

**SUPREME COURT OF THE STATE OF NEW YORK, APPELLATE DIVISION,
FIRST DEPARTMENT**

Wholey v. Amgen, Inc.

2018 NY Slip Op 06692 (App. Div. 2018) · No. 7253 · Decided October 9, 2018

SUMMARY

The Appellate Division, First Department, modified an order denying defendants' motion to dismiss claims arising from the use of Enbrel. The court limited the plaintiff's claims to injuries allegedly occurring after she ceased participating in the clinical trial, dismissed the General Business Law and fraud-related claims for insufficient pleading, and otherwise upheld claims concerning inadequate warnings and implied warranties. The court also held that punitive damages could be sought in connection with surviving claims, although there was no independent cause of action for punitive damages.

CASE DETAILS

COURT	Supreme Court of the State of New York, Appellate Division, First Department
WRITING FOR THE COURT	Renwick, J.P.; Manzanet-Daniels, J.; Webber, J.; Singh, J.
JURISDICTION	New York
DECIDED	October 9, 2018
DOCKET	7253
DISPOSITION	other
PROCEDURAL POSTURE	Defendants appealed from an order denying their motion to dismiss the complaint, except as to the defective-manufacturing claim.
STANDARD OF REVIEW	De novo review of the sufficiency of the complaint and the legal correctness of the order on a motion to dismiss.
PRECEDENTIAL VALUE	precedential
PARTIES	Amgen, Inc., et al. v. Lauren Wholey, et al.

TOPICS

products liability

consumer protection

punitive damages

appellate procedure

remedies

PRACTICE AREAS

QUESTIONS PRESENTED

1. Whether the clinical-trial sponsors owed Wholey a duty for injuries allegedly arising during her participation in the clinical trial.
2. Whether the complaint stated a consumer-oriented deceptive-practices claim under General Business Law §§ 349 and 350.
3. Whether the fraud, fraudulent-misrepresentation, and fraudulent-concealment claims were pleaded with the particularity required by CPLR 3016(b).
4. Whether the learned intermediary doctrine required dismissal of claims alleging inadequate drug warnings.
5. Whether the implied-warranty claims were sufficiently pleaded.
6. Whether punitive damages could be sought in connection with other substantive claims despite the absence of an independent cause of action for punitive damages.

HOLDINGS

1. As sponsors of a clinical trial, defendants owed no duty to Wholey as an enrollee for claims concerning injuries occurring during the clinical trial; those claims were therefore subject to dismissal.
2. The General Business Law §§ 349 and 350 claim was properly dismissed because the alleged practice of concealing information and failing to provide adequate warnings was not directed at consumers as a matter of law.
3. The claims for fraud, fraudulent misrepresentation, and fraudulent concealment were insufficiently pleaded because they did not satisfy the requisite particularity.
4. The learned intermediary doctrine did not require dismissal of claims alleging that Enbrel's warnings were inadequate because those claims were based on defendants' alleged failure to warn prescribing medical professionals, not on a failure to warn Wholey directly.
5. The claim that defendants breached the implied warranties of fitness and merchantability was sufficiently pleaded.
6. There is no independent cause of action for punitive damages, but plaintiffs may seek punitive damages in connection with otherwise viable substantive claims.

KEY QUOTATIONS

“As the sponsors of a clinical trial, defendants owed no duty to plaintiff Lauren Wholey, an enrollee in the trial.” ([*1])

“The learned intermediary doctrine does not compel dismissal of the claims that the drug's warning labels were insufficient” ([*1])

“However, their argument that plaintiffs cannot seek punitive damages in connection with their other claims

| *is incorrect*” ([*1])

FACTUAL BACKGROUND

Lauren Wholey enrolled in a clinical trial involving Enbrel sponsored by the defendants. She later stopped participating in the trial and was prescribed Enbrel as a patient. Her complaint alleged injuries and asserted claims based on inadequate warnings, deceptive practices, fraud, breach of implied warranties, and punitive damages.

PROCEDURAL HISTORY

Supreme Court, New York County, denied defendants' motion to dismiss most of the complaint. The Appellate Division modified the order to dismiss claims concerning injuries occurring during the clinical trial, the General Business Law §§ 349 and 350 claim, and the fraud-related causes of action, and otherwise affirmed.

DISPOSITION

other

CASES CITED

- Sykes v United States, 507 Fed Appx 455, 462 [6th Cir 2012]
- Abney v Amgen, Inc., 443 F3d 540, 550 [6th Cir 2006]
- Amos v Biogen Idec Inc., 28 F Supp 3d 164, 173-174 [WD NY 2014]
- Devore v Pfizer Inc., 58 AD3d 138, 143-144 [1st Dept 2008], lv denied 12 NY3d 703 [2009]
- Martin v Hacker, 83 NY2d 1, 9 [1993]
- Friedman v Medtronic, Inc., 42 AD2d 185 [2d Dept 1973]
- Rivera v City of New York, 40 AD3d 334, 344 [1st Dept 2007], lv dismissed 16 NY3d 782 [2011]
- Pludeman v Northern Leasing Sys., Inc., 40 AD3d 366, 369 [1st Dept 2007], affd 10 NY3d 486 [2008]

OPINION

PER CURIAM.

Wholey v Amgen, Inc. (2018 NY Slip Op 06692) Wholey v Amgen, Inc. 2018 NY Slip Op 06692 Decided on October 9, 2018 Appellate Division, First Department Published by New York State Law Reporting Bureau pursuant to Judiciary Law § 431. This opinion is uncorrected and subject to revision before publication in the Official Reports. Decided on October 9, 2018 Renwick, J.P., Manzanet-Daniels, Webber, Singh, JJ. 7253 162934/15 [*1]Lauren Wholey, et al., Plaintiffs-Respondents, vAmgen, Inc., et al., Defendants-Appellants.

Hogan Lovells US LLP, New York (Daryl L. Kleiman of counsel), and Arnold & Porter Kaye Scholer LLP, New York (Alan E. Rothman of counsel), for appellants. Excolo Law, PLLC, New York (Ari Kresch of counsel), for respondents. Order, Supreme Court, New York County (Eileen

A. Rakower, J.), entered May 9, 2017, which, to the extent appealed from, denied defendants' motion to dismiss the complaint except for the claim of defective manufacturing, unanimously modified, on the law, to grant the motion as to claims of injuries that occurred during the clinical trial and as to the cause of action for violation of General Business Law §§ 349 and 350 and the causes of action for "fraud," "fraudulent misrepresentation," and "fraudulent concealment," and otherwise affirmed, without costs.

As the sponsors of a clinical trial, defendants owed no duty to plaintiff Lauren Wholey, an enrollee in the trial (see *Sykes v United States*, 507 Fed Appx 455, 462 [6th Cir 2012]; *Abney v Amgen, Inc.*, 443 F3d 540, 550 [6th Cir 2006]).

Thus, her claims concerning the drug Enbrel must be limited to those that allegedly arose after she stopped participating in the trial and was prescribed the drug as a patient. The claim of violation of General Business Law §§ 349 and 350 must be dismissed, because the generally alleged deceptive practice of failing to provide adequate warnings by concealing information is, as a matter of law, not a practice directed at consumers (see *Amos v Biogen Idec Inc.*, 28 F Supp 3d 164, 173-174 [WD NY 2014]).

The complaint fails to plead the various claims of fraud with the requisite particularity (see CPLR 3016[b]; *Devore v Pfizer Inc.*, 58 AD3d 138, 143-144 [1st Dept 2008], lv denied 12 NY3d 703 [2009]). The learned intermediary doctrine does not compel dismissal of the claims that the drug's warning labels were insufficient, since the claims are premised not on defendants' failure to warn plaintiff directly but on their failure to provide proper warnings to her prescribing medical professionals (see *Martin v Hacker*, 83 NY2d 1, 9 [1993]).

Nor did defendants show that the warnings are sufficient as a matter of law (see *id.*). The claim that defendants breached the implied warranties of fitness and merchantability by holding Enbrel out as reasonably fit and suitable when it was actually unreasonably dangerous is sufficiently pleaded (see generally *Friedman v Medtronic, Inc.*, 42 AD2d 185 [2d Dept 1973]).

Defendants are correct that there is no independent cause of action for punitive damages (see *Rivera v City of New York*, 40 AD3d 334, 344 [1st Dept 2007], lv dismissed 16 NY3d 782 [2011]). However, their argument that plaintiffs cannot seek punitive damages in connection with their other claims is incorrect (see e.g. *Pludeman v Northern Leasing Sys., Inc.*, 40 AD3d 366, 369 [1st Dept 2007], *affd* 10 NY3d 486 [2008]).

We have considered defendants' remaining contentions and find them unavailing. THIS CONSTITUTES THE DECISION AND ORDER OF THE SUPREME COURT, APPELLATE DIVISION, FIRST DEPARTMENT. ENTERED: OCTOBER 9, 2018 CLERK

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