

United States Court of Appeals
For the Eighth Circuit

No. 16-1506

United States of America ex rel. Shara Ambrosecchia, States of CA, CO, CT, DE,
District of Columbia, FL, GA, HI, IL, IN, LA, MD, MS, MI, MN, MO, MT, NV,
NH, NJ, NM, NY, OK, RI, TN, TX, VA and WI

Plaintiff - Appellant

State of California; State of Colorado; State of Connecticut; State of Delaware;
District of Columbia; State of Georgia; State of Hawaii; State of Illinois; State of
Indiana; State of Louisiana; State of Massachusetts; State of Michigan; State of
Montana; State of Nevada; State of New Jersey; State of New Mexico; State of
New York; State of North Carolina; State of Oklahoma; State of Rhode Island;
State of Tennessee; State of Texas; State of Virginia; State of Wisconsin

Plaintiffs

v.

Paddock Laboratories, LLC, a wholly-owned subsidiary of Perrigo Co.; Perrigo
Company, PLC

Defendants - Appellees

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

Submitted: March 7, 2017

Filed: May 5, 2017

Before RILEY, Chief Judge,¹ GRUENDER, Circuit Judge, and GRITZNER, District Judge.²

GRUENDER, Circuit Judge.

Relator Shara Ambrosecchia appeals the district court's³ dismissal of claims she brought against two pharmaceutical manufacturers under the False Claims Act ("FCA"). For the following reasons, we affirm.

I. Background

In November 2012, Ambrosecchia filed suit on behalf of the United States of America, twenty-seven states, and the District of Columbia against Paddock Laboratories and Perrigo Company ("Defendants") for violations of the FCA and analogous state statutes. In 1962, amendments to the Food, Drug, and Cosmetic Act required drugs previously approved by the Food and Drug Administration ("FDA") to undergo a review for effectiveness under the Drug Efficacy Study Implementation Program ("DESI"). Drugs determined to be "less than effective" and for which a notice of opportunity for a hearing was published ("DESI-LTE") are not eligible for Medicare and Medicaid reimbursement unless re-approved. Ambrosecchia, a former employee of both Defendants, alleged that the Defendants reported reimbursement-

¹The Honorable William Jay Riley stepped down as Chief Judge of the United States Court of Appeals for the Eighth Circuit at the close of business on March 10, 2017. He has been succeeded by the Honorable Lavenski R. Smith.

²The Honorable James E. Gritzner, United States District Judge for the Southern District of Iowa, sitting by designation.

³The Honorable Ronnie L. White, United States District Judge for the Eastern District of Missouri.

eligible classification codes to the Center for Medicare and Medicaid Services (“CMS”) for certain DESI-LTE drugs, thereby causing the United States and relevant state governments to provide reimbursement for ineligible drugs.

Defendants filed a motion to dismiss the second amended complaint under Federal Rule of Civil Procedure 12(b)(6), arguing that the public disclosure bar, 31 U.S.C. § 3730(e)(4), requires dismissal. The public disclosure bar requires an FCA claim to be dismissed where the allegations are based on information that has been publicly disclosed, unless the person making the claim “is an original source of the information.” *Id.* § 3730(e)(4)(A). The district court granted the motion and dismissed the FCA claims, finding that the public disclosure bar applies and that Ambrosecchia does not fit within the original source exception. Additionally, the district court declined to exercise supplemental jurisdiction over the state law claims and dismissed them without prejudice. Ambrosecchia appeals, arguing that the public disclosure bar cannot be determined on a motion to dismiss and, in the alternative, that the public disclosure bar does not apply. Ambrosecchia also contends that the district court should have granted her leave to amend her complaint and that the court erred in permitting Perrigo Company, PLC to join Paddock’s motion to dismiss rather than entering default judgment against it. Ambrosecchia does not challenge dismissal of her state law claims. Defendants raise as an alternative basis for affirmance the argument that Ambrosecchia’s complaint does not satisfy Federal Rule of Civil Procedure 9(b).

II. Discussion

A. Motion to Dismiss

First, Ambrosecchia contends that it is not appropriate to resolve whether the public disclosure bar applies on a motion to dismiss because the public disclosure bar, as amended in 2010, is no longer jurisdictional. Prior to 2010, 31 U.S.C. § 3730(e)(4)

removed a court's subject matter jurisdiction where the allegations and transactions of an FCA action previously had been publicly disclosed. *U.S. ex rel. Newell v. City of St. Paul, Minn.*, 728 F.3d 791, 794-95 (8th Cir. 2013) (“No court shall have jurisdiction over an action under this section based upon the public disclosure of [the] allegations or transactions” (citation omitted)). Accordingly, courts determined at the outset of a suit whether the public disclosure bar applied under Federal Rule of Civil Procedure 12(b)(1). *See id.* at 795. In 2010, Congress amended § 3730(e)(4) as part of the Patient Protection and Affordable Care Act. *U.S. ex rel. Moore & Co. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 298-300 (3d Cir. 2016). The amended section 3730(e)(4) provides:

The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—

- (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
- (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
- (iii) from the news media

31 U.S.C. § 3730(e)(4)(A). Ambrosecchia argues that this amended language does not pose a jurisdictional question. Therefore, she argues, whether the public disclosure bar applies is a factual question that cannot be resolved prior to summary judgment.

However, this court has already determined that the amended public disclosure bar is appropriately resolved on a motion to dismiss, even assuming that it no longer poses a jurisdictional question. *U.S. ex rel. Paulos v. Stryker Corp.*, 762 F.3d 688, 696 (8th Cir. 2014) (“Assuming the motion is best viewed as one made under Rule 12(b)(6), a court may still consider matters incorporated by reference or integral to the claim, items subject to judicial notice, and matters of public record.” (quotation and

alterations omitted)); *U.S. ex rel. Kraxberger v. Kan. City Power & Light Co.*, 756 F.3d 1075, 1083 (8th Cir. 2014) (“Since the FCA *requires* a court to dismiss a claim based on public disclosure, a court necessarily considers the alleged public documents in its dismissal.”). We are not at liberty to disregard this authority as Ambrosecchia advocates. Indeed, neither party disagrees with the conclusion that the amended public disclosure bar is not jurisdictional. Defendants filed their motion to dismiss under Rule 12(b)(6), not 12(b)(1), and the key case Ambrosecchia cites held that the amended public disclosure bar should be evaluated under Rule 12(b)(6). *Moore*, 812 F.3d at 297 (“We agree that the public disclosure bar is no longer jurisdictional and that the motion therefore should have been decided under Rule 12(b)(6) rather than Rule 12(b)(1).”). Accordingly, we proceed to the merits of Defendants’ Rule 12(b)(6) motion.

B. Public Disclosure Bar

We review dismissal under Rule 12(b)(6) *de novo*. *Miller v. Redwood Toxicology Lab., Inc.*, 688 F.3d 928, 936 (8th Cir. 2012). To survive a motion to dismiss, “[a] complaint must ‘state a claim to relief that is plausible on its face,’” accepting the factual allegations in the complaint as true and viewing them in the light most favorable to the plaintiff. *Hager v. Ark. Dept. of Health*, 735 F.3d 1009, 1013 (8th Cir. 2013) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In evaluating whether the public disclosure bar applies, we may “consider matters incorporated by reference or integral to the claim, items subject to judicial notice, [and] matters of public record.” *Paulos*, 762 F.3d at 696 (quotation omitted). The district court determined that the public disclosure bar applies because two separate sources previously revealed substantially the same allegations or transactions as those contained in Ambrosecchia’s complaint: (1) various federal reports and (2) the complaint in a recent district court case, *U.S. ex rel. Conrad v. Abbott Labs., Inc.*, No. 02-11738-RWZ, 2013 WL 682740 (D. Mass. Feb. 25, 2013). Ambrosecchia challenges the district court’s reasoning as to *Conrad*, but she does not challenge the

district court's reasoning as to the federal reports until her reply brief. Because "[c]laims not raised in an opening brief are deemed waived," *FTC v. Neiswonger*, 580 F.3d 769, 775 (8th Cir. 2009) (quotation and citation omitted), Ambrosecchia has waived her opportunity to challenge the district court's finding that the federal reports publicly disclosed her claims. Because the federal reports are independently sufficient to apply the public disclosure bar, we need not decide whether the district court correctly assessed whether the *Conrad* case also qualified to raise the public disclosure bar. Accordingly, we proceed to consider Ambrosecchia's argument that she meets the criteria for the original source exception to the public disclosure bar. We conclude that she does not.

A relator who qualifies as an original source is exempt from the public disclosure bar. 31 U.S.C. § 3730(e)(4)(A). An original source is

an individual who either (i) prior to a public disclosure under subsection (e)(4)(a) [sic], has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) [sic] who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

Id. § 3730(e)(4)(B). The record reflects only that Ambrosecchia provided information concerning her contemplated suit to the Government prior to filing her lawsuit, not prior to the public disclosures. Ambrosecchia provided information to the Government in mid-November 2012, a short time before filing her initial complaint on November 20, 2012. The federal reports the district court found to publicly disclose Ambrosecchia's claims were published in the second quarter of 2012 or earlier. Accordingly, Ambrosecchia does not qualify as an original source under subsection (i).

To qualify under subsection (2),⁴ Ambrosecchia must have (1) independent knowledge that (2) “materially adds to the publicly disclosed allegations or transactions,” in addition to providing the information to the Government before filing.⁵ 31 U.S.C. § 3730(e)(4)(B)(2). “Independent knowledge is knowledge not derived from the public disclosure.” *Newell*, 728 F.3d at 797 (quotations omitted). Although the court is obligated to take the allegations in the complaint as true, it is not obligated to accept legal conclusions, and “[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotations omitted). Ambrosecchia conclusorily alleges that she has independent knowledge that materially adds to publicly available information but does not provide more. This is not sufficient. The complaint also conclusorily asserts that she gained the information from her employment with Defendants, but the complaint does not detail the nature of that information or explain how it relates to her employment. The complaint merely implies that because of her employment in the pharmaceutical industry, she was familiar with the regulatory framework underlying Medicare reimbursement. Thus, when a relative asked her whether a certain drug could be reimbursed, she knew that the drug in question was not eligible. The only independent knowledge in the complaint comes from this relative, who purportedly received reimbursement for an ineligible Paddock drug. This allegation only provides an example of a false claim; it does not materially add to information regarding how Defendants perpetrated the alleged fraud.

⁴The statute inconsistently numbers the subsections in this provision.

⁵The pre-2010 language required both independent and direct knowledge, which this court interpreted to be first-hand knowledge. *Newell*, 728 F.3d at 797. The post-2010 language requires only that the knowledge be independent, not that it be direct.

Ambrosecchia claims that her information materially adds to the existing information by demonstrating scienter. However, the complaint provides no more than the simple, conclusory allegation that Defendants' actions were knowing. The complaint does not elaborate, and this "formulaic recitation of the elements of [the] cause of action" alone is not sufficient. *See Iqbal*, 556 U.S. at 678 (quotations omitted). Accordingly, Ambrosecchia's complaint is insufficient to plausibly state that she qualifies as an original source.

As a result, the public disclosure bar applies, and the district court was correct to dismiss Ambrosecchia's FCA claims.⁶ Because we find in Defendants' favor on these grounds, we need not address their argument that Ambrosecchia's complaint does not satisfy Rule 9(b).

C. Motion to Amend

Next, Ambrosecchia challenges the district court's decision to deny her leave to amend her second amended complaint. "We review the denial of a motion for leave to amend a complaint for an abuse of discretion." *Fuller v. Sec'y of Def.*, 30 F.3d 86, 88 (8th Cir. 1994) (citation omitted). Although the district court "should freely give leave [to amend] when justice so requires," Fed. R. Civ. P. 15(a)(2), a district court does not abuse its discretion in denying leave to amend where the plaintiff "made no motion for leave to amend and did not explain the substance of his proposed amendment," *Misichia v. St. John's Mercy Health Sys.*, 457 F.3d 800, 805

⁶Ambrosecchia also argues that the district court should have addressed each defendant individually in resolving the motion to dismiss. However, she provides no authority for this proposition, citing only to a case that individually assessed several government officials' entitlement to qualified immunity. *See Wilson v. Northcutt*, 441 F.3d 586, 591-92 (8th Cir. 2006). Moreover, given that Ambrosecchia's complaint usually refers to Defendants collectively instead of individually, we see no reason why the district court could not frame its discussion in a similar manner.

(8th Cir. 2006). Ambrosecchia “raised this issue with a one line request in [her] brief opposing defendants’ motion to dismiss” and did not provide the substance of the proposed amendments.⁷ *See id.* Accordingly, the district court did not abuse its discretion in denying leave to amend.

D. Joinder Motion

Finally, Ambrosecchia’s contention that the district court should have entered a default judgment against Perrigo Company, PLC instead of allowing it to join Paddock’s motion to dismiss is without merit. Allowing one party to join another party’s motion is a matter well within the district court’s “substantial case management discretion.” *See United States v. Edwards*, 159 F.3d 1117, 1130 (8th Cir. 1998) (reviewing a district court’s decision to enforce the parties’ pretrial discovery agreement); *cf. Mosley v. Gen. Motors Corp.*, 497 F.2d 1330, 1332 (8th Cir. 1974) (reviewing the decision to allow parties to join litigation for abuse of discretion). Accordingly, we may reverse only if the district court abused its discretion. *See Edwards*, 159 F.3d at 1130. Ambrosecchia originally named Perrigo Company, Inc. (an American corporation) in her complaint. During the litigation, Perrigo reincorporated in Ireland. As a result, its name changed to Perrigo Company, PLC. The named party in the case remained Perrigo Company, Inc. Paddock and Perrigo Company, Inc. jointly filed a motion to dismiss the second amended complaint. Later, Ambrosecchia moved to amend the second amended complaint to correct the party’s name from Perrigo Company, Inc. to Perrigo Company, PLC. After the district court granted the motion, Perrigo Company, PLC filed a notice of joinder in the motion to dismiss. The district court allowed the joinder.

⁷ Ambrosecchia’s request to amend read as follows: “However, should the Court find Relator’s Second Amended Complaint lacking in detail or defective in any manner, Relator hereby requests leave to Amend her Complaint to correct any such defect.”

Ambrosecchia contends that this decision violates due process, but she fails to offer any relevant rationale for or cite any cases supporting this argument. Ambrosecchia cannot demonstrate that she lacked notice and the ability to brief arguments relating to Perrigo. *Cf. Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 542 (1985) (“An essential principle of due process is that a deprivation of life, liberty, or property be preceded by notice and opportunity for hearing appropriate to the nature of the case.” (quotation omitted)). Indeed, her response to the motion to dismiss included specific arguments regarding Perrigo. Thus, the district court did not abuse its discretion.

III. Conclusion

For the foregoing reasons, we affirm.
