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United States Court of Appeals, First Circuit.

METZLER ASSET MANAGEMENT GMBH, on behalf of itself and all other similarly situated parties; Erste-Sparinvest Kapitalanlagegesellschaft mbH, on behalf of itself and all other similarly situated parties, Plaintiffs, Appellants/Cross-Appellees,
v.
Stuart A. KINGSLEY; George A. Scangos; Paul J. Clancy; Biogen Inc., Defendants, Appellees/Cross-Appellants.

Nos. 18-1369
|
18-1472
|
June 27, 2019

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS [Hon. F. Dennis Saylor, IV, U.S. District Judge]

Attorneys and Law Firms

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Before Lynch, Stahl, and Barron, Circuit Judges.

Opinion

BARRON, Circuit Judge.

***1** Metzler Asset Management GmbH ("Metzler") and Erste–Sparinvest Kapitalanlagegesellschaft mbH ("Erste–Sparinvest") have been designated the lead plaintiffs, pursuant to the Private **Securities** Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4, in a federal **securities** class action that they brought against Biogen Inc. and three Biogen executives ("Biogen"). The suit alleges that Biogen and its executives committed fraud, in violation of regulations promulgated by the **Securities** and Exchange Commission pursuant to the **Securities** Exchange Act, 15 U.S.C. § 78a et seq, by falsely stating that Biogen's product, Tecfidera, was both safer and more widely used than it was. The putative class is comprised of all purchasers of Biogen common stock from July 23, 2014, through July 23, 2015.

The defendants moved to dismiss the suit on claim preclusion grounds, based on this Court's earlier decision in In re Biogen Inc. **Securities** Litigation, 857 F.3d 34 (1st Cir. 2017) ("Biogen I"), and for failing to plead facts "giving rise to a strong inference" of scienter, 15 U.S.C. § 78u-4(b)(2)(A), as the PSLRA requires that a complaint alleging fraud must in order for it to survive such a motion. The District Court rejected the defendants' claim preclusion argument but dismissed the suit under the PSLRA for failing to adequately plead scienter. We affirm.

I.

The corporate defendant, Biogen, is a multinational biotechnology company based in Cambridge, Massachusetts. Its stock trades on the NASDAQ. Id. at 37. The three individual defendants are George Scangos, who was Biogen's Chief Executive Officer from July 23, 2014, through July 23, 2015; Paul Clancy, who was Biogen's Chief Financial Officer and Executive Vice President of Finance during that time; and Stuart Kingsley, who was its Executive Vice President of Global Commercial Operations during the same period. Id.

The plaintiffs' complaint sets forth the following allegations. Biogen developed and sold a United States Food and Drug Administration ("FDA") approved drug for multiple sclerosis ("MS") called Tecfidera during the relevant time period. Tecfidera accounted for a third of Biogen's total revenue in this time frame. As of July 23, 2014, Tecfidera bore a label that warned patients taking the drug of an increased risk of developing lymphopenia -- a condition of having low lymphocyte counts, leading to a weakened immune system.

On October 22, 2014, Biogen held a third-quarter earnings call with its investors. The company announced for the first time publicly that an MS patient who had been regularly taking Tecfidera had died of progressive multifocal leukoencephalopathy ("PML"), a rare neurological disease which counts lymphopenia as one of its precursors. One month later, Biogen amended the Tecfidera label to include a warning about the risk of PML.

On January 29, 2015, Biogen provided full-year revenue guidance for 2015. It predicted a 14% to 16% overall growth rate for the company for the year. However, on April 24, 2015, Biogen released first-quarter financial results for the year that showed that Tecfidera's revenue had fallen below the market estimates.

***2** On July 24, 2015, Biogen released its second-quarter earnings report. The report amended the company's 2015 revenue guidance. It lowered Biogen's predicted revenue growth from 14-16% to 6-8% for the year. Biogen attributed its tempered expectations, in part, to slowing Tecfidera growth.

Biogen's stock fell by more than 20% in one day due to the second quarter earnings report. On October 9, 2015, Biogen announced that Kingsley was leaving the company. Less than two weeks later, the company announced that it was cutting roughly 11% of its workforce. Id. at 39.

On August 18, 2015, a putative federal **securities** fraud class action was filed in the District of Massachusetts against the company and the same three individual defendants in the case before us in this appeal. Id. at 36-39. The putative class in that action consisted of persons who had purchased common stock of Biogen between January 29, 2015, and July 23, 2015. Tehrani v. Biogen, Inc., No. 15-13189, 2015 WL 7302132, at *1 (D. Mass. Nov. 18, 2015). The suit alleged that Biogen and the three executives had fraudulently misled investors, in violation of Sections 10(b)[1] and 20(a)[2] of the **Securities** Exchange Act of 1934, see 15 U.S.C. §§ 78j(b), 78t(a), regarding Tecfidera's usage rates in light of the PML incident. Tehrani, 2015 WL 7302132, at *1.

Notice of the action was published pursuant to the PSLRA, which establishes procedures for bringing **securities** class actions. See id. at *2. In accordance with those procedures, on November 17, 2015, the District Court preliminarily appointed GBR Group Ltd. ("GBR") "lead plaintiff" in the matter, a status that Congress created in the PSLRA "to increase the chances that **securities** fraud cases are brought by investors who have substantial and genuine interests in the litigation." Id.

On January 19, 2016, GBR filed an amended complaint. The amended complaint changed the class period, such that it ran from December 2, 2014, through July 23, 2015. Biogen I, 857 F.3d at 36.

Biogen moved to dismiss the complaint. The District Court granted that motion as to both the Section 10(b) and 20(a) claims. See Biogen I, 193 F. Supp. 3d 5, 56 (D. Mass. 2016).

GBR moved to vacate the order of dismissal and for leave to file a second amended complaint with the District Court under Federal Rules 59(e) and 60(b)(2). In re Biogen Inc. Sec. Litig., No. 15-13189, 2016 WL 5660329, at *3 (D. Mass. Sept. 28, 2016). The motion requested that the District Court vacate the order of dismissal based on the new scienter allegations in the proposed second amended complaint. Id. The District Court denied the motion. Id. at *6. The District Court determined that the plaintiffs could have discovered the evidence on which they were based earlier with reasonable diligence. Id.

***3** GBR appealed both the dismissal of the complaint for failure to state a claim as well as the denial of its motion to vacate that dismissal and for leave to file the second amended complaint. As discussed below, that appeal ultimately ended in affirmance of the District Court. During the pendency of the appeal in that case, however, separate Biogen stockholders filed a subsequent putative class action in the District Court on October 20, 2016, against Biogen and certain of its executives on behalf of a class of investors in the company. Metzler Asset Mgmt. GmbH v. Kingsley ("Biogen II"), 305 F. Supp. 3d 181, 205, 202 (D. Mass. 2018). They alleged that, through its comments to investors, Biogen misled the market about Tecfidera's safety profile and discontinuation rates.

This new action is the one before us on appeal. It, too, asserts violations of Sections 10(b) and 20(a) of the **Securities** Exchange Act. Nonetheless, it differs from the first putative class action that had been filed against Biogen in three ways. First, the class period for the putative class in the new suit began on July 23, 2014, as opposed to December 2, 2014. Second, the complaint in the new suit alleged that Biogen had made additional misleading statements not referenced in the prior suit and also set forth statements from confidential witnesses ("CWs") to prove scienter that had not been referenced in the complaint in the earlier suit. These newly alleged statements included ones that had been set forth in the amended complaint in the earlier putative class action that the District Court rejected for not having been included in a timely manner. See Biogen I, 857 F.3d at 45-46. Third, the new suit alleged that, in addition to making fraudulent statements regarding Tecfidera's usage rate, Biogen executives also made fraudulent statements about the drug's safety profile.

On February 1, 2017, the District Court preliminarily appointed Metzler and Erste–Sparinvest -- not GBR -- to be the lead plaintiffs in this new suit pursuant to the PSLRA. See Metzler Asset Mgmt. GmbH v. Kinglsey, No. 16-12101, 2017 WL 438731 (D. Mass. Feb. 1, 2017). Plaintiffs also filed a motion to stay the District Court proceedings pending resolution of the appeal of the earlier action. That motion was denied. Id. at *4.

On May 12, 2017, we affirmed the District Court's order of dismissal for lack of sufficient allegations of scienter in Biogen I. Biogen I, 857 F.3d at 46. In so doing, we also held that the confidential witness statements provided by the plaintiffs were "insufficiently particular" to prove scienter. Id. at 41. Finally, we denied the plaintiffs' motion to vacate and file a second amended complaint. Id. at 45.

Following Biogen I, Biogen moved to dismiss the complaint in the putative class action that is now before us for failing to adequately plead scienter and on claim preclusion grounds. The District Court rejected the claim preclusion argument but agreed that the complaint in the new suit failed to plead facts sufficient to create a strong inference of scienter. Biogen II, 305 F. Supp. 3d at 205, 222. The appeal from that ruling then followed.

II.

To establish claim preclusion, the defendant must show that "(1) the earlier suit resulted in a final judgment on the merits, (2) the causes of action asserted in the earlier and later suits are sufficiently identical or related, and (3) the parties in the two suits are sufficiently identical or closely related." Airframe Sys., Inc. v. Raytheon Co., 601 F.3d 9, 14 (1st Cir. 2010). The District Court rejected Biogen's claim preclusion argument. See Biogen II, 305 F. Supp. 3d at 205. The District Court did not question whether Biogen I represented a final judgment, as it plainly did. Id. at 204. Nor did the District Court rule that that the causes of action in the two cases were not related or identical, as it found that they were. Id. Instead, the District Court rejected the contention that GBR, as lead plaintiff under the PSLRA in Biogen I, could "adequate[ly] represent" the class in Biogen II, such that the plaintiffs in the two actions may be deemed to be sufficiently "identical," as they must be for claim preclusion to apply. Id. at 205.

***4** The District Court explained that the putative class in Biogen I was not certified through Federal Rule of Civil Procedure 23 and thus remained merely a "proposed class action[.]" Id. (citing Smith v. Bayer Corp., 564 U.S. 299, 316 (2011)). For that reason, the District Court ruled, GBR could not, by virtue of its role as the lead plaintiff under the PSLRA in Biogen I, be deemed to have "adequate[ly] represented" the putative class in Biogen II.

In reaching this conclusion about whether the members of the putative class in Biogen II were adequately represented by GBR in Biogen I, the District Court relied on the Supreme Court's ruling in Smith. There, the Supreme Court held that a consumer's motion for class certification was not precluded by a previous decision denying a similar motion for class certification to a different party. Smith, 564 U.S. at 304-05. The Court stated, "[w]e could hardly have been more clear [in Taylor v. Sturgell, 553 U.S. 880 (2008)] that a 'properly conducted class action,' with binding effect on nonparties, can come about in federal courts in just one way -- through the procedure set out in Rule 23." Id. at 316.

Biogen argues that the District Court erred in this aspect of its claim preclusion analysis. Biogen contends that the PSLRA's process for appointing a lead plaintiff sufficed to ensure that GBR, in its role as lead plaintiff of the putative class in Biogen I, did adequately represent the interests of the putative class in Biogen II, even though the class in Biogen I had not been certified at the time of the dismissal of that action. Thus, Biogen contends that the dismissal in Biogen I could be preclusive of the claims brought by the putative class in Biogen II, even though GBR is not the lead plaintiff for that putative class.

In challenging Biogen's claim preclusion argument, the appellants contend that the protections afforded absent parties by the PSLRA are not as robust as those afforded by the requirements set forth in Rule 23 itself, due to the preliminary nature of the PSLRA's lead plaintiff appointment procedures. Indeed, as multiple courts have recognized, nothing about lead plaintiff appointment pursuant to the PSLRA is "dispositive with respect to the ultimate certification of the class and designation of a class representative." Greebel v. FTP Software, Inc., 939 F. Supp. 57, 62 n.4 (D. Mass 1996); Dempsey v. Vieau, 130 F. Supp. 3d 809, 813 (S.D.N.Y. 2015) ("Lead plaintiff designation does not abnegate the necessity of class certification ...."). Consequently, the argument proceeds, lead plaintiff appointment pursuant to the PSLRA is simply too preliminary for a lead plaintiff of an as-yet-uncertified class to be deemed on that basis alone to be an adequate representative for claim preclusion purposes of a class in a subsequent action. Dempsey, 130 F. Supp. 3d at 813.

In addition to this potential problem with Biogen's claim preclusion contention here, there is another that is more particular to this case. The proposed class in Biogen II includes stockholders who purchased Biogen **securities** between July 23, 2014, and December 2, 2014. This group of purchasers was not included in the class proposed in Biogen I. Biogen does not explain how the lead plaintiff in Biogen I could be thought to have adequately represented those members of the proposed class in Biogen II who are not only represented by different lead plaintiffs but also were not even members of the putative class in Biogen I.

***5** We need not, however, resolve the claim preclusion issue definitively here. Even if we were to assume that the adequate representation requirement could not be satisfied here, such that the plaintiffs' claim is not precluded, the suit in Biogen II would still have to be dismissed. As we next explain, the District Court properly ruled that, under the PSLRA, the plaintiffs failed to adequately plead scienter for purposes of surviving a motion to dismiss for failure to state a claim.

III.

To state a claim under Section 10(b)[3] of the **Securities** Exchange Act, plaintiffs must adequately plead "(1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a **security**; (4) reliance; (5) economic loss; and (6) loss causation." Biogen I, 857 F.3d at 41. Scienter is defined as either the "intentional or willful conduct designed to deceive or defraud investors" or "a high degree of recklessness." Id. (internal quotations omitted).

Under the PSLRA, to survive a motion to dismiss for failure to state a claim, plaintiffs must "state with particularity facts giving rise to a strong inference that the defendant acted with [scienter]." 15 U.S.C. § 78u-4(b)(2)(A) (emphasis added). "For an inference of scienter to be strong, 'a reasonable person would [have to] deem [it] cogent and at least as compelling as any opposing inference one could draw from the facts alleged.' " Biogen I, 857 F.3d at 41 (alterations in original) (quoting Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 324 (2007)).

The District Court dismissed the plaintiffs' suit in Biogen II after determining that none of the statements that the plaintiffs

allege that the individual Biogen executive defendants made were of a kind that could give rise to the "strong inference" of scienter that the PSLRA requires. On that basis, the District Court concluded that the claims against each of these executives individually, as well as the claims against Biogen itself, must be dismissed. Cf. Biogen I, 857 F.3d at 37, 41. Our review of the District Court's ruling on scienter is de novo. See id. at 41.

To make their case on appeal, the plaintiffs focus on six statements in their complaint that the District Court held, in making its scienter ruling, were at least "plausibly misleading." Biogen II, 305 F. Supp. 3d at 206, 212.[4] These statements fall into two general categories: (1) those that pertain to Tecfidera's safety profile, and (2) those that pertain to Tecfidera's usage rate. We consider the statements in each category in turn.

Before doing so, however, we note that although the statements that we focus on were made by, respectively, Alfred Sandrock (Biogen's Chief Medical Officer), Doug Williams (Biogen's Executive Vice President of Research and Development) and Kingsley, only Kingsley is a defendant in his own right. Thus, it is unclear what role, if any, the statements by Sandrock and Williams serve in the plaintiffs' fraud claims against Kingsley, Scangos, and Clancy. But, even if we assume that Williams's and Sandrock's statements somehow could be imputed to these three individual defendants, as the plaintiffs appear implicitly to assume in their briefing to us in contending that the District Court erred in dismissing the claims against them, the plaintiffs' argument would still fail.

A.

***6** The first category of statements on which the plaintiffs in this appeal rely with respect to the claims against the individual defendants concerns Tecfidera's safety profile. The plaintiffs point to two such statements, the first of which was made on September 11 by Sandrock. According to the complaint, Sandrock stated at that time that "Tecfidera continues to provide patients with effective oral treatment for MS that is supported by a growing body of data reinforcing its benefits and favorable safety profile."

The complaint alleges that Sandrock made this statement before Biogen's October announcement of the PML-related death, and the plaintiffs do not contend that any of the individual defendants knew about that death before Sandrock made this statement.[5] The plaintiffs nevertheless contend that the District Court erred in concluding that the complaint failed adequately to allege that Sandrock made the statement with the "intentional or willful" design to deceive investors.

To make this case, the plaintiffs point out that, in August and September of 2014, Dr. Ben Thrower, the medical director at the Shepherd Center in Atlanta, notified Keith Ferguson, the company's senior sales director, and Eric Hall, the medical science liaison for Biogen, that his research showed that patients who were taking Tecfidera had a higher risk of developing low lymphocyte counts than Biogen had originally disclosed. The complaint further alleges that, for this reason, Dr. Thrower chose to discontinue Tecfidera prescriptions for approximately 200 of his patients and to stop issuing new prescriptions for the drug. The complaint also alleges that he told Ferguson and Hall about this development.

But, according to the complaint, Sandrock in his September 2014 statement said only that Tecfidera was "effective" at treating MS and that its safety profile was "supported by a growing body of data." Nothing about Dr. Thrower's alleged statements to Hall and Ferguson about his own research findings -- especially given the limited slice of the market on which those findings were based -- contradicts the statements that the complaint alleges that Sandrock made. See Geffon v. Micrion Corp., 249 F.3d 29, 36 (1st Cir. 2001) ("Even if the statements at issue were material and false or misleading, the evidence does not support a finding that defendants knew the statements would materially mislead the investing public." (emphasis omitted)). Thus, even assuming that Sandrock's statement was "plausibly misleading" and made with knowledge of Thrower's conclusions, we find insufficient support for a "strong inference" that Sandrock spoke with the intent to deceive investors. And thus, the allegations regarding Sandrock fail to establish a "strong inference" of scienter as to even him, let alone as to any individual defendant.

The only other "plausibly misleading" statement that concerns the drug's safety profile to which the plaintiffs point is one

that, according to the complaint, Williams made in April of 2015. In it, Williams allegedly stated that "there's no real change in the benefit/risk profile of the drug for patients with MS. So it's pretty much status quo at the moment."

***7** By April of 2015, according to the complaint, Biogen had already disclosed the PML death and updated the drug's label to account for the increased understanding of its risk. Given that none of the findings by the researchers that the plaintiffs cite aver that the drug was less safe than these revised disclosures, we do not see how the plaintiffs can plausibly suggest that Williams was aware that the drug was less safe than these revised disclosures suggested. Therefore, even if, drawing all inferences in favor of the plaintiff, one could conclude that Williams's statement -- read in a vacuum -- was misleading, one could not draw a "strong inference" from that statement that it was said with an "intent to deceive," given what the record shows about Biogen's earlier disclosures and the state of Williams's knowledge of the drug's safety profile. See City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 760 (1st Cir. 2011) ("[A]ttempts to provide investors with warnings of risks generally weaken the inference of scienter." (alteration in original) (quoting Ezra Charitable Tr. v. Tyco Int'l, Ltd., 466 F.3d 1, 8 (1st Cir. 2006))).

We turn, then, to the four "plausibly misleading" statements that pertain to Tecfidera's usage rates. All four statements were allegedly made by Kingsley, who is an individual defendant. But, we find no basis for concluding that any of these statements permit us to infer the necessary intent to deceive that could suffice to create the "strong inference" of scienter that the PSLRA requires. And, even the cumulative weight of these statements and the CW evidence discussed below would not suffice.

We first address the January 29, 2015 statement by Kingsley that "Tecfidera [was] on track to become the most prescribed therapy for MS worldwide." The plaintiffs argue that this statement was misleading and creates the "strong inference" of scienter on Kingsley's part, because at the time of the statement, Kingsley knew about both the PML death and about Tecfidera's declining sales and discontinuation rates.

At the time that Kingsley made the statement, however, Biogen had already disclosed to the public the news of the PML death, had already changed the drug's label, had already publicized that it expected the drug's growth rate to "slow," and had already disclosed that the drug's discontinuation rates were higher than expected. Moreover, during the conference call on which Kingsley made the statement at issue, he also noted that the company had observed "moderating" growth for the drug at the end of 2014 and expected that trend to continue into the new year. Given these disclosures pointing against sales growth, it is hard to characterize Kingsley's statement that he believed Tecfidera would "become the most-prescribed therapy for MS worldwide" as anything other than misguided optimism. See Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 244 (1st Cir. 2015) (holding that defendants' informative disclosures "undercut any inference of scienter"). Accordingly, we fail to see how one could characterize Kingsley as having had the requisite intent to deceive when he made this statement, such that one could draw the "strong inference" of scienter required by the PSLRA.

We, turn, then, to three statements of Kingsley's from January 29, 2015, to February 25, 2015, in which, according to the complaint, he stated that there had not been any "meaningful change" in Tecfidera's discontinuation rates and that those rates were "consistent with historical averages." As previously mentioned, at the time that Kingsley made these statements, the company had already disclosed to investors that Tecfidera's discontinuation rate was higher than Biogen would have hoped but that the company aimed to "get better performance in the discontinuation rates over a longer period of time." Given the statements in which Kingsley had been forthcoming about the status of Tecfidera's discontinuation rates, we do not see how Kingsley's early 2015 refrain that the company had not seen "meaningful change" in the drug's discontinuation rate and that the rates were "consistent with historical averages" may fairly be characterized as having been made with the "intent to deceive." Id.

***8** In arguing otherwise, plaintiffs point to statements set forth in the complaint that were allegedly made by CWs. The complaint contains statements made by seventeen CWs regarding their observations on Tecfidera's sales, discontinuation rates, and safety profile. Ten of the seventeen CWs referenced in the complaint were also referenced in the complaint in Biogen I (CWs 1-10).[6] In addition to referring to seven new CWs (CWs 11-17), the Biogen II complaint also includes multiple new statements from four of the CWs (CWs 1, 3, 7, and 8) who were included in the original Biogen I complaint.

In Biogen I, our Court found that none of the CWs' statements included in that complaint were probative of the defendants' scienter because they were imprecise, did not contain information that was directly communicated to the individual

defendants, or concerned events that occurred after the individual defendants made the plausibly misleading statements at issue in that case. See Biogen I, 857 F.3d at 42-43. That logic applies with equal force here, insofar as the plaintiffs have reprised their argument that the statements by CWs set forth in the Biogen I complaint illustrate that Kingsley made his four plausibly misleading statements with the requisite scienter.

As to the additional statements not included in the Biogen I complaint, the District Court similarly rejected them as not probative of the defendants' scienter because they failed to "set forth specific facts" that directly conflicted with the six "plausibly misleading" statements that the District Court highlighted. Biogen II, 305 F. Supp. 3d at 214-15 (emphasis in original). The District Court went on to note -- based on logic similar to that which we applied in Biogen I -- that these statements' relevance is further diminished by the fact that the complaint does not allege that any of the CWs ever spoke with any of the individual defendants or otherwise shared with them their observations. Id. at 215 n.29.

On appeal, the plaintiffs do reference the statements of one CW in particular, CW 13. According to the plaintiffs, CW 13 explained that "everyone in leadership had access to reporting metrics" and that leadership frequently monitored the "new start" rates for Tecfidera as part of the process for producing their sales projections.

But, the fact that Biogen's leadership monitored Tecfidera's reporting metrics does not in and of itself suffice to create the "strong inference" that Kingsley made his four statements about Tecfidera's discontinuation rates with the requisite intent to deceive. We would expect responsible management to engage in such monitoring. As a result, before one could infer what plaintiffs ask, one would need to know what Kingsley learned from such monitoring, and whether what he learned was at odds with any of his "plausibly misleading" statements. Yet, the complaint alleges no facts that are illuminating in that regard.

The only additional confidential witness statement that the plaintiffs expressly reference in their brief's section on individual scienter is the statement made by CW 1. That witness allegedly said that Biogen instructed Area Business Managers to "downplay the significance of the PML death" when attempting to convince doctors to prescribe the drug. But, the complaint does not allege that Sandrock, Williams, or Kingsley was aware of this alleged instruction by the company. Nor do we see why such an instruction gives rise to an inference that Kingsley's public assessment of the drug's actual usage was inaccurate, let alone intentionally deceitful.

***9** As to the statements concerning safety, the plaintiffs do not dispute that Biogen disclosed the PML death to investors and the public. Moreover, nothing in CW 1's alleged statement reveals that what Sandrock and Williams actually said publicly about the drug's safety was known by them to be misleading.

In their briefing to us, the plaintiffs expressly reference a number of other confidential witness statements to support their arguments that the three individual defendants possessed the requisite scienter. But, the plaintiffs do not allege that any of the confidential witnesses who made these statements spoke with Kingsley before he made his statements about the discontinuation rates, and most of these confidential witnesses are, by the complaint's account, several levels removed from the company's executive team. See Biogen II, 305 F. Supp. 3d at 215 n.29 ("The complaint does not allege that any of the ... confidential witnesses ever spoke with one of the named defendants."); see also Fire & Police Pension Ass'n of Colo., 778 F.3d at 245 (noting that "none of the witnesses were in senior management positions, and they appear to have had relatively little ongoing contact with senior management" (internal quotations omitted)).

B.

The plaintiffs do separately argue that they can meet their burden to allege that Biogen (though, we presume, not any of the individual defendants) had the requisite scienter under a theory of "corporate scienter." Specifically, the plaintiffs contend that, if the complaint plausibly alleges that one of the company's employees made a misleading statement to investors without scienter and "an individual within Biogen's management team ... knew or had access to information" that showed that this misleading statement was not true, then Biogen can be found to have had the requisite scienter on a corporate

scienter theory. The plaintiffs then proceed to contend that the record provides support for finding a "strong inference" of scienter on this basis, in light of the six "plausibly misleading" statements in the complaint that we have just reviewed, the company's failure to correct them, and the allegations that the complaint sets forth regarding what persons within the company knew or what the company may itself be charged with having known. And, the plaintiffs further contend, the District Court erred by failing even to address this basis for finding scienter vis à vis the claims against Biogen.

The plaintiffs attempt to make the case for their showing of corporate scienter as follows. They allege that Ferguson and Hall knew, due to their conversation with Dr. Thrower, that Tecfidera was less safe than the company stated publicly when Sandrock said that "Tecfidera continues to provide patients with effective oral treatment for MS that is supported by a growing body of data reinforcing its benefits and favorable safety profile," and when Williams said that "there's no real change in the benefit/risk profile of the drug for patients with MS. So it's pretty much status quo at the moment." The plaintiffs argue that Ferguson and Hall may be understood to have had this knowledge because, as the complaint alleges, Dr. Thrower discussed with Ferguson and Hall his research that Tecfidera could cause lower lymphocyte counts than the company originally disclosed.

***10** But, the fact that Dr. Thrower and researchers like Dr. Zamvil concluded on the basis of their own research that Tecfidera could cause lower lymphocyte counts than was originally understood does not, in and of itself, suffice to contradict the assertions that Tecfidera was "effective" at treating MS and that this fact was "supported by a growing body of research." For that reason, even if we were to assume that the statement was plausibly misleading and that Hall's and Ferguson's knowledge of Dr. Thrower's research -- or any of the other research cited by the plaintiffs -- could be imputed to the company as a whole, that knowledge would still fail to create the "strong inference" of scienter on Biogen's part. That is so, we emphasize, even if we were to accept the plaintiffs' theory of corporate scienter.

Similarly, the plaintiffs argue that Dr. Thrower's statements to Hall and Ferguson show that the company knew that the drug's usage rates were lower than was publicized. But, we fail to see how the knowledge that one doctor -- whose patients constituted less than 0.2% of all Tecfidera users -- would no longer prescribe Tecfidera could suffice to show that the company understood the drug's usage rate to be at odds with any statement regarding its usage that had been made publicly. For that reason, once again, Ferguson and Hall's knowledge of what Dr. Thrower had allegedly told them about his own experience with the drug does not suffice to establish the "strong inference" of scienter, even if we were inclined to impute what Ferguson and Hall knew to the company overall in the way that the plaintiffs contend that we must under their expansive theory of "corporate scienter."[7]

The plaintiffs also point to statements made by the confidential witnesses to support their contention that the complaint adequately alleges that employees in the company knew that the statements by Kingsley that the District Court found to be "plausibly misleading" were untrue. They then proceed to argue from that contention that the complaint's allegations suffice to create a "strong inference" of scienter on the company's part, in consequence of Kingsley's plausibly misleading statements regarding the drug's usage. But, the alleged statements at issue either were not made with sufficient particularity, see Biogen I, 875 F.3d at 42 (noting that the confidential witness statements did not "quantify the magnitude of the sales decline at the company level. [Nor did they] explain with any precision" the cause of the decline in sale) or did not describe events that took place before Kingsley's three statements concerning the drug's discontinuation rates, see id. at 42-43 (describing "a significant timing problem" with many of the confidential witness statements, as most of them described declines in Tecfidera sale that occurred after Kingsley made the three plausibly misleading statements at issue here).

For example, plaintiffs reference the statements made by CW 11 that Biogen was aware that Tecfidera sales would decline after the PML death was announced and "drastically lowered sales targets for the drug." But, the plaintiffs never explain how reductions in sales targets in November of 2014 indicate that that anyone in the company was aware that discontinuation rates were higher than Kingsley's statements indicated in early 2015. After all, the fact that the company reduced sales targets does not, necessarily, mean that actual sales fell at a commensurate rate. Accordingly, while these statements do indicate that employees in the company were concerned about the impact the PML death would have on Tecfidera sales, they do not create a "strong inference" that someone in the company's management team knew that Kingsley's generalized statements about the drug's discontinuation rates were untrue.

***11** Similarly, CW 14's statements that there were "lots of discontinuations" in the New York region after the PML death was announced do not suffice to support the plaintiffs attempt to show that the District Court erred in dismissing the claims

against Biogen. The fact that one employee observed an unspecified increase in discontinuation rates in New York in November of 2014 does not create a strong inference that the Biogen management team knew that Kingsley's early 2015 statements about the drug's discontinuation rates company-wide were untrue. In fact, according to the complaint, at the time that Kingsley made those statements, the company had already disclosed to investors that the drug's discontinuation rates were higher than expected.

Finally, the plaintiffs point to CW 1's statement about having participated in "emergency" conference calls in December of 2014 and January of 2015 regarding Tecfidera's declining sales. But, the plaintiffs do not describe what specifically was communicated to the employees during those calls, and nothing in the complaint suggests that CW 1 received any information during them that directly conflicted with the four "plausibly misleading" statements attributed to Kingsley.

Moreover, the few confidential witness statements alleged in the complaint that were particularized and appropriately timed concerned narrow slices of the market for the sale of the drug. For example, CW 17 -- an Executive Territory Business Manager -- reported that his Tecfidera sales dropped 25% after the PML death. But, the fact that his individual sales experienced a decline does not indicate that he knew that Kingsley's generalized assessments of the magnitude of the change in discontinuation rates nationally for the company were untrue.[8]

C.

Finally, we address the plaintiffs "additional scienter" arguments. Here, the plaintiffs argue that the District Court did not properly credit their allegations that the defendants knew or should have known that the public statements that had been made by Kingsley regarding Tecfidera were misleading because Tecfidera was part of the company's "core operations"; many of the plausibly misleading statements were "repeated" and "specific"; and Biogen operates in a highly regulated industry. We disagree.[9]

In pressing the "core operations" theory, the plaintiffs contend that, when "facts critical to a business's core operations or an important transaction generally are so apparent[,] knowledge [of those facts] may be attributed to the company and its key officers," even if those officers did not, in actuality, know the critical information. Bodri v. GoPro, Inc., 252 F. Supp. 3d 912, 932 (N.D. Cal. 2017). But, as we have explained, the plaintiffs fail to identify any allegations in the complaint that show that anyone in the company had knowledge regarding the drug's safety profile and sales that contradicted the company's public representations. So, the "core operations" theory also does little to aid the plaintiffs' case. S. Ferry LP, No. 2 v. Killinger, 542 F.3d 776, 784-85 (9th Cir. 2008) ("As a general matter, 'corporate management's general awareness of the day-to-day workings of the company's business does not establish scienter -- at least absent some additional allegation of specific information conveyed to management and related to the fraud' or other allegations supporting scienter." (quoting Metzler Inv. GmbH v. Corinthian Colls., Inc., 534 F.3d 1068, 1087 (9th Cir. 2008))).

***12** In this regard, the precedents on which the plaintiffs rely -- see, e.g., Stratte-McClure v. Morgan Stanley, 784 F. Supp. 2d 373, 389 (S.D.N.Y. 2011); Crowell v. Ionics, Inc., 343 F. Supp. 2d 1, 19 (D. Mass. 2004) -- are distinguishable. In each, the record contained much stronger evidence of knowledge within the company of fraudulent practices than is set forth in the allegations in the plaintiffs' complaint here. Compare Crowell, 343 F. Supp. 2d at 19 (explaining that the low-level witnesses had received an email stating that a mid-level vice president ordered a company-wide practice of fraudulently inflating sales numbers and thus that, even if the corporate officers were personally unaware of the fraudulent sales practice, generally -- that knowledge could be imputed to them though the core operations theory), with Lenartz v. Am. Superconductor Corp., 879 F. Supp. 2d 167, 183 n.9 (D. Mass. 2012) (rejecting the plaintiffs' core operations theory where the facts offered to prove that the defendant's actions were fraudulent were "less clear" than the "particularized facts" of Crowell).

The plaintiffs' "highly regulated industry" theory suffers from the same defect. According to the plaintiffs, because "Biogen operates in the heavily regulated pharmaceuticals industry," one can infer "that the Individual Defendants were acutely aware of safety-related concerns [related to Tecfidera]." But, if by "safety concerns" the plaintiffs mean the alleged statements from Dr. Thrower to Ferguson and Hall regarding Dr. Thrower's research on Tecfidera, then we have already explained the

problem with this theory. Even if we were to assume that the individual defendants were aware of Dr. Thrower's comments to Ferguson and Hall, none of the six "plausibly misleading" statements so clearly conflicts with Dr. Thrower's assessment of the drug -- especially given the other safety disclosures the company made prior to those statements -- that there exists a "strong inference" that any of those six statements were made with the intent to deceive.

Nor can the plaintiffs succeed in pressing their case on appeal based on their contention that the defendants' repeated specific statements about the drug show that they knew that their public disclosures were misleading when made and thus that there is a "strong inference" of scienter not only as to them but also as to Biogen. We may assume that a plausibly misleading statement was made publicly more than once. But nothing in the complaint alleges facts that indicate that anyone in Biogen's management had knowledge that was sufficiently in conflict with any of the six "plausibly misleading" public statements to permit the conclusion that the company had the requisite intent to deceive in permitting those statements to have been made and in not having corrected them in some respect.

IV.

For the foregoing reasons we **affirm** the District Court's judgment granting the motion to dismiss.

All Citations

--- F.3d ----, 2019 WL 2635619

Footnotes

1 Section 10(b), as set forth in 15 U.S.C. § 78j(b), makes it unlawful "[t]o use or employ, in connection with the purchase or sale of any **security** ... any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe."

2 Section 20(a), as set forth in 15 U.S.C. § 78t(a), creates "[j]oint and [s]everal" liability for "[e]very person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder."

3 As the plaintiffs' Section 20(a) claims are necessarily dependent on the existence of a Section 10(b) violation, our analysis need only address the deficiencies in the plaintiffs' Section 10(b) claims in order to uphold the District Court's decision. See ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 67 (1st Cir. 2008) ("The plain terms of [S]ection 20(a) indicate that it only creates liability derivative of an underlying **securities** violation.").

4 For the purpose of this appeal, we will assume, favorably to plaintiffs, that the District Court was correct in concluding that these six statements were, in fact, "plausibly misleading." Although we do not definitively conclude that these six statements are plausibly misleading, we will nonetheless refer to them throughout the opinion as the six "plausibly misleading" statements for clarity's sake.

5 CW 15's statements that Biogen had already prepared a response for a potential PML-related death is not to the contrary. That the company had a PML-related contingency in place for a drug that it already knew -- and disclosed -- caused low lymphocyte counts is not surprising and does not indicate that Sandrock made the statement at issue deceitfully.

6 Of the seven "new" confidential witnesses included in the present complaint (CWs 11-17), two (CWs 11 and 12) were included in the Second Amended Complaint that our Court rejected as untimely in Biogen I. See Biogen I, 857 F.3d at 45-46.

7 Plaintiffs' reliance on CW 12's statements as evidence of corporate scienter does little to strengthen their position. According to the plaintiffs, Craig Brown, Biogen's Regional Director, noted that CW 12's regional sales numbers declined after Dr. Thrower stopped prescribing Tecfidera to his patients. This statement simply speaks to the fact that individuals in the company were aware that, at least for a time, Dr. Thrower's decision would have an impact on their sales in the Atlanta region where CW 12 was stationed. CW 12's observation does not indicate that anyone in the company knew Kingsley's statements about Tecfidera's

discontinuation rate nationally were in any way untrue such that those observations would create the "strong inference" of scienter necessary to survive a motion to dismiss under the PSLRA.

[8] The plaintiffs additionally point to CW 15's and CW 16's knowledge that the company had prepared a response to a PML-linked death well in advance of the October 2014 announcement. According to the plaintiffs, the fact that the company did so reveals that the company knew for some time that the drug could cause PML and yet failed to acknowledge this reality in its public disclosures. However, as stated previously with regard to the plaintiffs' individual scienter claims, we fail to see how a company's preparation for a worst-case scenario indicates that the company knew that such a scenario would come to pass. Consequently, we similarly reject the plaintiffs' reliance on CW 15's and CW 16's statements as they pertain to their corporate scienter contentions, as we conclude that even if we were to impute CW 15's and CW 16's knowledge to the company, the plaintiffs would still fail to create a "strong inference" of scienter.

[9] Plaintiffs also argue that, because only a short period of time passed between the defendants' "plausibly misleading" statements and the fraud's alleged "disclosure," it can be assumed that the plaintiffs knew that their statements were misleading at the time that they were made. However, it appears that the plaintiffs did not make this argument to the District Court below, and we thus do not consider it. See United States v. Swiss American Bank, Ltd., 191 F.3d 30, 37 (1st Cir. 1999).

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