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Amgen Asks 9th Circ. To Undo Shareholder Class Cert.

By **Zach Winnick**

Law360, Los Angeles (October 14, 2011, 5:42 PM ET) -- A lawyer for Amgen Inc. told the Ninth Circuit on Friday that a district judge erred by certifying a class of shareholders who allege the biotech company misled investors about two top-selling anemia dugs without considering the materiality of the purported false statements.

Amgen's attorney Steven Kramer asked the appellate panel to reverse U.S. District Judge Philip S. Gutierrez's certification order, saying the judge should have considered whether the information the company allegedly misstated or concealed concerning its Aranesp and Epogen treatments was even material before deciding to certify a class of shareholders who said they bought the company's stock at inflated prices.

"We're simply saying that if a statement is not material, it can't affect the market price, and you have to take some look at it," Kramer argued. "How much? That's in the discretion of the district court. ... But the court didn't even look at it, and that's what the substance of our appeal is."

The biotech giant faced a skeptical audience in attempting to shoot down the litigation at an early stage, as the judges repeatedly questioned whether there was legal support for weighing materiality as a part of the class certification analysis.

The lawsuit, filed in April 2007, stems from Amgen's commercialization of the drugs epoetin alfa and darbepoetin alfa, which Amgen markets in the United States as Epogen and Aranesp, respectively.

The two drugs have U.S. Food and Drug Administration approval to fight anemia caused by chemotherapy in cancer patients, but they are not approved for use in cases where the anemia is caused by cancer itself. Nevertheless, doctors often prescribe the drugs off-label for cancer-related anemia.

In October 2006 a group of researchers halted a clinical study of head and neck cancer patients treated with Aranesp because more deaths occurred in patients taking Aranesp than in those taking a placebo, according to court documents. But Amgen did not disclose these results to investors, the suit claims.

Then, in February 2007, a medical journal published the results of the study, and one month later the FDA issued a black box warning over the off-label use of the drugs.

Both of these events caused Amgen's price to decline, the complaint claims.

Judge Gutierrez certified a class of shareholders in December 2009, and Amgen appealed, arguing that the judge should have looked at whether the purportedly concealed or misstated information was material in light of the plaintiff's reliance on a fraud-in-the-market presumption. This presumption is based on the theory that investors rely on the integrity of the stock's trading price to reflect all public, material information.

"The Supreme Court says that if a statement is not material, it can't affect the market," Kramer argued Friday. "So in order to invoke the fraud-on-the-market presumption, one has to assume that the statement was material and that the statement was not in the market."

But Circuit Judge Kim M. Wardlaw questioned whether Kramer's argument was supported by precedent.

"We're the class stage, a very preliminary stage," Judge Wardlaw said. "I don't think you can point to any case where materiality was required at the stage of class certification, certainly not a [U.S.] Supreme Court case and certainly not a Ninth Circuit case."

Circuit Judge Barry G. Silverman and District Judge William K. Sessions III, sitting by designation, both expressed concern that allowed a materiality analysis at the class certification stage could lead judges into territory properly reserved for juries.

"The term materiality, I always thought of it as an objective term," Judge Sessions said. "You open up materiality way beyond [a] literal reasonable analysis to essentially a trial on materiality."

The plaintiff's attorney J. Michael Hennigan of McKool Smith PC said that materiality would be addressed at later stages of the litigation, and need not be addressed at certification.

"What I'm saying is we don't really need an extra moment in the federal rules where legal and factual issues come together and we get a judicial resolution," Hennigan argued

Judge Wardlaw thanked the attorneys at the close of arguments, taking the matter under submission.

Hennigan said Friday he was proud to appear before such a well-prepared panel but otherwise declined comment. Representatives for the defendants did not immediately respond to requests for comment.

Circuit Judges Kim M. Wardlaw and Barry G. Silverman and District Judge William K. Sessions III sat on the panel for the Ninth Circuit.

Plaintiff Connecticut Retirement Plans and Trust Funds is represented by Jonathan M. Plasse, Christopher J. McDonald and Richard T. Joffe of Labaton Sucharow LLP, Gretchen Nelson of Kreindler & Kreindler LLP, and J. Michael Hennigan and Michael Swartz of McKool Smith PC.

Amgen and individual defendants Kevin W. Sharer, Richard D. Nanula, Roger M. Perlmutter and George J. Morrow are represented by Steven O. Kramer, John P. Stigi III, John M. Landry and Jonathan D. Moss of Sheppard Mullin Richter & Hampton LLP.

The case is Connecticut Retirement Plans and Trust Funds v. Amgen Inc. et al., case number 09-56965, in the U.S. District Court for the Central District of California.

--Editing by Kat Laskowski.