United States Court of Appeals
For the First Circuit

No. 16-1976

IN RE: BIOGEN INC. SECURITIES LITIGATION

GBR GROUP, LTD.,

Plaintiff, Appellant,

NICOLE TEHRANI,

Plaintiff,

v.

BIOGEN INC.; GEORGE A. SCANGOS;
PAUL J. CLANCY; STUART A. KINGSLEY,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. F. Dennis Saylor, IV, U.S. District Judge]

Before

Lynch, Lipez, and Kayatta,
Circuit Judges.

Michael P. Canty, with whom Jonathan Gardner, Guillaume Buell, Labaton Sucharow LLP, Andrea M. Landry, Thornton Law Firm LLP, Peretz Bronstein, Yitzchak E. Soloveichik, and Bronstein Gewirtz & Grossman LLC were on brief, for appellants.

James R. Carroll, with whom Michael S. Hines, Sara J. van Vliet, and Skadden, Arps, Slate, Meagher & Flom LLP were on brief, for appellees.

May 12, 2017

LYNCH, **Circuit Judge**. This securities case involves allegations that corporate officials misled the public about the effect of one patient's death on sales of Tecfidera, a drug for multiple sclerosis ("MS") and the company's leading source of revenue.

GBR Group, Ltd. ("GBR") is the lead plaintiff in a putative class action against Biogen Inc. ("Biogen") and three Biogen executives (together, "the defendants") alleging violations under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). See 15 U.S.C. §§ 78j(b), 78t(a). The plaintiffs' initial amended complaint alleged that, from December 2, 2014 to July 23, 2015 (the "Class Period"), the defendants knowingly misled the investing public regarding the impact that the death of a patient taking Tecfidera had on sales of Tecfidera.

The district court dismissed the initial amended complaint with prejudice, for failure to meet the heightened pleading requirements of the Private Securities Litigation Reform Act ("PSLRA"). In re: Biogen Inc. Sec. Litig. (Biogen), 193 F. Supp. 3d 5, 12–13 (D. Mass. 2016); see 15 U.S.C. §§ 78u-4, 78u-5. The court then denied the plaintiffs' subsequent motion under Federal Rules of Civil Procedure 59(e) and 60(b)(2) to vacate the judgment and for leave to file a second amended complaint to include purportedly new evidence. GBR appeals the dismissal of

the initial amended complaint and particularly emphasizes its appeal from the denial of the motion to vacate the judgment and for leave to amend the complaint.

We reject these claims and affirm on both issues. We agree, on de novo review, that the initial amended complaint fails to plead particularized facts giving rise to a strong inference of scienter, as required by the PSLRA. And there was no error or abuse of discretion in the denial of the motion to vacate the judgment and for leave to file a second amended complaint.

I.

Biogen, whose stock trades on the NASDAQ, is a biopharmaceutical company that develops, manufactures, and markets medication for the treatment of neurological disorders. During the relevant period, defendant George Scangos was Biogen's Chief Executive Officer, defendant Paul Clancy was its Chief Financial Officer and Executive Vice President of Finance, and defendant Stuart Kingsley was its Executive Vice President of Global Commercial Operations. The Class Period is from December 2, 2014 to July 23, 2015.

One of the four principal drugs Biogen markets for MS treatment is Tecfidera, which the FDA approved for use in March 2013 and which Biogen began selling during the second fiscal quarter of 2013. Tecfidera has been a significant source of revenue for Biogen, and it was regularly accounting for a third of

Biogen's total quarterly revenues by the start of the Class Period. Tecfidera's revenue growth depended on three factors: (1) the number of patients recently diagnosed with MS who started their treatment on Tecfidera ("new starts"); (2) the number of patients who switched over to Tecfidera from other drugs; and (3) the growth of the MS drug market.

Biogen released its third-quarter 2014 financial results on October 22, 2014. The company reported total revenues of $2.51 billion, an increase of 3.7% from the previous quarter, as well as third-quarter revenue from Tecfidera alone of $787.1 million: a 12.4% increase from the previous quarter, but a lower growth rate than those of the previous four quarters (growth rates of 49.1%, 39.0%, 27.1%, and 38.5%, respectively). On the same date, Biogen held an earnings call to discuss the third-quarter report and announced, for the first time, that an MS patient had died of progressive multifocal leukoencephalopathy (the "PML death" or "PML incident"). The patient had taken Tecfidera for more than four years in a clinical study. At the time this information was released, Kingsley stated publicly that Tecfidera growth was "moderat[ing]."

The FDA issued a warning to the public about the PML death on November 25, 2014, and Tecfidera's label in the United States was updated to describe the risk of PML death on December 3, 2014, one day after the beginning of the Class Period. On

December 2, 2014, the first day of the Class Period, Clancy told analysts that investors should be "mindful" of the fact that Tecfidera discontinuation rates (the rates at which patients discontinued use of Tecfidera) were higher than the company had hoped.

On January 29, 2015, Biogen issued full-year revenue guidance for 2015, in which it stated that it expected overall revenue growth of 14% to 16%. The initial amended complaint alleges that the "[d]efendants reiterated that Tecfidera performance remained strong and stated that they had not seen any meaningful change in discontinuation rates," and that stock analysts accepted this characterization. At the time of this announcement, Kingsley also stated that there was a moderation in new Tecfidera starts and cited, among other things, the updated label describing the PML incident. He then made similar remarks during a conference on February 25, 2015 -- that is, about halfway through the first quarter of 2015.

On April 24, 2015, Biogen released its first-quarter results for 2015, announcing Tecfidera revenue of $825 million, "below the market's consensus estimates." Scangos stated at that time that "Tecfidera had a more challenging quarter, due to a number of issues, including an overall slowing of the MS market, the recent launch of Plegridy, the single PML case reported last year, and some first-quarter financial dynamics . . . ." He

emphasized that "our long-term outlook for Tecfidera, and for our entire MS portfolio, remains strong." From April to July, the defendants continued to express optimism about Tecfidera, stating that its performance had "stabilized" since the announcement of the PML incident and that data suggested positive "momentum." At four analyst conferences in May 2015, Biogen executives noted that Tecfidera's growth was slowing and named the PML incident as one factor in that slowed growth.

On July 24, 2015, the day after the end of the Class Period, Biogen released its second-quarter earnings report. Biogen announced revenue of $883 million from Tecfidera, which was a 7.1% increase from the first quarter but less than the $916 million of Tecfidera revenue from the last quarter of 2014. Also that day, the company revised its 2015 revenue guidance, lowering its estimate of overall revenue growth from 14–16% to 6-8%. The decrease in the guidance was "based largely on revised expectations for the growth of Tecfidera." Biogen's stock fell over 20% in one day in response to the announcement.

Nearly two months after the end of the Class Period, on September 18, 2015, Kingsley stated at a health care conference that "some kind of a downtick in the safety profile that would have some kind of an impact on physician behavior" had been expected in the wake of the PML incident, but that "we couldn't tell," and that the PML incident was "a pretty big change statement

for a broad base of physicians." [The plaintiffs characterize these as "evidentiary admissions."] On October 9, 2015, Biogen announced that Kingsley was leaving the company. On October 21, 2015, Biogen announced cuts that would eliminate about 11% of its workforce.

II.

Nicole Tehrani filed the initial "bare-bones" complaint alleging securities fraud on August 18, 2015. After a status conference on November 17, 2015, the district court appointed GBR as the lead plaintiff and granted the plaintiffs an additional sixty days, as they requested, to file an amended complaint.

The plaintiffs filed their amended complaint on January 19, 2016. The amended complaint alleges claims under Section 10(b) of the Exchange Act and Rule 10b-5 thereunder (Counts I & II), and under Section 20(a) of the Exchange Act (Count III).

The amended complaint alleges that throughout the Class Period, the defendants knowingly misled the investing public by never "provid[ing] any indication that the PML death had materially impacted Tecfidera sales, or caused physicians to stop prescribing Tecfidera or [to] switch patients onto other therapies out of safety concerns." The complaint specifies over twenty allegedly misleading statements that the defendants made across ten dates during the Class Period.

As proof that the statements were misleading and made with scienter, the complaint makes several other allegations, many of which are based on statements from ten confidential witnesses ("CWs"). The confidential witness statements purportedly establish that Biogen experienced a significant decline in Tecfidera sales following the announcement of the PML incident and throughout the Class Period. The confidential witness statements also describe corporate events and policy changes that purportedly establish the defendants' private acknowledgment of this decline in Tecfidera sales and its connection to the PML death.[1]

The complaint further alleges that Tecfidera was Biogen's core product and that the defendants had access to sales data and physician feedback following the PML death. It alleges that Kingsley, due to his proximity to the sales team, would have been aware of the significant impact the PML death had on Tecfidera sales. Finally, it alleges that Scangos and Clancy had motive and

[1] For example, CW 2 alleges that during a November 2014 Biogen town hall meeting, Scangos gave a presentation stating that "the overall sense of the trajectory [at Biogen] was changing," and that another speaker talked of "potential organizational changes," which CW 2 understood to come from "executive management's expectation that the PML death would have 'an impact on performance.'" CW 1 and CW 3 reported attending a March 2015 national sales meeting at which the PML incident was described as a "market event." "[S]peakers at the meeting stated that sales would need to pick up again if [Biogen] was going to meet expected 14–16% revenue growth [forecast publically in January]" and unidentified "senior Biogen leaders at the meeting acknowledged that the PML death definitely was impacting Tecfidera sales."

opportunity to make false statements concerning Tecfidera sales because they had personal bonus targets based on revenue growth, which in turn depended on Tecfidera sales.

The defendants moved to dismiss the complaint with prejudice. The plaintiffs conceded in their opposition to the motion to dismiss that Count II should be dismissed.

The district court granted the motion to dismiss in a careful and thoughtful opinion filed on June 23, 2016. Biogen, 193 F. Supp. 3d at 12–13. Drawing all reasonable inferences in favor of the plaintiffs, the court determined that, of the more than twenty statements alleged to be material misstatements or omissions, three were plausibly misleading or false.[2] Id. at 42–

[2] These three statements, all made in the first quarter of 2015, were:

- Kingsley on the January 29, 2015 earnings call: "Importantly, we have not noticed a meaningful change in [Tecfidera] discontinuation rates."
- Kingsley on the same earnings call: "[T]he lack of any meaningful change that we see -- or we believe we're seeing -- in the discon[tinuation] rate is encouraging, because it doesn't suggest there's such a change in the profile that people are anxious to pull patients out, but on the contrary."
- Kingsley at the February 25, 2015 health care conference: "We have not seen any change in the discontinuation rate. There is a natural discontinuation rate for a product like Tecfidera in terms of tolerability and other things. You'd obviously get very concerned if you saw a spike in the discontinuation rate. No evidence of that. . . . [The discontinuation rate has] been consistent with -- I mean, we look at it relative to the growth of the product. There's nothing that's a signal that says it's not consistent with historical averages."

43. But the court found that, although the complaint's allegations, including the statements from the confidential witnesses, gave rise to a plausible inference of scienter, they did not give rise to the strong one required by the PSLRA. Id. at 45. Moreover, the court found that the record gave rise to compelling inferences in the defendants' favor. Id. at 51–54.

The district court dismissed Count I's allegations under Section 10(b) with prejudice on June 23, 2016. Id. at 54. Given that the plaintiffs had not adequately pled an underlying violation of the Exchange Act, the district court also dismissed Count III's allegations under Section 20(a) with prejudice.[3] Id. at 54–55.

On July 21, 2016, the plaintiffs filed a proposed second amended complaint and moved under Federal Rules of Civil Procedure 59(e) and 60(b)(2) to vacate the dismissal based on newly discovered scienter evidence. The court found that the new evidence could have been discovered earlier with the exercise of reasonable diligence and denied the plaintiffs the "extraordinary"

Id. at 42–43.

[3] The district court noted that the plaintiffs had requested, on the final page of their opposition to the motion to dismiss, that they be given leave to amend their complaint if the motion to dismiss were granted. Id. at 55. The court refused, noting that the plaintiffs had had over five more months after the filing of the initial complaint to investigate and that the plaintiffs had not moved for leave to amend either after the filing of the motion to dismiss or after the motion hearing, during which the court had expressed skepticism about the complaint's viability. Id.

relief requested under Rules 59(e) and 60(b)(2). GBR's timely appeal followed.

III.

A. Allowance of Motion to Dismiss the Initial Amended Complaint

GBR argues that the district court erred by dismissing its claims under Sections 10(b) and 20(a) of the Exchange Act. In particular, GBR contends that the district court wrongly held that two statements[4] specified in the complaint were inadequately pled as misleading and that the complaint failed to give rise to a strong inference of scienter. We disagree. Our review is de novo. See ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008).

Plaintiffs alleging violations of Section 10(b) must 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. Fire &

[4] GBR argues that the district court improperly rejected the following two statements by defendants specified in the complaint: Kingsley's statement on April 24, 2015, that "internal market research" suggested that physician intent to prescribe Tecfidera was improving; and a May 13, 2015 statement by Doug Williams (Biogen's Executive Vice President of Research & Development) that "survey work" showed that "physicians have kind of digested" the PML death and that physician "perspective about the safety profile of the drug" was "back to where it was before the PML event." We agree with the district court that there were no allegations supporting any inference that these statements were misleading. But even assuming GBR were correct, the complaint would still fail to meet the PSLRA's requirements as to scienter.

Police Pension Ass'n of Colo. v. Abiomed, Inc. (Fire & Police Pension), 778 F.3d 228, 240 (1st Cir. 2015). A complaint alleging a violation of Section 10(b) must also meet the heightened pleading standards of the PSLRA, which requires that the complaint "specify each statement alleged to have been misleading" as well as "the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1).

As to scienter, the PSLRA requires that a complaint allege specific facts giving rise to a "strong inference," id. § 78u-4(b)(2)(A), either of "intentional or willful conduct designed to deceive or defraud investors by controlling or artificially affecting the price of securities," City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 757 (1st Cir. 2011) (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 199 (1976)), or of "a high degree of recklessness," id. (quoting Aldridge v. A.T. Cross Corp., 284 F.3d 72, 82 (1st Cir. 2002)). "Recklessness, as used in this context, 'does not include ordinary negligence, but is closer to being a lesser form of intent.'" Fire & Police Pension, 778 F.3d at 240 (quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 188 (1st Cir. 1999)). 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."

Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 324 (2007).

The complaint fails to meet this rigorous standard. The confidential witness statements are insufficiently particular, do not make misleading the defendants' public disclosures, and do not speak with specificity as to why the defendants' alleged misstatements were untrue or misleading. Likewise, the complaint's "core operations" allegations are consistent with the defendants' statements to investors. And the most cogent inferences from the record favor the defendants.

1. Confidential Witness Statements and "Evidentiary Admissions"

The complaint's allegations as to scienter rest substantially on the confidential witness statements and on the core operations allegations. The statements, very often made about events occurring after the defendants' statements at issue, are so lacking in connecting detail that they cannot give rise to a strong inference of scienter. At bottom, the majority of the confidential witness statements say merely that Biogen sales regions experienced a serious decline in Tecfidera sales after the PML incident and after the purportedly misleading statements were made, that corporate changes were discussed at company events in

relation to the PML incident, and that the company changed the sales goals of at least some employees.[5]

The statements do not even begin to quantify the magnitude of the sales decline at the company level. They do not explain with any precision whether the sales decline resulted from higher discontinuations, fewer new starts, changes in the market, or some combination of these factors.[6] Nor do they purport to contradict any of the financial information released by Biogen in its quarterly and yearly reports during the Class Period.

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[5] GBR's own briefing only confirms this point. In its argument that the confidential witness statements are sufficiently particularized to give rise to a strong inference of scienter, GBR writes "the seven former [Area Business Managers] indicate that sales 'dropped steeply and immediately,' [that] there was a 'large drop in new prescription sales,' that 'sales dropped dramatically' and 'appreciably,' [and] that there was a 'big slowdown' in market expansion and a 'serious downturn' in new prescriptions."

[6] Similarly, the internal meetings and policy changes described by the confidential witness statements do not make up for the complaint's deficiencies. Scangos's statement at the November 2014 town hall meeting that the "trajectory" of the company was changing has no content about that change or its connection to the PML incident. Likewise, the presentation at the November 2014 meeting that suggested there may be "organizational changes" and that the PML death had an "impact" on sales does nothing to show that the defendants' public statements were made with any knowledge of falsity.

The statements by unidentified "senior Biogen leaders" at the March 2015 national sales meeting that the PML event "definitely was impacting sales" and that the PML death was a "market event" are no more concrete, and, coming as they do in the middle of the Class Period, they shed no light on the alleged misrepresentations that occurred before March 2015. The confidential witness statements about lowered sales goals are not connected to the defendants.

Indeed, the confidential witness statements are consistent with the defendants' public disclosures. See In re Genzyme Corp. Sec. Litig., 754 F.3d 31, 42–43 (1st Cir. 2014) (noting that prompt disclosures by corporate defendants "undercut any inference of fraudulent intent"); Auto. Indus. Pension Tr. Fund v. Textron Inc., 682 F.3d 34, 40 (1st Cir. 2012) (declining to find a strong inference of scienter where confidential witness allegations and defendants' public statements were "not in conflict"). As the district court observed, the "defendants were cautious in projecting Tecfidera's growth, and they repeatedly warned investors about the downside risks, including moderating growth and the PML label change." Biogen, 193 F. Supp. 3d at 51–52. The defendants made such warnings on the first day of the Class Period and continued to make them throughout. See Fire & Police Pension, 778 F.3d at 243 ("The argument is undercut by the fact that [defendant] explicitly warned investors . . . .").

We emphasize that there is a significant timing problem. The later confidential witness statements do not go to how the defendants' statements, which were earlier, were knowingly or recklessly misleading at the time they were made. The three statements found plausibly misleading by the district court concerned Tecfidera discontinuation rates and were made in January and February 2015. The confidential witness statements concerning drops in Tecfidera sales after these months do not address what

the defendants knew about discontinuation rates at the time they spoke to the public. And none of the earlier confidential witness statements go specifically to what the defendants knew at the time they made those three statements.

One example suffices. Two of the statements that the district court found to be plausibly misleading were Kingsley's remark at a January 29, 2015 health care conference that the company had not seen a "meaningful change in [Tecfidera] discontinuation rates," and his remark at a February 25, 2015 health care conference that discontinuation rates were "consistent with historical averages." Clancy had told investors on December 2, 2014, the first day of the Class Period, that investors should be "mindful" of the fact that Tecfidera's discontinuation rates were "tracking in the teens," higher than the company had hoped. So scienter allegations would have to suggest strongly that between Clancy's statement on December 2, 2014 and Kingsley's statements in January and February, Kingsley came into possession of information that the Tecfidera discontinuation rates had risen above the teens and were clearly inconsistent with historical averages. The confidential witness statements provide no such particularized allegations.

As in Fire & Police Pension, confidential witness statements are "not described with sufficient particularity," 778 F.3d at 245, to give rise to a strong inference of scienter as to

senior management if none of the witnesses were senior managers and they had little contact with such managers. The statements here fail to give rise to a strong inference of scienter because they lack "specific descriptions of the precise means through which [the defendants' alleged fraud] occurred."[7] In re: Cabletron Sys., Inc., 311 F.3d 11, 30 (1st Cir. 2002); see also Brennan v. Zafgen, Inc., No. 16-2057, 2017 WL 1291194, at *5 (1st Cir. Apr. 7, 2017) (news articles insufficient for scienter because they did not "support . . . the complaint's allegation that the defendants knew, or were reckless in not knowing, that they risked misleading

[7] It is true that CW 10 served as an executive assistant in Biogen's "program leadership and management team," and had responsibilities including supporting Uthra Sundaram, the Tecfidera program director. Sundaram was a "dotted line" report to Scangos. According to CW 10, "Biogen's sales and commercial teams monitored sales numbers through various reports" after the PML incident and the company "reached out to the top prescribing doctors as well as big pharmaceutical companies such as CVS Caremark and Walgreens." CW 10 further asserted that the company's commercial team performed "deep drill downs" into sales data, and that Sundaram accompanied Biogen medical-science liaisons on "ride-alongs" to meet doctors and "discuss the PML death." CW 10 said that the Tecfidera team met weekly to discuss sales data and the effect of the PML death on sales, and that Sundaram regularly communicated with Scangos and senior management following that meeting.

But although CW 10's information has a tighter connection to the defendants, it still lacks the necessary particularity. And nothing about CW 10's statements contradicts the company's public position or gives further context to the alleged misstatements. The fact that the company's Tecfidera team was actively monitoring sales in the wake of the PML incident and reported findings to senior management is unremarkable. It comports with the defendants' public statements, which repeatedly returned to the PML incident as one factor impacting Tecfidera's performance.

investors" and they had no particularized connection to the defendants).

Likewise, the various "evidentiary admissions" GBR points to as indicative of scienter all involve statements made by the defendants, well after the end of the Class Period, that do not provide particularized insight into the defendants' knowledge at the time of the alleged misstatements. See In re: Ariad Pharm., Inc. Sec. Litig., 842 F.3d 744, 751 (1st Cir. 2016) (finding no strong inference of scienter where complaint failed to plead "any specific facts about when the defendants learned of the[] adverse events or even when the adverse events occurred"). The use of these statements amounts to little more than pleading fraud by hindsight. See Miss. Pub. Emps.' Ret. Sys. v. Bos. Sci. Corp., 523 F.3d 75, 90 (1st Cir. 2008) ("Fraud by hindsight refers to allegations that assert no more than that because something eventually went wrong, defendants must have known about the problem earlier."); M. Gulati et al., Fraud by Hindsight, 98 Nw. U. L. Rev. 773, 787 (2004) (discussing hindsight bias).

2. "Core Operations" Allegations

GBR claims that the district court wrongly discounted the amended complaint's "core operations" allegations because there was no "smoking gun" or "plus factor," and argues that to

impose such a requirement runs afoul of the Supreme Court's guidance in Tellabs.

We need not resolve the standard by which "core operations" allegations may give rise to a strong inference of scienter, because the allegations here clearly fall short. The allegations are inapt because the evidence does not establish that, at the time the challenged statements were made, there existed reasonably accessible data within the company materially contradicting those statements.

The defendants' compensation structure and stock holdings also weaken any inference of scienter. As the complaint says, Scangos's and Clancy's compensation was keyed in part to revenue growth. But the complaint never alleges that there was any misreporting of revenue. Further, the individual defendants increased their stock holdings in Biogen during the Class Period, and the defendants in fact suffered losses as a result of Biogen's decline in stock price. This too cuts against scienter. See Fire & Police Pension, 778 F.3d at 246 (finding that an increase in stock holdings during the Class Period on the part of a defendant "negate[d] any inference that he had a motive to artificially inflate [the company's] stock during that period"); Maldonado v. Dominguez, 137 F.3d 1, 12 n.9 (1st Cir. 1998) (defendants' personal losses cut against inference of scienter); cf. Brennan, 2017 WL 1291194, at *6 (finding insider trading allegations of only

"marginal" benefit because the corporate "insiders [had] kept the vast majority of their [stock] holdings").

Ultimately, the scienter analysis involves evaluating the complaint as a whole, including "plausible opposing inferences." Tellabs, 551 U.S. at 323. Here, we agree with the district court that the strongest inferences are in favor of the defendants. See Brennan, 2017 WL 1291194, at *8 ("[T]he facts alleged in the complaint at the very least support a strong competing inference that the defendants disclosed what they considered to be, at the time, the most relevant information . . . .").

3. Section 20(a) Claim

Given that the Section 10(b) claim fails, GBR's Section 20(a) claim necessarily fails as well, because GBR has not stated an underlying violation of the Exchange Act. See ACA Fin. Guar. Corp., 512 F.3d at 67–68.

B. Denial of Motion to Vacate and for Leave to File Second Amended Complaint

GBR argues that the district court erred by not granting its motion to vacate the judgment and for leave to file a second amended complaint. It insists it was put in an impossible situation. GBR claims that it diligently secured new evidence and that it could not have done so earlier. [The district court found to the contrary]. GBR argues that the obligations of Federal Rule

of Civil Procedure 11 -- which requires parties to "certif[y] that to the best of [their] knowledge, information, and belief, formed after an inquiry reasonable under the circumstances . . . the factual contentions [in the motion] have evidentiary support," Fed. R. Civ. P. 11(b) -- precluded the plaintiffs from raising this new information until they had completed an ethics review of the new materials and completely vetted the allegations. GBR argues that the district court did not properly evaluate the timeline in which the plaintiffs could reasonably secure and vet this new evidence in compliance with Rule 11 before moving for leave to amend the complaint. The argument fails.

"We review a district court's decision to grant or deny a motion for reconsideration under Rules 59(e) and 60(b) of the Federal Rules of Civil Procedure for manifest abuse of discretion." Ruiz Rivera v. Pfizer Pharm., LLC, 521 F.3d 76, 81 (1st Cir. 2008). There was no abuse of discretion at all in denying the motion. GBR has not shown either that the purportedly new evidence would have made a difference to the district court's decision whether to grant the motion to dismiss or that the plaintiffs could not have gotten the evidence earlier. GBR's argument that the district court abused its discretion by failing to account for the time needed for the plaintiffs to comply with Rule 11 is misplaced.

The new evidence consisted of allegations from two additional confidential witnesses, CW 11 and CW 12, and a sworn

declaration by Dr. Ben Thrower, Medical Director of the Shepherd Center Multiple Sclerosis Institute in Atlanta.

Dr. Thrower's declaration states that the Shepherd Center determined "in approximately August 2014 that Tecfidera compromised patients' immune systems (as was reinforced by the PML death announced on October 22, 2014)," and that the Center immediately "completely stopped prescribing Tecfidera for MS patients" and "discontinued at least half of the 400 patients taking Tecfidera."[8] As counsel for GBR conceded at oral argument, Dr. Thrower does not say that the Shepherd Center took its actions in response to the PML incident. His statement merely alleges that the Shepherd Center stopped prescribing Tecfidera and took many patients off the drug around August 2014, which was well before the PML incident and the start of the Class Period.[9] There can be no abuse of discretion in denying the motion, and GBR's Rule 11 argument does nothing to address this.

The district court also acted well within its discretion by denying the motion because the plaintiffs could have presented

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[8] CW 12, a former Biogen Area Business Manager in Atlanta, alleges that Biogen was aware of the Center's decision.

[9] The information from CW 11, a former Biogen Senior Territory Business Manager in Pennsylvania, is also inadequate. CW 11's information does not quantify the impact of the PML incident on Tecfidera sales nationally, it has no particularized connection to the defendants, and it does not contradict the defendants' public positions.

the evidence earlier.[10] It is undisputed that the plaintiffs were aware of all three of the new sources they now identify before the district court entered its order of dismissal. And GBR does not offer a "cogent reason" for why it could not have obtained information about Tecfidera discontinuations from medical institutions sooner. Fisher v. Kadant, Inc., 589 F.3d 505, 513 (1st Cir. 2009). Without showing that the plaintiffs could not in the exercise of reasonable diligence have obtained this new evidence earlier, GBR's argument that the district court abused its discretion by failing to account for the time the plaintiffs needed to vet the evidence to meet their Rule 11 obligations has no force.

The district court did not err in denying the second motion to amend, which was filed post-dismissal. It commented that the plaintiffs could have alerted the court to their intentions earlier, but did not. Here, the district court gave the plaintiffs the full time they requested in order to file the initial amendment and allowed that amended complaint, and the plaintiffs had the motion to dismiss in hand for nearly four months

[10] See Fed. R. Civ. P. 60(b)(2) (court may relieve party from final judgment if party presents "newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b)"); Emmanuel v. Int'l Bhd. of Teamsters, Local Union No. 25, 426 F.3d 416, 422 (1st Cir. 2005) (Rule 59(e) motions on the basis of new evidence succeed only when evidence could not "have been presented earlier" "in the exercise of due diligence").

before the district court ruled. As we have said before, under circumstances like these, we wish to discourage any expectation that there will be "leisurely repeated bites at the apple." ACA Fin. Guar. Corp., 512 F.3d at 57.

IV.

Affirmed. Costs are awarded to the defendants.