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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

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR RECONSIDERATION

Judge: Hon. William Q. Hayes
Courtroom: 14B
Hearing Date: December 5, 2022

NO ORAL ARGUMENT UNLESS REQUESTED BY THE COURT

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Lead Plaintiff City of Birmingham Relief and Retirement System and additional Plaintiff Ohio Carpenters' Pension Fund (together, "Plaintiffs") submit this Opposition to Defendants' Motion for Reconsideration (Dkt. 75 ("Motion")) and their memorandum of law in support thereof (Dkt. 75-1 ("Br.")).

INTRODUCTION

Defendants' Motion is frivolous. Unhappy with the Court's September 27, 2022 order denying in full their motion to dismiss (Dkt. 65 ("Order")), Defendants have now moved for reconsideration. But Defendants offer ***no*** new evidence or changes in controlling law that might justify reconsideration. *See* Br. at 1–2. Instead, they argue that the Court's carefully reasoned, 27-page Order is so off-base that it constitutes "clear error." *See id.* at 1. This is nonsense. Defendants' Motion does nothing more than recycle their previously rejected arguments in the hope that the Court will give them a "do over," but their displeasure with the Order and desire to avoid "the threat of discovery" (*id.*) provide no grounds for a "second bite at the apple," *Raya v. Calbiotech*, 2019 WL 11504688, at *2 (S.D. Cal. Nov. 26, 2019).

LEGAL STANDARD

"Reconsideration is an ***extraordinary*** remedy, to be used sparingly in the interests of finality and conservation of judicial resources." *City of San Diego v. Monsanto Co.*, 310 F. Supp. 3d 1057, 1062 (S.D. Cal. 2018) (Hayes, J.).[1] Accordingly, "[a] motion for reconsideration should not be granted, absent highly unusual circumstances, unless the district court is presented with newly discovered evidence, committed clear error, or if there is an intervening change in controlling law." *Id.* "A motion for reconsideration is not an opportunity to renew arguments considered and rejected by the court," *FTC v. Neovi, Inc.*, 2009 WL 56130, at *2 (S.D. Cal. Jan. 7, 2009), nor should it be "used to raise arguments or present evidence for the first time" that "could reasonably have been raised earlier," *Marlyn*

[1] Unless otherwise indicated, in quoted materials, all emphasis is added, and all internal quotation marks and citations are omitted.

Nutraceuticals, Inc. v. Mucos Pharma GmbH & Co., 571 F.3d 873, 880 (9th Cir. 2009). Thus, "a party seeking reconsideration must show more than a disagreement with the Court's decision." *Raya*, 2019 WL 11504688, at *2.

Here, Defendants assert that the Order was "clearly erroneous" – which only occurs "when the reviewing court on the entire record is left with the definite and firm conviction that a mistake has been committed." *Miholich v. Senior Life Ins. Co.*, 2022 WL 1505865, at *1 (S.D. Cal. May 12, 2022) (Hayes, J.). "A clear error, or manifest error, is an error that is ***plain and indisputable***[] and that ***amounts to a complete disregard of the controlling law*** or the credible evidence in the record." *Biller v. Peter Rodgers Org. Ltd.*, 2008 WL 11336943, at *1 (C.D. Cal. Nov. 18, 2008). "As the Ninth Circuit has explained the clear error standard, [t]o be clearly erroneous, a decision must strike us as more than just maybe or probably wrong; ***it must . . . strike us as wrong with the force of a five-week old, unrefrigerated dead fish***." *Stroud v. Gore*, 2022 WL 2181576, at *1 (S.D. Cal. June 16, 2022) (citing *Fisher v. Roe,* 263 F.3d 906, 912 (9th Cir. 2001)). No error – let alone some kind of grossly odorous one – happened here.

ARGUMENT

There is no basis on which to grant the Motion. Defendants do not (and cannot) show that the Order turns on "a complete disregard of the controlling law" or otherwise contains clear error, *Biller*, 2008 WL 11336943, at *1, and concede that the Court "quoted" the correct legal standards (*e.g.*, Br. at 2). Instead, what Defendants label as "clear errors" are mere disagreements with how the Court weighed the facts and applied the law, after it reviewed ***60 pages*** of briefing, heard ***one-and-a-half hours*** of oral argument, and prepared its ***27-page*** Order. Where, as here, "[t]here is no indication that [the Court] did not carefully consider the law and the facts," reconsideration for clear error is unwarranted. *Wargnier v. Nat'l City Mortg. Inc.*, 2013 WL 3810592, at *3 (S.D. Cal. July 22, 2013). Indeed, as in *Wargnier*, Defendants' conclusory assertions that the Court's findings are "clear

error" crumble in the face of the ample record that the Order was built on the Court's careful application of the facts alleged to the correct legal standards. Because the Court thoroughly considered all relevant factual allegations in denying Defendants' motion to dismiss – and because Defendants "ha[ve] not identified any controlling law that the Court failed to consider and apply" – there is no purported "clear error" (or any error), and reconsideration is patently unwarranted. *Cummings v. Starbucks Corp.*, 2014 WL 12597110, at *2 (C.D. Cal. May 27, 2014).[2]

I. There Is No Basis to Revisit the Court's Holding on Scienter.

Defendants wrongly assert that the Court's "scienter analysis departs from the requisite application" of the pleading standards. Br. at 2. In doing so, Defendants again urge the Court to "slice and dice" Plaintiffs' allegations by asking it to focus on certain facts in isolation, and by claiming that when viewed separately each is insufficient to plead scienter. *Id.* at 2–6. However, as the Court noted in previously rejecting Defendants' arguments, controlling Supreme Court precedent mandates the opposite approach: "To determine if the scienter requirement is satisfied, a 'court's job is not to scrutinize each allegation in isolation ***but to assess all the allegations holistically***.'" Order at 21 (quoting *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 326 (2007)). And Defendants raise a "red herring" by suggesting that the Court improperly "dr[ew] all [scienter] inferences in favor of Plaintiffs" (Br. at 2), when in fact the Court did no such thing – but instead properly applied *Tellabs*'

[2] Defendants' conspicuous failure to comply with Local Rule 7.1(i)(1) also provides an independent basis to deny reconsideration. That Rule "requires a party seeking reconsideration to show [in a certificate or affidavit] what new or different facts and circumstances are claimed to exist which did not exist, or were not shown," in the "prior application" for which reconsideration is sought. *Strobel v. Morgan Stanley Dean Witter*, 2007 WL 1053454, at *2 (S.D. Cal. Apr. 10, 2007) (quoting CivLR 7.1(i)(1)) (denying motion for reconsideration ***solely*** for failure to identify "any [such] new or different facts and circumstances"); *see also Neovi*, 2009 WL 56130, at *2 (when a reconsideration motion is "based on judicial error," a movant's failure to "offer[] the Court new facts or circumstances that were not presented in the[] prior" application in an accompanying affidavit or certification is a "legal deficienc[y]"). Defendants' attorney declaration in support of the Motion fails to identify any new or different facts and circumstances that did not exist, or were not shown, in Defendants' motion-to-dismiss papers. Dkt. 75-2 ¶¶1–6.

mandate to "weigh[] ***competing inferences*** from the underlying allegations" to determine "if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference." Order at 21 (quoting *Tellabs*, 551 U.S. at 324). In sum, in assessing scienter, the Court properly "[w]eigh[ed] all of the allegations holistically" and "f[ound] that a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw." *Id.* at 25. Defendants' other scienter arguments are equally unavailing.

A. Acadia's "Agreement" with the FDA Was Not "Unspecified."

Defendants assert that the Court "improperly credit[ed] conclusory allegations of Defendants' 'access' to unspecified information," and improperly relied on "unspecified information" that was "not link[ed to] any specific reports." Br. at 2–3. This baffling assertion reprises their prior argument[3] that Plaintiffs were somehow required to plead the exact contents of confidential, non-public "FDA minutes" that ***Defendants*** claim to exist – but which ***Defendants*** have steadfastly continued to conceal. In all events, any contention that Acadia's "agreement" with the FDA was "unspecified" ignores Plaintiffs' allegations. Instead, as the Court held, ***Defendants' own*** statements purported to describe the material terms of their (alleged) agreement with the FDA, even if its terms can only be found in non-public "FDA minutes." *E.g.*, Order at 5–7, 15–17, 22–23.

Indeed, as the Court properly held, the Complaint's quotations of ***Defendants' own*** statements, read as a whole and in context, provide ample "specific" allegations of how Defendants ***publicly represented*** "that the FDA agreed to the Harmony Study's design, agreed to analyze DRP as a single group, and did not require statistical significance by subgroup" (*id.* at 23–25), and also specified how and why such representations were adequately alleged to be materially false and misleading.

[3] Alternatively, if viewed as a "new" argument, Defendants would fare no better, as reconsideration motions "[are] not the correct vehicle to relitigate arguments that should have been made in a prior motion." *Raya*, 2019 WL 11504688, at *2; *see also, e.g.*, *Stroud*, 2022 WL 2181576, at *2.

Id. at 13–16. ***And***, as the Court concluded, "[Plaintiffs'] assertions support an inference" of scienter because the existence of the kind of agreement that ***Defendants*** claim to exist was "ultimately not consistent with the FDA's rationale for denying approval." *Id.* at 23. Defendants' bizarre argument that Plaintiffs must allege specific facts ***from*** "the FDA minutes" where the agreement was documented (Br. at 3) simply misses the point in two ways. *First*, it is ***Defendants*** who are relying on terms of a purported agreement that Plaintiffs believe do not exist (and which Defendants continue to conceal). *Second*, as the Court correctly held, the relevant scienter issue is whether Plaintiffs adequately allege that "[Defendants] intended that ***their . . . statements*** be understood by investors as suggesting Acadia and the FDA had reached agreements concerning test design and analysis," when such statements were inconsistent with the FDA's subsequent reasons for denying approval. Order at 23. None of the inapposite cases on which Defendants rely are to the contrary.[4]

Defendants also argue that the Court failed to grasp basic scienter pleading standards when it weighed "[t]he FAC's allegations that Defendants affirmatively misrepresented the terms of the purported agreement with the FDA" and concluded that they "support[ed] an inference that Defendants acted with intent or deliberate recklessness." *Id.* at 22; *see* Br. at 4. But under *Tellabs*, "the court's job is not to scrutinize each allegation in isolation but rather to reassess all the allegations holistically." Order at 21. And here, contrary to Defendants' insinuations, the Court considered ***all*** plausible scienter inferences that could be drawn from the facts alleged (including that Defendants would have been aware of the terms of any

[4] *See Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1062 (9th Cir. 2014) (no inference of scienter where complaint "lack[ed] allegations of specific admissions by the individual defendants regarding their involvement with Intuitive's operations"); *In re Silicon Graphics, Inc. Sec. Litig.*, 183 F.3d 970, 985 (9th Cir. 1999) (no inference of scienter where plaintiff alleged "a belief that certain unspecified sources will reveal, after appropriate discovery," that internal reports would detail "chip shortages, volume shortages, [and negative] projections").

agreement with the FDA), weighed them against any competing inferences, and concluded that the inference of scienter was at least as compelling as any alternative. *Id.* at 25. No aspect of the Court's analysis was error (let alone "plain error").

B. The Court Properly Weighed Defendants' Suspicious Stock Sales.

Defendants next argue the Court erred because (they claim) the allegations of insider stock sales here "cannot" support a strong inference of scienter. Br. at 4.

First, this argument recycles the ***same*** points and ***same*** cases that Defendants already made at the motion-to-dismiss stage. Specifically, they assert that "stock sales suggest only a motive [and opportunity] to commit fraud," which "cannot support a strong inference of scienter." Br. at 4 (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009)). This is exactly what they unsuccessfully argued before. Dkt. 53-1 ("Defs.' MTD Br.") at 22 ("At best, Plaintiffs allege a motive to commit fraud and [the] opportunity to do so, which is insufficient." (citing *Zucco*, 552 F.3d at 990–91)). A "motion for reconsideration is not an opportunity to renew arguments [previously] considered and rejected," *Neovi*, 2009 WL 56130, at *2, "[n]or is it a mechanism . . . to ask the court to rethink what the court has already thought through," *Wargnier*, 2013 WL 3810592, at *3. And to reconsider Defendants' rehashed arguments concerning 10b5–1 plans (*compare* Defs.' MTD Br. at 22–23, *with* Br. at 4 n.3) would be equally inappropriate.

Second, Defendants' argument is also meritless because it falsely assumes that the Court based its entire scienter analysis on only the stock-sale allegations, when it is obvious that such sales were just one piece of the Court's holistic review. Order at 21, 23–24. Having "carefully and correctly set out the law governing the issues raised, and clearly articulate[d] the reasons underlying its decisions," the Court's consideration of stock sales, as just one part of its analysis, was not clear error – or anything close. *Ausmus v. Lexington Ins. Co.*, 414 F. App'x 76, 77 (9th Cir. 2011).

C. The Court Properly Considered Competing Inferences of Scienter.

Equally meritless is Defendants' argument that the Court failed to

"appropriately weigh all nonculpable inferences against those favoring Plaintiffs." Br. at 4. Nothing in the Order suggests such a failure. To the contrary, the Court expressly stated that "[w]eighing ***all*** of the allegations holistically, . . . a reasonable person would deem the inference of scienter cogent and ***at least as compelling as any opposing inference*** one could draw." Order at 25.

First, attempting to manufacture such a failure, Defendants claim that the Court, in its scienter analysis, "improperly discount[ed] ***any*** nonculpable inference arising from [their] December 4, 2019[] release of the HARMONY trial results." Br. at 4. Not so. The Court expressly reasoned that "Defendants' release of the Harmony Study's dataset in connection with a presentation to medical professionals" provided ***some*** support for a "competing inference" that "Defendants did not intentionally or recklessly mislead investors." Order at 24. The Court properly held, however, that this nonculpable inference was outweighed here because the "disclosure occurred almost three months after the initial actionable omission," and "was followed by Defendants' [further misleading] assurances that Acadia had an agreement with the FDA." *Id.* Also, disclosure of Harmony's bare top-line results is not what mattered here. Instead, what mattered was the selective disclosure of those results ***in this context***, where Defendants knew (or recklessly disregarded) that, because of its questionable design, Harmony was likely insufficient to support FDA approval absent either (i) exceptionally strong sub-group performance, or (ii) clear agreement by the FDA that sub-group performance was irrelevant – and they also knew (at the time of disclosure) that neither condition was met. *Id.* at 19.

Second, Defendants challenge the Court's inference of scienter, from the facts alleged, "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." Br. at 5 (quoting Order at 23). But Defendants do not explain how the Court allegedly erred in this regard, and instead resort to a "bald assertion

that [the Court's] findings" in this regard were "a clear error of law," *Wargnier*, 2013 WL 3810592, at *3 – while turning a blind eye to the Order's clear and detailed explanation of why the Court drew an inference of fraudulent intent, rather than one of less culpable behavior. *See, e.g.,* Order at 21–25.

Third, Defendants argue that the Court should have "consider[ed] the nonculpable inference" that Acadia was "just as surprised as investors" when the FDA denied its sNDA. Br. at 5–6. However, the Order plainly shows that the Court ***did*** carefully consider both culpable and nonculpable inferences arising from the facts alleged. Order at 21–25. Having "carefully and correctly set out the law governing the issue[] raised, and clearly articulate[d] the reasoning underlying its decision," there is simply no basis for the Court to find clear error (or any error at all). *Ausmus*, 414 F. App'x at 77.

II. There Also Is No Basis to Revisit the Court's Holding on Falsity.

Defendants' suggestion that the Court's "falsity analysis departs from controlling law in two ways" is also baseless. Br. at 6.

A. Defendants Did Omit Material Information About Their Studies That Rendered Their Statements Materially False or Misleading.

With respect to falsity, Defendants primarily argue that the Court should have found Plaintiffs' allegations to be "disagreements over statistical methodology and study design," which are insufficient to allege a materially false statement or constitute mere pleading of "fraud by hindsight." *Id.* at 6–7.

Defendants are once again improperly rehashing prior arguments that were fully addressed in the parties' prior briefing (MTD Br. at 17–18; Dkt. 56 (Pls.' MTD Opp'n) at 15–16), and which the Court considered and properly rejected. Order at 17–20; *see also Wargnier*, 2013 WL 3810592, at *2 ("The Court will not reconsider arguments and law that were previously considered and ruled upon by the Court.").

Moreover, Defendants' reliance on *In re Rigel Pharmaceuticals, Inc. Securities Litigation*, 697 F.3d 869 (9th Cir. 2012) and *Padnes v. Scios Nova Inc.*,

1996 WL 539711 (S.D. Cal. Sept. 18, 1996) is unavailing because the issue in this case is ***not*** a bare disagreement on the statistical methodology to be used in a clinical trial. *See, e.g.*, Order at 18–19. Instead, as the Court correctly found, Plaintiffs allege that Defendants (i) ***misrepresented a purported agreement with the FDA about the design*** of their Harmony trial (*id.* at 14–17), ***and*** (ii) misleadingly touted Harmony's purported "success" even though they knew that FDA approval for using pimavanserin to treat additional DRP sub-types was ***unlikely*** absent either exceptionally strong sub-group results or clear FDA agreement that sub-group data would be irrelevant (*id.* at 17–20).

Neither *Rigel* nor *Padnes* involved remotely similar allegations. For example, in *Rigel*, plaintiff's falsity allegations were based on the contention that "defendants should have used a particular statistical methodology" that differed from the one that they actually used to calculate a study's results. 697 F.3d at 877. Here, by contrast, Plaintiffs' falsity allegations do not involve second-guessing how Defendants ***calculated*** the studies' results. Similarly, Defendants cite *Padnes* to argue that they had "no obligation to second-guess the[ir] methodology."[5] Br. at 7. But in *Padnes*, the district court simply found that plaintiffs had "not pled facts sufficient to explain why defendants' summaries of the [relevant] study were false or misleading when made." 1996 WL 539711, at *5. And, in all events, the Ninth Circuit authority that the Court properly relied on has taken a broader view of a drug company's duty to disclose adverse information about clinical trials, in order to prevent defendants from using selective disclosures of positive data to materially mislead investors as to, *e.g.*, the actual risks of FDA rejection. *See Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1010 (9th Cir. 2018) ("[O]nce Orexigen chose to tout the apparently positive 25 percent interim results, [it] had the obligation also to disclose that they were likely unreliable."); *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 707

[5] Defendants did not previously cite *Padnes,* but that 25-year-old, non-binding district court case adds nothing and could have been cited before.

(9th Cir. 2016) ("[O]nce defendants chose to tout [lorcaserin's likely approval by referencing allegedly positive animal and preclinical studies], they were bound to do so in a manner that wouldn't mislead investors as to [potentially negative information within their possession]." (alteration in original)); Order at 19–20.

B. The Court Did Consider Defendants' Purported Disclosures.

Defendants next contend that the Court "disregarded" that certain allegedly omitted material information had been disclosed. Br. at 8–9. The Court, however, plainly ***did*** consider this argument – and properly rejected it (Order at 17–21) – so this is no basis for reconsideration. *E.g.*, *Neovi*, 2009 WL 56130, at *2.

Defendants also gloss over the Court's findings that (i) disclosure of the Harmony data set "did not occur until . . . almost three months after the first allegedly misleading statement"; and (ii) the "omitt[ed]" information about the studies' designs and results must be viewed in the ***context*** of "Defendants' alleged misrepresentations concerning the agreement with the FDA" (including Defendants' false assurances that the FDA had "agreed" that it would not require Harmony to produce strong sub-group data before it would approve expanding pimavanserin's indication). Order at 19, 21. As the Court found, these misrepresentations show that "Defendants knew that the studies' shortcomings would materially increase risk that the [supplemental pimavanserin drug application] would not be approved." *Id.* at 19.

The Court also correctly found that Defendants' "disclosure" arguments were, alternatively, also insufficient to merit dismissal because they were based on what was ultimately a premature "truth-on-the-market" defense. *Id.* at 20. Defendants try to relitigate this point by asserting that "truth-on-the-market" doctrine only applies when "the information was made credibly ***available*** to the market ***by other sources***." Br. at 8. But Defendants' cited authority, *In re Obalon Therapeutics, Inc.*, 2019 WL 4729461, at *6 (S.D. Cal. Sept. 25, 2019), is narrower than the controlling Ninth Circuit cases that the Court relied on. *See* Order at 20 ("[I]n a 'fraud on the market' case 'an omission is materially misleading only if the information has not already

entered the market.'" (quoting *Provenz v. Miller*, 102 F.3d 1478, 1492 (9th Cir. 1996))); *see also Conn. Ret. Plans & Tr. Funds v. Amgen Inc.*, 660 F.3d 1170, 1174 (9th Cir. 2011) (same). Moreover, "before the truth-on-the-market doctrine can be applied" at all, Defendants first "must prove that the [omitted] information . . . was transmitted to the public with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression," which the Court found they had not done. Order at 20 (quoting *Provenz*, 102 F.3d at 1492–93). Indeed, even assuming *arguendo* that certain sub-group data had entered the market, none of the critical ***contextual*** information as to the FDA's views about the importance of such data had entered the market (let alone with sufficient intensity to dispel Defendants' misrepresentations about the FDA's purported agreement that sub-group data would be immaterial). *Id.* at 19, 21.

Finally, Defendants argue that the Court's finding that the December 4 presentation "was made only to medical professionals" was "unsupported by the allegations in the [Complaint]." Br. at 9. Not so. The Complaint alleges that Acadia "would present the Harmony Study results at the 12th Clinical Trials on Alzheimer's Disease . . . meeting in December 2019," *i.e.*, a healthcare conference for medical professionals, and that "[o]n December 4, 2019, Acadia presented the Harmony Study's top-line results." Dkt. 45 ¶¶61–62. Thus, the Court did not ignore any relevant allegations or erroneously fail to accept ***Defendants'*** view of the credible weight of evidence on a matter for which they (and not Plaintiffs) bear the burden of proof.[6] *See, e.g.*, *Provenz*, 102 F.3d at 1492–93 ("The defendants bear a heavy

[6] Defendants' conclusory argument that "statements made at healthcare conferences were rapidly digested by the market" (Br. at 9) is simply another rehash of their previously rejected truth-on-the-market ***defense***. The Court's rejection of Defendants' loss-causation arguments and the Court's unwillingness to take judicial notice of two analyst reports attached to their motion-to-dismiss reply brief (*see* Dkt. 59 at 9 n.7) were not only plainly correct on the merits, but were also correct based on Defendants' failure to raise them in their opening briefs. *See, e.g.*, *De Souza v. Dawson Tech., Inc.*, 2022 WL 3006045, at *3 n.2 (S.D. Cal. July 28, 2022) ("[A]rguments raised for the first time in a reply brief are waived.").

burden of proof" to establish that "the truth-on-the-market doctrine can be applied.").

CONCLUSION

Having identified no error – much less one rising to the level of a "complete disregard of the controlling law or the credible evidence," *Biller*, 2008 WL 11336943, at *1 – Defendants' Motion for Reconsideration should be denied.

DATED: November 21, 2022

Respectfully submitted,

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