

20-3488

*Liu et al. v. Intercept Pharm. Inc. et al.*

UNITED STATES COURT OF APPEALS  
FOR THE SECOND CIRCUIT

SUMMARY ORDER

RULINGS BY SUMMARY ORDER DO NOT HAVE PRECEDENTIAL EFFECT. CITATION TO A SUMMARY ORDER FILED ON OR AFTER JANUARY 1, 2007, IS PERMITTED AND IS GOVERNED BY FEDERAL RULE OF APPELLATE PROCEDURE 32.1 AND THIS COURT'S LOCAL RULE 32.1.1. WHEN CITING A SUMMARY ORDER IN A DOCUMENT FILED WITH THIS COURT, A PARTY MUST CITE EITHER THE FEDERAL APPENDIX OR AN ELECTRONIC DATABASE (WITH THE NOTATION "SUMMARY ORDER"). A PARTY CITING TO A SUMMARY ORDER MUST SERVE A COPY OF IT ON ANY PARTY NOT REPRESENTED BY COUNSEL.

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 16<sup>th</sup> day of June, two thousand twenty-two.

PRESENT:

SUSAN L. CARNEY,  
RICHARD J. SULLIVAN,  
*Circuit Judges,*  
J. PAUL OETKEN,  
*District Judge.\**

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HOU LIU, AMY FU,

*Plaintiffs-Appellants,*

JUDITH DESMET,  
INDIVIDUALLY AND ON BEHALF  
OF ALL OTHERS SIMILARLY SITUATED,

*Plaintiff,*

v.

No. 20-3488

INTERCEPT PHARMACEUTICALS, INC.,  
MARK PRUZANSKI, SANDIP S. KAPADIA,

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\* Judge J. Paul Oetken, of the United States District Court for the Southern District of New York, sitting by designation.

RICHARD KIM, RACHEL MCMINN,

*Defendants-Appellees.*

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FOR PLAINTIFFS-APPELLANTS: MEGAN M. REMMEL (Richard W. Gonnello, *on the brief*), Faruqi & Faruqi, LLP, New York NY.

FOR DEFENDANTS-APPELLEES: SHAY DVORETZKY (James R. Carroll, Scott D. Musoff, Alisha Q. Nanda, *on the brief*), Skadden, Arps, Slate, Meagher & Flom LLP, New York, NY.

Appeal from an order of the United States District Court for the Southern District of New York (Kaplan *J.*).

**UPON DUE CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED** that the order entered on September 9, 2020, is **AFFIRMED.**

Plaintiffs-Appellants Hou Liu and Amy Fu (“Plaintiffs”) appeal from an order of the district court denying their requests for reconsideration and for leave to amend their Amended Class Action Complaint (the “Complaint”). In the Complaint, they allege that Intercept Pharmaceuticals, Inc., (“Intercept”) and certain of its officers and directors (the latter, the “Individual Defendants”), knowingly made statements concerning Ocaliva,<sup>1</sup> an Intercept-manufactured drug, that were rendered false or misleading by their failure to disclose that patients taking Ocaliva were experiencing Serious Adverse Events (“SAEs”), Potential Side Effects (“PSEs”), and were mistakenly overdosing. The Complaint charges that, through these material misrepresentations and omissions, Defendants violated sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”). In March 2020, the district court dismissed the Complaint, ruling that Plaintiffs failed plausibly to

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<sup>1</sup> Ocaliva is designed to treat primary biliary cholangitis, a chronic autoimmune disease in which the bile ducts in the liver deteriorate over the course of many years.

allege that Defendants' statements were materially false or misleading and, in the alternative, that they failed plausibly to allege that the alleged conduct gave rise to a strong inference of scienter, thus failing to satisfy Rule 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). *See* Fed. R. Civ. P. 9(b); 15 U.S.C. §§ 78u-4, *et seq.* Judgment was entered accordingly on March 27, 2020. On April 20, 2020, Plaintiffs filed a request for an extension of time within which to file a motion for reconsideration, and on April 21, the district court granted the requested extension.<sup>2</sup> They filed their motion on May 8, 2020, within the extended deadline set by the district court. In September 2020, the district court denied Plaintiffs' motion for reconsideration under Rule 59(e), for relief under Rule 60(b), and for leave to file a Proposed Second Amended Complaint (the "PSAC"), principally on the grounds of futility. On October 9, 2020, Plaintiffs filed their Notice of Appeal.

Plaintiffs' Notice of Appeal reflects their intention to appeal the district court's March 2020 dismissal of their Complaint, as well as the district court's pre-judgment orders denying their motion to lift the PSLRA's automatic stay of discovery and their request for leave to file new evidence in support of their motion to lift the stay. *Jt. App.* 1298. Defendants argue that we are without jurisdiction to do so, asserting that Plaintiffs' notice of appeal was untimely under Federal Rule of Appellate Procedure 4 as to the pre-judgment orders and March dismissal order. They submit on that basis that in this appeal we may consider only the district court's September 2020 denial of Plaintiffs' motion for reconsideration.

We agree with Defendants that Plaintiffs' notice of appeal was untimely as to the entry of judgment and the pre-judgment rulings, notwithstanding the district court's grant of an extension of time to file their motion under Rule 59(e) and Rule 60. The relevant substantive issues concerning the initial stay denial and complaint dismissal are nonetheless properly before us because their merits were implicitly addressed in the district court's order

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<sup>2</sup> Plaintiffs cited "the current health crisis in the United States caused by the COVID-19 pandemic, resulting health issues for one of the attorneys on the team as well as their family, and the shut-down of businesses in New York city due to Governor Cuomo's New York State on PAUSE executive order" as constituting "good cause . . . to extend the filing deadline for the Motion by fourteen (14) days, to May 8, 2020." *Jt. App.* 572.

denying Plaintiffs' motion for reconsideration under Rule 59(e) and for relief under Rule 60(b), for which the notice of appeal was timely filed. We treat them nonetheless in the context of the standard of review applicable on appeal of such orders.

“A district court’s denial of a party’s motion to alter or amend judgment under Rule 59(e) is . . . reviewed for an abuse of discretion.” *Empresa Cubana del Tabaco v. Culbro Corp.*, 541 F.3d 476, 478 (2d Cir. 2008) (internal quotation marks omitted). We review *de novo* the denial of a Rule 60(b) motion to the extent that the denial is based solely on futility grounds. *See Indiana Pub. Ret. Sys. v. SAIC, Inc.*, 818 F.3d 85, 92 (2d Cir. 2016). We assume the parties’ familiarity with the underlying facts, procedural history, and arguments on appeal, to which we refer only as necessary to explain our decision to affirm.

1. The PSAC and scienter

Plaintiffs contend that the district court erred when it determined that filing the PSAC would be futile because it fails to plead facts supporting a strong inference of scienter. *See Hou Liu v. Intercept Pharms., Inc.*, No. 17-CV-7371 (LAK), 2020 WL 5441345, at \*3–9 (S.D.N.Y. Sept. 9, 2020). A proposed amendment is futile if it “would fail to cure prior deficiencies or to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure.” *IBEW Loc. Union No. 58 Pension Tr. Fund & Annuity Fund v. Royal Bank of Scotland Grp., PLC*, 783 F.3d 383, 389 (2d Cir. 2015) (internal quotation marks omitted). For the reasons discussed below, we affirm the district court’s ruling that the Complaint was deficient in its scienter-related allegations, that the PSAC does not cure those deficiencies, and therefore that the district court correctly denied leave to amend.

To state a claim for securities fraud under Section 10(b) a plaintiff must allege that a defendant made misstatements or omissions of material fact with the requisite culpable intent. *See Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 100 (2d Cir. 2015). This task may be accomplished “either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.” *Kalnit v. Eichler*, 264 F.3d 131, 138 (2d Cir. 2001) (internal quotation marks omitted). Plaintiffs here contend primarily that the

PSAC alleges “strong circumstantial evidence of conscious misbehavior or recklessness” in its charges that, before touting the drug’s performance, the Individual Defendants either knew of reports of SAEs and PSEs or failed to review Ocaliva’s safety data.<sup>3</sup>

The PSAC’s allegations provide an insufficient basis from which to infer reckless or conscious misbehavior under the heightened pleading standards imposed by Rule 9(b) and the PLSRA. In the securities fraud context, reckless conduct must be “highly unreasonable, representing an extreme departure from the standards of ordinary care, not merely a heightened form of negligence.” *In re Advanced Battery Techs., Inc.*, 781 F.3d 638, 644 (2d Cir. 2015) (internal quotation marks and citation omitted). The PSAC’s primary theory of scienter is Plaintiffs’ deduction that Individual Defendants had access to internal documentation concerning Ocaliva’s safety performance and that they then knowingly concealed the full extent of the SAEs and PSEs that were linked to Ocaliva.

But the PSAC does not allege with any specificity at all when the Individual Defendants reviewed internal data, or even should have reviewed internal data, or how that data rendered their public comments about Ocaliva’s performance false or misleading. We agree with the district court that speculative allegations concerning data that Individual Defendants “must have reviewed” or were “already aware [of]” are insufficient to carry Plaintiffs’ pleading burden. *Hou Liu*, 2020 WL 5441345, at \*5; Jt. App. 613, 673–74, 676–77 (PSAC ¶¶ 67, 179, 184). Rule 9(b) and the PLSRA require more. *See, e.g., Teamsters Loc. 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 196 (2d Cir. 2008) (allegation that the defendant “knew facts or had access to information suggesting that their public statements were not accurate,” without identifying where specifically such information was found, insufficient to raise an inference of scienter); *see also Kalnit*, 264 F.3d at 142 (plaintiffs “cannot base securities fraud claims on speculation and conclusory allegations”).

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<sup>3</sup>The PSAC offers no new allegations from which to infer that Defendants “had both motive and opportunity to commit fraud.” *Kalnit*, 264 F.3d at 138. Instead, the PSAC simply repeats verbatim Plaintiffs’ defective motive and opportunity allegations, as originally presented in the Complaint. Tellingly, Plaintiffs do not discuss the PSAC’s motive and opportunity allegations in their briefs on appeal.

We conclude that the district court properly denied Plaintiffs' request for leave to file the PSAC because such amendments as proposed in the PSAC would be futile.

2. Plaintiffs' motions to lift the stay and file new evidence

Plaintiffs also challenge the district court's pre-judgment denial of their motions to lift the PLSRA automatic discovery stay and to submit new evidence. Both motions concern documents that Plaintiffs requested from the European Medicines Agency ("EMA") and that, according to Plaintiffs, are related to Intercept's alleged attempt to block Plaintiffs' access to periodic safety update reports ("PSURs") that Intercept filed with the EMA concerning Ocaliva.<sup>4</sup> Plaintiffs charge that the district court erred when it denied their motions without explanation in a minute entry on the docket and then granted Defendants' motion to dismiss without allowing them an opportunity to access the EMA documents.

Although the district court's order denying reconsideration referenced its denial of Plaintiffs' motions only in a footnote, *Hou Liu*, 2020 WL 5441345, at \*10 n.90, the district court's analysis makes clear that – even if it were true that the requested documents demonstrated that “Intercept had knowledge of or access to Ocaliva's safety data,” or that Defendants “attempt[ed] to shield” access to the PSURs – Plaintiffs' additional allegations would *still* be insufficient to cure their pleading deficiencies. *Id.* at \*11. We identify no error in that ruling. *See Cornielsen v. Infinium Cap. Mgmt., LLC*, 916 F.3d 589, 601 (7th Cir. 2019) (explaining that the PSLRA's automatic discovery stay “prevents a plaintiff from bringing an action without first possessing the information necessary to satisfy the heightened pleading requirements of the PSLRA”); *SG Cowen Sec. Corp. v. U.S. Dist. Ct. for N. Dist. of Cal.*, 189

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<sup>4</sup> A PSUR is a document that the EMA requires a drug manufacturer to submit at prescribed intervals. In it, the manufacturer evaluates and summarizes the most up-to-date safety data regarding its product, “to present a comprehensive and critical analysis of the risk-benefit balance of the product, taking into account new or emerging safety information in the context of cumulative information on risk and benefits.” *See* European Medicines Agency, Periodic Safety Update Reports (Sept. 26, 2018), <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/periodic-safety-update-reports-psurs> (emphasis omitted).

F.3d 909, 913 (9th Cir. 1999) (“[A]s a matter of law, failure to muster facts sufficient to meet the [PSLRA’s] pleading requirements cannot constitute the requisite ‘undue prejudice’ to the plaintiff justifying a lift of the discovery stay under [the PSLRA].”). Even if Plaintiffs had obtained the EMA documents, they still lack the necessary specific allegations to support an inference of scienter. In the PSAC, Plaintiffs allege merely a deduction that when drafting the PSURs, “Intercept and its employees necessarily evaluated and summarized Intercept’s most up-to-date safety data, including any SAEs or [PSEs].” Jt. App. 684 (PSAC ¶ 197). As discussed above, such conclusory and speculative allegations fail to adequately allege scienter as to the Individual Defendants, *see Teamsters*, 531 F.3d at 196.

### 3. Plaintiffs’ request for leave to amend

Finally, Plaintiffs assert that the district court abused its discretion when it denied their request for leave to amend, even apart from any failures located in the PSAC. They point out that, in preparing a proposed amended complaint, they “never had the benefit of a ruling” on their request for leave and urge us to conclude that, because Rule 15 promotes a liberal policy of granting leave and because their chances of addressing the district court’s concerns would have been enhanced with the benefit of its ruling, the district court erred by denying their request. Appellants’ Br. at 33.

Plaintiffs’ request was at best cursory, however: at the conclusion of their opposition brief to Defendants’ motion to dismiss, they included a casual two-line mention that they would like leave to amend if the district court dismissed Complaint. We conclude that, in these circumstances, the district court did not abuse its discretion by denying the request. We have stated that “[i]t is within the court’s discretion to deny leave to amend implicitly by not addressing the request when leave is requested informally in a brief filed in opposition to a motion to dismiss.” *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 220 (2d Cir. 2006), *abrogated on other grounds by FTC v. Actavis, Inc.*, 570 U.S. 136 (2013)). Although the district court did not expressly address Plaintiffs’ request in its order dismissing the Complaint, it thoroughly reviewed the PSAC when denying Plaintiffs’ motion for reconsideration and determined that amendment would be futile. *See Hou Lin*, 2020 WL 5441345, at \*3. We see no grounds for disturbing that decision.

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We have considered Plaintiffs' remaining arguments and find in them no basis for reversal. The order of the district court is **AFFIRMED**.

FOR THE COURT:

Catherine O'Hagan Wolfe, Clerk of Court

  
Catherine O'Hagan Wolfe