



In its [June 10, 2020, opinion in \*Nguyen v. Endologix\*](#), the U.S. Court of Appeals for the Ninth Circuit applied the plausibility standard to a plaintiff's securities fraud claims and affirmed the district court's dismissal, with prejudice, of the purported class action complaint. Hewing closely to the heightened pleading standards imposed on such claims by the Private Securities Litigation Reform Act (PSLRA), and the attendant interests in curbing meritless or abusive securities litigation, the Ninth Circuit concluded that plaintiff's scienter allegations—indeed, her entire fraud thesis—did "not resonate in common experience" or "make a whole lot of sense." In rejecting plaintiff's implausible thesis, the court reiterated that the PSLRA's heightened pleading requirements "ha[ve] teeth" and "neither allow[] nor require[] us to check our disbelief at the door." The court's analysis provides guidance for district courts in the Ninth Circuit in critically evaluating the plausibility of federal securities fraud claims at the motion to dismiss stage.

## **Factual Background**

Endologix, Inc. is a publicly traded company that manufactures and sells medical devices for the treatment of abdominal aortic aneurysms. In 2013, Endologix announced the launch of its new endovascular aneurism sealing system called Nellix. A primary potential hazard of Nellix was "migration," which occurs when an implanted device moves in the body and causes additional health risks.

Endologix pursued parallel efforts to obtain regulatory approval for Nellix in Europe and the United States. As part of the European approval process, Endologix monitored Nellix's performance in a global registry of patients. A few months later, Endologix initiated an FDA-approved clinical trial. With European approval proceeding ahead of the schedule in the United States, Endologix began obtaining data from the global registry before the FDA clinical trial results were available. Through this data, Endologix and its executives allegedly learned that Nellix was migrating in some European patients. Plaintiff, a purported Endologix shareholder, theorized that these instances of migration would have negative consequences for FDA approval, because if "Nellix was unsafe for European patients, it would prove equally unsafe for U.S. patients."

Plaintiff alleged that, notwithstanding their knowledge of these migration issues, Endologix's executives assured investors that the FDA would likely approve Nellix within months. Plaintiff alleged that these statements were false or misleading, arguing that the executives knew the European migration data would delay or derail FDA approval in the United States. Plaintiff relied on three sources to support this thesis—a confidential witness (CW1) who had served in various senior roles at Endologix, and two reports describing the migration issues identified in the European study.

Endologix's projections about the FDA approval process did not materialize and, after a series of modifications to the projected scope and timeline, the company announced that it was abandoning its efforts to obtain FDA approval. Endologix's share price dropped more than 36% on this news. Plaintiff sued Endologix and certain of its executives, alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5. The district court dismissed plaintiff's second amended complaint with prejudice and plaintiff appealed.

## **Illogical Theories Premised on Unfounded, Factually Deficient Allegations Are Insufficient**

To successfully plead a securities fraud claim, a complaint must allege facts establishing the defendants' scienter, defined as "a mental state embracing the intent to deceive, manipulate, or defraud." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007). Federal Rule of Civil Procedure 9(b) requires a securities fraud plaintiff to "state with particularity the circumstances constituting fraud." *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 705 (9th Cir. 2016); *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009). Additionally, the PSLRA requires plaintiffs to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." Under this "strong inference" standard, 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." *Tellabs, Inc.*, 551 U.S. at 324.

In its *Endologix* opinion, the Ninth Circuit clarified the heavy burden a plaintiff must satisfy to successfully plead scienter. As the court explained, "[g]iven the substantial costs that securities fraud litigation can impose, the 'strong inference' [pleading] standard reflects Congress's attempt to halt early on securities litigation that lacks merit or is even abusive..." Weighing these interests, the court dismantled plaintiff's fraud theory—that the defendants falsely assured investors the FDA would approve Nellix while knowing that the European migration data would impede that approval. The court identified two main problems with plaintiff's scienter theory.

First, "the theory does not make a whole lot of sense." The court questioned plaintiff's assertion that defendants would assure investors of FDA approval if they knew the FDA would ultimately deny approval due to the migration problem discovered during the European study. The court observed that plaintiff's fraud theory assumed that the defendants would be motivated to temporarily prop up the company's stock price until the migration problem was inevitably revealed to the market. The court explained that, although this theory might make sense if defendants had sold their stock before abandoning FDA approval, the complaint did not contain any such allegations. Absent such facts, plaintiff's fraud thesis was illogical.

Thus, the court concluded that plaintiff's scienter thesis failed the plausibility test. This test is a common law fraud concept that "is no less relevant in the context of the heightened pleading standards of Rule 9(b) or the PSLRA." Quoting the U.S. Court of Appeals for the Fourth Circuit's decision in *Cozzarelli v. Inspire Pharms Inc.*, 549 F.3d 618 (4th Cir. 2008), the court emphasized that "[i]t is improbable that [a company] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure." The court held that, without more, the belief that a company would promise FDA approval it knew would not materialize does not create a strong inference of intent to deceive or deliberate recklessness.

Second, the court concluded that plaintiff's allegations attributed to confidential witness CW1 did not support scienter. Because many of the alleged misstatements occurred after CW1 left the company, the court found "ample basis to question CW1's claimed knowledge and his effort to impute scienter to the defendants." CW1's account also lacked any of the necessary details about the migration issues faced in the European study. While "high on alarming adjectives," the allegations attributed to CW1 in the complaint were insufficient to satisfy the heightened scienter pleading standards because "[s]trong rhetoric is not a substitute" for particularized facts.

The court discounted CW1's alleged reliance on several incident reports from Europe that, according to plaintiff, created a general concern about the migration issues in the United States. Absent specific references to or details about these incident reports, the court observed that negatively characterizing the reports did not establish any inference of scienter, much less a strong one. Bolstering this conclusion, the complaint conceded that the company openly acknowledged the reports, disclosed them to the public, and candidly discussed them during investor calls.

Given these shortcomings, the court held that plaintiff's allegations did not raise an inference of scienter that was "at least as compelling as any opposing inference one could draw from the facts alleged." Instead, the court drew the "more plausible inference" that Endologix's executives relied on initial results from their U.S. clinical trials in making optimistic statements about the FDA approval process. As the clinical results came in, the company modified its statements, informing investors about the changes to the anticipated FDA approval timeline. But nothing in the complaint established "that defendants were intentionally or with deliberate recklessness seeking to mislead the market about an FDA approval that they knew would never come through." Construing plaintiff's allegations in the light most favorable to plaintiff while still engaging in a thorough plausibility analysis, the court concluded that plaintiff failed to adequately plead the "critical ingredient" of scienter and affirmed dismissal of the complaint with prejudice.

## ***Endologix* Emphasizes the Importance of Common Sense in Assessing Plausibility**

The *Endologix* decision is important because it endorses a common-sense plausibility standard in weighing the adequacy of a plaintiff's allegations to support the "strong inference" requirement for successfully pleading scienter. The decision supports this common-sense approach in identifying and balancing the competing inferences to be drawn from the facts alleged. Although the pleading standards require courts to draw inferences in plaintiff's favor on a motion to dismiss, those inferences must be logical and plausible. Acknowledging that the PSLRA is designed to weed out securities fraud lawsuits that lack merit, and recognizing the substantial costs that such litigation impose on defendants, the *Endologix* decision provides strong guidance to district courts in enforcing these "exacting" pleading standards at the motion to dismiss stage by rigorously analyzing whether the source and content of plaintiff's fact allegations—along with the fraud theory itself—are plausible.

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