Cooley

# Cooley Obtains Complete Dismissal of Securities Class Action for Biopharmaceutical Company

August 18, 2021

Earlier this month, a team of Cooley litigators achieved a significant victory on behalf of French biopharmaceutical company GENFIT, S.A., obtaining complete dismissal of a putative class action alleging violations of Sections 11 and 15 of the Securities Act of 1933.

On August 10, 2021, Justice Jennifer G. Schecter of the Commercial Division of the New York Supreme Court issued a ruling from the bench dismissing all claims with prejudice, holding that the plaintiff failed to allege an actionable misrepresentation. The ruling is a bright spot for defendants facing federal securities claims in state court, an increasingly popular venue for the securities plaintiffs' bar in recent years.

Cooley lawyers Sarah Lightdale, Luke Cadigan, Aric Wu, Chris Martin and Zach Sisko participated in the winning effort for GENFIT. Koji Fukumura, Elizabeth Wright and Craig TenBroeck were also involved, defending the matter when it was initially brought in Massachusetts state court.

## Background

GENFIT is a French late-stage clinical biopharmaceutical company that develops novel therapeutic and diagnostic solutions, focusing primarily on metabolic and liver diseases. Its lead product candidate is elafibranor, a drug candidate with potential use in treating various liver diseases.

In 2016, following a Phase 2b clinical trial of elafibranor as a treatment of non-alcoholic steatohepatitis, GENFIT concluded the drug did not achieve its primary efficacy endpoint. A post-hoc analysis of those Phase 2b trial results, however, showed statistical significance based on a modified efficacy endpoint. Based on the post-hoc analysis, GENFIT elected to proceed to a Phase 3 trial of elafibranor.

In March 2019, GENFIT conducted an initial public offering of American Depositary Shares, disclosing in offering documents the company's reliance on the post-hoc analysis in proceeding to a Phase 3 trial, the substantial obstacles to achieving regulatory approval of elafibranor and the risks inherent in investing in a biopharmaceutical company with no track record of profitability.

In May 2020, GENFIT announced interim results of the Phase 3 elafibranor study, concluding that the drug had not demonstrated statistical significance on the Phase 3 endpoint. In the wake of the Phase 3 interim results announcement, GENFIT's stock price declined 68%.

## Complaint and Oral Argument

Following these disappointing Phase 3 results, an individual investor in GENFIT brought putative class action claims under Sections 11 and 15 of the Securities Act against GENFIT, certain officers and directors and underwriters. The complaint asserted GENFIT's offering documents contained material misstatements and omissions related to GENFIT's post-hoc analysis of its Phase 2b trial results, GENFIT's Phase 3 trials and elafibranor's prospects for regulatory approval.

The plaintiff initially brought his claims in Massachusetts state court. When GENFIT moved to transfer the matter to the business litigation session, the plaintiff voluntarily dismissed his complaint and subsequently refiled in New York state court, where GENFIT moved to dismiss.

At oral argument, Cooley partner Sarah Lightdale directed the court to *Kleinman v. Elan Corp., plc*, 706 F.3d 145 (2d Cir. 2013), which addressed similar claims based on a pharmaceutical company's alleged failure to disclose the methodology underlying a post-hoc analysis. Ms. Lightdale also addressed the inadequacies of plaintiff's reliance on confidential witnesses, and argued that plaintiff's attempt to predicate his Section 11 claims on dishonestly held opinions was foreclosed by the First Department's recent decision in *Labourers' Pension Fund of Cent. & E. Canada v. CVS Health*

*Corp.*, 192 A.D.3d 424 (1st Dep't 2021).

During the hearing, Justice Schecter reviewed GENFIT's offering materials, reading into the record the numerous risk disclosures highlighted by the defendants that warned of the precise risks the plaintiff claimed had been concealed. Justice Schecter also focused on *Kleinman* and other cases holding that mere disagreement with a drug company's methodology does not give rise to a Securities Act claim. At the conclusion of Ms. Lightdale's oral argument, Justice Schecter announced that she would dismiss the complaint with prejudice.

### Impact

The ruling is significant for pharmaceutical companies that must comply with disclosure obligations while pursuing regulatory approval of experimental drugs. Justice Schecter's decision indicates that courts will respect the reasoned decisions of drug developers based on science and experience, and will not allow the plaintiffs' bar to use securities litigation as a vehicle for scientific second guessing.

More broadly, the dismissal marks another victory for the defense bar in New York state court, which has quickly become a popular forum for Securities Act cases following the Supreme Court's decision in *Cyan, Inc. v. Beaver Cty. Emps. Ret. Fund*, 138 S. Ct. 1061 (2018). Following *Cyan*, corporate defendants have been faced with the prospect of parallel state and federal securities litigation, with many plaintiffs choosing the ostensibly plaintiff-friendly state forum to bring such claims. Justice Schecter's decision adds another brick to the emerging structure of state court Securities Act jurisprudence.

## Contributors


**Luke Cadigan**
**Bio**

**Sarah Lightdale**
**Bio**

**Zach Sisko**
**Bio**

**Aric Wu**
**Bio**