1-25-2022

Serghei Lungu v. Antares Pharma Inc

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 21-1624

SERGHEI LUNGU;
RANDY SMITH, Individually and on behalf of all others similarly situated

v.

ANTARES PHARMA INC; ROBERT F. APPLE; FRED M. POWELL;
LEONARD S. JACOB

Serghei Lungu,
Appellant

On Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 3:17-cv-08945)
District Judge: Honorable Michael A. Shipp

Submitted Under Third Circuit L.A.R. 34.1(a)
on November 19, 2021

Before: CHAGARES, *Chief Judge*; BIBAS and FUENTES, *Circuit Judges*

(Filed: January 25, 2022)

OPINION[*]

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[*] This disposition is not an opinion of the full Court and, under I.O.P. 5.7, is not binding precedent.

FUENTES, *Circuit Judge*.

Plaintiff-Appellant Serghei Lungu ("Plaintiff") challenges the District Court's decision to grant Defendants-Appellees' ("Defendants") motion to dismiss for failure to state a claim. Plaintiff, an individual investor, brought a federal securities class action on behalf of purchasers of Antares Pharma Inc. stock between December 21, 2016 and October 12, 2017 ("Class Period"). The District Court concluded that Plaintiff failed to sufficiently plead a violation of Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder by the Securities and Exchange Commission ("SEC"), 17 C.F.R. § 240.10b-5. As a result, the District Court determined that Plaintiff's claim under Section 20(a) also failed. For the following reasons, we will affirm.

I. Factual Background

Plaintiff sued Antares, as well as three senior officers and directors—Robert Apple, Fred Powell, and Leonard Jacob[1]—in the United States District Court for the District of New Jersey claiming they made material misstatements and omissions while bringing a certain drug delivery device to market.

Antares develops, manufactures, and commercializes therapeutic products using its drug delivery systems. The product at issue—Xyosted[2]—is an auto injector product designed for testosterone replacement therapy. It is currently approved by the Food and

[1] Robert Apple is Antares's chief executive officer and president; Fred Powell is Antares's chief financial officer; and Leonard Jacob is the chair of Antares's board of directors.

[2] Xyosted is the brand name for QuickShot Testosterone.

Drug Administration ("FDA") but with certain labeling requirements, including a black box warning[3] and a "Warnings and Precautions" section.

In his third amended complaint,[4] Plaintiff alleges that Defendants made materially false and misleading statements related to product safety during the FDA approval process of Xyosted, resulting in a 37.8% decline in Antares's stock. Specifically, Plaintiff alleges that Defendants misled investors by downplaying and misstating the incidence of certain adverse events—hypertension, suicidality, and depression—observed in the two Phase 3 clinical studies of Xyosted. Based on these allegedly false and misleading statements, Plaintiff asserts that Antares overstated the approval prospects for Xyosted and artificially inflated its share price.

The statements that Plaintiff challenges were made at different points during the Class Period and are grouped accordingly.

> 1) Antares stated that "the study data demonstrated that [Xyosted] can provide patients with physiologically normal and steady levels of testosterone over the course of therapy" and that Xyosted offered a "virtually painless treatment experience as demonstrated by the pain data collected."[5]

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[3] A black box warning is an FDA warning to alert consumers about serious or life-threatening side effects the drug may have. It is the most serious warning given by the FDA. The black box warning here stated that Xyosted "can cause blood pressure increases that can increase the risk for major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death, with greater risk for MACE in patients with cardiovascular risk factors or established cardiovascular disease." App. 171.

[4] Plaintiff's first two complaints were similarly dismissed by the District Court for failure to adequality plead securities fraud. Each time, Plaintiff was granted leave to file an amended complaint.

[5] These statements were made in (1) a press release dated December 21, 2016; and (2) a press release dated February 27, 2017. App. 159–61.

> 2) Antares stated that, with respect to the first clinical study, "[t]he most common adverse reactions (incidence ≥5%) in this phase 3 study were increased hematocrit, hypertension, increased prostate-specific antigen, upper respiratory tract infection, sinusitis, injection site bruising[,] and headache. Serious adverse events (SAE's) reported included one case each of worsening depression, vertigo[,] and suicide."[6]
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> 3) CEO Apple stated, in response to an analyst question, that "nothing unusual" had occurred with respect to the FDA's review of Xyosted.[7]
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> 4) CEO Apple stated that "anyone who is diagnosed with testosterone deficiency, we believe, is the perfect candidate for Xyosted." CEO Apple further stated that "I think that there isn't any particular patient population that has testosterone deficiency that we're excluding or that we think is a better candidate."[8]

Defendants moved to dismiss the complaint, contending that Plaintiff failed to state a claim pursuant to the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u *et seq*., and Federal Rule of Civil Procedure 12(b)(6).

The District Court granted Defendants' motion to dismiss Plaintiff's third amended complaint with prejudice. The District Court determined, among other things, that Plaintiff failed to sufficiently plead the first element of a Section 10(b) claim because the statements in question were either opinions interpreting clinical data that were not actionable or vague and general statements of optimism that were not material. Because Section 20(a) of the Exchange Act requires an underlying violation of Section 10(b) by

[6] These statements were made in (1) a form 10-K dated March 14, 2017; (2) a press release dated April 3, 2017; (3) a form 10-Q dated May 9, 2017; and (4) a form 10-Q dated August 8, 2017. App. 161–67.

[7] This statement was made during a quarterly earnings conference call on May 9, 2017. App. 164.

[8] These statements were made during a quarterly earnings conference call on August 8, 2017. App. 165–66.

the controlled person, the District Court also dismissed Plaintiff's Section 20(a) claim against Apple, Powell, and Jacob. Plaintiff timely appealed.

II. Jurisdiction and Standard of Review

The District Court had jurisdiction over this action under Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. §§ 1331, 1337. This Court has jurisdiction under 28 U.S.C. § 1291.

Our review of a district court's dismissal under Federal Rule of Civil Procedure 12(b)(6) is plenary and we may affirm a dismissal on any ground supported by the record. *Hassen v. Gov't of V.I.*, 861 F.3d 108, 114 (3d Cir. 2017).

III. Analysis

Section 10(b) of the Exchange Act prohibits the "use or employ[ment], 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 [SEC] may prescribe." 15 U.S.C. § 78j(b). SEC Rule 10b-5 implements this provision by making it unlawful to, among other things, "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).

"[T]o state a claim under Rule 10b-5, a plaintiff must demonstrate: (1) [a] material misrepresentation (or omission); (2) scienter (a wrongful state of mind); (3) a connection between the misstatement and the purchase or sale of a security; (4) reliance upon the misstatement; (5) economic loss; and (6) loss causation." *Fan v. StoneMor Partners LP*,

927 F.3d 710, 714 (3d Cir. 2019) (citing *City of Cambridge Ret. Sys. v. Altisource Asset Mgmt. Corp.*, 908 F.3d 872, 879 (3d Cir. 2018)).

A plaintiff must also satisfy the particularity requirements for a fraud claim under Federal Rule of Civil Procedure 9(b) and the PSLRA, 15 U.S.C. § 78u-4. *City of Cambridge Ret. Sys.*, 908 F.3d at 879. The plaintiff "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). A complaint involving securities fraud must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation . . . is made on information and belief . . . all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1).

For allegations of securities fraud, statements are actionable only if, "when read in light of all the information then available to the market or a failure to disclose particular information, [they] conveyed a false or misleading impression." *Fan*, 927 F.3d at 715–16 (quoting *In re Bell Atl. Corp. Sec. Litig.*, No. 91-0514, 1997 WL 205709, at *23 n.86 (E.D. Pa. Apr. 17, 1997), *aff'd*, 142 F.3d 427 (3d Cir. 1998)). Even more, the alleged misstatement or omission must be material. *Id.* at 716. The materiality requirement "is satisfied when there is 'a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988)). We must distinguish material representations from statements of opinion, motive, or statements that "constitute no more than 'puffery' and are understood by reasonable

investors as such." *EP Medsystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865, 872 (3d Cir. 2000) (quoting *In re Advanta Corp. Sec. Litig.*, 180 F. 3d 525, 538 (3d Cir. 1999)). "Interpretations of clinical trial data are considered opinions[, which] 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). Although traditionally appropriate for the trier of fact, statements that are "obviously unimportant" may be immaterial as a matter of law. *EP Medsystems, Inc.*, 235 F.3d at 875.

A. False or Misleading Statements

The District Court correctly concluded that Plaintiff failed to sufficiently plead an actionable material misrepresentation or omission. We address each of the four statements in turn.

1. Physiologically normal and virtually painless

In two different press releases, Antares stated that Xyosted can provide patients with "physiologically normal and steady levels of testosterone over the course of therapy" and a "virtually painless treatment experience as demonstrated by the pain data collected."[9] Plaintiff contends that these statements were false or misleading because the clinical data did not substantiate "physiologically normal" outcomes or a "virtually painless treatment experience" as the data included one case of completed suicide, one

[9] App. 159–61.

case of attempted suicide, two cases of depression, and a clear tendency towards a high rate of hypertension.

Contrary to plaintiff's assertion, the occurrence of hypertension, suicide, or depression do not render false or misleading Antares's statements about the treatment pain experienced by patients, or the levels of testosterone administered over the course of therapy. Potential adverse reactions to Xyosted are not implicated by either statement. These statements are not actionable.

2. Incidence ≥5% and one case of each

In annual and quarterly company filings, as well as one press release, Antares stated that, in its first clinical study, "[t]he most common adverse reactions (incidence ≥5%) . . . were[, among other things,] increased . . . hypertension[.]"[10] Antares also stated that, for the first clinical study, the "[s]erious adverse events . . . reported included one case each of worsening depression, vertigo[,] and suicide."[11] Plaintiff contends that these statements were false or misleading because (1) the clinical studies showed a clear tendency towards a high risk of hypertension; (2) the first clinical study showed a hypertension rate more than 200% higher than comparable, approved testosterone replacement therapies, which was obscured by listing hypertension among the other adverse effects as merely ≥5%; (3) the risk of suicide was far greater than with any other currently marketed testosterone replacement therapies; and (4) an additional suicide attempt and case of depression were not disclosed.

[10] App. 161–67.
[11] *Id.*

First, the risk of hypertension was disclosed. *See Cal. Pub. Emps.'s Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 156 (3d Cir. 2004) (holding that plaintiffs failed to meet the threshold pleading requirements where the allegedly false or misleading statements were actually disclosed). Indeed, as shown above, hypertension was listed among the most common adverse reactions. Second, Plaintiff fails to point to any duty of Antares to disclose the rate of hypertension, suicide, or any other adverse reaction as compared to other testosterone replacement therapies. *See Matrixx Initiatives*, 563 U.S. at 45 ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5.") (quoting *Basic*, 485 U.S. at 239 n.17); *Oran v. Stafford*, 226 F.3d 275, 285 (3d Cir. 2000) ("Even non-disclosure of material information will not give rise to liability under Rule 10b-5 unless the defendant had an affirmative duty to disclose that information."). Similarly, including the risk of hypertension among the other six common adverse events as ≥5% was not misleading. Plaintiff has not pled facts showing that the rate of hypertension observed was significantly higher than these other adverse events. And although Plaintiff may have wanted to know how much greater than 5% the risk of hypertension was, Antares had no duty to disclose the exact statistical risk of any adverse event and its disclosure was factually accurate.

Last, we turn to the allegedly undisclosed incidences of attempted suicide and depression. As an initial matter, the adverse reaction/event disclosures above relate to only the first clinical study, not both. But Plaintiff's complaint alleges that (1) "an

additional suicide attempt . . . occurred during the [Xyosted] clinical *studies*";[12] and (2) "the [Xyosted] clinical *studies* included two cases of depression, not one."[13] As noted by the District Court, Plaintiff fails to show how these statements misrepresent the observed incidence of suicide and depression in this *one* Phase 3 study.

One allegation, however, does limit itself to the first clinical study. *See* App. 167 ("[The first clinical study] had included two cases of depression, not one . . . ."). But the complaint just alleges that the additional case of depression occurred, not that Xyosted *caused* this event. This is not enough. The "mere existence of reports of adverse events," without some indication that the drug at issue caused those events, does not satisfy *Basic*'s "total mix" materiality standard. *Matrixx Initiatives*, 563 U.S. at 44, 42–43 ("Adverse event reports are daily events in the pharmaceutical industry . . . .").

More critically, the FDA's clinical review of Xyosted—which Plaintiff himself expressly referenced and relied upon in the complaint—cuts against Plaintiff's own argument.[14] Specifically, the clinical review noted that, in the first clinical study, the only serious adverse events were (1) a case of completed suicide, (2) a case of worsening depression, and (3) a case of moderate vertigo. Supp. App. 426. Although Antares conceded that the case of completed suicide may have had its roots in depression, *see* Supp. App. 424–25, it was neither false nor misleading to categorize the event as a

[12] App. 162–63 (emphasis added), 165 (emphasis added), 167 (emphasis added).
[13] App. 162–63 (emphasis added), 165 (emphasis added).
[14] When an allegation in the complaint is contradicted by a document incorporated in it by reference, the document controls and the allegation is not accepted as true. *See, e.g.*, *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 n.8 (3d Cir. 1994); *Amidax Trading Grp. v. S.W.I.F.T. SCRL*, 671 F.3d 140, 147 (2d Cir. 2011).

completed suicide. Indeed, the correlative relationship between depression and suicide is so commonplace that no reasonable investor would be materially misled by a disclosure of a completed suicide that omitted that the person who died of suicide was also depressed.[15] Thus, Plaintiff's allegation about the allegedly undisclosed occurrence of depression is not actionable. *See Winer Fam. Tr. v. Queen*, 503 F.3d 319, 330 (3d Cir. 2007) ("Liability may exist under Rule 10b–5 for misleading or untrue statements, but not for statements that are simply incomplete."); *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002) ("Rule 10b–5 . . . prohibit[s] *only* misleading and untrue statements, not statements that are incomplete . . . . Often, a statement will not mislead even if it is incomplete or does not include all relevant facts.") (emphasis in original and internal citation omitted).

3. Nothing unusual

While on a quarterly earnings conference call with an analyst, CEO Apple stated that "nothing unusual" occurred with the FDA's review of Xyosted.[16] Plaintiff contends that this statement was false or misleading because the FDA told Defendants in late 2016

[15] *See, e.g.*, *Colacicco v. Apotex Inc.*, 521 F.3d 253, 257 (3d Cir. 2008) (quoting a warning from the FDA stating: "The possibility of a suicide attempt is inherent in depression"), *cert. granted, judgment vacated on other grounds*, 556 U.S. 1101 (2009); *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 807 (7th Cir. 2018) (same); *In re Neurontin Mktg., Sales Pracs. & Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 157 n.70 (D. Mass. 2009) ("It is . . . well-established and undisputed that depression is a risk factor for suicide.") (citing González–Maeso, *Neurotransmitter Receptor-Mediated Activation of G-Proteins in Brains of Suicide Victims with Mood Disorders*, 7 Molecular Psychiatry, 755, 762 (2002) ("Depression is the most important risk factor for suicide.")).

[16] App. 164.

that hypertension, suicide, and depression would be a review issue; that the adverse events might impact labeling; and that an advisory committee might be needed.

Read in context, however, the statement is an opinion about the timing of Xyosted's regulatory milestones. It does not speak to the substance or contents of the FDA's review, only that Xyosted was "working with [the FDA] to hit the [application review period end-date] of October 20[, 2017]." Supp. App. 378. Plus, there is no basis to conclude (nor is one alleged) that Apple did not genuinely believe what he was saying at the time he said it. Nowhere in the complaint does Plaintiff allege that the risks arising out of the FDA's feedback were out of the ordinary or that they presented a special challenge not normally confronted by pharmaceutical companies seeking FDA approval for their drugs. Finally, Antares did not need to disclose the 2016 interim feedback from the FDA. *See In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 541–42 (S.D.N.Y. 2015) (collecting cases in which "courts have rejected claims of material omissions where pharmaceutical companies did not reveal procedural or methodological commentary, or other interim status reports, received from the FDA as to drugs under review"), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016). This allegation is not actionable.

4. Perfect candidate and no one excluded

While on a different quarterly earnings conference call, CEO Apple stated that "anyone who is diagnosed with testosterone deficiency, we believe, is the perfect candidate for Xyosted" and that "there isn't any particular patient population that has

testosterone deficiency that we're excluding or that we think is a better candidate."[17] Plaintiff contends that these statements were false or misleading because (1) the clinical studies demonstrated that patients suffering from hypertension, depression, and suicidal ideation were objectively less suitable for Xyosted; and (2) Defendants themselves had excluded patients with high blood pressure from the second clinical study.

The first statement is non-actionable corporate puffery. CEO Apple is not relaying a "concrete" representation about Xyosted; he instead uses a "vague and subjective" superlative in making a "positive portrayal[]" of the company's product. *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 284 (3d Cir. 2010); *see also All-Tech Telecom, Inc. v. Amway Corp.*, 174 F.3d 862, 868 (7th Cir. 1999) (explaining that statements are puffery if they are "empty superlatives on which no reasonable person would rely"). The materiality of the statement is further diminished by the knowledge that suicidal ideation and depression are symptoms of testosterone deficiency and occur in subjects using testosterone replacement therapies, which the FDA highlighted in its clinical review. Supp. App. 459. Similarly, the FDA noted that "[e]levated blood pressure is a treatable condition that providers who are treating patients with Xyosted should be able to manage." Supp. App. 463.

The next statement presents a closer call. Like the District Court, we conclude that Apple's statement that no particular patient population was excluded has the potential to mislead investors. It is not puffery because it is an objectively verifiable fact;

[17] App. 165–66.

patients either were or were not excluded. *See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 184 (2015). Nonetheless, we find the statement immaterial because it would not alter the total mix of relevant information available to a reasonable investor. Given that the FDA approved the methods and procedures employed in the second clinical study, no reasonable investor would be concerned with patient enrollment data with which the FDA did not take issue.[18] *See In re Sanofi Sec. Litig.*, 87 F. Supp. 3d at 533 ("Had the FDA at any point concluded that there were 'serious defects in study design that would render the study incapable of producing valid evidence of safety and effectiveness,' it had 'authority to issue a clinical hold.'") (quoting 52 Fed. Reg. 8798).

B. Section 20(a) Liability

Control-person liability under Section 20(a) hinges on liability under Section 10(b). *See City of Edinburgh Council*, 754 F.3d at 177. Because plaintiff failed to adequately allege a primary violation of Section 10(b), his section 20(a) claim against the individual defendants also fails, as the District Court correctly concluded.

IV. Conclusion

For the foregoing reasons, we will affirm the judgment of the District Court granting Defendants' Rule 12(b)(6) motion to dismiss.

[18] We also note that the FDA eventually approved Xyosted without any additional clinical studies.