SUPREME COURT OF THE STATE OF NEW YORK
Appellate Division, Fourth Judicial Department

1055

CA 20-00048

PRESENT: SMITH, J.P., CURRAN, TROUTMAN, AND DEJOSEPH, JJ.

JOSEPH BARONE, PLAINTIFF-RESPONDENT,

V MEMORANDUM AND ORDER

BAUSCH & LOMB, INC., DEFENDANT,
MORCHER GmbH AND FCI OPHTHALMICS, INC.,
DEFENDANTS-APPELLANTS.

REED SMITH LLP, NEW YORK CITY (OLIVER BEIERSDORF OF COUNSEL), FOR DEFENDANTS-APPELLANTS.

THE SULTZER LAW GROUP, P.C., POUGHKEEPSIE (JEREMY FRANCIS OF COUNSEL), FOR PLAINTIFF-RESPONDENT.

Appeal from an order of the Supreme Court, Monroe County (James J. Piampiano, J.), entered December 9, 2019. The order, insofar as appealed from, denied the motions of defendants Morcher GmbH and FCI Ophthalmics, Inc. to dismiss the amended complaint against them.

It is hereby ORDERED that the order insofar as appealed from is unanimously reversed on the law without costs, the motions of defendants Morcher GmbH and FCI Ophthalmics, Inc. are granted and the amended complaint is dismissed against those defendants.

Memorandum: In this products liability action, Morcher GmbH (Morcher) and FCI Ophthalmics, Inc. (FCI) (collectively, defendants) appeal from an order insofar as it denied their respective motions to dismiss the amended complaint against them. We reverse the order insofar as appealed from.

We agree with Morcher that Supreme Court erred in denying its motion. Although the ultimate burden of proof rests with the party asserting jurisdiction, in opposition to a motion to dismiss pursuant to CPLR 3211 (a) (8), the plaintiff need only make a prima facie showing that the defendant is subject to personal jurisdiction (*see Aybar v Goodyear Tire & Rubber Co.*, 175 AD3d 1373, 1373 [2d Dept 2019]; *Halas v Dick's Sporting Goods*, 105 AD3d 1411, 1412 [4th Dept 2013]). "To determine whether a non-domiciliary may be sued in New York, we first determine whether our long-arm statute (CPLR 302) confers jurisdiction over it in light of its contacts with this State. If the defendant's relationship with New York falls within the terms of CPLR 302, we determine whether the exercise of jurisdiction comports with due process" (*LaMarca v Pak-Mor Mfg. Co.*, 95 NY2d 210, 214 [2000]). Defendants do not dispute that their relationship with

New York falls within the terms of CPLR 302, and thus the only issue before us is whether due process requirements are satisfied. Due process requires that the defendant "have certain minimum contacts with [New York] such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice' " (*International Shoe Co. v Washington*, 326 US 310, 316 [1945]). In opposing Morcher's motion, plaintiff failed to make the requisite prima facie showing here, where he seeks to extend jurisdiction over a German company that manufactures medical devices in Germany and sells them through FCI, which is an independent distributor in Massachusetts (*see J. McIntyre Mach., Ltd. v Nicastro*, 564 US 873, 887-888 [2011, Breyer, J., concurring]). Plaintiff has not shown a regular flow of Morcher's goods into New York, advertising directed at New York, the delivery of Morcher's goods into the stream of commerce with the expectation of purchase in New York, or any other facts that may arguably have established jurisdiction (*see id.* at 889-890; *cf. Darrow v Hetronic Deutschland*, 119 AD3d 1142, 1144 [3d Dept 2014]). Therefore, the court should have granted Morcher's motion and dismissed the amended complaint against it (*see Aybar*, 175 AD3d at 1373).

Further, we agree with FCI that the claims against it are expressly preempted by the Medical Device Amendments (MDA) to the Federal Food, Drug and Cosmetic Act of 1938 (21 USC § 360c *et seq.*; *see* 21 USC § 360k [a]). It is undisputed that the device in question is a class III medical device with respect to which the federal government has established requirements. Thus, we must determine whether plaintiff's "common-law claims are based upon New York requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness" (*Riegel v Medtronic, Inc.*, 552 US 312, 321-322 [2008]). If so, those claims are preempted by the MDA (*see id.*). If, on the other hand, the common-law claims provide a damages remedy and are premised on a violation of the regulations of the Food and Drug Administration (FDA), they " 'parallel,' rather than add to, federal requirements" and are not preempted (*id.* at 330). Plaintiff, in effect, concedes that most of his causes of action are preempted (*see id.* at 323-324; *Mitaro v Medtronic, Inc.*, 73 AD3d 1142, 1142-1143 [2d Dept 2010]), but asserts that his failure to warn claims survive because they parallel the federal regulations. Plaintiff points to FDA regulations that require a manufacturer to report to the FDA known incidents in which their products cause serious injury or death (*see* 21 CFR 803.50 [a]; *Stengel v Medtronic Inc.*, 704 F3d 1224, 1227 [9th Cir 2013], *cert denied* 573 US 930 [2014]). Even assuming, arguendo, that the regulation applies to a distributor such as FCI, we conclude that the claims set forth in the amended complaint are not premised on any alleged failure to report incidents to the FDA, but rather on defendants' alleged failure to provide adequate warnings to plaintiff and his eye doctor. Plaintiff, however, fails to identify any federal statute or regulation that requires defendants to provide warnings to consumers or their physicians (*see Doe v Bausch & Lomb, Inc.*, 443 F Supp 3d 259, 272-273 [D Conn 2020]; *see also Webb v Mentor Worldwide LLC*, 453 F Supp 3d 550, 559-560 [ND NY 2020]). Therefore, the court should have granted FCI's motion and dismissed the amended complaint

against it (*see generally Mitaro*, 73 AD3d at 1143).

Entered: February 5, 2021

Mark W. Bennett
Clerk of the Court