UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2020

Argued: March 23, 2021 Fully Submitted Post-Certification: July 22, 2022

Decided: August 8, 2022

Docket No. 20-1156-cv

MARJORIE GLOVER, CHARLES GLOVER,

Plaintiffs-Appellants,

— v. —

BAUSCH & LOMB INCORPORATED, BAUSCH HEALTH COMPANIES INC. (F/K/A VALEANT PHARMACEUTICALS INTERNATIONAL, INC.), BAUSCH HEALTH US, LLC (F/K/A VALEANT PHARMACEUTICALS NORTH AMERICA LLC), BAUSCH HEALTH AMERICAS, INC. (F/K/A VALEANT PHARMACEUTICALS INTERNATIONAL), DOES 1 through 50, inclusive,

Defendants-Appellees.[*]

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[*] The Clerk of the Court is respectfully directed to amend the caption as set forth above.

B e f o r e:

LYNCH and NARDINI, *Circuit Judges*.[**]

Plaintiffs-Appellants appeal from a district court judgment dismissing, as preempted by the federal Food, Drug, and Cosmetic Act ("FDCA"), their claims under the Connecticut Product Liability Act ("CPLA") for injuries caused by a medical device, and denying leave to amend the complaint to include a claim under the Connecticut Unfair Trade Practices Act ("CUTPA"). Because both issues turned on unresolved questions of state law, we certified two questions to the Supreme Court of Connecticut to clarify the scope of the CPLA and CUPTA. In view of the Connecticut Supreme Court's answers to those questions, we hold: (1) that the Plaintiffs-Appellants' CPLA claims are not preempted by the FDCA because traditional Connecticut tort law provides a cause of action for failing to provide adequate warnings to regulators such as the United States Food and Drug Administration; and (2) that Plaintiffs-Appellants' proposed CUTPA claim would be precluded by the CPLA. Accordingly, we vacate the district court's dismissal of the CPLA claims, affirm the district court's denial of leave to amend the complaint, and remand for further proceedings.

WENDY R. FLEISHMAN, Lieff Cabraser Heimann & Bernstein, LLP, New York, NY (Hugh W. Cuthbertson, Glenn A. Duhl, Zangari Cohn Cuthbertson Duhl & Grello P.C., New Haven, CT, *on the brief*), *for Plaintiffs-Appellants*.

ELLIOT H. SCHERKER , Greenberg Traurig, P.A., Miami, FL (Brigid F. Cech Samole, Miami, FL, Lori G. Cohen, Atlanta, GA, Daniel I.A. Smulian, Robert J. Kirshenberg,

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[**] Judge Robert A. Katzmann, originally a member of the panel, died on June 9, 2021. The two remaining members of the panel, who agree, have determined the matter. *See* 28 U.S.C. § 46(d); 2d Cir. IOP E(b); *United States v. Desimone*, 140 F.3d 457, 458-59 (2d Cir. 1998).

Sarah H. Richardson, New York, NY, *on the brief*), *for Defendants-Appellees*.

GERARD E. LYNCH, *Circuit Judge*:

Plaintiffs-Appellants Marjorie Glover and Charles Glover appeal from a judgment of the United States District Court for the District of Connecticut (Kari A. Dooley, *J.*) dismissing, as preempted by the federal Food, Drug, and Cosmetic Act ("FDCA"), their claims under the Connecticut Product Liability Act ("CPLA") for injuries allegedly resulting from use of a medical device, and denying leave to amend the complaint to include a claim under the Connecticut Unfair Trade Practices Act ("CUTPA"). Because both issues turned on unresolved questions of state law, we certified two questions to the Supreme Court of Connecticut to clarify the scope of the CPLA and CUTPA. *Glover v. Bausch & Lomb, Inc.* (*Glover I*), 6 F.4th 229, 243-44 (2d Cir. 2021).

The Connecticut Supreme Court confirmed that the CPLA creates a cause of action, rooted in traditional Connecticut tort law, against medical device manufacturers that fail to provide adequate warnings to the relevant regulators best positioned to take or recommend precautions against the potential harm. *Glover v. Bausch & Lomb, Inc.* (*Glover II*), 343 Conn. 513, 537-38 (2022).

Accordingly, in view of the principles laid out in our previous decision, we conclude that the Glovers' CPLA claims are not preempted by the FDCA, and **VACATE** the district court's dismissal of the CPLA claims. The Connecticut Supreme Court also held that the proposed CUTPA claim would be precluded by the CPLA. *Id*. at 563. Accordingly, we conclude that the proposed amendment would be futile, and **AFFIRM** the district court's denial of leave to amend the complaint. The matter is **REMANDED** to the district court for further proceedings.

DISCUSSION

We assume the parties' familiarity with the procedural history and facts of the case set forth in our prior opinion. *See Glover I*, 6 F.4th at 233-35. In brief, the Glovers brought negligence and failure-to-warn claims against Bausch & Lomb Incorporated and related entities (collectively, "B&L") under the CPLA, Conn. Gen. Stat. §§ 52-572h and 52-572q, for injuries allegedly resulting from the use of B&L's Trulign Toric intraocular lenses. The district court dismissed the complaint, concluding that the Glovers' claims under the CPLA were expressly and impliedly preempted by the FDCA. The court also denied leave to amend the complaint to add a claim under CUTPA, Conn. Gen. Stat. § 42-110a, *et seq.*, based

on wrongful marketing, concluding that the CUTPA claim would also be preempted by the FDCA. This appeal followed.

Our previous opinion explained that the Glovers' CPLA claims would not be preempted provided that they: (1) were cognizable causes of action under traditional state tort law; and (2) did not impose additional requirements beyond the FDCA. *See Glover I*, 6 F.4th at 237-38. Because the preemption analysis turned on unresolved questions of state law, we certified a question to the Supreme Court of Connecticut asking "[w]hether a cause of action exists under the negligence or failure-to-warn provisions of the [CPLA], or elsewhere in Connecticut law, based on a manufacturer's alleged failure to report adverse events to a regulator like the [United States Food and Drug Administration ("FDA")] following approval of [a] device, or to comply with a regulator's post-approval requirements." *Id.* at 244. We also certified a second question asking whether, as a matter of state law, the CPLA's exclusivity provisions barred the Glovers' proposed CUTPA claim. *Id.* The Connecticut Supreme Court answered both questions in the affirmative. *Glover II*, 343 Conn. at 563.

On July 6, 2022, we ordered the parties to show cause why, in light of the Connecticut Supreme Court's opinion, we should not vacate the district court's

dismissal of the Glovers' CPLA claims and affirm the denial of leave to amend the complaint to include an additional claim under CUTPA. *See* Order to Show Cause, No. 20-1156, Dkt. 108, (2d Cir. July 6, 2022). The parties agree that the Connecticut Supreme Court's opinion effectively forecloses the CUTPA claim. *See* Appellants' Letter Br. at 2-3; Appellees' Letter Br. at 3. We agree: the proposed amendment would be futile and we therefore affirm the district court's denial of leave to amend.

However, B&L maintains that we should affirm the dismissal of the CPLA claims for being preempted by federal law. We reject that contention.

In the course of its analysis, the Supreme Court of Connecticut stated that while there would be no duty for a manufacturer "to report adverse events associated with the device *to the FDA* in the absence of federal law requiring such reports," it does not follow that "no state law duty to report adverse events to the FDA exists." *Glover II*, 343 Conn. at 551 (emphasis in original). B&L points to that statement as evidence that the duty to warn under the CPLA exists *"solely by virtue* of the FDCA" reporting requirements and is thus preempted by the FDCA. Appellees' Letter Br. at 1. That argument misreads the Connecticut Supreme Court's opinion.

The Connecticut Supreme Court explained, *inter alia*, that the CPLA imposes a duty on manufacturers "to provide suitable warnings to the person best able to take or recommend precautions against the potential harm." *Glover II*, 343 Conn. at 532 (internal citations omitted). That "person," the Court held, is not restricted to healthcare providers, and may include regulators such as the FDA. *Id.* at 537-39. The Court did not create a cause of action against parties that violate the FDCA or fail to comply with orders of the FDA. Rather, the portion of the opinion cited by B&L highlights that a manufacturer may need to report "*to the FDA*," as opposed to some other learned intermediary, because the role of that agency under federal law renders it the entity best able to take or recommend precautions against the dangers posed by certain medical devices. *Id.* at 551. The duty recognized by the Supreme Court of Connecticut does not exist solely by virtue of the FDCA; rather, it is "based on well established state law principles governing the statutory and common-law duty to provide warnings about a product to the person in the best position to take or recommend precautions and the general duty to use care." *Id.* at 551 n.26.

We previously stated that the Glovers' CPLA claims "can proceed, if at all, only if the CPLA provides a cause of action based on a manufacturer's failure to

report adverse events to a regulator like the FDA, or to comply with post-approval requirements set by that regulator." *Glover I*, 6 F.4th at 239. The Supreme Court of Connecticut has advised that the CPLA provides precisely that cause of action. The CPLA claims pleaded in the complaint thus fall into the "narrow gap" that is neither implicitly nor explicitly preempted under the FDCA: the Glovers are "suing for conduct that violates the FDCA . . . , but [they are not] suing *because* the conduct violates the FDCA." *Id.* at 237 (internal quotation marks omitted; emphasis added). Rather, their cause of action is based on "traditional state tort law which . . . predated the federal enactments in question[]." *Id.* (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001)).

CONCLUSION

For the reasons set forth above, we **VACATE** the district court's dismissal of the Glovers' CPLA claims, **AFFIRM** its denial of leave to amend the complaint to include a claim under CUTPA, and **REMAND** for further proceedings to adjudicate the Glovers' CPLA claims.