see also* Mot. at 9.)

Finally, Plaintiffs do not even address—much less dispute—the fatal contradiction in their complaint. They challenge as false multiple statements made by Defendants at healthcare conferences, which they allege were rapidly digested by the market and incorporated into Acadia's stock price. (Mot. at 9.) But, if as argued by Plaintiffs, healthcare conferences are attended by only medical professionals and any associated disclosure is insufficient to inform the market, then how did Plaintiffs (or any other Acadia stockholder) rely on any purported false statement made at a healthcare conference? Defendants, of course, did not present this argument in their Motion to Dismiss because Plaintiffs did not plead their insufficient-disclosure-to medical-professionals argument in the FAC.[4] Thus, it is patently unfair for the Court to rely on this argument to find falsity when the very same argument undermines the separate, essential element of reliance.

* * *

For these reasons, Defendants respectfully ask the Court to reconsider its falsity findings in accordance with binding Ninth Circuit authority regarding disputes about trial design, the standard for pleading omissions, and the prohibition against relying on facts not alleged in the complaint.

IV. CONCLUSION

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. Defendants

[4] It was in response to Plaintiffs' unsupported argument that the December 4 presentation was made only to medical professionals and thus insufficient to inform the market that Defendants sought judicial notice of analyst reports that included the HARMONY subgroup data presented on December 4. (*See* Mot. at 9 n.7; *see also* ECF No. 58 at 6, 8 n.7; ECF No. 59-1.) These reports are properly subject to judicial notice for the purpose of demonstrating what information was publicly available and when—which goes to the heart of whether the information was presented in a manner sufficient to inform the market. (*See* Mot. at 9–10 n.7.) Accordingly, it was also clear error for the Court to deny judicial notice of these reports.

further request the opportunity to present their arguments orally on December 5, 2022 (or at the Court's convenience) and respond to any questions the Court may have.

Dated: November 28, 2022

Respectfully submitted,

/s/ Peter M. Adams
Peter M. Adams

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