

Ninth Circuit Affirms Dismissal of Securities Class Action Against Endologix, Inc.

June 15, 2020

On June 10, 2020, the Ninth Circuit issued a decision in *Nguyen v. Endologix, Inc.*, No. 18-56322, affirming the dismissal of a putative class action securities fraud complaint due to the plaintiff’s failure to plead facts establishing a strong inference of scienter. The decision confirms that courts must closely scrutinize complaints, using “logic and common experience,” to determine whether the allegations create a strong inference of scienter under the Private Securities Litigation Reform Act. The decision also rejects the use of non-specific confidential witness statements to evade dismissal.

The complaint pursued a common theory in securities cases in the life sciences space: a company’s supposed failure to disclose the true risk that the FDA would decline to approve a medical device.

Plaintiff brought suit under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5. The complaint alleged that executives of Endologix—a publicly traded company that manufactures and sells medical devices for the treatment of abdominal aortic aneurysms—knew that the FDA would deny premarket approval for its medical device, Nellix, but nonetheless “repeatedly assured investors that the FDA would likely approve Nellix.” Slip op. at 4, 9. According to the complaint, those executives knew that Nellix had encountered problems in Europe, and that those same problems would arise again in U.S. clinical trials, but told investors that Nellix would be approved by the FDA even though they “knew the FDA would not approve Nellix, or at least that it would not do so on the timeline defendants were telling the market.” *Id.* at 9-13, 18. When Endologix eventually announced that the FDA would not approve Nellix within the timeline the company had previously announced, its shares fell more than 20%. *Id.* at 12-13. Half a year later, Endologix announced that it would no longer seek FDA approval of Nellix, and its shares fell by more than 36%. *Id.*

The Ninth Circuit affirmed the district court’s dismissal of the complaint for failure to plead scienter, i.e., “a mental state embracing intent to deceive, manipulate, or defraud.” *Id.* at 16 (citation omitted). The court noted that under the Private Securities Litigation Reform Act (the “PSLRA”), a complaint must “state with particularity facts giving rise to a *strong inference*” of scienter and emphasized that this “strong inference” requirement “has teeth.” *Id.* at 17 (emphasis added). In determining whether a complaint passes muster, the court explained that it looks to “logic and common experience” to assess the plausibility of the allegations—since allegations “that are implausible do not create a strong inference of scienter.” *Id.* at 3-4; see also *id.* at 19 (explaining that “the PSLRA neither allows nor requires us to check our disbelief at the door”).

Applying this standard, the Ninth Circuit held that plaintiff’s “core theory”—i.e., that defendants promised the market that the FDA would approve a medical device that they knew was “unapprovable”—failed, because it “does not resonate in common experience.” *Id.* at 19. The court reasoned that the defendants would not have promised that the FDA would approve Nellix if they knew that Nellix *could not* be approved due to “intractable” and “unresolvable” problems with the device, as plaintiff alleged. *Id.* at 18; see also *id.* (noting that the “theory does not make a whole lot of sense”). The court explained that the theory might have been more plausible if defendants had sought to profit off the misleading statements by

keeping the stock price high, and then selling the stock before the FDA denied approval—but that plaintiff alleged no such facts. *Id.* at 18-19.

The court also rejected plaintiff's attempt to "surmount her plausibility problem" through her reliance on a confidential witness. *Id.* at 20. The court noted that while the allegations sourced to the confidential witness were "high on alarming adjectives," they failed to identify sufficient *facts* to establish the requisite strong inference of scienter. *Id.* (explaining that "[s]trong rhetoric is not a substitute for" particular facts). In particular, the court found that the allegations attributable to the confidential witness "lack [] any detail about the supposed . . . problems" with the device. *Id.* at 21.

The opinion is by Circuit Judge Daniel A. Bress, joined by Circuit Judge Daniel P. Collins and Circuit Judge Jay S. Bybee.

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