UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Glover v. Bausch & Lomb, Inc.

No. 20-1156-cv, United States Court of Appeals for the Second Circuit (July 20, 2021)

SUMMARY

The Second Circuit certified two questions to the Connecticut Supreme Court regarding federal preemption of state tort claims arising from injuries caused by a medical device (intraocular lenses). The court asked whether Connecticut law recognizes a cause of action for a manufacturer's failure to report adverse events to the FDA or comply with post-approval safety requirements, and whether the Connecticut Product Liability Act's exclusivity provision bars a Connecticut Unfair Trade Practices Act claim based on deceptive marketing of a product known to present a substantial risk of injury. The decision turns on the "narrow gap" between express preemption under the Medical Device Amendments and implied preemption under Buckman, requiring a state-law duty that parallels federal requirements without existing solely by virtue of the FDCA.

CASE DETAILS

COURT	United States Court of Appeals for the Second Circuit
WRITING FOR THE COURT	Gerard E. Lynch; William J. Nardini
JURISDICTION	Federal
DECIDED	July 20, 2021
DOCKET	20-1156-cv
DISPOSITION	other
PROCEDURAL POSTURE	Appeal from order granting motion to dismiss and denying leave to amend; certification of questions to state supreme court.
STANDARD OF REVIEW	de novo
PRECEDENTIAL VALUE	Published
PARTIES	Marjorie Glover, Charles Glover v. Bausch & Lomb Incorporated, Bausch Health Companies Inc., Bausch Health US, LLC, Bausch Health Americas, Inc., Does 1 through 50

TOPICS

civil procedure · appellate procedure · products liability · negligence · supremacy clause

PRACTICE AREAS

Torts | Product Liability | Medical Device Regulation | Preemption

QUESTIONS PRESENTED

1. Whether the negligence and failure-to-warn claims under the Connecticut Product Liability Act are preempted by federal law, specifically whether Connecticut law recognizes a duty to warn a regulator or comply with post-approval requirements.
2. Whether the Connecticut Unfair Trade Practices Act claim is barred by the exclusivity provision of the Connecticut Product Liability Act.

HOLDINGS

1. The court held that the issues on appeal turn on unsettled questions of Connecticut law for which no controlling authority exists, and certification to the Supreme Court of Connecticut is appropriate.

KEY QUOTATIONS

> *"The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman)."* (at 17)

> *"Nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."* (at 14-15)

> *"We have long recognized the appropriateness of according to state courts the opportunity to decide significant issues of state law through the certification process."* (at 33)

FACTUAL BACKGROUND

Marjorie Glover underwent cataract surgery and was implanted with Trulign Toric intraocular lenses, an FDA-approved Class III medical device. She developed Z Syndrome, a post-operative complication causing permanent vision loss. The Glovers alleged that B&L failed to report adverse events to the FDA, failed to comply with post-approval study requirements, and deceptively marketed the lens despite known risks.

PROCEDURAL HISTORY

The United States District Court for the District of Connecticut (Kari A. Dooley, J.) granted B&L's motion to dismiss the Glovers' CPLA negligence and failure-to-warn claims as preempted, and denied leave to amend to add a CUTPA claim as futile. The Glovers appealed.

DISPOSITION

other

CASES CITED

- Riegel v. Medtronic, Inc., 552 U.S. 312 (2008)
- Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)
- Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001)
- Stengel v. Medtronic Inc., 704 F.3d 1224 (9th Cir. 2013) (en banc)
- Hughes v. Boston Scientific Corp., 631 F.3d 762 (5th Cir. 2011)
- Mink v. Smith & Nephew, Inc., 860 F.3d 1319 (11th Cir. 2017)
- In re Medtronic, Inc., 623 F.3d 1200 (8th Cir. 2010)
- Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010)
- Brooks v. Mentor Worldwide LLC, 985 F.3d 1272 (10th Cir. 2021)
- Soto v. Bushmaster Firearms Int'l, LLC, 331 Conn. 53 (2019)
- Vitanza v. Upjohn Co., 257 Conn. 365 (2001)
- Hurley v. Heart Physicians, P.C., 278 Conn. 305 (2006)
- Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2d Cir. 2006)
- Goodspeed Airport LLC v. E. Haddam Inland Wetlands & Watercourses Comm'n, 634 F.3d 206 (2d Cir. 2011)
- Orchard Hill Master Fund Ltd. v. SBA Commc'ns Corp., 830 F.3d 152 (2d Cir. 2016)
- Densberger v. United Technologies Corporation, 297 F.3d 66 (2d Cir. 2002)
- Conklin v. Medtronic, Inc., 245 Ariz. 501 (2018)
- Coleman v. Medtronic, Inc., 223 Cal. App. 4th 413 (2014)

CITED IN

- Glover v. Bausch & Lomb, Inc., Glover v. Bausch & Lomb Inc., 6 F.4th 229 (2d Cir. 2021)