United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 07-3285

Little Gem Life Sciences LLC, individually and on behalf of a class of persons similarly situated,	*	
Appellant,	*	
v.	*	Appeal from the United States District Court for the District of Minnesota.
Orphan Medical, Inc.; John H. Bullion; and Timothy G. McGrath,	*	
Appellees.	*	

Submitted: May 15, 2008
Filed: August 11, 2008

Before WOLLMAN, MURPHY, and SMITH, Circuit Judges.

SMITH, Circuit Judge.

Little Gem Life Sciences, LLC ("Little Gem") filed this securities class action against Orphan Medical, Inc. ("Orphan") on behalf of all individuals who held Orphan stock at the time Orphan was acquired by Jazz Pharmaceuticals, Inc. ("Jazz"). Little Gem alleged that Orphan and two of its principal executive officers, John H. Bullion and Timothy G. McGrath, negligently failed to disclose material information to Orphan's stockholders before asking the stockholders to approve Orphan's merger

with Jazz, in violation of §§ 14(a) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78n and 78t, and Securities and Exchange Commission (SEC) Rule 14a-9, 17 C.F.R. 240.14a-9. The district court[1] granted the defendants' joint motion to dismiss, finding that Little Gem failed to meet the heightened pleading standards required by the Private Securities Litigation Reform Act (PSLRA), 15 U.S.C. § 78u-4(b)(1) and (2). Little Gem appeals, arguing that the district court erred (1) by failing to convert Orphan's motion to dismiss into a motion for summary judgment, and (2) in finding that Little Gem's claims failed as a matter of law. We affirm.

I. *Background*[2]

Orphan is a specialty pharmaceutical company whose focus is on sleep disorders, pain, and other central nervous system disorders. At the time of the events giving rise to this lawsuit, Orphan's lead product was Xyrem. Bullion was Orphan's CEO and served on its Board of Directors ("Board"). McGrath was Orphan's CFO, Principal Accounting Officer, and Vice-President. In June 2004, Orphan merged, with shareholder approval, with Jazz, and in this merger, Jazz purchased all of Orphan's common stock at a price of $10.75 per share.

Little Gem, the lead plaintiff of this putative class action, was an Orphan shareholder at the time of the merger and at all other relevant times. Little Gem brought this suit in 2006, alleging violations of §§ 14(a) and 20(a) of the Exchange Act and SEC Rule 14a-9.

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[1]The Honorable Ann D. Montgomery, United States District Judge for the District of Minnesota.

[2]Because this matter was decided on a motion to dismiss, the facts are presented in the light most favorable to the plaintiffs. *Davenport v. Farmers Ins. Group*, 378 F.3d 839, 841 (8th Cir. 2004).

Orphan faced financial difficulties in the years leading up to 2005 and sought a company to buy out its stock. Orphan had several bidders, but these companies passed on the opportunity to purchase Orphan due to the company's uncertain future profitability. Orphan relied heavily on Xyrem, and it was uncertain whether Xyrem could have a broader medical application. Before the merger with Jazz, Orphan was testing Xyrem's effectiveness in treating fibromyalgia and had initiated Phase I of its Food and Drug Administration (FDA) clinical trial in June 2004. Orphan announced in its March 16, 2005, Form 10-K that it expected the results of Phase II of the clinical trial in the second half of 2005. While Phase II was completed by April 2005, the results would not be available for several more months. If Xyrem successfully completed Phase II, it would have to proceed to, and pass, Phase III of testing before the FDA would approve its use in the treatment of fibromyalgia.

On April 18, 2005, Orphan's Board unanimously approved a merger agreement. Under the agreement, Jazz would acquire most of Orphan's publicly-owned stock, and Orphan would become a Jazz subsidiary. Shortly after the merger agreement was signed, Bullion, an Orphan board member, informed shareholders in a conference call that the proxy statement would explain why the company should merge before the Xyrem results were complete.

On May 20, 2005, Orphan filed a proxy statement with the SEC in which Orphan provided details for the proposed merger. The proxy statement justified the merger, in part, based upon an opinion prepared by Banc of America Securities LLC ("Banc of America"), the financial advisor to Orphan's Board. Banc of America opined that the proposed merger was financially fair to the holders of Orphan common stock.

On June 20, 2005, shortly before the shareholder vote on the merger, Jazz raised $100 million. The record does not provide a clear purpose for raising these funds. Orphan's shareholders approved the merger on June 22, 2005. In July 2005, the results

of the Xyrem trial were released, indicating that Xyrem could move to the next phase of testing. Following the announcement of these positive results, Little Gem brought this action, claiming that the defendants negligently made false or misleading statements. Little Gem contends that Orphan should have informed its shareholders of Xyrem's positive completion of the Phase II clinical trial and its moving to Phase III FDA testing before the shareholders voted on the merger agreement.

Orphan moved to dismiss this action, and in support of its motion, Orphan asserted factual allegations that went beyond the face of Little Gem's complaint. The district court expressly declined to consider these additional facts but did utilize certain documents outside the pleadings to "establish context regarding the Xyrem clinical trial." The district court granted Orphan's motion to dismiss, finding that Little Gem failed to meet the heightened pleading standards mandated by the PSLRA. Little Gem now appeals.

II. *Discussion*

A. *Standard for Evaluating the Motion to Dismiss*

Little Gem argues that the district court erred in not converting the motion to dismiss into a motion for summary judgment because the district court considered matters outside the pleadings. The district court stated that it considered information in public records to put the Xyrem drug testing into context. Because this information served a permissible limited purpose, we conclude that the district court did not err by not converting Orphan's motion to dismiss into one for summary judgment.

"If, on a motion under Rule 12(b)(6) . . . , matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56." Fed. R. Civ. P. 12(d). The court, however, "may consider some materials that are part of the public record or do not contradict the complaint, as well as materials that are necessarily embraced by the pleadings."

Porous Media Corp. v. Pall Corp., 186 F.3d 1077, 1079 (8th Cir. 1999) (internal citation and punctuation omitted).

The SEC filings relied upon by the district court for dates and details are the type of public records contemplated by *Porous Media*. The parties' dispute, however, concerns the extent to which the district court used these filings in deciding the present case. A number of our sister circuits have limited the purposes for which information in the public record may be considered on a motion to dismiss. *See e.g. Bryant v. Avado Brands, Inc.*, 187 F.3d 1271, 1276 (11th Cir. 1999); *Lovelace v. Software Spectrum, Inc.*, 78 F.3d 1015, 1018 (5th Cir. 1996); *Kramer v. Time Warner Inc.*, 937 F.2d 767, 773–74 (2d Cir. 1991). We need not identify these various limited purposes because it is not necessary for the resolution of the matter before us. The district court did consider matters outside the pleadings by reviewing Orphan's SEC filings to obtain background facts regarding the Phase II Xyrem drug trial. Notably, the facts considered did not contradict Little Gem's complaint and were not critical to the outcome of Orphan's motion. The district court's decision appropriately rested on consideration of the parties' pleadings. Accordingly, we hold that the district court properly denied Little Gem's request to convert the motion to dismiss into a motion for summary judgment.

B. *Merits of Orphan's Motion to Dismiss*

Little Gem also asserts that the district court erred in determining that it failed to meet the heightened pleading standards required by the PSLRA. We disagree and affirm.

"We review de novo the district court's dismissal of [Little Gem's] complaint." *In re NVE Corp. Sec. Litig.*, 527 F.3d 749, 751 (8th Cir. 2008). Pursuant to the PSLRA, to state a claim, a complaint must "1) specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading, and 2) state with particularity facts giving rise to a strong inference that the defendant acted

with the required state of mind." *Id*. (citations and punctuation omitted). "When considering a motion to dismiss, we take the complaint's material allegations as true and liberally construe the complaint in the plaintiff's favor." *Davenport*, 378 F.3d at 842 (citation and punctuation omitted).

Little Gem first argues that the heightened pleadings standards of the PSLRA do not apply to negligent misrepresentation actions because negligence is not a state of mind. We find this argument unpersuasive and unsupported by precedent. *See United States v. Robinson*, 439 F.3d 777, 780 (8th Cir. 2006) (rejecting the appellant's argument due to an absence of case law support).

Little Gem next argues that the district court erred because it considered the facts alleged in the complaint in isolation rather than taken as a whole. In assessing whether a party has met the heightened pleading standards, the district court must consider all of the facts taken as a whole. *See Cornelia I. Crowell GST Trust v. Possis Med., Inc.*, 519 F.3d 778, 782 (8th Cir. 2008) (requiring the district court to examine the facts "collectively"). The record before us does not support an argument that the district court did not properly consider the evidence as a whole.

Essentially, Little Gem's case alleges that several comments in Orphan's proxy statement were false or misleading because Orphan's officers could have had access to the Xyrem test results and negligently failed to gain access. Had Orphan's executives advised themselves and the company's shareholders of the trial's probable success, perhaps a better stock price could have been attained in the Jazz merger. "Negligence requires a duty, an obligation of conduct to another person." *Paul v. Missouri Pac. R. Co.*, 963 F.2d 1058, 1061 (8th Cir. 1992). Whether the defendants had early access to the raw test data is a disputed fact matter. But the issue before us, however, is whether Orphan's officers had a legal duty to search out and disclose such information while it remained under professional analysis in accordance with FDA

drug trial regulations. We hold that they did not. In fact, the blinding[3] of the Xyrem trial was critical to ensuring the validity of the test results. *See* 21 C.F.R. § 314.126(b)(5) (stating that among the characteristics of "[a]n adequate and well-controlled study" is that "[a]dequate measures are taken to minimize bias on the part of the subjects, observers, and analysts of the data. The protocol and report of the study should describe the procedures used to accomplish this, such as blinding"). Because there was no duty for the officers to find out the results of the study early, we conclude that Orphan and its officers cannot be negligent in failing to do so.

III. *Conclusion*

Accordingly, we affirm the judgment of the district court.

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[3]In a double-blinded study, "neither the clinical trial participant nor the administering doctor knows whether the actual drug or a placebo is being used." Joanna R. Cerino, *The Statutory Limits of Compassion: Can Treatment INDS Provide Meaningful Access to Investigational Drugs for the Terminally Ill?*, 27 Temp. J. Sci. Tech. & Envtl. L. 79, 89 (2008).