20-1208
Frei, et al. v. Taro Pharmaceutical U.S.A., Inc.

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

SUMMARY ORDER

RULINGS BY SUMMARY ORDER DO NOT HAVE PRECEDENTIAL EFFECT. CITATION TO A SUMMARY ORDER FILED ON OR AFTER JANUARY 1, 2007, IS PERMITTED AND IS GOVERNED BY FEDERAL RULE OF APPELLATE PROCEDURE 32.1 AND THIS COURT'S LOCAL RULE 32.1.1. WHEN CITING A SUMMARY ORDER IN A DOCUMENT FILED WITH THIS COURT, A PARTY MUST CITE EITHER THE FEDERAL APPENDIX OR AN ELECTRONIC DATABASE (WITH THE NOTATION "SUMMARY ORDER"). A PARTY CITING TO A SUMMARY ORDER MUST SERVE A COPY OF IT ON ANY PARTY NOT REPRESENTED BY COUNSEL.

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 20th day of April, two thousand twenty-one.

PRESENT:

DEBRA ANN LIVINGSTON,
Chief Judge,
RICHARD C. WESLEY,
SUSAN L. CARNEY,
Circuit Judges.

JUDITH FREI, SANDRA RHODES, CHARLES RHODES, SHIRLEY HART, WILLIAM MURPHY, BONNIE MURPHY, JAMES WALTZ, MARY BETH WALZ, TRIO CALDWELL, BEVERLY CALDWELL, ALBERT DELSANTRO, CHARLOTTE DELSANTRO, ANNA THOMAS, CHARLES DAVID SMEDLEY, EDWARD FRISCO, LARRY E. ROBINSON, CECIL BARKLEY, NANCY MILLER, LARRY JUNKIN, ARTHUR L. CHURCH, MABLE CHURCH, JACQUELINE BOYD, CORTIS BOYD, BRIAN SUKENIK, SANDRA WHITE, ROGER WHITE, MARY WATERS, KEVIN HILTON, CLINTON HUMPHREY, TENNA HUMPHREY, BONNIE GREENE, MICHAEL HESS, SANDRA BONEKEMPER, NANCY HAGERMAN, GARY MELTON, CHRISTOPHER FREEMAN, JUDITH FREEMAN, CAROLYN SUE BEAN, MARK THOMPSON, ADA DUFFY, JEFFRIE HARRISON, CHRISTEN HARRISON, RANIERE CASERTA, COUCHITA CASERTA, DON AMBURGEY, JOYCE AMBURGEY, MONA SIMMONS, TRINA OWEN, RUBIE HODA, BILLY WEST, MONA WINDHAM, RONNIE WINDHAM, JEANNE COLBORNE, TRACIE SHOLLENBARGER, WILLIAM SHELTON, PINK JONES, ANNIE JONES, CYNTHIA SKILES, RAYMOND SKILES, EARL HINES, DAVID WHITLOCK, JACQUELINE WHITLOCK,

CONNIE LUTE, JANICE SHELTON, JAMES SKINNER, DIXIE MELTON, DIANA HINES,

Plaintiffs-Appellants,

RAY HUBLER, MARIE HUBLER, REBECCA FRISCO, DEBRA HINES,

Plaintiffs,

v. No. 20-1208

TARO PHARMACEUTICAL U.S.A., INC.,

Defendant-Appellee,

ABC CORPORATIONS OR ENTITIES 1-50, JOHN AND JANE DOES 1-50, DOES 1-10,

Defendants.[*]

FOR PLAINTIFFS-APPELLANTS: SAMUEL C. COLE, Cole Legal Services, PLLC, Richardson, TX (Joseph P. Guglielmo, Scott+Scott Attorneys at Law LLP, New York, NY; Alan M. Mansfield, Consumer Law Group of California, San Diego, CA; Edward K. Wood, Jr., Wood Law Firm LLC, Birmingham, AL, *on the brief*).

FOR DEFENDANT-APPELLEE: ARTHUR J. LIEDERMAN (Nicole Battisti, *on the brief*), Morrison Mahoney LLP, New York, NY.

Appeal from a judgment of the United States District Court for the Southern District of New York (Briccetti, *J.*).

UPON DUE CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the judgment entered on March 11, 2020, is **AFFIRMED**.

Plaintiffs-Appellants appeal from the dismissal of their First Amended Complaint (the "Complaint"), alleging that they suffered injuries from taking Amiodarone, a generic drug manufactured by Taro Pharmaceutical U.S.A., Inc., for the off-label treatment of atrial fibrillation.

---

[*] Although Judith Frei was dismissed as a plaintiff, the parties have retained her name in the caption for consistency, because she was the "first listed Plaintiff" for much of the litigation. *See* App'x at 22 n.1.

The Complaint pleads seven claims against Taro: strict liability and negligent failure to warn (Counts I-II), negligent marketing and sale (Count III), negligence *per se* (Count IV), violation of New York General Business Law §§ 349 & 350 (Count V), fraud (Count VI), and wrongful death (Count VII).[1] The District Court dismissed the entire Complaint, finding that the failure-to-warn and negligent marketing and sale claims were preempted under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and that the remaining claims were not plausibly pled. We assume the parties' familiarity with the underlying facts, the procedural history of the case, and the issues on appeal, to which we refer only as necessary to explain our decision to affirm.

"We review a district court's grant of a motion to dismiss de novo." *In re Synchrony Fin. Sec. Litig.*, 988 F.3d 157, 166 (2d Cir. 2021).[2] This Court is "free to affirm on any ground that finds support in the record, even if it was not the ground upon which the trial court relied." *Wells Fargo Advisors, LLC v. Sappington*, 884 F.3d 392, 396 n.2 (2d Cir. 2018).

We affirm the dismissal of the Complaint under Federal Rule of Civil Procedure 12(b)(6) because none of the claims are plausibly pled under Rule 8 and, in the case of the fraud claim, Rule 9. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007))). Accordingly, we do not reach the questions whether, as Taro argues, certain claims are federally preempted or are barred by the state-law learned intermediary doctrine.

The thrust of the allegations is that Plaintiffs were seriously harmed when they took Amiodarone for the "off-label" treatment of atrial fibrillation, a heart condition for which the U.S. Food and Drug Administration (the "FDA") has not officially approved the drug. Manufacturers—

---

[1] The parties suggest that the state law of each Plaintiff's domicile, where the respective injuries occurred, may apply to each Plaintiff's claims. At this stage of the litigation, however, the parties cite only to New York law as an exemplar, on the assumption that "Plaintiff's home states all have equivalent common law." Appellants' Br. at 15 n.4.

[2] Unless otherwise noted, in quotations from caselaw, this Order omits all alterations, brackets, citations, emphases, and internal quotation marks.

in particular, Wyeth Pharmaceuticals Inc., which produced the original brand-name version of Amiodarone—allegedly encouraged this off-label use.

The Complaint pleads that Taro, as a subsequent generic manufacturer of Amiodarone, also bears responsibility. Underlying all seven claims against Taro are three basic factual theories: (1) Taro failed to make available to patients "Medication Guides" on the proper use and risks of Amiodarone as mandated in 21 C.F.R. § 208.24; (2) Taro failed to ensure the accuracy of information regarding Amiodarone in prescribing reference materials relied on by physicians, like the Physicians' Desk Reference and Epocrates; and (3) Taro concealed information in its exclusive possession regarding adverse events that occurred from the use of Amiodarone to treat atrial fibrillation. Each of these three theories—and in turn, the seven claims they support—is fatally flawed because the Complaint does not plausibly allege Taro's own involvement in wrongdoing.

First, the Complaint conclusorily asserts that Taro failed to make Medication Guides available to patients "in the manner required by law." App'x at 200. But the Complaint offers no supporting allegations other than that Plaintiffs did not receive Medication Guides at the point of sale for Amiodarone. That this was the end result does not support a plausible inference that Taro committed wrongdoing. To the extent the theory is that Taro failed to ensure availability of the Medication Guides in accordance with 21 C.F.R. § 208.24, that regulation is minimally satisfied so long as Taro maintained "the *means to produce* Medication Guides." *Id.* (b)(2) (emphasis added). It does not require that Taro distribute Medication Guides, let alone to patients at the point of sale, notwithstanding the Complaint's suggestion otherwise. The Complaint lacks any allegation that Taro violated the minimal requirements of § 208.24. To the extent the theory is that Taro had a duty to provide Medication Guides beyond the manner set out in § 208.24, the Complaint does not say so or plead how Taro violated this hypothetical enhanced duty. *See* App'x at 200 (the allegations framing Taro's "failure to provide each patient a Medication Guide" only in terms of a "violation of the FDA's mandate" in § 208.24).

Nor is the theory that Taro failed to ensure the accuracy of the prescribing reference materials viable. The Complaint alleges that "[i]n connection with Defendants' unlawful promotion and/or sale of Amiodarone . . . they either directly or indirectly provided . . . to the distributor of the Physician[s'] Desk Reference ("PDR") and the developer of Epocrates" "indications and usage information regarding Amiodarone" that was misleading. App'x at 171. But the Complaint does not allege what that misleading information was or adduce any examples, beyond vaguely asserting that

the effect of the reference materials was to "deceive[] physicians into believing" that Amiodarone safely treated atrial fibrillation. App'x at 172. More critically, these allegations are not tailored to Taro. The Complaint suggests that the content of the reference materials is "considered 'labeling'" subject to FDA approval, App'x at 173, but Taro, as a generic manufacturer, does not have control over this labeling. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011) (explaining that only brand-name manufacturers are "responsible for the accuracy and adequacy" of drug labeling and a generic manufacturer must "ensur[e] that its warning label is the same as the brand name's"). The Complaint does not explain what Taro's contribution to or authority to correct the reference materials was. Indeed, the allegations are not framed in terms of Taro's misconduct, but rather that of "Defendants" generally, presumably referring to the numerous unidentified Doe Defendants not parties to this appeal. The only allegation specific to Taro is that images of Amiodarone pills that it manufactured appear in Epocrates, but we cannot plausibly infer from this fact that Taro controlled the medical content of the reference materials.

Finally, the theory that Taro did not report adverse events from the use of Amiodarone is not plausibly pled. As Plaintiffs' counsel conceded at oral argument, this theory is based on a broad statistical allegation, and is not specifically tied to Taro's conduct. The Complaint alleges 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. 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.

App'x at 191. This 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. We cannot draw from this allegation an inference that Taro itself concealed information in its possession.

Because none of the three theories on which all the claims depend is viable, the Complaint fails to state a plausible claim for relief under Rules 12(b)(6), 8, and 9.

* * *

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.