Ninth Circuit Addresses High Standard for Pleading Scienter under Private Securities Litigation Reform Act

Parties asserting claims for securities fraud under Section 10(b) of the Securities Exchange Act must satisfy the dual pleading requirements of both Federal Rule of Civil Procedure Rule 9(b) and the Private Securities Litigation Reform Act (PSLRA). To plead scienter successfully under the PSLRA, a plaintiff must allege with particularity "facts giving rise to a *strong inference* that the defendant acted with the required state of mind."[1] On June 10, 2020, in *Nguyen v. Endologix*[2], the Court of Appeals for the Ninth Circuit held that allegations that lacked any "basis in logic or common experience" fail to meet that standard. *See* 2020 WL 3069776, at *1. Nor could the complaint be salvaged by the allegations of a confidential witness that the Court found were "high on alarming adjectives" but short on facts. *Id*. at *9. These requirements are well known under the law. But in *Nguyen*, the Ninth Circuit made it clear just how substantial a showing is needed to satisfy the scienter requirements under Rule 9(b) and the PSLRA.

I. Factual Background

Endologix, Inc. is a publicly traded company that manufactures and sells medical devices to treat aortic disorders. In 2013, Endologix received premarket approval from the FDA to conduct a clinical trial for an endovascular sealing product, Nellix. *Id*. at *2. On June 11, 2016, Endologix submitted to the FDA the data from the first year of the clinical trial. *Id*. at *4. The results showed that, in a small percentage of patients, the Nellix device had migrated (moved from the location where it had originally been placed in the patients' bodies).

Both before and after submitting the data to the FDA, Endologix made several statements throughout 2016 that Nellix was doing well and FDA approval was expected. *Id*. at *4. On November 16, 2016, however, Endologix issued a press release disclosing that the FDA requested that Endologix provide two years of follow-up data, pushing off the timeline for approval substantially. *Id*. at *5. Endologix subsequently announced it had abandoned its application for FDA approval of Nellix in order to focus on an improved device. *Id*. Following these two separate disclosures, Endologix's share price dropped 20.5% and 36%, respectively. *Id*.

Relying heavily on information allegedly provided by a confidential witness, a former Endologix employee who served as the head of Aortic Procedure Development, Plaintiff Vicky Nguyen brought a complaint against Endologix under Rule 10b-5 of the Securities Exchange Act, alleging that company executives knew that Nellix had demonstrated migration issues in European patients and therefore knew the FDA would deny approval, while making statements to the contrary. *Id*. at *1, *3, *4.

II. The Ninth Circuit's Decision in *Nguyen*

Applying a *de novo* review standard, the Ninth Circuit affirmed the District Court's dismissal, determining that Nguyen did not "adequately alleg[e] a 'strong inference' of scienter." *See* 2020 WL 3069776, at *7. The Ninth Circuit emphasized that the heightened pleading standard under the PSLRA is an "exacting" obligation that has "teeth," and that allegations of scienter will pass muster only if "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw." *Id*. at *8 (internal citations omitted).

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[1] 15 U.S.C. § 78u-4(b)(2)(A) (emphasis added).

[2] ---F.3d----, 2020 WL 3069776 (June 10, 2020).

Specifically, the Court concluded that Nguyen's "theory does not make a whole lot of sense," questioning why the defendants would want to publicly promise FDA approval that they allegedly knew would not come to pass. *Id*. at *8. Significantly, there were no allegations the defendants had sought to profit from the scheme in the interim, such as by selling off their stock, which might give "legs" to the allegations. *Id*. Moreover, the Ninth Circuit found "persuasive" a Fourth Circuit case, *Cozzarelli v. Inspire Pharmaceuticals Inc.*, 549 F.3d 618 (4th Cir. 2008), in which the Court rejected a theory of scienter based on allegations that a company made misleading statements about the success of a drug while a study of its safety and effectiveness was ongoing. Even though the defendants in *Cozzarelli* had sold stock while the study was ongoing, the Fourth Circuit found it "'improbable that [a company] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure.'" *Nguyen*, 2020 WL 3069776, at *9 (quoting *Cozzarelli*, 549 F. 3d at 627). Like the Fourth Circuit, the Ninth Circuit reasoned that the more plausible inference to be drawn was that defendants made optimistic statements about the timing of FDA approval based on promising initial results of the U.S. clinical trial, but adjusted their outlook when the results started to present issues for the FDA. *Id*.

Nguyen also failed to show scienter through allegations attributed to a confidential witness, identified in the complaint as "CW1." Putting aside that CW1 had later recanted many of the allegations, the Court noted that his departure from Endologix in June 2016, before many of the statements alleged to be misleading were made, provided "ample basis" to question his knowledge about defendants' scienter. *Id*. at *9. Looking at the level of detail provided by the confidential witness, the Court concluded that CW1 provided few facts that would otherwise give rise to the requisite strong inference of scienter. For example, CW1 referenced general concern caused by several incident reports, but the complaint did not provide details of the contents of the reports. *Id*. Overall, CW1's allegations — including that the migration issue was a "serious problem," "dangerous," and "urgent" — consisted of "alarming adjectives," but not specific substance. *Id*. The Ninth Circuit held that these were insufficient to state a valid 10b-5 claim.

III. Implications

The decision reaffirms the high bar securities fraud plaintiffs, particularly in the pharmaceutical and biotechnology industries, must meet to plead securities fraud in cases involving FDA or other regulatory approval. More broadly, the decision is also a reminder that a court must "'only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference.'" *Id*. at *12 (quoting *Zucco Partners, LLC* v. *Digimarc Corp*., 552 F.3d 981, 989 (9th Cir. 2009)).

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If you have any questions about the issues addressed in this memorandum, or if you would like a copy of any of the materials mentioned in it, please do not hesitate to call or email Joel Kurtzberg at 212.701.3120 or jkurtzberg@cahill.com; Lauren Perlgut at 212.701.3558 or lperlgut@cahill.com; or Anna Wittman at 212.701.3446 or awittman@cahill.com; or email publications@cahill.com.