6-14-2022

In re: Amarin Corp PLC

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 21-2071

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IN RE: AMARIN CORPORATION PLC SECURITIES LITIGATION

Dan Kotecki and Catherine Little-Hunt, as Trustee of the Gaetano Cecchini Living Trust,
Appellants

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On Appeal from the United States District Court
for the District of New Jersey
(D.C. Civil No. 3:19-cv-06601)
District Judge: Honorable Brian R. Martinotti

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Submitted Pursuant to Third Circuit L.A.R. 34.1(a)
June 9, 2022

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Before: CHAGARES, Chief Judge, AMBRO and FUENTES, Circuit Judges

(Opinion filed: June 14, 2022)

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OPINION*

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

CHAGARES, Chief Judge.

This putative securities fraud class action alleges that pharmaceutical company Amarin Corporation, PLC ("Amarin") and its executives misled investors when it disclosed the topline results of a Phase III trial for its lead drug product. Because we agree with the District Court that the complaint fails to allege adequately a materially false or misleading statement, we will affirm its dismissal under Federal Rule of Civil Procedure 12(b)(6).

I.

We write primarily for the parties and recite only the facts essential to our decision. Amarin's lead product is Vascepa, a drug intended to treat heart disease. Amarin has conducted three Phase 3 trials for Vascepa. The Food and Drug Administration ("FDA") approved Vascepa for limited use following the first trial. In the second trial, called ANCHOR, Amarin was denied FDA approval of Vascepa for use in an expanded patient population.[1]

The plaintiffs' allegations focus on the final Phase 3 trial, called REDUCE-IT, and more specifically, the results from the trial's placebo arm. This trial evaluated whether Vascepa, when combined with statin therapy, could reduce major adverse cardiac events ("MACE"). FDA approval of Vascepa for this indication would greatly expand the eligible patient population. Amarin used the same mineral oil placebo in both the

[1] A securities fraud class action was filed against Amarin due to its alleged failure to disclose accurately Vascepa's prospects for FDA approval based on the ANCHOR trial. We affirmed the district court's dismissal of this action in In re Amarin Corp. PLC Sec. Litig., 689 F. App'x 124 (3d Cir. 2017).

ANCHOR and REDUCE-IT trials. The FDA, notably, had previously raised "concerns that the placebo data in the ANCHOR trial indicated that the mineral oil placebo may not have been inert (i.e., chemically inactive), and thus may have biased the treatment effect of Vascepa." Appendix ("App.") 143.

On September 24, 2018, Amarin announced topline results for the REDUCE-IT trial, and the company's share price increased. The topline results announced that the REDUCE-IT trial demonstrated "an approximately 25% relative risk reduction" in MACE as compared to the placebo group. App. 153. The company further noted that the full results would not be released until a conference later that year. When the full results were made available, some health experts and medical professionals raised concerns that the mineral oil placebo used in the REDUCE-IT trial was not inert. If the placebo was chemically active, it could have affected the trial's results and thereby exaggerated Vascepa's efficacy. Amarin's share price dropped approximately 27% after the full REDUCE-IT trial data was released.[2]

Lead plaintiffs Gaetano Cecchini, as Trustee of the Gaetano Cecchini Living Trust, and Dan Kotecki brought this action, asserting violations of sections 10(b) and 20(a) of the Exchange Act on behalf of a putative class action of Amarin stockholders.[3] The complaint asserts that the September 24, 2018 press release announcing the topline

[2] The FDA ultimately approved the use of Vascepa to reduce the risk of cardiovascular events based on the results of the REDUCE-IT trial.

[3] The amended complaint names Amarin and the following Amarin executives and board members as defendants: John Thero, Steven Ketchum, Craig Granowitz, and Joseph Zakrzewski.

results of the REDUCE-IT trial and statements made in a conference call that same day were materially misleading.[4] The complaint's primary theory of liability is that at the time Amarin disclosed the trial's topline results, it failed to tell investors that the mineral oil placebo was not inert. This caused the topline results to overstate the relative risk reduction in MACE for patients receiving Vascepa as compared to the placebo group. The defendants moved to dismiss under Federal Rule of Civil Procedure 12(b)(6). The District Court granted this motion, concluding that the complaint failed to allege adequately both a materially false or misleading statement and scienter. The plaintiffs have timely appealed.

II.[5]

Our review of a district court's grant of a motion to dismiss is plenary. See OFI Asset Mgmt. v. Cooper Tire & Rubber, 834 F.3d 481, 489 (3d Cir. 2016). On a Rule 12(b)(6) motion, "we accept all factual allegations in the complaint as true and construe those facts in the light most favorable to the plaintiff[ ]." Newark Cab Ass'n v. City of Newark, 901 F.3d 146, 151 (3d Cir. 2018). The complaint must "contain sufficient factual allegations, taken as true, to state a claim to relief that is plausible on its face." Id. (citation and quotation marks omitted). Because this is a private securities fraud class

[4] The complaint alleges that the defendants made similar statements regarding the topline results during a CNBC show on September 24, 2018, a healthcare conference presentation on October 3, 2018, and the announcement of its third quarter 2018 financial results.

[5] The District Court had subject matter jurisdiction under 28 U.S.C. § 1331 and 15 U.S.C. § 78aa. We have jurisdiction under 28 U.S.C. § 1291.

action, we must also apply the heightened pleading requirements for allegedly misleading statements or omissions as set forth in the Private Securities Litigation Reform Act ("PSLRA"). See 15 U.S.C. § 78u-4(b)(1) ("[T]he complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.").

III.

Section 10(b) of the Securities Exchange Act prohibits the "use or employ, in connection with the purchase or sale of any security . . . [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). Securities and Exchange Commission ("SEC") Rule 10b–5, which implements § 10(b), provides that it is unlawful "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b–5(b). To a state a claim under § 10(b) and Rule 10b–5, a plaintiff must allege: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentations or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; (6) and loss causation." Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 37–38 (2011) (quotation marks and citation omitted).

The plaintiffs focus on three categories of material misrepresentations or omissions: (1) statements of opinion that Amarin made when disclosing the REDUCE-IT trial's topline results; (2) a duty to disclose further information regarding the mineral oil placebo due to the topline results putting this information "in play"; and (3) statements in Amarin's quarterly and annual SEC filings that disclosed certain risks as theoretical, which in fact had already materialized. We address each of these arguments in turn.

The plaintiffs argue that the topline results for the REDUCE-IT trial were false or misleading because Amarin failed to disclose that the mineral oil placebo may have impeded statin absorption in the placebo group.[6] By failing to disclose this information, the plaintiffs contend that the topline results exaggerated the benefits and effectiveness of Vascepa relative to the placebo group. The plaintiffs maintain that the full trial data "undermined the notion that there was a true 'placebo' group, with well-controlled cholesterol, and would have given investors reasons to distrust the [25% relative risk reduction in MACE] that [d]efendants reported." Appellants' Br. 20. These allegations are buttressed, according to the plaintiffs, by the earlier concerns raised by the FDA

[6] The plaintiffs identify three categories of allegedly misleading statements regarding the topline results: (1) the data "demonstrate[ed] an approximately 25% relative risk reduction, to a high degree of statistical significance . . . in [MACE] . . . as compared to placebo," App. 153; (2) "REDUCE-IT topline results . . . confirm our hypothesis that [Vascepa] . . . can provide additional cardiovascular risk reduction benefit on top of LDL-C [cholesterol] control with standard of care statin therapy in studied patients," App. 154; and (3) other statements that characterized the complete data set for the REDUCE-IT trial, such as the results were "representative of an overall robust study result." App. 156.

during the ANCHOR trial regarding the possibility that the mineral oil placebo was not inert.

The parties agree that the disclosures in the topline results are statements of opinion. In a similar context, we have noted that "[i]nterpretations of clinical trial data are considered opinions. . . . Opinions are only actionable under the securities laws if they are not honestly believed and lack a reasonable basis." City of Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 170 (3d Cir. 2014) (internal citations omitted).

We conclude that the complaint fails to allege adequately a false or misleading statement of opinion because the topline results announced by Amarin did not lack a reasonable basis. While the disclosures at issue discuss the REDUCE-IT trial data with reference to the placebo group, they make no characterizations regarding the impact of the mineral oil placebo. Relying on the opinions of certain medical professionals that are discussed in news articles, the complaint only alleges a difference of opinion regarding the impact of the mineral oil placebo. These differing interpretations as to whether the placebo was biologically active, and thereby affected the trial's results, are not sufficient to establish that the defendants' interpretations of the data in the topline results "lacked a reasonable basis." City of Edinburgh, 754 F.3d at 170.[7]

[7] The plaintiffs rely on the Supreme Court's decision in Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund, 575 U.S. 175 (2015), which considered whether an issuer's statements of opinion were actionable under § 11 of the Securities Act, 15 U.S.C. § 77k(a). We have not yet decided whether the framework in Omnicare is applicable to claims under § 10(b) of the Exchange Act. See Jaroslawicz v. M&T Bank Corp., 962 F.3d 701, 717 & n.16 (3d Cir. 2020) ("We have not considered whether Omnicare applies to claims brought under the Exchange Act and under Section 14(a). But it is unnecessary to resolve that question here. Even assuming Omnicare's

We further agree with the District Court that the plaintiffs' theory of omission liability is unpersuasive given Amarin's contemporaneous disclosures regarding the mineral oil placebo. In Amarin's quarterly and annual SEC filings, the defendants "warned of the exact risk [the] [p]laintiffs argue they failed to disclose—that the use of mineral oil as a placebo may exaggerate the effect of Vascepa in the REDUCE-IT trial." App. 31–32. The statements announcing the topline results, moreover, noted that the full results for the trial were to be released at a later date. We conclude that the complaint fails to allege adequately a false or misleading statement of opinion in Amarin's disclosure of the topline results.

The next theory advanced by the plaintiffs is that Amarin put information regarding the mineral oil placebo "in play," and therefore it had a duty to disclose further information when announcing the REDUCE-IT trial topline results. Disclosure is required under § 10(b) and Rule 10b–5 when "necessary 'to make . . . statements made, in light of the circumstances under which they were made, not misleading.'" Matrixx Initiatives, 563 U.S. at 44 (quoting 17 C.F.R. § 240.10b–5(b)) (alteration in original). There is no affirmative duty to disclose all material information, but such a duty may arise when a company chooses "to speak about a material subject to investors." City of Edinburgh, 754 F.3d at 174; accord Williams v. Globus Med., Inc., 869 F.3d 235, 241 (3d

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holding applies, the Shareholders have failed to allege an actionably misleading opinion."). We also find it unnecessary to resolve the question in this case. For the same reasons that Amarin's statements of opinion do not lack a reasonable basis under our Court's pre-Omnicare precedent, the statements are not actionable under the framework set forth in Omnicare.

Cir. 2017) ("Once a company has chosen to speak on an issue—even an issue it had no independent obligation to address—it cannot omit material facts related to that issue so as to make its disclosure misleading."). While the disclosures at issue describe the REDUCE-IT trial results with reference to the placebo group, they did not make any affirmative characterizations regarding the effectiveness of the mineral oil placebo. See Oran v. Stafford, 226 F.3d 275, 284–85 (3d Cir. 2000). We therefore conclude that Amarin's disclosure of the topline results did not put into play either the full trial data or additional information regarding the mineral oil placebo.

The plaintiffs lastly contend that Amarin's disclosures in its quarterly and annual SEC filings were misleading because the company "continued to reiterate theoretical risks, without disclosing that they had already shown signs of manifesting." Appellants' Br. 14. The plaintiffs point to Amarin's Q3 2018 Form 10-Q as an example of the company warning about a hypothetical, future risk related to the mineral oil placebo that had already been realized due to the results from the REDUCE-IT trial.[8] This argument fails for two reasons. The complaint, first, does not identify the statements in Amarin's SEC filings alleged to be materially false or misleading and therefore is subject to dismissal under the PSLRA. The risk disclosed in these filings, in addition, had not

[8] See App. 220 (". . . [A]s part of its review of our ANCHOR [supplemental new drug application], a discussion regarding observed, nominally statistically significant changes from baseline in an adverse direction, while on background statin therapy . . . in the placebo group, raised questions about the possibility that the mineral oil placebo used in the ANCHOR trial (and in the REDUCE-IT trial) might not be biologically inert and might be viewed as artificially exaggerating the clinical effect of Vascepa when measured against placebo in the ANCHOR trial. . . .").

actually materialized at the time that the statements were made. The complaint only alleges a difference in opinion as to whether the mineral oil placebo might be biologically inert. And this is exactly what Amarin disclosed in its quarterly and annual SEC filings.

We agree with the District Court that the plaintiffs have failed to allege adequately a false or misleading statement. Because we will affirm on these grounds, we decline to reach the issue of scienter. We further find it unnecessary to consider whether the District Court abused its discretion by taking judicial notice of certain documents because all of the documents at issue were only relevant to the court's scienter analysis.

Having concluded that the plaintiffs failed to state a claim under § 10(b), we will also affirm the District Court's dismissal of their claims under § 20(a). See Williams, 869 F.3d at 246.

IV.

For the foregoing reasons, we will affirm the District Court's order.