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Second Circuit: Nonspecific Fraud Allegations Aren't Enough

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On April 20, in *Frei v. Taro Pharmaceutical U.S.A., Inc.*, the U.S. Court of Appeals for the Second Circuit affirmed a Southern District of New York opinion from U.S. District Court Judge Vincent Briccetti, which dismissed, among other claims, a fraud claim brought under New York law for failure to meet the heightened pleading standard of Federal Rule of Civil Procedure 9(b).[1] Critically, the court found the complaint "fatally flawed" for failure to plausibly allege the drug manufacturer's own involvement in any wrongdoing with respect to warnings (or lack thereof) regarding the off-label use of its generic drug for treating atrial fibrillation (A-fib), a heart condition.[2]

The plaintiffs — all patients, or family members of patients, who died — alleged that they were harmed when they took a generic drug manufactured by Taro Pharmaceutical U.S.A., Inc.'s (Taro) called Amiodarone for the off-label treatment of A-fib. In support of their fraud claim, among others, the plaintiffs alleged that Taro: (1) failed to make "medication guides" on the proper use and risks of the drug available to patients in violation of applicable law; (2) failed to ensure the accuracy of information regarding the drug in reference materials used by physicians; and (3) concealed information on adverse events that occurred from the use of the drug in the exclusive possession of Taro.

Taro moved to dismiss the state law fraud claim under Federal Rule of Civil Procedure 9(b). The district court granted Taro's motion and dismissed the fraud claim, among others, on the grounds that it was not plausibly pled.

On appeal, the Second Circuit affirmed the Southern District's dismissal of the plaintiffs' claims, finding all three of the plaintiffs' theories of liability "flawed" because they were not based on sufficient supporting allegations.

First, the Second Circuit found that the complaint only made the conclusory assertion that Taro failed to provide information to patients "in the manner required by law" but offered "no supporting allegations" other than the plaintiffs' failure to receive the information. Accordingly, the court concluded "[t]hat this was the end result does not support *a plausible inference* that Taro committed wrongdoing."[3]

Second, the Second Circuit found that the allegations that Taro either directly or indirectly provided misleading information to the distributors of reference materials used by physicians were "vague[]" and failed to "allege what th[e] misleading information was or adduce any examples."[4] But, "[m]ore critically," the allegations of the plaintiffs' complaint were deficient because they were "not tailored to Taro," which by virtue of its role as a generic drug manufacturer did not have control over the challenged labeling but was constrained to follow the labeling of the original manufacturer.[5] Moreover, the complaint failed to explain "what Taro's contribution to or authority to correct the reference materials was."[6] The court further criticized these allegations because, rather

than being “framed in terms of Taro’s misconduct,” they were aimed at “that of ‘Defendants’ generally, presumably referring to the numerous unidentified Doe Defendants not parties to this appeal.”[7] Indeed, “[t]he only allegation specific to Taro” was that images of pills that it manufactured appeared in certain prescribing reference materials relied on by physicians, but the court held that it could not “plausibly infer from this fact that Taro controlled the medical content of the reference materials.”[8]

Third and finally, the Second Circuit found the plaintiffs’ theory that Taro failed to report adverse events from the use of the drug was not plausibly pled. Rather, this theory relied on “a broad statistical allegation” and was “not specifically tied to Taro’s conduct.”[9] In particular, the complaint alleged that: “There are millions or [sic] persons who are diagnosed with A-fib annually. Amiodarone over the years has become the number one prescribed drug for the treatment of A-fib.”[10] From this allegation, the complaint jumped to the conclusion that: “Based on the percentages of persons diagnosed just with pulmonary toxicity, there would be tens of thousands or [sic] adverse event reports submitted each year. Yet that does not appear to be even close to the number of these reports submitted to the FDA in connection with Amiodarone.”[11] The court firmly dispensed with the plaintiffs’ view, holding that the allegation “merely posits that all entities in the Amiodarone market should have collectively reported more adverse events of pulmonary toxicity in light of the frequency of these events in the general population.”[12] As the court stated, this alone did not provide a basis for it to “draw from this allegation an inference that Taro itself concealed information in its possession.”[13]

Consequently, the court affirmed dismissal of the complaint under Federal Rules of Civil Procedure 12(b)(6), (8), and (9), finding none of these theories viable to support a fraud claim or the plaintiffs’ other claims.

Critical to the court’s finding is a recognition of the high bar set by Rule 9(b) when pleading a fraud claim. Vague and conclusory allegations of wrongdoing, especially when not specifically attributed with particularity to a specific defendant, simply will not suffice to establish a plausible inference of fraud. Likewise, a plaintiff’s reliance on broad statistical allegations cannot suffice where they “merely posit” that several actors in a particular drug market should have collectively reported an increased number of adverse events but include no allegations specific to a particular drug manufacturer and provide no support for an inference that such drug manufacturer possessed specific information or concealed it. While decided in the context of a New York common law fraud claim, the court’s decision emphasizes the high bar set for all claims subject to Rule 9(b), which cannot be satisfied by broad, nonspecific, and conclusory allegations whether aimed at generic drug manufacturers or otherwise.

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[1] No. 20-1208, 2021 WL 1541141 (2d Cir. Apr. 20, 2021).

[2] As recognized by the district court below, “Federal Rule of Civil Procedure 9(b) requires that ‘in alleging fraud or mistake, a party must state with particularity the circumstance constituting fraud or mistake.’ To comply with Rule 9(b), the complaint must: (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent. And ‘to meet the requirement of Rule 9(b) a plaintiff must show the manner in which he was damaged by the implementation of a deceptive or manipulative practice or by a misrepresentation or omission.’” *Frei v. Taro*

Pharms. U.S.A., Inc., 443 F. Supp. 3d 456, 470-71 (S.D.N.Y. 2020) (citations omitted).

[3]*Frei*, 2021 WL 1541141, at *2 (emphasis added).

[4]*Id.*

[5]*Id*.

[6]*Id.*

[7]*Id.*

[8]*Id.*

[9]*Id.* at *3.

[10]*Id.*

[11]*Id.*

[12]*Id.*

[13]*Id.*

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