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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-MSB

CLASS ACTION

DEFENDANTS' SURREPLY IN OPPOSITION TO PLAINTIFFS' MOTION FOR CLASS CERTIFICATION AND APPOINTMENT OF CLASS REPRESENTATIVES AND CLASS COUNSEL

Courtroom: 14B
Judge: Hon. William Q. Hayes

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I. INTRODUCTION

Plaintiffs' Reply is dumbfounding. It ignores binding legal authority and asks the Court to do the same. It fails to meaningfully address, much less overcome, Defendants' evidence demonstrating a lack of price impact. It concedes that there was an agreement between the FDA and Acadia (in fact, several agreements), which Defendants repeatedly disclosed to investors. And, it abandons Plaintiffs' entire theory of fraud in favor of a new one that is not alleged in their Complaint.[1]

For the reasons set forth in Defendants' Opposition, as well as the additional reasons addressed herein, Plaintiffs' motion for class certification should be denied.

II. ARGUMENT

A. The Court Must Consider Defendants' Price Impact Evidence Despite Any Overlap with Materiality or Loss Causation.

Defendants' Opposition and the accompanying expert report of Rene Stulz (ECF No. 117-3, "Stulz Opening Rpt.") presented evidence demonstrating that the alleged misrepresentations had no price impact. (Opp'n at 8–21; Stulz Opening Rpt. at ¶¶ 61–138; *see also* ECF No. 117-2 (appendices identifying public disclosures to support price impact analysis).) This included, among other things, evidence that Acadia ***publicly disclosed all of the allegedly omitted information*** about the Harmony Study design and results ***well in advance*** of the alleged corrective disclosures—thus demonstrating a complete lack of price impact with respect to such allegations. (Opp'n at 10–15.) Defendants' Opposition also demonstrated that the allegedly omitted information about the -019 Study design and results was publicly disclosed before the alleged corrective disclosures.[2] (*Id.* at 15–17.)

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[1] Unless otherwise noted, emphasis is added, internal quotation marks and alterations are omitted, and defined terms have the same meaning as set forth in Defendants' Opposition to Plaintiffs' Motion for Class Certification and Appointment of Class Representative and Class counsel (ECF No. 117, "Opposition" or "Opp'n").

[2] Although the disclosures about certain protocol deviations in the -019 Study were less robust, Defendants have identified sufficient information to meet their burden to

Plaintiffs ***do not dispute*** that all of this information ***was*** publicly disclosed. Nor does their expert, Professor Feinstein. (*See generally,* ECF No. 122-4 ("Feinstein Rebuttal Rpt.").) Instead, Plaintiffs argue that the Court should ***disregard*** this evidence because, according to Plaintiffs, it is nothing more than a dispute about materiality (*i.e.*, truth on the market) and loss causation. (Reply (ECF No. 122) at 12–13.) Plaintiffs are wrong.

The Supreme Court instructs that courts "***must*** take into account all record evidence relevant to price impact, regardless [of] whether that evidence overlaps with materiality or any other merits issue." *Goldman Sachs Grp., Inc. v. Ark. Tchr. Ret. Sys.*, 141 S. Ct. 1951, 1961 (2021) (emphasis modified). To do so, a district court must "(a) decide whether reliance can be proven by common evidence without (b) delving too far into the merits of the materiality or falsity of the representations at issue, while still (c) reserving loss causation entirely for the merits phase[.]" *In re Allstate Corp. Sec. Litig.*, 966 F.3d 595, 608 (7th Cir. 2020). This is no easy task, but the Seventh Circuit has explained how district courts can reconcile what may seem to be contradictory guidance in *Halliburton I*, *Amgen*, and *Halliburton II*[3]:

> We are obliged to follow all three cases, and we must read them together. A district court deciding whether the *Basic* presumption applies must consciously avoid deciding materiality and loss causation. *Halliburton I* and *Amgen* require that much. At the same time, a district court ***must be willing to consider evidence offered by the defense to show that the alleged misrepresentations did not actually affect the price of the securities***. *Halliburton II* requires that. And yes, the same evidence is likely to have obvious implications for the off-limits merits issues of materiality and loss causation. *Halliburton II* teaches, however, that a district court ***may not use the overlap to refuse to consider the evidence.*** The court ***must still consider the evidence as relevant to price impact*** (also known as transaction causation).

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demonstrate that it was more likely than not that this alleged omission had no price impact. (*See* Stulz Opening Rpt., ¶¶ 100–01, 116–17 (identifying disclosures about certain protocol deviations).)

[3] *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804 (2011) (*Halliburton I*); *Amgen Inc. v. Conn. Ret. Plans and Tr. Funds*, 568 U.S. 455 (2013) (*Amgen*); *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258 (2014) (*Halliburton II*).

Allstate, 966 F.3d at 608 (vacating class certification order for failure to consider evidence relevant to price impact).

Plaintiffs invite this Court to do exactly the opposite: "embrac[e] *Amgen* at the expense of *Halliburton II*." *Id.* at 609. (*See* Reply at 12–13 (relying on *Amgen* but ignoring *Halliburton II*).)[4] The Court should reject Plaintiffs' misguided invitation, and instead "engag[e] in the messier but required process of simultaneously complying with the instructions from the Supreme Court in both [*Amgen* and *Halliburton II*]." *Allstate*, 966 F.3d at 609. In other words, the Court must consider Defendants' price impact evidence, regardless of any overlap it may have with materiality or loss causation. *Id.*; *see also Goldman*, 141 S. Ct. at 1963.

And here, that evidence allows for only one conclusion: the stock price drops following the alleged corrective disclosures do not support the inference that the alleged omissions about the Harmony and -019 Studies designs or results had any price impact at the time the purported misrepresentations were made. (Opp'n at 8–10.) That is because Plaintiffs "try to prove the amount of inflation indirectly: They point to a negative disclosure about a company and an associated drop in its stock price; allege that the disclosure corrected an earlier misrepresentation; and then claim that the price drop is equal to the amount of inflation maintained by the earlier misrepresentation." *Goldman*, 141 S. Ct. at 1961. But, because "the [alleged] corrective disclosures did not actually contain new information correcting the alleged misrepresentations, it becomes less likely that their announcement caused the back-end price drops and less reasonable to assume that Defendants' alleged misrepresentations caused front-end inflation in the first place." *See In re Qualcomm*

[4] Plaintiffs' reliance on *Junge* and *Karinski* is equally misguided. (Reply at 13 (citing *Junge v. Geron Corp.*, 2022 WL 1002446, at *6 (N.D. Cal. Apr. 2, 2022) and *Karinski v. Stamps.com*, 2020 WL 6572660, at *7 (C.D. Cal. Nov. 9, 2020)).) The defendants in *Junge*, did not raise—and therefore the court did not even consider—price impact arguments. And *Karinski* predates the Supreme Court's admonition in *Goldman* that the court "***must*** take into account all record evidence relevant to price impact, regardless [of] whether that evidence overlaps with materiality or any other merits issue." *Goldman*, 141 S. Ct. at 1961 (emphasis modified).

Inc. Sec. Litig., 2023 WL 2583306, at *13 (S.D. Cal. Mar. 20, 2023). This is precisely what the evidence presented in Defendants' Opposition, and in Dr. Stulz's accompanying expert report, proved. (*See* Opp'n at 8–21; Stulz Opening Rpt. at ¶¶ 61–138.) Nothing in Plaintiffs' Reply undermines that evidence or refutes Defendants' price impact arguments. And nothing in Plaintiffs' expert's report rebuts Dr. Stultz's price impact opinions. (*See* Ex. A ("Stulz Reply Rpt.") (addressing mischaracterizations and absence of meaningful analysis in Prof. Feinstein's rebuttal report).)

Accordingly, Defendants have rebutted the *Basic* presumption as to any alleged misrepresentations based on the purported omissions (regarding the design and results of the Harmony and -019 Studies). Any certified class definition, therefore, must ***exclude*** that theory of liability. *See Qualcomm*, 2023 WL 2583306, at *14, *17 (denying class certification on theories for which defendants successfully rebutted *Basic* presumption by demonstrating lack of price impact).

B. The Only Disputed Issue Identified in Plaintiffs' Reply Is One that Plaintiffs Did Not Allege in the Complaint.

Defendants have demonstrated lack of price impact with respect to the alleged omissions about the design and results of the Harmony and -019 Studies. Thus, only one issue remains: whether a class can be certified based on the alleged misrepresentations about the FDA agreement. That issue, as Plaintiffs' Reply makes clear, is the linchpin of their entire case. Indeed, Plaintiffs insist that Defendants' disclosures about the Harmony Study design and results cannot be analyzed separately from the disclosures about Acadia's agreement with the FDA because the two are "necessarily interrelated." (Reply at 2, 13–16.)

This, of course, is a cop-out. Plaintiffs cannot dispute that the Harmony Study design and results were publicly disclosed well before any alleged corrective disclosures. So, they argue that the issue was never about the design and results ***in isolation***, but rather, Defendants' statements about the design and results ***coupled***

with misstatements about the FDA agreement. But that is simply a round-about way of admitting that no alleged omission about the Harmony Study design or results inflated Acadia's stock price.[5]

All, then, that remains is a dispute about the FDA agreement. But Plaintiffs have changed their theory on this too. The Complaint alleges that "Defendants [f]abricate[d] the [e]xistence of an 'Agreement'" (Compl. at 21), that "no such agreement actually existed" (*id.*, ¶ 92), and that "no such agreement was reached" (*id.*, ¶¶ 110, 129; *see also* ¶¶ 112, 118, 126, 133, 136). ***But Plaintiffs now concede that Acadia and FDA "reached 'several' agreements on May 15, 2017," and that "[t]hese agreements were documented in FDA's meeting minutes***." (Reply at 2.)

In other words, Plaintiffs' Reply does far more than simply narrow the issues in dispute: it rewrites Plaintiffs' entire theory of fraud. On the pleadings, this was a dispute about the ***existence*** of an agreement with the FDA. It has now morphed into a dispute about whether Defendants misled investors by failing to disclose a single sentence ***about labeling*** from the FDA's 15-page End of Phase 2 meeting minutes: "Labeling will reflect the actual composition and response of patients enrolled in the study." (Reply at 16–18.)[6]

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[5] Plaintiffs dedicate a surprising amount of space to arguments about the statistical significance of the stock price increase at the start of the proposed class period, and of the stock price declines following the alleged corrective disclosures. (Reply at 10–13.) As Plaintiffs concede, however, such evidence demonstrates only that "***something*** Acadia-specific was impacting Acadia's share price on September 9, 2019 and March 9 and April 5, 2021"; it does not resolve "what ***caused*** the price impact on those days." (*See id.* at 12.) And it is the ***cause*** of that price impact that matters. Unless the price impact was ***caused by the alleged misrepresentations***, Plaintiffs cannot rely on the *Basic* presumption, and individual issues of reliance will predominate. *See Halliburton II*, 573 U.S. at 282–83. Thus, Plaintiffs' arguments about the statistical significance of the stock price movements on these dates are irrelevant to this analysis.

[6] In their recitation of the "Background," Plaintiffs make passing reference to the FDA's comments (in the EOP2 meeting minutes) expressing some initial concerns with the randomized withdrawal trial design (Reply at 3). But, tellingly, Plaintiffs do not claim that the omission of this information rendered ***any statement*** materially false or misleading. This is unsurprising because Defendants expressly told investors

The Complaint, however, contains no allegations that Defendants misled investors about what the label might reflect if pimavanserin were approved for DRP. (*See generally* Compl.) And "Plaintiffs may not certify a class based on claims not asserted in the complaint." *Waine-Golston v. Time Warner Ent.-Advance/New House P'ship*, 2012 WL 6591610, at *3 (S.D. Cal. Dec. 18, 2012) *see also Rivera v. Invitation Homes, Inc.*, 2022 WL 504161, at *4 (N.D. Cal. Feb. 18, 2022) ("Class certification is not a time for asserting new legal theories that were not pleaded in the complaint.") (quoting *Brown v. Am. Airlines, Inc.*, 285 F.R.D. 546, 560 (C.D. Cal. 2011)); *Bathe v. United States*, 2021 WL 981230, at *2 n.1 (N.D. Cal. Mar. 16, 2021) ("It is axiomatic that the complaint may not be amended by the briefs.").

If Plaintiffs intend to pursue a new theory of liability, as it appears they do, the proper course is to seek leave to amend the Complaint.[7] Plaintiffs have had ample time and opportunity to do so, given that their new theory of fraud is premised entirely on the End of Phase 2 meeting minutes and the Complete Response Letter, which were produced in April and May 2023, respectively. (Declaration of Christopher B. Durbin in Support of Defendants' Surreply in Opposition to Plaintiffs' Motion for Class Certification ("Durbin Decl."), ¶ 4–5.)[8]

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that Acadia's policy is to not comment on the specific back-and-forth with the FDA. (¶ 132). And this position is fully supported by a wealth of legal authority. *See In re Dynavax Sec. Litig.*, 2018 WL 2554472, at *7 (N.D. Cal. June 4, 2018) (company's "failure to disclose the subject of an ongoing dialogue with the FDA does not constitute a material omission.");*Yan v. ReWalk Robotics Ltd.*, 973 F.3d 22, 40 (1st Cir. 2020) ("a failure to divulge the details of interim regulatory back-and-forth with the FDA when the defendants do provide warnings in broader terms does not generate a strong inference of scienter."); *In re Sanofi Secs. Litig.*, 87 F. Supp. 3d 510, 534 (S.D.N.Y. 2015) ("The law [does] not impose an affirmative duty to disclose the FDA's interim feedback just because it would be of interest to investors.").

[7] Although it is not the focus of their Reply, Plaintiffs also argue that Defendants misleadingly omitted details about Acadia's back-and-forth with the FDA regarding the lack of priority review. (Reply at 5–6.) As with their new theory about labeling, this theory was not alleged in the Complaint and is, thus, improper to raise now.

[8] Adding insult to injury, Plaintiffs accuse Defendants of "sophistry or sleight-of-hand" for failing to "grapple with Plaintiffs' ***actual*** falsity theory" (Reply at 9, 14 (emphasis in original)). But it is Plaintiffs who waited until their ***Reply*** to class certification to ambush Defendants (and the Court) with this new theory.

C. A Class Cannot Be Certified Based on Plaintiffs' New Unpled Theory of Fraud.

In addition to the procedural improprieties addressed above, deciding class certification on Plaintiffs' unpled theory of fraud is both unworkable and prejudicial.

First, it is unworkable because Plaintiffs do not specifically identify which statements are allegedly rendered misleading by this new "labeling" omission. Because this is the ***only*** undisclosed information that Plaintiffs contend supports price impact,[9] the class period cannot begin before any such alleged misstatement. Indeed, Plaintiffs themselves read Judge Ohta's recent *Qualcomm* decision as requiring the Court to consider the specific statements that are alleged to be misleading and the reasons why each statement is alleged to be misleading. (Reply at 18–20 (citing *Qualcomm*, 2023 WL 2583306, which details the alleged misstatements applicable to each theory of liability and excludes alleged misstatements about licensing from the certified class).)

Here, the earliest alleged misstatements (those made on September 9, 2019), have nothing to do with labeling. (¶¶ 107, 109.) How, then, could any purported omission about labeling requirements render such statements materially false or misleading? Plaintiffs have no answer, because an actionable omission "***must be misleading***; in other words it must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002); *see also id.* ("No matter how detailed and accurate disclosure statements are, there are likely to be additional details that could have been disclosed but were not."). And despite Defendants' repeated attempts to get clarity from Plaintiffs on which specific

[9] Plaintiffs also make passing reference to the protocol deviations in the -019 Study but ignore Defendants' analysis that certain disclosures about those deviations were, in fact, made prior to the alleged corrective disclosures. (Stulz Rpt., ¶¶ 100–01, 116–17.)

statements are at issue and why they are allegedly misleading, Plaintiffs have refused. (Durbin Decl., ¶¶ 6–17.)

Second, proceeding directly to class certification on an unpled theory of fraud is prejudicial because it deprives Defendants of the opportunity to seek dismissal on the pleadings as a matter of law. On this point, *In re NCAA Student-Athlete Name & Likeness Licensing Litigation* is particularly instructive. 2013 WL 4830967 (N.D. Cal. Sept. 10, 2013). Like here, the plaintiffs in that case raised a new theory of liability at class certification. *Id.* at *1–2. The court agreed with defendants that "it would be useful for [p]laintiffs to file an amended complaint explicitly addressing their new theory of antitrust liability," and ordered plaintiffs to amend their complaint to conform to their class certification motion. *Id.* at *1. However, rather than allowing defendants to file new motions to dismiss, the court required defendants to defer those arguments until summary judgment. *Id.* The defendants objected and sought leave to file further motions to dismiss because they "must be permitted to test the legal sufficiency of any new theory in the [amended complaint] before the Court certifies a class." *Id.* at *2. Despite the court's "reluctan[ce] to delay this case further," the court recognized that "[d]efendants may intend to seek an interlocutory appeal of any class certification order" and the court "d[id] not wish to leave open a claim that [defendants] were not allowed to present all of their arguments." *Id.* at *1–2. The court thus felt "compelled to allow an additional round of motions [to dismiss] . . . due to Defendants' insistence on pursuing all available procedural steps, and the untimely changes in Plaintiffs' theory of the case." *Id.* at *1. In doing so, the court retracted its prior order that would have prevented defendants from addressing plaintiffs' new theory of liability until summary judgment. *Id.* at *1–2.

Likewise, the fact that Defendants will have the opportunity to seek dismissal at summary judgment is not a solution here for at least two reasons. First, without an amended complaint, Defendants remain in the dark as to which statements were

allegedly rendered misleading by Plaintiffs' new "labeling" theory. Second, it ignores the fact that Defendants will spend millions of dollars and countless hours on depositions based on a theory of fraud that has not even been tested at the pleading stage.

The point here is not to debate the merits of Plaintiffs' new unpled theory in this briefing. Defendants would not even know where to start such a debate until Plaintiffs identify specifically which statements were purportedly rendered misleading by the labeling omission. The point is that a class cannot be certified based on an unpled theory of fraud, ***especially*** where there is not even enough information to determine what the class period would be if this theory were found sufficient to survive a motion to dismiss. *See O'Connor v. Boeing N. Am., Inc.*, 197 F.R.D. 404, 416 (C.D. Cal. 2000) ("A class definition should be precise, objective, and presently ascertainable.").

III. CONCLUSION

For the reasons above and those in Defendants' Opposition, the Court should deny Plaintiffs' Motion for Class Certification and Appointment of Class Representatives and Class Counsel.

Dated: January 12, 2024

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By: */s/ Peter M. Adams*
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