NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 13-4777

In re: COLUMBIA LABORATORIES, INC., SECURITIES LITIGATION

PAUL SOLL; JERRY STERN IRA;
JERRY STERN FAMILY TRUST DATED 5/11/94,
Appellants

On Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 2-12-cv-00614)
District Judge: Honorable Faith S. Hochberg

Argued: December 9, 2014

Before: FUENTES, FISHER, and KRAUSE, Circuit Judge

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OPINION*

KRAUSE, Circuit Judge

This is an appeal from a final judgment of the United States District Court for the District of New Jersey dismissing a putative class action securities complaint for failing

* This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

to allege facts sufficient to plead scienter. For the reasons set forth below, we will affirm.[1]

The Appellants, a putative class of investors, claimed that Columbia Laboratories, Inc. ("Columbia"), Watson Pharmaceuticals, Inc. ("Watson"), and various Columbia and Watson executives violated sections 10(b) and 20(a) of the Securities Exchange Act of 1934[2] and SEC Rule 10b-5[3] when they knowingly or recklessly misled investors about the results of a clinical trial study ("Study 302"). Specifically, Appellants alleged in their complaint that Columbia and Watson's statements that Study 302 achieved "statistical significance" and "topline results" were misleading because these parties either knew or recklessly disregarded that the Food and Drug Administration ("FDA") required Study 302: (1) to achieve a p-value of 0.01; (2) to attain statistical significance for the United States subgroup alone; and (3) not to be driven by anomalous results from the two foreign testing sites. Study 302, according to Appellants, did not meet these criteria.

A plaintiff claiming securities fraud must satisfy the heightened pleading rules of the Private Securities Litigation Reform Act ("PSLRA").[4] To sufficiently plead scienter,

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[1] We have jurisdiction under 28 U.S.C § 1291. We review de novo the District Court's decision to grant the motion to dismiss. *Ballentine v. United States*, 486 F.3d 806, 808 (3d Cir. 2007). Because we write for the parties, we recite only those facts necessary to our conclusion.

[2] 15 U.S.C. §§ 78j(b), 78t(a).

[3] 17 C.F.R. § 240.10b-5.

[4] *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 241 (3d Cir. 2013).

the complaint must state with particularity the facts constituting the alleged violation and giving rise to a "strong inference" that the defendants acted with the required state of mind,[5] *i.e.* that the defendants intended to deceive, manipulate, or defraud.[6] To qualify as strong, the inference "must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent."[7] And to make this determination, a court must review the complaint in its entirety, considering "not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged."[8]

Here, the facts alleged by Appellants do not create a strong inference that Columbia and Watson even knew that the alleged benchmarks would be required by the FDA, let alone that these parties intended to deceive, manipulate, and defraud investors by failing to disclose that Study 302 had not reached them.[9] Appellants assert that Columbia and Watson were "fully aware" that Study 302 would be required to achieve a p-value of 0.01.[10] Their only basis for that contention, however, is that the FDA

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[5] 15 U.S.C. § 78u-4(b)(2)(A).

[6] *Rahman,* 736 F.3d at 241-42 (citing *Tellabs, Inc. v Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007)).

[7] *Tellabs, Inc.*, 551 U.S. at 314.

[8] *Id.*

[9] *See id.* at 313.

[10] J.A. 138.

guidelines generally require that single-trial studies achieve "[s]tatistically very persuasive finding[s],"[11] and, two years earlier, the FDA recommended that a different Prochieve single-trial study achieve a 0.01 p-value to meet that standard.[12] Appellants do not allege that the FDA ever recommended that Study 302 itself achieve a 0.01 p-value or instructed Columbia and Watson to rely on the p-value suggested for the earlier study. Moreover, the FDA guidelines for single-trial studies—incorporated by reference in the complaint—do not require a 0.01 p-value for a new drug to be approved and do not identify any particular p-value for "statistical significance." On the contrary, as an example of "statistical significance," the FDA actually describes a single-trial study that achieved only a 0.05 p-value.[13]

As for the subgroup data, Appellants do not allege that the FDA ever informed Columbia or Watson that statistical significance, or any specific p-value, would be required for the United States subgroup, and it is clear from the materials incorporated by reference in the complaint that the FDA imposed no such requirement.[14] Nothing in the FDA guidelines requires that clinical trials meet statistical significance for subgroups based on geographic location. Rather, the FDA guidelines recommend that a single-trial study be "consisten[t] across key patient subsets" because large studies may involve

[11] J.A. 695.

[12] J.A. 66.

[13] J.A. 692-96.

[14] J.A. 261; 545-46.

many participants that may be diverse with regard to "important covariates" unrelated to geographic location, "such as concomitant or prior therapy, disease stage, age, gender or race."[15]

Appellants' arguments regarding subgroup data from the foreign test sites is similarly unavailing. Appellants point out that Study 302 did not achieve statistical significance when the results from South Africa and Belarus were excluded, but nothing in either the FDA guidelines or the approved Statistical Analysis Plan indicated that statistical significance would be required when those sites were excluded.[16] Nor do Appellants allege that the FDA ever informed Columbia or Watson that Study 302 would be required to meet statistical significance for any subgroups.

The FDA guidelines do recommend that a single study site should not be "largely responsible" for a clinical trial study's "favorable effect."[17] However, there are no allegations that the study sites in either South Africa or Belarus were, on their own, largely responsible for Study 302's favorable effect, and the documents referenced in the complaint indicate that Study 302 achieved a favorable effect even when the allegedly "suspect" results from the test sites in South Africa and Belarus were excluded.[18] Moreover, the FDA's concerns with the foreign test sites arose after Study 302 had been

[15] J.A. 693.

[16] J.A. 195-96; 692-96.

[17] J.A. 693.

[18] J.A. 381.

conducted.[19] Appellants' allegations about a requirement of achieving statistical significance for the United States subgroup, or excluding the test sites in South Africa and Belarus, thus do not support an inference of scienter.[20]

Finally, Appellants frame the issue in terms of FDA "requirements." As the FDA representative at the Advisory Panel explained, however, "[W]e don't necessarily dictate. We tell them our advice. It's guidance. It's not rules or regulations. It's just guidance."[21] Likewise, while Appellants point out the FDA guidelines identify "statistical significance" among the five "characteristics" that may inform single-trial studies, the guidelines then caution that none of the five characteristics is "necessarily determinative." Instead, "the presence of one or more in a study" can contribute to a conclusion that a single-trial study would be sufficient to support an effectiveness claim.[22] Thus, these alleged benchmarks were, at the very most, FDA recommendations and were not, as Appellants argue, either required or dispositive of Study 302's success.

In sum, Appellants' allegations do not raise a strong inference of scienter. Rather, given the competing inferences rationally drawn from the complaint—including the publication of Study 302 in a professional journal, the FDA's decision to convene an Advisory Panel to analyze Study 302, four members of the Advisory Panel voting to

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[19] *See, e.g.*, J.A. 135-36; 294; 491-92.

[20] *Rahman*, 736 F.3d at 241-42.

[21] J.A. 408.

[22] J.A. 693.

approve Prochieve based on Study 302, and Columbia and Watson's continued investment in Study 302 and Prochieve—the District Court properly held that the more compelling inference is that Columbia and Watson did not act with an intent to deceive, manipulate, or defraud investors. Accordingly, we will affirm the judgment of the District Court.