Schwartz v Genfit, S.A.
2022 NY Slip Op 06892
Decided on December 06, 2022
Appellate Division, First Department
GISCHE, J.P.,
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Decided and Entered: December 06, 2022 SUPREME COURT, APPELLATE DIVISION
First Judicial Department
Judith Gische
Ellen Gesmer Jeffrey K. Oing Tanya R. Kennedy Saliann Scarpulla

Index No. 657123/20 Appeal No. 16575-16575A Case No. 2021-04513

[*1]Daryl Schwartz, Plaintiff-Appellant,

v

Genfit, S.A., et al., Defendants-Respondents.

Plaintiffs appeal from the judgment of the Supreme Court, New York County (Jennifer G. Schecter, J.), entered August 30, 2021, dismissing the complaint with prejudice. Plaintiffs also appeal from the order, same court and Justice, entered on or about August 10, 2021, which granted defendants' motion to dismiss the complaint pursuant to CPLR 3211(a)(1) and/or (7).

Pomerantz LLP, New York (Michael J. Wernke and Jeremy A. Lieberman of counsel), Pomerantz, LLP, Chicago, IL (Patrick V. Dahlstrom of counsel), and Bronstein, Gewirtz & Grossman, LLC, New York (Peretz Bronstein of counsel), for appellant.

Cooley LLP, New York (Sarah M. Lightdale, Aric H. Wu and Christopher L. Martin, Jr. of counsel), for Genfit, S.A., Jean-Francois Mouney, Nathalie Huitorel, Xavier Guille Des Buttes, Catherine LaRue, Anne-HÉlÈne Monsellato, FrÉdÉric Desdouits, Florence SÉjournÉ and Philippe Moons, respondents.

Skadden, Arps, Slate, Meagher & Flom LLP, New York (Susan L. Saltzstein, Scott D. Musoff and Maria da Silva of counsel), for SVB Leerink LLC, Barclays Capital Inc., H.C. Wainwright & Co., Roth Capital Partners, LLC, Bryan, Garnier & Co. Limited and Natixis, respondents.

GISCHE, J.P.,

Defendant Genfit is a French pharmaceutical company. Its main product is a drug called elafibranor, which Genfit hoped would treat a liver disease known as nonalcoholic steatohepatitis (NASH). In order to obtain FDA approval, Genfit conducted clinical trials to determine the drug's efficacy. After it had completed clinical trial phase 2b, but before it concluded clinical trial phase 3 (also known as RESOLVE-IT), Genfit conducted an initial public offering (IPO) as American Depository Shares (ADS). About a year later, the interim results of RESOLVE-IT failed to support elafibranor's efficacy and ADS's share price fell precipitously. The drug never obtained FDA approval.

Plaintiff is an investor who, on behalf of a putative class, brought this complaint against Genfit and the individual defendants (collectively Genfit) alleging violations of sections 11 and 15 [FN1] of the 1933 Federal Securities Act. Supreme Court granted Genfit's motion to dismiss the complaint pursuant to CPLR 3211(a)(1) and (7). This appeal ensued.

The gravamen of plaintiff's complaint is that Genfit made misrepresentations and/or omissions in the registration statement and prospectus (collectively offering documents) it filed with the Securities and Exchange Commission in connection with the IPO. Before a company may sell securities in interstate commerce, it must file a registration statement with the SEC. Pursuant to section 11 of the 1933 Securities Act, if, at the time of its effective date, the registration statement contains an untrue statement of material fact or omits a material fact necessary to make the statement therein not misleading, a purchaser of the stock may sue for

damages (15 USC § 77 [k]*; Omnicare v Laborers Dist. Council Const.*, __US__, 135 S Ct 1318, 1323 [2015]). Notwithstanding the [*2]statutory references to untrue and misleading statements, the underlying claim under these SEC provisions is not one for fraud (*Litwin v Blackstone Group, LLP*, 634 F3d 706, 715 [2d Cir 2011], *cert denied* 565 US 878 [2011]). Consequently, the heightened pleading requirements of CPLR 3016(b) do not apply (*Feinberg v Marathon Patent Group, Inc.*, 193 AD3d 568, 570-571 [1st Dept 2021]). In order to state a claim, however, a plaintiff, who purchased a security pursuant to a registration statement, must still plead facts supporting a conclusion that the offering documents: (1) contained a material misrepresentation of fact; or (2) omitted material facts in contravention of an affirmative obligation of disclosure; or (3) omitted facts necessary to prevent other disclosures from being misleading (*In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F3d 347, 358-360 [2d Cir 2010]; *see Herman & Maclean v Huddleson*, 459 US 375, 382 [1983]).

Whether a statement is misleading depends on the perspective of a reasonable investor (*Omnicare*, 575 US at 186). It must be evaluated in the context of the total mix of information available to the reasonable investor (*see Jianming Lyu v Ruhnn Holdings, Ltd.*, 189 AD3d 441 [1st Dept 2021]). An omission is actionable if there is an affirmative duty to disclose or the omission rendered the actual disclosure made materially misleading (*see Morgan Stanley*, 592 F3d at 360-361). If additional disclosures would not have provided a more accurate picture of the facts, then the disclosures that were made are not actionable (*Matter of Sundial Growers, Inc. Sec. Litig.*, 191 AD3d 543, 544 [1st Dept 2021]).

In evaluating this pleading motion, the offering documents are irrefutable documentary evidence of what they say, regardless of the allegations in the complaint (*see AG Capital Funding Partners, L.P. v State St. Bank & Trust Co.*, 5 NY3d 582 [2005]; *Prudential Bache Metal Co. v Binder*, 121 AD2d 923, 926 [1st Dept 1986]). To the extent plaintiff's claims rely on matters outside the offering documents, the allegations in the complaint are presumed true and are given the benefit of every favorable inference (*Sassi v Mobil Life Support Servs., Inc.*, 37 NY3d 236 [2021]). Conclusions that are not supported by factual allegations, however, are not sufficient to state a claim (*Robinson v Robinson*, 303 AD2d 234, 235 [1st Dept 2003]).

In 2012, Genfit began a double-blind placebo controlled clinical trial known as Phase 2b. In 2015, prior to the IPO, Genfit publicly disclosed that it had not achieved its pre-specified primary endpoint for Phase 2b. The unblinded data revealed that the resolution of NASH among those taking elafibranor was virtually indistinguishable from the patients receiving a

placebo. There is no dispute that these results were well disclosed in the offering documents. There also can be no dispute that Genfit made robust disclosure that the ultimate success of elafibranor, its approval by the FDA and the profitability of the [*3]company could not be guaranteed and held risk.

Following the unblinding of the Phase 2b clinical trial results, Genfit engaged in a post hoc analysis of the data, concluding that elafibranor did demonstrate efficacy in treating NASH at a certain dosage. Although Genfit disclosed in the offering documents that its opinion regarding the efficacy of elafibranor was based solely upon its post hoc analysis of the data, plaintiff generally claims that Genfit misrepresented information related to its post hoc analysis and also omitted information that should have been presented about its post hoc analysis.

Plaintiff alleges that the post hoc analysis was scientifically unsound and that Genfit knew it as such. He further alleges that, relying on its post hoc analysis, Genfit improperly proceeded to RESOLVE-IT, a further clinical trial. Based on statements he obtained from a confidential witness, plaintiff claims that there were serious doubts within Genfit about proceeding with further clinical trials following the dismal results of Phase 2b. Plaintiff claims that the real motivation was not to put the drug on the market, but rather to maintain the high salaries earned by management. The interim results of RESOLVE-IT were released in May of 202o, a little over a year after the offering documents had been filed. Genfit disclosed at that time that the RESOLVE-IT data did not demonstrate a statistically significant effect on the primary endpoint of NASH resolution without worsening of fibrosis. RESOLVE-IT was discontinued thereafter and Genfit terminated the development of elafibranor as a treatment for NASH. The per share price of the ADS fell more than 67% below the IPO price.

Plaintiff specifically argues that there were misrepresentations and omissions in the offering documents because Genfit, relying on the post hoc data affirmatively asserted that "We believe this [post hoc] analysis provides a good assessment of the efficacy of elafibranor;" "based on the [post hoc] results. . . we are currently evaluating elafibranor for the treatment of NASH in a global pivotal Phase 3 clinical trial, RESOLVE-IT," and that "elafibranor's results on NASH resolution. . .make it well positioned among late stage NASH programs." Plaintiff alleges that these statements are misleading because the registration statement only disclosed a few of the company's post hoc analyses as statistically significant

and then falsely asserted that the reason elafibranor did not achieve statistical significance under the blinded Phase 2b study was because of errors in the original study design. According to plaintiff, Genfit was intentionally datadredging; the SEC had already warned Genfit against including statements in its offering documents about elafibranor's expected efficacy and Genfit's real motivation in filing an IPO and proceeding with RESOLVE-IT was to ensure its officers and directors would maintain high levels of compensation.

There are no allegations in the complaint [*4]that Genfit affirmatively falsified data or that it concealed any clinical trial data. The underlying premise of plaintiff's claims is that Genfit's opinions concerning the possibility of elafibranor's future success relied on a critically flawed post hoc analysis of the Phase 2b clinical trial data and that Genfit knew the analysis was flawed. The offering documents clearly disclose that Genfit's opinion about the future success of elafibranor was based only upon its post hoc analysis (*see Kleinman v Elan Corp., plc*, 706 F3d 145 [2d Cir 2013]). Moreover, the offering documents explain in detail Genfit's post hoc analysis, they identify the population from which the new data was obtained, stated that the analysis was based on a different definition of NASH, and it took into account differences in the standard of care across treatment centers and baseline severity. Plaintiff's disagreement with the use of the new criteria does not negate the actual fact of its disclosure to the investors. Genfit also referred investors to a publicly available peer reviewed medical journal that set forth the full results of the Phase 2b trial and included Genfit's post hoc analysis (Vlad Ratziu et al; *Elafibranor, An Agonist of the Peroxisome Proliferator. . .,* Gastroenterology, Vol. 150, No. 5 at 1147-1159). Plaintiff does not claim that Genfit did not analyze the data in accordance with reported criteria.

Plaintiff's general attacks on Genfit's post hoc scientific methodology do not support a misstatement claim under the securities laws. Where a company accurately reports the results of a scientific study, it is under no obligation to second guess its own methodology of the study. Plaintiff does not claim that the data Genfit reported was inaccurate, only that its method to find that data was unsound and that other less favorable post hoc analysis should have been reported. Just as there is no requirement that companies report only information from alleged optimal studies, there is no requirement that companies include exhaustive disclosures of alternatives not used and opinions with respect to those alternatives that were not considered (*see Kleinman*, 706 F3d at 154; *Rigel Pharmaceuticals, Inc. Sec. Litig*., 697

F3d 869, 879 [9th Cir 2012]; *MedImmune Inc. Sec. Litig.*, 873 F Supp 953, 966 [D MD 1995]; *Padnes v Scios Nova, Inc.*, 1996 WL 539711 [ND Ca]).

Despite plaintiff's claim that Genfit failed to disclose other post hoc testing that did not produce favorable results, the offering documents do disclose five other post hoc analyses by Genfit. In any event, there is no liability where, as here, there is an absence of a duty to disclose.

Plaintiff argues that the duty to disclose additional information arises because Genfit knew at the time of the disclosure that its post hoc analysis was flawed and despite that knowledge, forged ahead with the clinical trials. These allegations are conclusory, supported only by generalized facts that management knew members of [*5]the clinical and marketing team had doubts about elafibranor's success and disregarded their opinion that RESOLVE-IT "was going to go badly," by going ahead with the Phase 3 study. This is, however, conjecture. Although plaintiff relies on statements it obtained from one confidential witness in particular, identified in the complaint as CW1, the statements attributed to CW1 are insufficiently specific to overcome the express disclosures made in the offering documents. Disagreement by some employees with Genfit's interpretation of results or data does not by itself support plaintiff's allegation that Genfit's decision to proceed with a clinical trial lacked a rational basis or was unreasonable, or was intended to intentionally mislead investors (*see City of Edinburgh Council v Pfizer, Inc.,* 754 F 3d 159, 171 [3d Cir 2014]; *see also Kleinman,* 706 F 3d at 153). The offering documents disclosed that the company "did not achieve statistical significance on the pre-specified primary endpoint of [their] Phase 2b clinical trial" (Offering Documents at 2) and that it "elected to proceed to Phase 3 study without conducting additional Phase 2 studies after not achieving statistical significance on [their] prescribed endpoints in [their] Phase 2b trial" (Offering Documents at 16).

Plaintiff also objects to certain statements in the offering documents, which we characterize as opinions. They are: "We believe this [post hoc] analysis provides a good assessment of the efficacy of elafibranor;" "based on the [post hoc] results. . . we are currently evaluating elafibranor for the treatment of NASH in a global pivotal Phase 3 clinical trial, RESOLVE-IT" and that "elafibranor's results on NASH resolution. . .make it well positioned among late stage NASH programs." Opinions in offering documents are subject to an analysis under the Supreme Court Decision in *Omnicare, Inc. v Laborers Dist. Council Constr. Indus. Pension Fund* (575 US 175, 184 [2015]). Under *Omnicare*, an opinion is actionable if (1) the

speaker does not actually hold the stated belief (*Omnicare,* 575 US at 184); or (2) the opinion affirms an underlying fact (*id.* at 185); or (3) a registration statement omits material facts about the issuer's inquiry into or knowledge concerning a statement of opinion, and if those facts conflict with what a reasonable investor would take from the statement itself (*id.* at 189).

These statements of opinion do not affirm underlying facts. Moreover, Genfit has fully disclosed that the basis for its statements is based only on its post hoc analysis. Plaintiff claims, however, these statements are misleading because Genfit does not actually believe the opinions stated and that the offering documents omit material facts and knowledge. The complaint, however, alleges no facts supporting these conclusions. At most, the complaint alleges that the confidential witnesses it identifies did not, themselves, believe that the Phase 3 study would be successful.

As previously stated, [*6]CW1 does not provide a sufficient factual basis for concluding what Genfit actually believed at the time the offering documents were filed.

Plaintiff's claim that the Genfit executives were motivated by money, which we assume is true, is too equivocal to support a conclusion that Genfit's belief in the success of elafibranor was not honestly held. Profit motive can also support a conclusion that Genfit believed in elafibranor and wanted it to succeed (*see In re Rigel Pharmaceuticals, Inc. Securities Litigation*, 697 F3d 869, 884 [9th Cir 2012]). Nor can the fact that the drug did not succeed and the price per share of the offering fell precipitously be a basis for concluding that Genfit did not hold a honest belief in the opinions it offered concerning elafibranor. Statements are not rendered misleading simply because the FDA disagrees with a developer's interpretation of the data (*see Tongue v* Sanofi, 816 F3d 199, 214 [2d Cir 2016]). Moreover, "we cannot infer that the statements were false or misleading from the movement of the stock price alone" (*see Silver v H&R Block, Inc.*, 105 F3d 394, 396 [8th Cir 1997]).

The SEC warning to Genfit, that the offering documents should not imply an expectation of FDA approval, was not a determination by the SEC one way or another that elafibranor would or would not be effective. It was only instruction that Genfit revise and moderate the language used in its offering documents. Only the FDA can assess and decide the issue of a drug's efficacy and SEC's requested revision was not based upon any conclusion by the FDA regarding the bona fides of Genfit's post hoc analysis. While Genfit continued to state its opinion about the drug's efficacy, those statements were tempered by language fully

disclosing to investors that only the FDA has the authority to determine elafibranor's efficacy by approving or disapproving of it, and the FDA might not agree with Genfit's assessment. Indeed, under the heading "Risk Factors," Genfit disclosed in bold italics that its "ability to be profitable in the future will depend on our ability to obtain marketing approval for and commercialize our product candidates, particularly our lead product candidate, elafibranor" (Offering Documents at 13). The company noted that it "may not be successful" in its efforts with respect to these "challenging activities" (*id.*). Significantly, GenFit also disclosed that it has "never generated profits" from its products, that it did not have a single product approved for commercial sale at the time of the IPO, and that, as such, its "ability to reduce [its] losses and reach profitability is unproven, and we may never achieve or sustain profitability" (Offering Documents at 13).

FDA's general statements that post hoc analysis is not as reliable as blinded clinical trial data does not mean that post hoc data can never support approval of a product and it is an insufficient basis to conclude that Genfit did not honestly hold its opinion. As of the [*7]time of the offering documents, there was no FDA determination relating to this particular drug. Moreover, the general relative merits of blinded versus post hoc analysis is a concept that is accessible to the investing public. Here it was clear from the offering documents that the blinded studies did not achieve their stated end point and that Genfit's opinion was based only on post hoc analysis.

Plaintiff separately claims that Genfit falsely represented the status of RESOLVE-IT in the offering documents by stating that "[Genfit] has not had difficulties in the past retaining patients after enrollment in our clinical trials." The clinical trial was dependent upon comparison of a patient's initial liver biopsy with a second one taken 72 weeks after the treatment period. Plaintiff alleges that confidential witnesses advised that when these statements were made in the offering documents, Genfit pathologists were having difficulty reading liver biopsies of patients and that these difficulties negatively impacted the enrollment, the study and the results.

Genfit, however, specifically disclosed in the offering documents that: "In the past, we have experienced some delays in enrollment in our clinical trials"; "our clinical programs are subject to a number of variables and contingencies, such as . . . patient enrollments. Genfit also stated: "The commencement, enrollment and completion of clinical trials can be delayed . . . for a variety of reasons, including: . . .difficulty . . . recruiting and enrolling patients . . .

the risks of procedures that may be required as part of the trial, such as a liver biopsy . . .; and inability to retain enrolled patients . . ." It further stated: "For example, . . . RESOLVE-IT . . . is a . . . trial in 2,000 patients, in a disease . . . the diagnosis of which generally involves invasive procedures such as liver biopsies . . . While we announced the completion of enrollment of the first approximately 1,000 patients . . . in April 2018, . . . there can be no assurance that we will be able to enroll and retain a sufficient number of patients." These disclosures were therefore in accord with the information provided to plaintiffs by all six confidential witnesses referred to in the complaint. Reading these disclosures as a whole, a reasonable investor would not be misled about the issues faced in enrolling and retaining patients and that these difficulties could impact the results of the clinical trial.

We have considered plaintiff's other claims and find them unavailing.

Accordingly, the judgment of the Supreme Court, New York County (Jennifer G. Schecter, J.), entered August 30, 2021, dismissing the complaint with prejudice should be modified, on the law, to delete the phrase "with prejudice," and otherwise affirmed, without costs**.** The appeal from the order, same court and Justice, entered on or about August 10, 2021, which granted defendants' motion to dismiss the complaint pursuant to CPLR 3211(a)(1) and/or [*8](7), should be dismissed, without costs, as subsumed in the appeal from the judgment.

Judgment, Supreme Court, New York County (Jennifer G. Schecter, J.), entered August 30, 2021, modified, on the law, to delete the phrase "with prejudice," and otherwise affirmed, without costs**.** Appeal from order, same court and Justice, entered on or about August 10, 2021, dismissed, without costs, as subsumed in the appeal from the judgment.

Opinion by Gische, J.P. All concur.

Gische, J.P., Gesmer, Oing, Kennedy, Scarpulla, JJ.

THIS CONSTITUTES THE DECISION AND ORDER

OF THE SUPREME COURT, APPELLATE DIVISION, FIRST DEPARTMENT.

ENTERED: December 6, 2022

Footnotes

Footnote 1: Section 15 of the Federal Securities Act makes certain individuals liable under section 11 of the Act (15 USCA § 77o).

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