11-3-2020

Andrea Irizarry v. Abbott Laboratories

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 19-3574

ANDREA IRIZARRY; MANUEL IRIZARRY,
Appellants

v.

ABBOTT LABORATORIES; ABBOTT LABORATORIES, INC.; ABBOTT VASCULAR, INC.; JOHN DOE DISTRIBUTION, INC.

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Civ. No. 5-18-cv-04232)
District Judge: Honorable Edward G. Smith

Argued September 29, 2020

Before: SHWARTZ and PHIPPS, *Circuit Judges*.[†]

(Filed: November 3, 2020)

OPINION[*]

[†] After oral argument in this matter, the Honorable D. Michael Fisher determined that it was necessary to recuse. This opinion is filed by a quorum of the panel pursuant to 28 U.S.C. § 46(d) and Third Circuit I.O.P. Chapter 12.1.

[*] This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

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PHIPPS, *Circuit Judge*.

This suit involves four claims under Pennsylvania law premised on the alleged failure of a medical device. That device, the Perclose Closure Device, received premarket approval by the Food & Drug Administration as a Class III medical device under the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act. Nonetheless, when used during a coronary and peripheral vascular catheterization at Lehigh Valley Hospital–Muhlenberg, the device failed to retract. Afterwards, the patient, Manuel Irizarry, a citizen of Pennsylvania, suffered a lacerated femoral artery, resulting in a serious groin bleed that required emergency surgery to save his life. Now joined by his wife, Andrea, who is also a citizen of Pennsylvania, Irizarry sues the manufacturer of the device, Abbott Laboratories, along with its subsidiaries and the distributor of the

device (collectively "Abbott"), none of whom are citizens of Pennsylvania either by incorporation or through principal place of business. The Irizarrys seek over $75,000 each in damages.

In response to the third amended complaint, the operative complaint, Abbott moved to dismiss for failure to state a claim for relief. *See* Fed. R. Civ. P. 12(b)(6). In that motion, Abbott asserted two affirmative defenses – express preemption under 21 U.S.C. § 360k(a) and implied preemption under 21 U.S.C. § 337(a). The Irizarrys opposed that motion by arguing that they stated plausible, non-preempted claims, and to bolster that contention, they relied on an expert report attached to the complaint.

Exercising diversity jurisdiction over this suit, *see* 28 U.S.C. § 1332, the District Court granted Abbott's motion. *Irizarry v. Abbott Lab'ys*, 2019 WL 5061127, at *1 (E.D. Pa. Oct. 8, 2019). In doing so, the District Court excluded the expert report and analyzed whether the Irizarrys stated a non-preempted claim. *Id.* at *1 n.1. It concluded that express and implied preemption left only a "narrow gap" for state law claims, and that the Irizarrys had not stated a claim within that gap. *Id.* On that basis, the District Court dismissed the third amended complaint with prejudice.

The Irizarrys timely appealed that order, bringing the case within the jurisdiction of this Court. *See* 28 U.S.C. § 1291. Reviewing *de novo* the District Court's order, *see City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 166 (3d Cir. 2014), we will affirm, resolving this case not directly on preemption grounds but indirectly.

Abbott argues that the order dismissing the complaint should be upheld on either express or implied preemption grounds. In anticipation of Abbott's preemption defenses, the Irizarrys attempted to plead only non-preempted claims, commonly referred to as "parallel" claims. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008). For a claim to be parallel in the context of Class III medical devices, which have received premarket approval from the FDA, *see* 21 U.S.C. § 360e, the state law on which the claim is based must not differ from or add to the FDA-approved premarket requirements. *See id.* § 360k(a)(1) (expressly preempting state requirements for medical devices that are "different from, or in addition to" federal requirements); *Riegel*, 552 U.S. at 330 (explaining that state-law claims that parallel federal requirements are not subject to preemption). But those premarket approval requirements are generally not subject to public disclosure. *See* 21 C.F.R. § 814.9(h)(1) (providing that, absent previous public disclosure or the abandonment of premarket approval, a new device's required "[m]anufacturing methods or processes, including quality control procedures" are not available for public disclosure). And here, in their complaint, the Irizarrys do not set forth the premarket approval requirements for the Perclose Closure Device. Without doing so, they do not provide any non-conclusory, non-speculative allegations to support a parallel claim. *See, e.g.,* Third Am. Compl. ¶ 54(h) (JA178–79) (alleging the conclusion that Abbott "manufactur[ed] the device in deviation of the manufacturing specifications approved by the FDA in the defendants' premarket approval application in violation of the Federal Food, Drug and Cosmetic Act"); *accord id.* ¶ 74(h) (JA185).

Absent reference to actual premarket approval requirements, the Irizarrys do not plausibly allege that Abbott abridged a state-law duty that neither adds to nor differs from the federal premarket approval requirements.

As a workaround, the Irizarrys rely on an expert, whose report they attach to the complaint. But that report does not constitute a "written instrument" and therefore cannot be incorporated into the complaint for purposes of the plausibility analysis. Fed. R. Civ. P. 10(c); *see Rose v. Bartle*, 871 F.2d 331, 339 n.3 (3d Cir. 1989). Nor do the allegations in the complaint based on the expert report – that two devices from the same manufacturing lot failed – carry the case past the threshold of plausibility for stating parallel claims, even with all reasonable inferences drawn in favor of the Irizarrys. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007))); *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012) ("While the plausibility standard does not impose a 'probability requirement,' it does demand 'more than a sheer possibility that a defendant has acted unlawfully.'" (quoting *Iqbal*, 550 U.S. at 678)).

In sum, the civil rules do not require the Irizarrys to plead parallel, non-preempted claims. But in anticipation of Abbott's preemption affirmative defenses, the Irizarrys attempt to plead not merely state-law claims, but parallel, non-preempted state-law claims. The Irizarrys fail to meet their self-imposed heightened pleading standard

because, by not setting forth the federal premarket approval requirements for the Perclose Closure Device, they do not plausibly allege a violation of state law parallel to those requirements. Accordingly, we will affirm the District Court's judgment dismissing this case with prejudice.