
IN THE UNITED STATES COURT FOR THE DISTRICT OF UTAH
CENTRAL DIVISION

IN RE NPS PHARMACEUTICALS, INC.
SECURITIES LITIGATION,

This Order relates to: All Actions

ORDER DENYING MOTION TO
DISMISS

Master File Case No. 2:06-cv-00570

(Consolidated with 2:06-cv-00597 TS,
2:06-cv-00647 DB, 2:06-cv-00648
BSJ, and 2:06-cv-00699 TS)

This case, a private securities litigation action, arises from the consolidated plaintiff's claims that it invested in a new drug based on the defendants' knowing misrepresentations. NPS Pharmaceuticals, Inc., is the developer of PREOS, a new drug for the treatment of osteoporosis. When NPS filed a New Drug Application for PREOS with the Food and Drug Administration, the FDA indicated that although PREOS demonstrated some efficacy in reducing fracture risk, the FDA needed additional information before it considered approving the drug for sale. In this suit against NPS and various individual defendants, the plaintiff alleges the defendants knew of significant problems with PREOS early on, yet intentionally and knowingly made misleading statements regarding the safety, efficacy, potential for FDA approval, and potential market size of

PREOS in violation of § 10(b) of the Securities Exchange Act. The plaintiff also alleges the individual defendants face liability under § 20(a) of the Exchange Act by virtue of the underlying § 10(b) violations and their positions as controlling persons of NPS.

The defendants (collectively referred to as “NPS”) have moved to dismiss the case, claiming the plaintiff has failed to plead facts supporting the falsity of the alleged statements and the scienter requirement under § 10(b), and contending that the plaintiff’s insufficient allegations of a primary § 10(b) violation negate its claims under § 20(a). The court, however, finds the plaintiff pleaded facts sufficiently under both § 10(b) and § 20(a) to withstand the defendants’ motion to dismiss. In light of the parties’ extensive and detailed briefing, the court finds oral argument to be unnecessary.

BACKGROUND

NPS is a pharmaceutical company involved in the discovery, development, and commercialization of drugs. PREOS, an injectable parathyroid hormone for the treatment of osteoporosis, is one of the drugs NPS has in development. NPS has conducted various clinical trials of PREOS, including Phase III trials, in pursuit of FDA approval of the drug. NPS filed a New Drug Application with the FDA for PREOS on May 10, 2005. On July 11, 2005, NPS announced the FDA had accepted PREOS for review.

Then, on March 10, 2006, NPS announced that the FDA had issued an “approvable letter” for PREOS. In the letter, the FDA expressed concern about the incidence of hypercalcemia in patients administered PREOS. In addition, the FDA requested more information regarding the drug’s injection device. NPS communicated with the FDA regarding

the best way to address the FDA's concerns. NPS announced, on May 2, 2006, that the FDA had proposed NPS conduct an additional clinical trial to further investigate the hypercalcemia concerns associated with PREOS. With this announcement, the price of NPS stock rapidly declined, dropping over 37% after the announcement of the approvable letter, and another 39% after the announcement of the proposal of additional clinical trials.

Various plaintiffs filed suit against NPS in 2006. On September 15, 2006, the court granted the parties' motion to consolidate five actions into one. The court later appointed a lead plaintiff and approved the lead plaintiff's selection of counsel. On January 16, 2007, pursuant to the court's order, the lead plaintiff filed a consolidated amended complaint against NPS and various individual defendants. In the complaint, the plaintiff alleges the defendants violated § 10(b) and § 20(a) of the Securities and Exchange Act. Specifically, the plaintiff alleges numerous public statements made by the defendants between August 7, 2001, and May 2, 2006, were knowingly false or misleading to investors. The plaintiff also alleges the defendants are subject to liability pursuant to § 20(a) as controlling persons.

STANDARD OF REVIEW

In reviewing Rule 12(b)(6) motions, the court accepts "as true all well pleaded factual allegations in the amended complaint," and views them "in the light most favorable to the nonmoving party."¹ Such motions will not be granted "unless it appears beyond doubt that the

¹ *County of Santa Fe, N.M. v. Public Serv. Co. of N.M.*, 311 F.3d 1031, 1034 (10th Cir. 2002) (quotations and citation omitted); *see also Pirraglia v. Novell, Inc.*, 339 F.3d 1182, 1187 (10th Cir. 2003).

plaintiff can prove no set of facts in support of his claim that would entitle him to relief.”² The court does “not weigh potential evidence” but assesses “whether the plaintiff’s complaint alone is legally sufficient to state a claim for which relief may be granted.”³ If, when assessing a Rule 12(b)(6) motion, a court considers matters outside the pleadings, the court must treat the motion as a motion for summary judgment under Rule 56. In this case, the defendants have submitted significant materials outside of the pleadings for the court’s review. However, the court excludes this material from its review, so the defendants’ motion remains a 12(b)(6) motion.

DISCUSSION

I. SECTION 10(B) CLAIM

The defendants move to dismiss the plaintiff’s § 10(b) claim on the grounds that the plaintiff has not pleaded facts supporting the falsity of the defendants’ statements or the scienter requirement. The court finds the plaintiff has adequately pleaded facts supporting both falsity and scienter.

A. Allegations of Falsity

NPS makes various claims in support of its argument that the plaintiff has failed to plead particularized facts establishing the defendants’ statements were false and misleading when made. The problem with all of NPS’s claims is that they require the court to weigh evidence. Therefore, they are inappropriate at the motion to dismiss stage.

To state a claim under § 10(b), the plaintiff’s complaint

² *County of Santa Fe*, 311 F.3d at 1035 (quotations and citation omitted).

³ *Id.* (quotations and citation omitted).

must contain allegations addressing the following five elements: (1) the defendant made an untrue or misleading statement of material fact, or failed to state a material fact necessary to make statements not misleading; (2) the statement complained of was made in connection with the purchase of securities; (3) the defendant acted with scienter, that is, with intent to defraud or recklessness; (4) the plaintiff relied on the misleading statements; and (5) the plaintiff suffered damages as a result of his reliance.⁴

In addition, securities fraud claims are subject to the heightened pleading requirements of Rule 9(b)⁵ and the Private Securities Litigation Reform Act.⁶ Rule 9(b) requires that “the circumstances constituting fraud . . . be stated with particularity.”⁷ Basically, this means the complaint must “set forth the time, place and contents of the false representation, the identity of the party making the false statements and the consequences thereof.”⁸ The PLSRA imposes additional, yet similar, requirements. In a private securities action where the plaintiff alleges false or misleading statements by the defendant, the PSLRA requires the plaintiff to “specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.”⁹ But

⁴ *Adams v. Kinder-Morgan, Inc.*, 340 F.3d 1083, 1095 (10th Cir. 2003).

⁵ Fed. R. Civ. P. 9(b).

⁶ Pub. L. No. 104-67, 109 Stat. 737 (1995) (codified in scattered sections of 15 U.S.C.).

⁷ Fed. R. Civ. P. 9(b).

⁸ *Schwartz v. Celestial Seasonings, Inc.* 124 F.3d 1246, 1252 (10th Cir. 1997) (quoting *Lawrence Nat'l Bank v. Edmonds (In re Edmonds)*, 924 F.2d 176, 180 (10th Cir. 1991)).

⁹ 15 U.S.C. § 78u-4(b)(1)(B).

this does not require the plaintiff to disclose the source of its facts,¹⁰ nor does it require the court to take a splintered approach to its analysis. Rather, the court must evaluate “the facts alleged in a complaint to determine whether, taken as a whole, they support a reasonable belief that the defendant’s statements identified by the plaintiff were false or misleading.”¹¹

Although NPS styles its motion to dismiss as a challenge to the particularity of the plaintiff’s pleading, NPS does not cite to specific pleading failures, instead making substantive challenges. For instance, NPS challenges whether the plaintiff’s allegations that the defendants’ statements were knowingly made ought to be believed, and whether the statements were actually misleading or were, instead, accompanied by the necessary and appropriate disclaimers. But at the motion to dismiss stage, the court cannot and does not weigh the evidence. And the consolidated complaint, viewed as a whole, sufficiently alleges that the defendants made false or misleading statements to meet the requirements of Rule 9(b) and the PLSRA. Indeed, the plaintiff has gone to great detail describing the misleading statements and the surrounding circumstances — providing facts supporting a reasonable belief that the statements were misleading. To avoid a comprehensive recitation of the plaintiff’s complaint, the court cites but a few examples here.

With regard to the safety of PREOS, the plaintiff alleges, among other things, that the defendants misled investors by claiming the hypercalcemia caused by PREOS was un concerning, “a reasonably small incident,” “little to talk about,” and that the studies showed only

¹⁰ *Kinder-Morgan*, 340 F.3d at 1101–02.

¹¹ *Id.* at 1099.

“inconsequential . . . ‘generally transient’ increases in calcium levels during the studies and not hypercalcemia.”¹² Allegedly, with such statements, the defendants concealed information relating to the high incidence of hypercalcemic toxicity in patients receiving PREOS, even though they were fully aware of the hypercalcemia risks. NPS claims the statements about the risks of hypercalcemic toxicity simply reveal a difference of opinion regarding data interpretation. But even if the NPS’s claim is true, at the motion to dismiss stage, the court takes the plaintiff’s well-pleaded factual allegations as accurate and does not weigh evidence. In other words, at this juncture, the court will not assess whether the evidence shows the statements to actually be false. The plaintiff pleaded facts supporting a reasonable belief the statements were misleading or false.

With regard to PREOS’s efficacy, the plaintiff alleges, among other things, that the defendants claimed PREOS could treat osteoporosis of both the spine and the hip, despite their knowledge (and concealment) of information showing PREOS only had demonstrated efficacy in treating osteoporosis of the spine. NPS claims the defendants’ statements regarding the efficacy of PREOS reflected their reasonable beliefs about what the clinical trial data would reveal. But again, the court does not weigh evidence at this stage, so it does not evaluate the defendants’ proffered evidence of the context of the statements or the reasonableness of the defendants’ beliefs regarding the clinical data. The plaintiff has sufficiently alleged the statements about PREOS’s efficacy were false or misleading.

¹² Consolidated Amended Complaint ¶¶ 95, 106, 112.

With regard to PREOS's market prospects, the plaintiff alleges the defendants falsely stated the market for PREOS would be "a large percentage of the millions of women around the world who have osteoporosis and that PREOS would be a "billion dollar drug."¹³ The plaintiff contends such statements were misleading because the defendants knew and concealed that the market for PREOS was (1) limited to a subgroup of postmenopausal women with osteoporosis who had suffered a prior fracture, were seeking treatment for the spine, and could not tolerate the standard drug, Fosamax, (2) limited to women willing to perform daily injections, and (3) limited to women willing to take the drug despite an FDA "black box" warning about PREOS's hypercalcemic toxicity. The defendants claim PREOS's market limitations were well-known and not firm specific, so the statements were not false or misleading. In response, the plaintiff alleged any available information was not disseminated to the investing public with enough force to dispel the defendants' misleading statements. To find for the defendants, the court would have to weigh the evidence to find the statements were well-known and market specific enough to negate the plaintiff's allegations — an inappropriate approach at this juncture.

With respect to the likelihood of FDA approval of PREOS, the plaintiff details numerous claims by the defendants that the FDA would approve PREOS by 2005, leading to its global launch. The plaintiff claims the statements were misleading because the defendants knew and concealed that PREOS demonstrated a high incidence of hypercalcemia, making FDA approval of the drug by 2005 extremely unlikely. The defendants contend any statements regarding the prospects of obtaining FDA approval of PREOS are protected under the PSLRA's Safe Harbor

¹³ *Id.* ¶¶ 65, 105.

provision or the “bespeaks caution doctrine,” as forward-looking statements accompanied by cautionary language. But neither doctrine protects fraud, and the plaintiff has alleged many of the defendants had actual knowledge that their misleading statements were false when they were made. In other words, the statements were allegedly not forward-looking predictions but, rather, knowing falsifications of historical fact. The plaintiff’s allegations with respect to actual knowledge are well-pleaded, and the court must take the plaintiff’s well-pleaded allegations as true.

The defendants also allege the complaint should be dismissed with respect to some individual defendants because the plaintiff failed to tie specific wrongful acts directly to the defendants, that is, the plaintiff did not identify the individual sources of specific statements in every case. But the plaintiff did specifically allege that all of the individual defendants were corporate directors or officers who possessed power and authority to control the contents of the market statements made through press releases and other means. Such allegations are sufficient, under the group-published doctrine, to state a claim against all the individual defendants under § 10(b).¹⁴

Similarly, the plaintiff has adequately alleged fraud-on-the-market damages — that the defendants’ fraud caused its losses. The plaintiff has alleged the drastic decrease in value of NPS stock correlated exactly with the public announcements of the FDA’s refusal to approve PREOS. The defendants try to negate this by claiming that the information the defendants concealed from

¹⁴ See *Schwartz*, 124 F.3d at 1254; *In re Qwest Commc’ns Int’l Sec. Litig.*, 387 F. Supp. 2d 1130, 1144 (D. Colo. 2005).

investors was publicly available, so the plaintiff is not entitled to a fraud-on-the-market presumption of reliance. But to make such a finding, the court would have to undertake an evidentiary exploration to determine if the information severed “the link between the alleged misrepresentation and either the price received (or paid) by the plaintiff, or his decision to trade at a fair market price.”¹⁵ Again, at this early stage in the process, the court confines its inquiry to the pleadings and does not explore the evidence.

Finally, the defendants also attack the credibility of the plaintiff’s confidential witnesses in an attempt to establish that the defendants’ statements regarding PREOS were not false or misleading when made. But just as the court will not weigh evidence at this stage, it will not entertain a challenge to the credibility of confidential witnesses. As to reliability, the confidential witness statements are sufficiently specific, detailed, and concrete to be reliable upon at this juncture.

In sum, once the court extracts NPS’s explicit and implicit requests for the court to weigh substantive evidence from its brief, the defendants are left with no challenges to the specificity of the plaintiff’s pleading. The court finds the plaintiff pleaded with adequately particularity to survive the motion to dismiss.

B. Inference of Scienter

The defendants also allege the plaintiff failed to plead particularized facts giving rise to a strong inference of scienter as to each defendant. But the defendants’ claim fails because looking

¹⁵ *Basic, Inc. v. Levinson*, 485 U.S. 224, 248 (1988).

at the facts alleged as a whole, the inference of scienter is at least as compelling as any alternative inference.

“The appropriate level of scienter in securities fraud cases is ‘a mental state embracing intent to deceive, manipulate, or defraud.’¹⁶ But rather than the general scienter averment under Rule 9(b), the PSLRA requires that “the complaint . . . , with respect to each act or omission alleged to violate [the Exchange Act], state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.”¹⁷ To conduct this inquiry, the court must accept all factual allegations in the complaint as true and consider the complaint in its entirety because the relevant inquiry “is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.”¹⁸ Additionally, along with the plaintiff’s facts, the court must consider all “plausible nonculpable explanations for the defendant’s conduct.”¹⁹ Because the inference of scienter must be strong, a complaint will survive a motion to dismiss “only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.”²⁰

¹⁶ *City of Philadelphia v. Fleming Cos.*, 264 F.3d 1245, 1249 (10th Cir. 2001) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976)).

¹⁷ 15 U.S.C. § 78u-4(b)(2).

¹⁸ *Tellabs. Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 1, 2007 U.S. LEXIS 8270, *27 (June 21, 2007).

¹⁹ *Id.* at * 29.

²⁰ *Id.* at *30.

In this case, the court has considered both the plaintiff's allegations of scienter and the defendants' nonculpable explanations, but in light of the complaint as a whole, the court finds a reasonable person would deem the inference of scienter more compelling than the defendants' opposing inference. The plaintiff's inference arises, in part, from its allegations that the defendants knew of the hypercalcemic toxicity of PREOS yet concealed it and, additionally, that they concealed the truth about the efficacy of PREOS, its market potential, and the likelihood of FDA approval. The plaintiff also alleges the defendants knew that failure to reveal this information would likely mislead investors — yet they failed to reveal it nonetheless. Because PREOS was allegedly the only product NPS had that was even close to fruition, the defendants had motives to bring PREOS to the market despite knowledge of its problems and limitations. The inference of scienter created by these allegations is further supported by the statements from six confidential witnesses, who were directly involved with PREOS, confirming the defendants' knowing concealment of certain information and false dissemination of other information.

In addition, the plaintiff alleges the defendants participated in a fraudulent scheme to defraud investors and that the defendants' motive and opportunity to exploit the fraud further supports the allegations of scienter. Basically, the plaintiff alleges the defendants intentionally misled investors about PREOS in order to inflate NPS stock prices so that the defendants could cash in on their backdated stock options. The plaintiff provides specific details of the buy/sell practices of many of the individual defendants in support of this claim. NPS claims the defendants' buying and selling practices might also constitute legitimate transactions in the absence of any backdating. But the court must take the plaintiff's well-pleaded allegations as

true, in light of the other facts supporting an inference of scienter, the plaintiff's "backdating" explanation is at least as viable as the defendants' nonculpable explanation. Therefore, the court finds that its totality, the complaint sufficiently alleges scienter.

In sum, the plaintiff has alleged a § 10(b) claim against the defendants with sufficient particularity to survive the NPS's motion to dismiss.

II. SECTION 20(A) CLAIM

The defendants also ask the court to dismiss the plaintiff's claim under § 20(a) of the Exchange Act, saying the plaintiff did not successfully allege a primary violation under § 10(b) and did not plead "control." However, the court finds the plaintiff has stated a § 20(a) claim.

Under § 20(a), "a person who controls a party that commits a violation of the securities laws may be held jointly and severally liable with the primary violator."²¹ "To state a prima facie case of control person liability, the plaintiff must establish (1) a primary violation of the securities laws and (2) 'control' over the primary violator by the alleged controlling person."²²

As long as a plaintiff pleads facts from which the court can reasonably infer the defendants were control persons, "the control person determination is a factual question not ordinarily subject to resolution on a motion to dismiss."²³ To allege control, a plaintiff need not "show the defendant actually or culpably participated in the primary violation," but need only allege facts indicating the defendant had "possession, direct or indirect, of the power to direct or cause the direction of

²¹ *Maher v. Durango Metals*, 144 F.3d 1302, 1305 (10th Cir. 1998); *see also* 15 U.S.C. § 78t.

²² *Maher*, 144 F.3d at 1305.

²³ *Id.* at 1306.

the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise.”²⁴

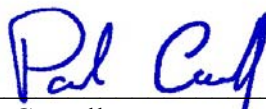
The plaintiff has successfully alleged primary violations of § 10(b), so it has alleged the first element of § 20(a) liability. The plaintiff shows control, under the second element, by alleging that NPS and each individual defendant had direct and supervisory involvement in the day-to-day operations of NPS. Specifically, the plaintiff alleges that each individual defendant occupied a high-level position, and participated in and knew of NPS’s operations and the publicly-disseminated statements on PREOS. The plaintiff further alleges each defendant had the power to influence and control the content and dissemination of the allegedly false statements giving rise to the alleged § 10(b) violations, and that they actually exercised this control. NPS claims the individual defendants lacked sufficient direct and supervisory involvement in NPS operations. This claim, like NPS’s other claims, require the court to weigh evidence. As the court does not weigh evidence at the motion to dismiss stage, the claim fails. The plaintiff has sufficiently alleged “control” to state a claim under § 20(a).

CONCLUSION

For these reasons, the defendants’ motion to dismiss the plaintiff’s consolidated amended complaint is DENIED [#83].

DATED this 3rd day of July, 2007.

BY THE COURT:



Paul G. Cassell
United States District Judge

²⁴ *Id.* at 1305.