UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Levi v. Atossa Genetics, Inc.

868 F.3d 784 (9th Cir. 2017) · No. 14-35933 · Decided August 18, 2017

SUMMARY

The Ninth Circuit reviewed the dismissal of a securities-fraud class action alleging that Atossa Genetics and its chief executive officer made materially false or misleading statements about FDA clearance of breast-cancer screening products. The court held that plaintiffs adequately pleaded falsity and materiality as to certain statements concerning the ForeCYTE Test, an SEC Form 8-K disclosure, and FDA-clearance risk, but not as to other statements concerning the MASCT System and the company's confidence in its responses to the FDA. The court affirmed in part, reversed in part, vacated in part, and remanded.

CASE DETAILS

COURT	United States Court of Appeals for the Ninth Circuit
WRITING FOR THE COURT	Ronald M. Gould, Circuit Judge; Richard A. Paez, Circuit Judge; Ivan L.R. Lemelle, District Judge, sitting by designation
JURISDICTION	Federal
DECIDED	August 18, 2017
DOCKET	14-35933
DISPOSITION	reversed_and_remanded
PROCEDURAL POSTURE	Plaintiffs appealed the dismissal without prejudice of their amended securities-fraud class-action complaint under Federal Rules of Civil Procedure 12(b)(6) and 9(b). The appeal challenged the dismissal of claims under Section 10(b) of the Securities Exchange Act, Section 20(a), and SEC Rule 10b-5.
STANDARD OF REVIEW	De novo review of dismissal under Federal Rule of Civil Procedure 12(b)(6) and dismissal for failure to plead fraud with particularity under Rule 9(b); allegations were accepted as true and construed in the plaintiffs' favor.
PRECEDENTIAL VALUE	Published Ninth Circuit opinion; precedential
PARTIES	Miko Levi, Bandar Almosa, Gregory Harrison, Nicholas Cook, all other persons similarly situated v. Atossa Genetics, Inc., Steven C.

Quay, Christopher Benjamin, Kyle Guse, Shu-Chih Chen, John Barnhart, Stephen J. Galli, Alexander Cross, H. Lawrence Remmel

TOPICS

securities fraud | fda regulation | standard of review | appellate procedure | commercial litigation

PRACTICE AREAS

Securities law | Food and drug regulation | Commercial litigation | Appellate procedure

QUESTIONS PRESENTED

1. Whether plaintiffs sufficiently pleaded falsity and materiality under Section 10(b) and Rule 10b-5 as to statements describing the ForeCYTE Test as FDA-cleared.
2. Whether plaintiffs sufficiently pleaded that Atossa's February 25, 2013 Form 8-K, which disclosed the FDA warning letter but omitted the FDA's concerns about the ForeCYTE Test, was materially misleading.
3. Whether statements describing the MASCT System as FDA-cleared were false or misleading.
4. Whether Atossa's statement that it was reasonably confident in its responses to the FDA was false or misleading.
5. Whether Quay's statement that FDA-clearance risk had been achieved was a materially misleading opinion by omission, and whether the Section 20(a) claims should be vacated after partial reversal of the primary-violation rulings.

HOLDINGS

1. Plaintiffs adequately pleaded falsity and materiality as to Quay's statement in the December 20, 2012 Form 8-K that the ForeCYTE Test was FDA-cleared and his statement in the News-Medical.Net interview that the test had gone through the FDA-clearance process.
2. Plaintiffs did not sufficiently plead that Atossa's general statements that the MASCT System was FDA-cleared were false or misleading.
3. Plaintiffs adequately pleaded that Atossa's Form 8-K was materially misleading because it omitted the FDA's concerns that the ForeCYTE Test lacked clearance and that Atossa's marketing materials were false or misleading.
4. Plaintiffs did not sufficiently plead that Atossa's statement in its Form 10-Q that it was reasonably confident in its responses to the FDA was false or misleading.
5. Plaintiffs adequately pleaded that Quay's statement that FDA-clearance risk had been achieved was a materially misleading opinion by omission.
6. The district court's dismissal of the Section 20(a) claims was vacated because it was based on dismissal of the Section 10(b) and Rule 10b-5 claims, some of which were reinstated.

KEY QUOTATIONS

> *"Because the ForeCYTE Test was allegedly central to Atossa's business strategy, the knowledge that the test was not FDA-cleared would have, for a reasonable investor, "significantly altered the 'total mix' of information made available.""* (868 F.3d at 799)

> *"We conclude that, though not literally false, the alleged omissions in the Form 8–K filing were misleading."* (868 F.3d at 802)

> *"We conclude that Quay's opinion statement that FDA clearance risk has been achieved is misleading by omission."* (868 F.3d at 811)

FACTUAL BACKGROUND

Atossa marketed the MASCT System, a breast-fluid collection device, together with the ForeCYTE Test, a laboratory test used to evaluate collected samples for cancer indications. The FDA had cleared the MASCT System for sample collection but had not cleared the ForeCYTE Test or the combination of the products. Atossa and its chief executive, Steven Quay, made public statements describing the ForeCYTE Test as FDA-cleared and minimizing FDA-clearance risk, while an FDA warning letter identified the lack of clearance and marketing concerns. Atossa later recalled both products, and its share price fell more than 46 percent.

PROCEDURAL HISTORY

Nicholas Cook filed a putative class action against Atossa, its officers and directors, and IPO underwriters. The district court appointed lead plaintiffs and dismissed the amended complaint without prejudice, concluding that the Section 10(b) and Rule 10b-5 claims failed to plead falsity and materiality with sufficient particularity and that the Section 20(a) claims failed because no primary securities-law violation had been adequately alleged. Plaintiffs appealed only the Section 10(b), Section 20(a), and Rule 10b-5 rulings. The Ninth Circuit affirmed in part, reversed in part, vacated in part, and remanded.

DISPOSITION

reversed_and_remanded

REMAND INSTRUCTIONS

Proceed with the Section 10(b) and Rule 10b-5 claims based on the four statements or omissions found adequately pleaded, maintain dismissal of the other challenged misstatements and omissions, and reconsider the Section 20(a) claims consistently with the reinstated primary-violation claims.

CASES CITED

- In re Quality Sys., Inc. Sec. Litig., 2017 WL 3203558, at *6-*9 (9th Cir. July 28, 2017)
- S. Ferry LP, No. 2 v. Killinger, 542 F.3d 776, 782 (9th Cir. 2008)
- WPP Luxembourg Gamma Three Sarl v. Spot Runner, Inc., 655 F.3d 1039, 1047 (9th Cir. 2011)
- City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc., 856 F.3d 605, 612, 615-16 (9th Cir. 2017)

- Reese v. Malone, 747 F.3d 557, 567-68 (9th Cir. 2014)
- Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 990 (9th Cir. 2009), as amended (Feb. 10, 2009)
- Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988)
- TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976)
- In re VeriFone Sec. Litig., 11 F.3d 865, 868 (9th Cir. 1993)
- Paracor Fin., Inc. v. Gen. Elec. Capital Corp., 96 F.3d 1151, 1159 (9th Cir. 1996)
- In re Apple Comput. Sec. Litig., 886 F.2d 1109, 1114 (9th Cir. 1989)
- Miller v. Thane Int'l, Inc., 519 F.3d 879, 887 (9th Cir. 2008)
- Brody v. Transitional Hosps. Corp., 280 F.3d 997, 1006 (9th Cir. 2002)
- In re Amylin Pharm., Inc. Sec. Litig., 2003 WL 21500525, at *8 (S.D. Cal. May 1, 2003)
- In re Worlds of Wonder Sec. Litig., 35 F.3d 1407, 1413, 1415 (9th Cir. 1994)
- Livid Holdings Ltd. v. Salomon Smith Barney, Inc., 416 F.3d 940, 947 (9th Cir. 2005)
- Kline v. First W. Gov't Sec., Inc., 24 F.3d 480, 489 (3d Cir. 1994)
- Emp'rs Teamsters Local Nos. 175 & 505 Pension Tr. Fund v. Clorox Co., 353 F.3d 1125, 1132 (9th Cir. 2004)
- Outdoor Media Grp., Inc. v. City of Beaumont, 506 F.3d 895, 900 (9th Cir. 2007)
- In re Cutera Sec. Litig., 610 F.3d 1103, 1109, 1111 (9th Cir. 2010)
- Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc., 759 F.3d 1051, 1060-61 (9th Cir. 2014)
- Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 135 S. Ct. 1318, 1325, 1327-29 (2015)
- Warshaw v. Xoma Corp., 74 F.3d 955, 959 (9th Cir. 1996)
