United States Court of Appeals
For the Eighth Circuit

No. 14-2592

Frank Julianello, on behalf of himself and all others similarly situated

Plaintiff

Lori Anderson

Plaintiff - Appellant

v.

K-V Pharmaceutical Company; Gregory J. Divis, Jr.; Scott Goedeke; Thomas McHugh

Defendants - Appellees

Appeal from United States District Court
for the Eastern District of Missouri - St. Louis

Submitted: March 12, 2015
Filed: July 2, 2015

Before MURPHY and SHEPHERD, Circuit Judges, and HARPOOL,[1] District Judge.

SHEPHERD, Circuit Judge.

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[1]The Honorable M. Douglas Harpool, United States District Judge for the Western District of Missouri, sitting by designation.

This securities fraud class action involves a class of plaintiffs who purchased or otherwise acquired shares of K-V Pharmaceutical Company stock during the period in which the company launched and marketed Makena, its new prescription drug. The plaintiffs allege that K-V and three of its officers (collectively K-V) made materially false or misleading statements or omissions related to the product launch. The district court[2] granted K-V's motion to dismiss, holding the challenged statements were protected by the safe-harbor provision of the Private Securities Litigation Reform Act of 1995 (PSLRA), 15 U.S.C. § 78u-4(b), and that the plaintiffs failed to adequately plead scienter under the PSLRA. The district court also denied the plaintiffs' motion for reconsideration of the scope of leave to amend the complaint, denying the plaintiffs the opportunity to amend the complaint as it related to allegations from confidential witnesses. The plaintiffs appeal, and we affirm.

I.

The plaintiffs in this action are holders of publicly traded shares of K-V stock who purchased or otherwise acquired shares between February 14, 2011, and April 4, 2011. Plaintiffs allege that K-V made materially false or misleading statements and omissions during this period regarding K-V's marketing, distribution, and sale of its prescription drug Makena, designed to reduce the risk of pre-term labor for at-risk pregnant women. In 2008, K-V acquired the rights to the drug, then known as Gestiva, rebranded it as Makena, and sought exclusive sales rights under the Orphan Drug Act, 21 U.S.C. §§ 360aa-360ee, from the Food and Drug Administration (FDA). The Orphan Drug Act, which encourages drug manufacturers to develop drugs for the treatment of rare diseases or disorders, provides that, with FDA approval, manufacturers of drugs designed to treat diseases or disorders that affect fewer than

[2]The Honorable Audrey G. Fleissig, United States District Judge for the Eastern District of Missouri.

200,000 people may obtain seven years of exclusive sales rights. On February 3, 2011, the FDA granted K-V's request for exclusive sales rights.

On February 14, 2011, K-V held a conference call with investors and filed a Form 8-K with the Securities and Exchange Commission (SEC), which incorporated the information discussed in the conference call. At the beginning of the call, K-V made the following statements:

> [C]ertain information provided on this conference call may contain various forward-looking statements within the meaning of the [PSLRA] and may be based on or include assumptions concerning the Company's operations, future results and prospects. Such statements may be identified by the use of words such as plan, expect, believe, anticipate, intend, will, should, could, potential and other expressions that indicate future events and trends.
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> All statements that address expectations or projections about the future, including without limitation statements about . . . the Company's strategy for growth, product development, product launches, regulatory approvals, market position, acquisitions, revenues, expenditures and other financial results are forward-looking statements. These statements involve various risks and uncertainties that could cause our actual results to differ materially from those expressed in such forward-looking statements. These include the risks and uncertainties under the heading risk factors in our most recent annual report on Form 10-K and other periodic reports filed with the SEC which are available on our website . . . and on the SEC's website.
>
> Investors are cautioned not to place undue reliance on such forward-looking statements, as there is no assurance that these matters contained in such statements will occur. The forward-looking statements we make on today's call are based on our beliefs and expectations . . . as

> of today, February 14, 2011 only. We do not undertake any obligation to revise or update such forward-looking statements.

R. Doc 91-2, at 2-3.

The non-exclusive risk factors listed in the Form 10-K mentioned at the beginning of the call included the following: "new product development and launch, including the possibility that any product launch may be delayed or unsuccessful, including with respect to Gestiva™," "acceptance of and demand for our new pharmaceutical products, including Gestiva™," and "the possibility that any period of exclusivity may not be realized, including with respect to Gestiva™, a designated Orphan Drug." R. Doc. 91-1, at 3.

On the February 14, 2011 investor call, K-V announced that the FDA had approved Makena and granted it orphan-drug status. K-V informed investors that it planned to charge $1,500 per injection, with the average patient requiring nearly $30,000 worth of injections. K-V also announced a program called Makena Care Connection, which would offer administrative, educational, and financial assistance to patients, and indicated that women with household incomes of up to $100,000 would be eligible for this program. K-V asserted that this would include approximately 85% of households in the United States. K-V also indicated that it believed health insurers would provide coverage for Makena because the average cost relating to a pre-term birth—$51,000—was higher than the average cost of Makena injections—$30,000. The price point of $1,500 an injection marked a 14,900% increase from the price at which compounding pharmacies offered a previous version of the drug. The parties do not dispute that the success of Makena was critical to K-V's survival.

During the call, K-V was asked specifically about the possibility of off-label compounding pharmacies joining the market for Makena. K-V explained that it

believed the FDA regulations to be very clear and that the FDA generally prohibits distribution of compounded products that are the same as FDA-approved products. With respect to the FDA's enforcement of exclusivity, K-V made the following statements:

> [W]e believe that the regulations and laws are very clear. I think it's fair to say that compounding pharmacies are not FDA-approved manufacturing facilities and that FDA regulations and state pharmacy laws generally prohibit the distribution of compounded products that are the same or essentially the same as FDA-approved products.
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> We also believe that compounded pharmacies are aware of these laws and regulations, and our expectation is that they will adhere to them. I think it's also fair to say that, despite the availability of compounded product, there have been moms on the sidelines because of significant logistical and financial barriers to access that are typically associated with non-FDA approved products.
>
> And I'll just close by saying that everything we have designed around Makena is to remove these barriers and to make sure that we fulfill our corporate commitment, which is to make Makena accessible to all eligible patients.

R. Doc. 91-2, at 12-13. Asked about the price point of $1,500 per injection, K-V reiterated its belief that, because of the high cost of pre-term birth, Medicaid and insurers would cover the cost. K-V also stated that "we've done a lot of homework around this particular decision. And we believe our pricing approach is supported by a very comprehensive market research plan which included all stakeholders." R. Doc. 91-2, at 14.

On February 17, 2011, K-V sent a letter to compounding pharmacies informing them that they should no longer make unapproved formulations of Makena and warned that if the pharmacies continued production they would be subject to FDA

enforcement actions. On March 8, 2011, K-V issued a press release indicating Makena would become available for prescribing on March 14, 2011, and describing the financial assistance program. K-V also filed a Form 8-K with the SEC that included financial projections based on the sales launch of Makena. K-V released Makena to the public and, after K-V revealed the pricing structure, a swift negative reaction erupted. The March of Dimes withdrew its support and refused to allow K-V to use its name in association with Makena. Two United States senators issued a press release expressing their concerns over the price point and the insufficiency of the financial assistance program. They also released a letter they sent to the Federal Trade Commission urging an investigation and mentioned their concerns during an appropriations hearing.

On March 30, 2011, the FDA issued a statement that it did not intend to take enforcement action against compounding pharmacies that compounded the equivalent of Makena, informing the pharmacies that the "FDA understands that the manufacturer of Makena, KV Pharmaceuticals, has sent letters to pharmacists indicating that FDA will no longer exercise enforcement discretion with regard to compounded versions of Makena. This is incorrect." R. Doc. 91-8, at 1. The FDA further explained, "[i]n order to support access to this important drug, at this time and under this unique situation, FDA does not intend to take enforcement action against pharmacies that compound [the chemical equivalent of Makena] . . . ." R. Doc. 91-8, at 1. On April 1, 2011, in the wake of this backlash, K-V announced that it was reducing the price of Makena to $690 an injection. Nevertheless, the price of K-V stock plummeted, dropping from $9.75 a share on March 17, 2011, to $5.00 a share on April 4, 2011.

The plaintiffs initiated this action alleging that K-V knew, or should have known, that charging $1,500 per injection without an effective financial assistance program would hinder Makena's commercial success. The plaintiffs presented four specific allegations. First, the plaintiffs alleged that K-V made both false statements

and omissions about the risk of the FDA not enforcing exclusive sales rights. Second, the plaintiffs alleged that K-V's statement that they expected health insurers to cover the cost of Makena was materially false or misleading when K-V knew the price per dosage would face stiff opposition. Third, the plaintiffs alleged that K-V's statements about working to give all patients access to Makena, creating a financial assistance program, and creating a marketing strategy were similarly misleading. Finally, the plaintiffs alleged that K-V's Form 8-K contained revenue assumptions that lacked a factual basis because they did not account for the negative reaction to Makena's price point. The plaintiffs based their allegations upon information from unnamed confidential witnesses, who plaintiffs identified as four former employees or sales representatives.

K-V filed a motion to dismiss, which the district court granted based both on the applicability of the PSLRA's safe-harbor provision and on the plaintiffs' failure to adequately plead scienter. In the same order, the district court granted the plaintiffs leave to amend the complaint with respect to their allegations regarding the financial assistance program but denied their motion as it related to the FDA's likelihood of enforcing exclusivity. The plaintiffs declined to amend the complaint regarding the financial assistance program and filed a motion for reconsideration. The district court denied the motion for reconsideration, finding that it had already considered the plaintiffs' legal arguments in its previous order and that plaintiffs did not present any arguments sufficient to grant the motion. The district court also dismissed the remaining claims regarding the financial assistance program. The plaintiffs appeal, arguing that the district court erred: (1) in holding K-V's statements regarding the FDA's likelihood of enforcing exclusivity were protected by the PSLRA's safe-harbor provision, (2) in holding that the complaint failed to allege a strong inference of scienter regarding the likelihood of FDA exclusivity, and (3) in denying the motion for reconsideration of the scope of leave to amend the complaint.

II.

We first consider whether the district court erred in dismissing the plaintiffs' complaint on the grounds that the safe-harbor provision of the PSLRA covered K-V's statements about FDA exclusivity and that the plaintiffs failed to adequately plead scienter. The plaintiffs assert that the district court erred with respect to the safe-harbor provision because the challenged statements were not forward-looking or accompanied by meaningful cautionary language and erred in holding the plaintiffs failed to adequately plead scienter when they provided detailed allegations from four confidential witnesses showing K-V knew or should have known the FDA would not enforce exclusivity. We review a dismissal under Federal Rule of Civil Procedure 12(b)(6) and the PSLRA de novo, "review[ing] the claims to determine their compliance with the heightened pleading standards of the PSLRA" and "accept[ing] Plaintiffs' factual allegations as true and [] draw[ing] all reasonable inferences in their favor." McCrary v. Stifel, Nicolaus & Co., Inc., 687 F.3d 1052, 1056 (8th Cir. 2012). "For claims with a scienter component, which includes claims under Rule 10b–5, the allegations should give rise to more than just a plausible or reasonable inference of scienter." Id. "For material misrepresentation and omission claims, the court must also determine whether the claims 'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading.'" Id. (alteration in original) (quoting 15 U.S.C. § 78u-4(b)(1)).

Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and SEC Rule 10b–5, 17 C.F.R. § 240.10b–5, "prohibit fraudulent conduct in the sale and purchase of securities." Ferris, Baker Watts, Inc. v. Ernst & Young, LLP, 395 F.3d 851, 853 (8th Cir. 2005). To successfully state a claim for a securities fraud action under Section 10(b) and Rule10b–5, a plaintiff must establish six elements: (1) a material misrepresentation or omission, (2) scienter, (3) a connection to the purchase or sale of a security, (4) reliance, (5) economic loss, and (6) loss causation. Horizon Asset Mgmt. Inc. v. H & R Block, Inc., 580 F.3d 755, 760 (8th Cir. 2009). The

PSLRA contains a safe-harbor provision, which protects defendants from liability when: (1) they have made forward-looking statements accompanied by meaningful cautionary language, (2) the forward-looking statement is immaterial, or (3) the statement is made without actual knowledge that it was false or misleading. 15 U.S.C. § 78u-5(c)(1).

The plaintiffs specifically challenge the statements K-V made in relation to the investor call and the statements K-V made in the letter to compounding pharmacies warning them not to produce compounded Makena. Under the PLSRA, protected forward-looking statements include, among others: (1) projections of revenues or other financial items, (2) statements of plans and objectives for future operations, and (3) statements of the assumptions underlying the previous two categories. 15 U.S.C. § 78u-5(i)(1). "In determining whether a statement is truly forward-looking, the determinative factor is not the tense of the statement; instead, the key is whether its 'truth or falsity is discernible only after it is made.'" W. Wash. Laborers-Emp'rs Pension Trust v. Panera Bread Co., 697 F. Supp. 2d 1081, 1093 (E.D. Mo. 2010) (quoting Harris v. Ivax Corp., 182 F.3d 799, 805 (11th Cir. 1999)).

K-V's statements were forward-looking. First, they fall within the category of statements regarding plans and objectives for further operations because they detailed K-V's future launch of Makena and the anticipated results. Second, the veracity of the statements could only be determined after they were made. The statements during the call expressed that K-V felt the laws and regulations were clear and that they anticipated that the FDA would enforce exclusivity once Makena was launched. Critically, this statement is tied to a future event: the launch of Makena. Until this future event occurred, it could not be determined whether the FDA would vary from its usual practice of enforcing exclusivity. And there was no evidence at the time K-V made the statement that the FDA would not enforce exclusivity. Further, the use of the present tense in the challenged statements does not undermine our determination that they were forward-looking. The critical inquiry in determining

whether a statement is forward-looking is whether its veracity can be determined at the time the statement is made, not the tense of the statement. For the same reasons discussed above, K-V's statements utilizing the present tense satisfy this inquiry. Moreover, these statements may also fairly be categorized as the underlying assumptions that are recognized as part of the protected forward-looking statements. Finally, any statements that K-V made in a letter to compounding pharmacies informing them that K-V would have exclusive sales rights related to the production of Makena are not actionable because K-V never offered these statements to investors and these statements were never used in connection with the purchase or sale of securities. See Ferris, Baker Watts, 395 F.3d at 853 (requiring a connection to the purchase or sale of a security to state a claim for securities fraud action).

With respect to the requirement that forward-looking statements be accompanied by meaningful cautionary language, "[c]autionary language must be extensive, specific, and directly related to the alleged misrepresentation. Cautionary statements disclosed in SEC filings may be incorporated by reference; they do not have to be in the same document as the forward-looking statements." In re Aetna, Inc. Sec. Litig., 617 F.3d 272, 282 (3d Cir. 2010) (internal quotation marks and citations omitted). "The requirement for 'meaningful' cautions calls for 'substantive' company-specific warnings based on a realistic description of the risks applicable to the particular circumstances, not merely a boilerplate litany of generally applicable risk factors." Southland Sec. Corp. v. INSpire Ins. Solutions, Inc., 365 F.3d 353, 372 (5th Cir. 2004).

K-V's forward-looking statements were accompanied by meaningful cautionary language. While boilerplate language reciting a list of generally applicable risk factors is insufficient to satisfy this requirement, we reject plaintiffs' assertion that K-V's language was boilerplate. K-V's cautionary language was specific and related directly to the circumstances of Makena's planned launch. The language K-V used in its Form 10-K, which was incorporated by reference in the February 14, 2011

investor call, cautioned investors about the launch of Makena and warned them of precisely the risks about which they now complain. K-V's Form 10-K explicitly identified the risks associated with the FDA's presumed enforcement of exclusivity. As this was specific to Makena and its orphan-drug status, we cannot conclude the cautionary language about this risk was "boilerplate" and only recited generally applicable risk factors in a generic manner.

K-V's statements fall within the PSLRA's safe-harbor provision as forward-looking statements accompanied by meaningful cautionary language and are not actionable as a basis for a securities fraud action. Because we conclude that the challenged statements fall within the PSLRA's safe-harbor provision, we need not consider whether the plaintiffs adequately pled scienter. We therefore affirm the district court's dismissal of the complaint.

III.

We next consider whether the district court erred in denying plaintiffs' motion for reconsideration of the scope of leave to amend the complaint. The plaintiffs assert that the district court erred in denying the motion because a court should freely give leave to amend and the plaintiffs identified new facts concerning the confidential witnesses that would demonstrate the statements and omissions regarding the FDA's likelihood of enforcing exclusivity were materially false and misleading. We review a district court's denial of a motion for reconsideration for abuse of discretion. K.C. 1986 Ltd. P'ship v. Reade Mfg., 472 F.3d 1009, 1017 (8th Cir. 2007). We also review a district court's denial of leave to amend a complaint for abuse of discretion. Popoalii v. Correctional Med. Servs., 512 F.3d 488, 497 (8th Cir. 2008). "A court abuses its discretion when it denies a motion to amend a complaint unless there exists undue delay, bad faith, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the non-moving party, or futility of the amendment." Id.

Under Federal Rule of Civil Procedure 15(a), "[t]he court should freely give leave [to amend] when justice so requires." But "[a]lthough amendment of a complaint should be allowed liberally to ensure that a case is decided on its merits, there is no absolute right to amend." Ferguson v. Cape Girardeau Cnty., 88 F.3d 647, 650-51 (8th Cir. 1996) (citations omitted). "[P]arties should not be allowed to amend their complaint without showing how the complaint could be amended to save the meritless claim." Wisdom v. First Midwest Bank, of Poplar Bluff, 167 F.3d 402, 409 (8th Cir. 1999). But, when considering a motion for reconsideration, the inquiry is more narrow. "Motions for reconsideration cannot be used to introduce new evidence that could have been produced while the [] motion was pending." Chism v. W.R. Grace & Co., 158 F.3d 988, 992 n.4 (8th Cir. 1998).

The district court did not abuse its discretion in denying the motion for reconsideration of the scope of leave to amend the complaint. The court granted the plaintiffs leave to amend the complaint regarding the financial assistance program, but denied the plaintiffs leave to amend their allegations relating to the confidential witnesses' knowledge of what K-V knew about the likelihood of the FDA enforcing exclusivity. In denying the motion for reconsideration, the court applied Federal Rule of Civil Procedure 54(b) and determined that none of the plaintiffs' arguments was sufficient to warrant expanding the scope of leave to amend.[3] The scope of the

[3]K-V argues that the district court could have considered the motion under Federal Rule of Civil Procedure 60(b) rather than under Federal Rule of Civil Procedure 54(b). We disagree. Rule 54(b) allows a district court to revise a decision that adjudicates, but does not enter final judgment on, fewer than all claims in an action with multiple claims. Fed. R. Civ. P. 54(b) ("[A]ny order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities."). The district court concluded that because it had not yet entered final judgment on any of plaintiffs' claims when the plaintiffs filed the motion for reconsideration, Rule 54(b) is the appropriate rule

motion for reconsideration is critical in our determination that the district court did not err in denying the motion. A motion for reconsideration is not a vehicle to identify facts or legal arguments that could have been, but were not, raised at the time the relevant motion was pending. That is precisely the situation before us. Nothing in the record indicates that the allegedly new information from the confidential witnesses was not available to the plaintiffs at the time they opposed the motion to dismiss. The witnesses were the plaintiffs' own witnesses and the plaintiffs had every opportunity to utilize this evidence in opposition to the motion to dismiss. Plaintiffs are seeking to use a motion for reconsideration for the impermissible purpose of raising evidence they could have previously raised. The district court thus did not abuse its discretion in denying the plaintiffs' motion.

IV.

For the foregoing reasons, we affirm the judgment of the district court.

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under which to consider the motion. We agree. See Auto Servs. Co., Inc. v. KPMG, LLP, 537 F.3d 853, 856 (8th Cir. 2008) (noting that district court must direct entry of judgment for purposes of a final judgment when issuing an order dismissing fewer than all of the claims). The district court did not enter final judgment until after denying the motion for reconsideration.