[PUBLISH]

In the

# United States Court of Appeals

## For the Eleventh Circuit

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No. 20-10132

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LALITHA E. JACOB,
MD,

Plaintiff-Appellant,

*versus*

MENTOR WORLDWIDE, LLC,

Defendant-Appellee.

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Appeal from the United States District Court
for the Middle District of Florida
D.C. Docket No. 8:19-cv-00229-MSS-SPF

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Before LAGOA, BRASHER, and TJOFLAT, Circuit Judges.

BRASHER, Circuit Judge:

The question in this appeal is whether a federal medical-device statute preempts state-law manufacturing defect claims. Lalitha Jacob received MemoryGel Silicone Gel Breast Implants made by Mentor Worldwide, LLC. After one of her implants ruptured, she sued Mentor *pro se*, alleging negligence and negligence per se, strict liability failure to warn, and strict liability manufacturing defect. The district court dismissed her complaint without prejudice and later dismissed her amended complaint with prejudice as preempted and foreclosed by Florida law. Jacob appealed. After careful review and with the benefit of oral argument, we conclude that Jacob's manufacturing defect claims are sufficiently pleaded to survive a motion to dismiss. We therefore reverse and remand.

## I. BACKGROUND

Congress enacted the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act to "provide for the safety and effectiveness of medical devices intended for human use." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996) (quoting Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539); *see also* 21 U.S.C. § 301 *et seq*. The Amendments establish three classes of medical devices—Class I, Class II, and Class III—based on the level of oversight required to ensure their safety. *See* 21 U.S.C. § 360c(a)(1). Classification is based on the level of risk posed by the

device. *Lohr*, 518 U.S. at 476– 77. Class I devices involve the least risk and require only general regulatory controls. *Id.* Class II devices involve more risk and require both general and special regulatory controls. *Id.* Class III devices involve the most risk and require general regulatory controls and pre-market approval before being sold to consumers. *Id.*

Mentor's MemoryGel Silicone Gel Breast Implant is a Class III medical device that has been deemed safe and effective via the FDA's pre-market approval process. Once approved, the Amendments forbid unauthorized changes to "design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319 (2008) (citing 21 U.S.C. § 360e(d)(6)(A)(i)). Makers of approved devices are also subject to ongoing reporting requirements related to device safety. *See id.* For example, a manufacturer must inform the FDA of studies of its devices and incidents of the device injuring consumers. *Id.* The FDA retains authority to withdraw its approval based on this information. *Id.*

In January 2007, Jacob was surgically implanted with Mentor's MemoryGel implants. Jacob alleges that after she received her implants she developed "severely disabling and life-threatening medical problems related to lupus-like syndrome. . . ." Twelve years later, Jacob underwent surgery to remove her implants. At that point she discovered that her left implant had ruptured, creating "a severe systemic[-]chemical and heavy metal toxicity adversely affecting [her] entire body."

Jacob then sued Mentor in the United States District Court for the Middle District of Florida, asserting claims for (1) negligence and negligence per se, including negligent failure to warn and negligent manufacturing (Count I); (2) strict products liability—failure to warn (Count II); and (3) strict products liability—manufacturing defect (Count III).

Mentor moved to dismiss under Federal Rule of Civil Procedure 12(b)(6). Mentor argued that Jacob's claims were both expressly and impliedly preempted by federal law. Jacob filed a two-page response stating that she "strongly fe[lt] [her] case should not be dismissed" and that her medical issues "were very severe, life-threatening and totally different from the similar cases usually encountered in the courts across the country." She also filed an "addendum" to that response, stating that Mentor's product "failed" to "meet very basic standards of safety" because "the shell of the implants in question were *porous*." She later filed another addendum stating that she was "personally aware of a case similar to [hers] that [had] passed 'preemption' in another state," and that "[t]he factors surrounding [her] case [were] equally strong, if not more."

The district court granted Mentor's motion to dismiss. It held that Jacob's failure to warn claims were preempted by federal law, explaining that "claims based upon failure to provide warning are preempted by federal law" and thus "cannot be sustained . . . ." It added that although Jacob's manufacturing defect claims purported to allege "parallel" violations of state and federal law and

"may theoretically be sustainable," they were nonetheless dismissed because they suffered from procedural defects under Federal Rules of Civil Procedure 8 and 10. Though Jacob attached a supplement to her five-page complaint, the court held that the supplement did not meet Rule 8's requirement that a complaint contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." The court also held that because the operative allegations in the complaint were not in numbered paragraphs, the complaint violated Rule 10(b).

The district court ordered that "to the extent" Jacob sought recovery for claims that were preempted, those claims were dismissed with prejudice. And to the extent that she sought recovery for claims that survived preemption, those claims were dismissed without prejudice under Rules 8 and 10 and should be realleged with greater clarity in an amended complaint. The court's dismissal order granted Jacob leave to amend.

Jacob then filed an amended complaint. In it, she alleged three new claims: violation of the FDA's pre-market approval (Count I), breach of implied warranty (Count II), and lack of informed consent—failure to warn (Count III). Mentor again moved to dismiss under Rule 12(b)(6), and the district court again granted Mentor's motion. As to Count I, violation of pre-market approval, the district court dismissed on preemption grounds. As to Count II, breach of implied warranty, the district court dismissed because a warranty claim requires privity of contract under Florida law, and Jacob did not allege that she bought her implants directly from

Mentor. As to Count III, lack of informed consent/failure to warn, the district court held that "under the learned intermediary doctrine, a manufacturer's duty to warn runs only to the prescribing physician, not to the patient." And to the extent Jacob argued that Mentor had a duty to provide warnings broader than those approved by the FDA, any such claim was preempted. Jacob timely appealed.

## II. STANDARD OF REVIEW

We review *de novo* a district court's dismissal of a complaint for failure to state a claim under Rule 12(b)(6). *EEOC v. STME, LLC*, 938 F.3d 1305, 1313 (11th Cir. 2019). Dismissal under Rule 12(b)(6) is appropriate when a plaintiff fails to allege facts sufficient "to raise a right to relief above the speculative level" or fails to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56, 570 (2007).

Because Jacob is a *pro se* litigant, we liberally construe her pleadings, holding them "to a less stringent standard than pleadings drafted by attorneys." *Tannenbaum v. United States*, 148 F.3d 1262, 1263 (11th Cir. 1998).

## III. DISCUSSION

Jacob appeals the district court's dismissal of the manufacturing defect claims in Counts I and III of her initial complaint. We divide our discussion of her appeal into two parts. First, we address Mentor's argument that Jacob waived the "theoretically

sustainable" manufacturing defect claims in her initial complaint by failing to replead them in her amended complaint. We conclude that she did not. Second, we address whether Jacob's pleadings stated a plausible claim against Mentor. We conclude that they do.

### *A. Jacob's Claims are not Waived*

Jacob appeals the dismissal of the manufacturing defect claims in her initial complaint. Mentor argues that Jacob waived those claims when she omitted them from her amended complaint. Jacob replies that she did not waive the claims because, under our precedent, she was not required to replead claims that the district court held were meritless simply to preserve them for appeal. We agree.

Ordinarily, an amended pleading supersedes the former pleading. "[T]he original pleading is abandoned by the amendment, and is no longer a part of the pleader's averments against his adversary." *Dresdner Bank AG v. M/V Olympia Voyager,* 463 F.3d 1210, 1215 (11th Cir. 2006) (citation and quotation omitted). But we have also held that "a plaintiff does not waive his right to appeal the dismissal of a claim in the original complaint by amending the complaint and omitting the dismissed claim," provided that repleading the dismissed claim would have been futile. *Reynolds v. Behrman Cap. IV L.P.*, 988 F.3d 1314, 1319 (11th Cir. 2021); *see also Dunn* v. *Air Line Pilots Ass'n*, 193 F.3d 1185, 1191 n.5 (11th Cir. 1999) ("[W]e do not require a party to replead a claim following a dismissal under Rule 12(b)(6) to preserve objections to

the dismissal on appeal" where "repleading would have been futile.").

Under our caselaw, we conclude that Jacob did not waive her right to appeal the district court's dismissal of her manufacturing defect claims by omitting them from her amended complaint. *See Reynolds*, 988 F.3d at 1319 (quoting *Dunn*, 193 F.3d at 1191 n.5). Whether on preemption grounds or procedural grounds, the district court rejected as insufficient Jacob's claims alleging that Mentor committed parallel violations of state and federal law. To be sure, the district court said that some of Jacob's claims "may theoretically be sustainable" and granted her leave to amend. But the district court did not identify which claims, if any, it thought could "theoretically" survive a motion to dismiss or how. *See U.S. ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 517 (3d Cir. 2007) ("[Where] there is uncertainty as to whether a dismissal is on the merits, doubts should be resolved *against* the party asserting waiver."). Because Jacob apparently had no additional facts to allege in support of her allegations, she reasonably concluded that repleading her claims in the same way would have been futile. Under these circumstances, Jacob did not waive her right to appeal the district court's dismissal of her manufacturing defect claims.

### *B. The District Court Erred in Dismissing Jacob's Claims on Preemption Grounds*

We turn now to whether Jacob has stated a plausible claim under Rule 12(b)(6). We divide this portion of our discussion into

two parts. First, we briefly explain preemption under the Act and the Amendments. Second, we apply that framework to Jacob's case, concluding that she has plausibly pleaded parallel violations of state and federal requirements that survive Mentor's motion to dismiss.

1. Preemption Under the Amendments

To ensure that FDA oversight is not undermined by state law, Congress included an express preemption provision in the Medical Device Amendments. That provision says that state law may not impose requirements that (1) are "different from, or in addition to" a federal requirement, and (2) "relate[] to the safety or effectiveness of the device." 21 U.S.C. § 360k(a). The Supreme Court has laid out a two-step process for analyzing the Amendments' express preemption provision. *Riegel*, 552 U.S. at 321–23. First, a court must decide whether the FDA has established "requirements" specific to the device at issue. *Id.* at 321–22. If so, the court must then determine whether the state-law claim would impose any requirement that "relates to the safety or effectiveness of the device" and is "different from, or in addition to" the federal requirement. *Id.* at 323 (quoting 21 U.S.C. § 360k(a)). If the court answers "yes" at both steps, the claim is expressly preempted. *See id.*

Because the pre-market approval process imposes device-specific requirements, and because state-law tort claims often impose requirements "different from, or in addition to" those requirements, many state-law claims involving devices subject to pre-market approval are preempted. *See id.* at 322–25. But Section 360k

"does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations" provided that "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330 (quoting *Lohr*, 518 U.S. at 495). For a state requirement to "parallel" a federal requirement and avoid express preemption under Section 360k(a), the requirements must be "genuinely equivalent." *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011) (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)); *see also Lohr*, 518 U.S. at 495 (holding that acceptable additional elements "make the state requirements narrower, not broader, than the federal requirement"). Ordinarily, state and federal requirements are not equivalent if a manufacturer could be held liable under state law without having violated federal law. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005).

The Amendments also contain an implied preemption provision. That provision states that all actions to enforce FDA requirements for medical devices "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Put another way: a plaintiff cannot seek to privately enforce a duty that is owed to the FDA. *See Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017). So, even if a plaintiff's claim is not expressly preempted, it is impliedly preempted if it is cognizable only because of duties owed to the FDA. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001) ("fraud-on-the-FDA" claims are impliedly preempted because they "exist solely by virtue of the [Food, Drug,

and Cosmetic Act's] disclosure requirements"). State-law claims based on conduct that violates the Act can escape implied preemption only if the alleged wrongdoing would give rise to liability under state law even if the Act did not exist. *Mink*, 860 F.3d at 1330; *Godelia v. Doe 1*, 881 F.3d 1309, 1320 (11th Cir. 2018).

We have explained that express and implied preemption leave a "narrow gap" through which a plaintiff's claim must pass to survive: "a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption) but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption)." *Mink*, 860 F.3d at 1327 (citing *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). In other words, when a plaintiff's claim implicates the safety or effectiveness of a federally regulated medical device, her claim survives preemption "so long as she claims the 'breach of a well-recognized duty owed to her under state law' and so 'long as she can show that she was harmed by a violation of applicable federal law.'" *Godelia*, 881 F.3d at 1317 (quoting *Mink*, 860 F.3d at 1327)).

2. Jacob has Stated a Plausible Claim Under Rule 12(b)(6)

Turning now to whether Jacob's claims pass through the "narrow gap" between express and implied preemption, Jacob argues that the district court erred in dismissing the manufacturing defect claims in her initial complaint. Mentor responds that Jacob is barred from making arguments supporting her manufacturing defect claims because she failed to make them in district court.

Mentor also argues that Jacob's manufacturing defect claims are preempted because she failed to sufficiently allege that Mentor violated parallel state and federal duties. Jacob replies that she plausibly alleged that Mentor violated parallel state and federal duties—which is enough for her *pro se* pleading to survive a Rule 12(b)(6) motion—and developed those arguments in later filings. We agree with Jacob.

As an initial matter, Jacob preserved the arguments supporting her manufacturing defect claims in the district court. Jacob was a *pro se* litigant. Nonetheless, Jacob opposed Mentor's motion to dismiss her initial complaint, arguing that Mentor's product "failed" to "meet very basic standards of safety" because "the shell of the implants in question were *porous*." She also specifically opposed Mentor's preemption argument, contending that she was "personally aware of a case similar to mine that has passed 'preemption' in another state" and that "[t]he factors surrounding my case are equally strong, if not more." Furthermore, we have held that, though litigants can "waive positions and issues on appeal," they cannot waive "individual arguments" in support of those positions. *Sec'y, U.S. Dep't of Labor v. Preston*, 873 F.3d 877, 883 n.5 (11th Cir. 2017). Thus, even if a plaintiff fails to respond to individual arguments in a defendant's motion to dismiss, that failure does not amount to a waiver of her position that her complaint stated a plausible claim, provided that the district court "considered the merits" of those arguments and "relied on them in granting the motion to dismiss." *Hi-Tech Pharms., Inc.* v. *HBS Int'l Corp.*, 910

F.3d 1186, 1194 (11th Cir. 2018). Because the district court adopted Mentor's preemption argument in dismissing Jacob's complaint, Jacob may challenge the district court's ruling accepting those arguments on appeal.

Turning to the merits of whether Jacob has stated a plausible claim, we begin by acknowledging that Jacob has plausibly pleaded viable state-law claims. Florida law recognizes common law negligence claims based on a manufacturing defect theory of liability. *See Mink*, 860 F.3d at 1329 (citing *Ford Motor Co. v. Evancho*, 327 So.2d 201, 202 (Fla. 1976) (holding that manufacturers may be liable for a manufacturing defect that causes or enhances injury)). Jacob's initial complaint alleges that Mentor owed her a duty, that it breached that duty, and that the breach caused her injury. Florida law also recognizes that a manufacturer "may be held strictly liable for an injury to the user of its product." *Id.* at 1331 (citing *West v. Caterpillar Tractor Co.*, 336 So.2d 80, 86–87 (Fla. 1976)). Jacob alleges that Mentor manufactured the implants using "improper and non-conforming component parts and materials, in violation of Florida law" and that the design was also "inconsistent with [the] specifications and conditions of the FDA's Quality System Regulations and design control requirements." She also alleges that these defects created a "porous or weak containment in the [i]mplant shell" which led to "rupture, leakage, and bleeding of silicone" into her body.

We next apply the Amendments' preemption framework, beginning with express preemption. Again, if a state-law claim is

based on a violation of federal law, "it survives [an express preemption challenge] if it does not impose new requirements on the medical device." *Id.* at 1330–31. Here, "Florida law allows the violation of a federal requirement to serve as prima facie evidence of negligence." *Id.* at 1330 (citing *Fla. Dep't of Corr. v. Abril*, 969 So. 2d 201, 205 (Fla. 2007)). Such a claim does not subject an approved medical device to any other safety requirements beyond those set by federal law. *Id.*

As currently pleaded, Jacob's manufacturing defect claims plausibly allege violations of "parallel" state and federal requirements. Jacob specifically alleges that Mentor violated "a duty under Federal law, and a *parallel duty* under Florida law, to exercise reasonable care . . . to ensure that [the implant] was safe and further that it was made in conformity with the manufacturing and design specifications mandated by the FDA as part of Mentor's [pre-market approval]." Her state-law claims are based on allegations that Mentor: (1) manufactured implants "that differed from the specifications agreed to by the FDA"; (2) "fail[ed] to properly meet the applicable standard of care by not complying with applicable federal regulations and failing to adhere to the manufacturing protocols approved by the FDA"; and (3) "fail[ed] to use the components and/or materials approved by the FDA[.]" The heart of her claim is that "[b]ecause Mentor failed to follow specifications . . . required by the FDA," her implants "were defective and were further vulnerable to degradation, deterioration, rupture and leakage." Because Jacob relies on Mentor's violation of federal requirements as

evidence that it violated state law, her claims do not impose new requirements on the federally regulated implants.

Mentor argues that Jacob's claims fail because they are not pleaded with sufficient detail, relying heavily on our decision in *Wolicki-Gables*. There, we held that a product liability claim was expressly preempted because a plaintiff failed to "set forth any specific problem, or failure to comply with any FDA regulation that [could] be linked to the injury alleged." *Wolicki-Gables*, 634 F.3d at 1301–02 (quoting *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009)). But *Wolicki-Gables* is distinguishable in several respects. First, *Wolicki-Gables* was an appeal from summary judgment, whereas Jacob has not advanced beyond the pleading stage. Second, Jacob's manufacturing defect claims are pleaded with much greater detail than the claims in *Wolicki-Gables*, which alleged simply that the defendant "fail[ed] to reasonably design the [approved device] in a manner which would have prevented injury," and "fail[ed] to reasonably manufacture the [approved device] in a reasonable manner." *Id.* at 1301. As described above, Jacob alleges that Mentor violated FDA-approved controls regulating both Mentor's manufacturing process and the materials used in making the implants. And she explains a theory of how those violations injured her. Third, unlike the plaintiff in *Wolicki-Gables*, Jacob is a *pro se* litigant whose pleadings are "held to a less stringent standard than pleadings drafted by attorneys and will, therefore, be liberally construed." *Tannenbaum*, 148 F.3d at 1263.

Mentor similarly argues that Jacob's claims fail because she "has not pointed to any device-specific federal requirements" that Mentor allegedly violated. But Jacob was not required to do so at this stage. Section 360k makes express preemption a defense if state law imposes on a device "any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device[.]" 21 U.S.C. § 360k(a). In other words, preemption does not depend on state law imposing a requirement that differs from the *device-specific* requirements approved by the FDA. Instead, state law is preempted where it imposes a requirement that differs from *any* federal requirement. *See Mink*, 860 F.3d at 1331 n.3 ("To the extent [the defendant] argues that some of the federal regulations cited by [the plaintiff] are not sufficiently device-specific, we reject its argument . . . . [T]he plain text of § 360k refers to 'any requirement.'" (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 560 (7th Cir. 2010))); *Godelia*, 881 F.3d at 1320 (same). Accordingly, it is enough that Jacob plausibly alleges that Mentor committed parallel violations of state and federal law—the federal requirements at issue need not be device specific.

Jacob's state-law claims also avoid implied preemption. We have held that a Florida state-law negligence claim based on a manufacturing defect theory "falls into the category of traditional state tort law that is not impliedly preempted." *Mink*, 860 F.3d at 1330. We explained in *Mink* that the duty of a manufacturer to use due care in manufacturing a medical device predates the Amendments and is a duty that a manufacturer owes the consumer, not the FDA.

*Id.* Similarly, a Florida state-law strict liability claim based on a manufacturing defect theory enforces "the traditional state tort duty of a manufacturer to use care in manufacturing the medical device. No duty is owed to the FDA." *Id.* at 1331.

In sum, construing her *pro se* pleadings liberally, Jacob's manufacturing defect claims are sufficiently pleaded to survive Mentor's motion to dismiss. She plausibly alleges that Mentor violated a duty it owed to her, not the government. Specifically, she alleges that the implants' manufacturing process differed from the specifications agreed to by the FDA and that Mentor used materials that differed from those approved by the FDA, violating both state law and the device-specific regulatory controls the FDA approved under 21 C.F.R. § 820.30. These allegations are enough to state a plausible claim against Mentor under Rule 12(b)(6), and the district court erred by holding otherwise.

## IV. CONCLUSION

For the reasons stated above, we **REVERSE** the district court's dismissal of Jacob's complaint and **REMAND** for further proceedings consistent with this opinion.