No. 20-10132

In the United States Court of Appeals for the Eleventh Circuit

LALITHA E. JACOB, M.D.,

Plaintiff-Appellant,

v.

MENTOR WORLDWIDE, LLC,

Defendant-Appellee.

On Appeal from the United States District Court
for the Middle District of Florida, Tampa Division
Case No. 8:19-cv-229, Hon. Mary S. Scriven

APPELLANT'S BRIEF OF LALITHA E. JACOB, M.D.

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rules 26.1-1 and 26.1-3, the following is an alphabetical list of the trial judges, attorneys, persons, and firms with any known interest in the outcome of this case.

1. Burns, Thomas A. (of Burns, P.A. in Tampa, Florida) – Appellate counsel for Plaintiff-Appellant;
2. Ethicon, Inc. – Sole member of Defendant-Appellee;
3. Flynn, Hon. Sean P. – United States Magistrate Judge;
4. Hampton, Caycee D. (of Carlton Fields, P.A. in Tampa, Florida) – Appellate counsel for Defendant-Appellee;
5. Jacob, Dr. Lalitha – Plaintiff-Appellant;
6. Johnson & Johnson (NYSE: JNJ) – Parent corporation of Ethicon, Inc.;
7. Lang, Jr., Joseph H. (of Carlton Fields, P.A. in Tampa, Florida) – Appellate counsel for Defendant-Appellee;
8. Mentor Worldwide, LLC – Defendant-Appellee;
9. Rawlin, Dustin B. (of Tucker Ellis LLP in Cleveland, Ohio) – Appellate counsel for Defendant-Appellee;
10. Reese, Shannon C. (of Burns, P.A. in Tampa, Florida) – Appellate counsel for Plaintiff-Appellant;
11. Scriven, Hon. Mary S. – United States District Judge;
12. Sindelar Jr., Jeffrey C. (of Tucker Ellis LLP in Cleveland, Ohio) – Appellate counsel for Defendant-Appellee; and

13. Walz, David J. (of Carlton Fields, P.A. in Tampa, Florida) – Appellate counsel for Defendant-Appellee.

Defendant-Appellee Mentor Worldwide, LLC is a limited liability company whose sole member is Ethicon, Inc. In turn, Ethicon, Inc. is a New Jersey corporation wholly owned by Johnson & Johnson (NYSE: JNJ). Johnson & Johnson has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

May 21, 2021

/s/ Thomas Burns
Thomas A. Burns

STATEMENT REGARDING ORAL ARGUMENT

Plaintiff-Appellant, Dr. Lalitha E. Jacob, requests oral argument. Although the record isn't extensive, it's somewhat confusing because it was compiled in part by a *pro se* litigant. Additionally, the federal preemption issues at stake in this medical device litigation are complex. Oral argument will assist the Court.

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STATEMENT OF JURISDICTION

The district court had subject-matter jurisdiction under 28 U.S.C. § 1332(a)(1) because the complaint (Doc. 1 at 3) alleged Dr. Jacob was a citizen (not a mere resident) of Florida, *see Taylor* v. *Appleton*, 30 F.3d 1365, 1367 (11th Cir. 1994), whereas Mentor Worldwide, LLC was a citizen of California (its place of incorporation and headquarters), *see* 28 U.S.C. § 1332(c)(1); *Hertz Corp.* v. *Friend*, 559 U.S. 77, 80-81 (2010).

This Court has appellate jurisdiction under 28 U.S.C. § 1291 because the district court entered an interlocutory order that dismissed the *pro se* complaint without prejudice (Doc. 26) and a subsequent final order that dismissed the *pro se* amended complaint and the lawsuit with prejudice (Doc. 41), all of which Dr. Jacob timely appealed (Doc. 42).[1]

[1] The clerk never entered a final judgment, but that makes no jurisdictional difference because Rule 58's requirement that judgments be set out on separate documents is waivable. *See* Fed. R. Civ. P. 58(a); *Bank* v. *Pitt*, 928 F.2d 1108, 1111 (11th Cir. 1991) (Rule 58 is waivable). This appeal is timely because the final order was rendered on December 10, 2019 (Doc. 41), and the *pro se* notice of appeal was filed 30 day later on January 9, 2020 (Doc. 42). *See* Fed. R. App. P. 4(a)(1)(A) (30 days to appeal in civil cases). By appealing the final order without limitation, the *pro se* notice of appeal "'draws in question all prior non-final orders and rulings which produced the judgment.'" *Toomey* v. *Wachovia Ins. Servs.*, 450 F.3d 1225, 1228 n.1 (11th Cir. 2006) (citation omitted).

STATEMENT OF THE ISSUES

1. In *Mink* v. *Smith & Nephew, Inc.*, 860 F.3d 1319, 1331 (11th Cir. 2017), and *Godelia* v. *Doe 1*, 881 F.3d 1309, 1318 (11th Cir. 2018), this Court held manufacturing defect claims based on violations of parallel federal and state requirements aren't federally preempted. Without citing *Mink* or *Godelia* or considering the parallel duties Dr. Jacob had alleged, the district court ruled her manufacturing defect claims were federally preempted and dismissed them. Did the district court err?

2. Rules 8(a)(2), 8(d)(1), and 10(b) require complaints to set forth a "short and plain statement of the claim" in "simple, concise, and direct" language using "numbered paragraphs." The district court dismissed the *pro se* complaint (Doc. 1) without prejudice for supposedly violating those rules even though it contained a supplement (Doc. 1.1) that met all those requirements. Did the district court abuse its discretion?

STATEMENT OF THE CASE

This appeal primarily concerns the supposed federal preemption of manufacturing defect claims about leaky breast implants. The district court dismissed a *pro se* complaint without prejudice and a *pro se*

amended complaint with prejudice. Docs. 26; 41. This is the plaintiff's appeal. Doc. 42.

On January 30, 2007, Dr. Lalitha E. Jacob, a neurologist, had breast augmentation surgery during which she received silicone breast implants.[2] Doc. 1.1 at 2. Within months, she became very sick. Doc. 1.1 at 2. In particular, she developed severely disabling and life-threatening lupus-like symptoms that affected almost every organ in her body. Doc. 1.1 at 2. By 2017, she was no longer able to practice medicine, and her 25-year marriage had ended due to her health problems. Doc. 1 at 4.

On January 2, 2019, Dr. Jacob had her silicone implants removed. Doc. 1.1 at 2. That procedure, performed by a Harvard-trained surgeon, revealed that her left implant had ruptured and was leaking. Doc. 1.1 at 2. Because the implant was stuck to Dr. Jacob's ribs and the deep muscles on her chest wall, the surgeon was forced to drain the implant while it was still inside her body. Docs. 28 at 2; 28.1 at 1-2. The contents of the implants were of a thin, oily consistency rather than a thick, gummy gel. Doc. 28 at 2. The left implant was also a dark yellow instead of colorless.

[2] This appeal doesn't concern the saline breast implants Dr. Jacob received in 2005. *See* Doc. 28.1 at 1.

Doc. 28 at 2. A complete heavy metals test performed on Dr. Jacob in January 2019 revealed the presence of high levels of aluminum, manganese, zinc, barium and lead, among others, in her body. Doc. 1.2 at 1-5. As a result, the rupture had riddled Dr. Jacob's body with systemic chemical and heavy metal toxicity. Docs. 1.2 at 1-5; 28.1 at 3-11.

The manufacturer of Dr. Jacob's MemoryGel Silicone Gel Breast Implants was Mentor Worldwide, LLC. Doc. 1.1 at 1.

Course of proceedings

Proceeding *pro se*, Dr. Jacob sued Mentor Worldwide in federal district court for $30 million. Doc. 1 at 4. Raising tort claims under Florida law, the *pro se* complaint alleged three counts. Doc. 1.1 at 15-37. Count one asserted negligence and negligence *per se*, including negligent failure to warn and negligent manufacturing defects. Doc. 1.1 at 15-24. Count two asserted strict liability failure to warn. Doc. 1.1 at 24-35. Count three asserted strict liability manufacturing defects. Doc. 1.1 at 35-37. The *pro se* complaint demanded a trial by jury. Doc. 1.1 at 38.[3]

[3] This appeal doesn't concern the failure to warn claims alleged in counts one or two; instead, it concerns only the negligent and strict liability manufacturing defect claims alleged in counts one and three.

Instead of answering, Mentor Worldwide moved to dismiss for failure to state a claim. Doc. 11. In particular, Mentor Worldwide argued Dr. Jacob's manufacturing defect claims were federally preempted in two different but related ways. Doc. 11 at 1-2.

First, Mentor Worldwide argued Dr. Jacob's claims were expressly preempted under *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008). Doc. 11 at 1, 7-11. Second, Mentor Worldwide argued Dr. Jacob's claims were impliedly preempted under *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Mentor Worldwide's motion disclosed, but didn't emphasize, that this Court had held manufacturing defect claims that involved violation of parallel federal and state requirements weren't federally preempted. *See* Doc. 11 at 21-22 (citing *Mink* v. *Smith & Nephew, Inc.*, 860 F.3d 1319, 1331 (11th Cir. 2017), and *Godelia* v. *Doe 1*, 881 F.3d 1309, 1318 (11th Cir. 2018)).

After. Dr. Jacob filed various *pro se* supplemental papers (Docs. 13; 16; 17; 22; 23; 24), the district court granted the motion to dismiss without prejudice and allowed leave to amend. Doc. 26. In particular, the district court ruled:

> Defendant is correct that Plaintiff's claims are preempted *to the extent* that Plaintiff is seeking to recover for

> Defendant's alleged labeling or manufacturing requirements that are different from, or in addition to, those imposed by the FDA. Similarly, Defendant is correct that Plaintiff's claims are preempted *to the extent* that Plaintiff is seeking to enforce federal requirements that are not grounded in traditional state-tort law.

Doc. 26 at 5 (emphases added).

But the order never mentioned this Court's decisions in *Mink*, 860 F.3d at 1331, or *Godelia*, 881 F.3d at 1318, which held manufacturing defect claims involving parallel duties aren't federally preempted. Nor did the district court analyze the extent to which the *pro se* complaint and its supplement alleged violations of parallel state and federal requirements with respect to manufacturing defects. *See* Doc. 26 at 4-5.

For instance, the district court didn't mention the *pro se* complaint's allegation that "Mentor had a duty under Federal law, and a *parallel* duty under Florida law, to exercise reasonable care in developing, manufacturing, testing, inspecting and selling its product to ensure that it 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 PMA." Doc. 1.1 at 21. Nor did the district court consider the *pro se* complaint's allegations that Mentor Worldwide breached those parallel

obligations by using "nonconforming materials and uncertified components, in violation of the FDA requirements." Doc. 1.1 at 24.

Rather than shouldering its own burden to analyze the *pro se* complaint's allegations and actually affording them a liberal construction, the district court instead shirked that duty and placed the onus on Dr. Jacob—notwithstanding her *pro se* status—by pointing out, "Notably, however, Plaintiff does not provide any argument in either the Response or the Addendum to challenge Defendant's assertions that her claims are entirely preempted by federal law." Doc. 26 at 5. In short, Dr. Jacob's claims were dismissed with prejudice "to the extent" that the district court found them to be preempted and without prejudice to replead any non-preempted claims, although it wasn't clear precisely which claims the district court had ruled to be preempted. *See* Docs. 26 at 5; 30 at 2.

Additionally, the district court buttressed its dismissal for failure to state a claim by *sua sponte* dismissing all claims "theoretically" stated in the *pro se* complaint due to its purported failure to contain a short and plain statement of the claim using allegations that are simple, concise, and direct in numbered paragraphs. *See* Doc. 26 at 6 (citing Fed. R. Civ.

P. 8(a)(2), 8(d)(1), 10(b)).[4] Without citing any authority other than the rules themselves, the district court ruled that the supplement to the complaint (Doc. 1.1)—which appeared to be a sophisticated legal document that contained a short and plain statement of the claims, used allegations that were simple, concise, and direct, and set forth the claims in separate counts with numbered paragraphs (Doc. 1.1 at 1-38)—wasn't sufficient. *See* Doc. 26 at 6-7. In so ruling, the district court didn't distinguish or even cite this Court's decision in *Weiland* v. *Palm Beach County Sheriff's Office*, 792 F.3d 1313, 1319-26 (11th Cir. 2015), which had reversed the dismissal of a complaint for purported violation of Rules 8(a)(2) and 10(b).

In response, Dr. Jacob filed a *pro se* amended complaint.[5] Docs. 28; 28.1; 28.2; 28.3; 28.4; 28.5. This handspun document was harder to understand than the legally sophisticated supplement to the original *pro se* complaint. *Compare* Doc. 28, *with* Doc. 1.1. But like the original *pro se*

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[4] Rule 8(a)(2) requires pleadings to include a "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Rule 8(d)(1) requires allegations to use language that is "simple, concise, and direct." *Id.* 8(d)(1). Rule 10(b) requires claims to be set forth in "numbered paragraphs." *Id.* 10(b).

[5] This appeal doesn't concern the claims raised for the first time in the *pro se* amended complaint against Dr. John O'Brien, the American Society of Plastic and Reconstructive Surgeons, or the FDA (Doc. 28 at 4-5), which the district court dismissed with prejudice (Doc. 41 at 2, 4-6).

complaint's supplement (Doc. 1.1), it also alleged the violation of parallel FDA and state tort requirements (*see* Doc. 28 at 1-2).

Specifically, it alleged Mentor Worldwide had violated FDA requirements about completing post-approval studies, which were related to the "defective or porous" shells it manufactured that ultimately caused "'gel bleed' or leakage of the contents to the rest of my body, leading to severe immune dysfunction and systemic chemical toxicity." Doc. 28 at 1-2. As Dr. Jacob summarized this manufacturing defect, "the defendant ensuring an intact shell is a basic requirement of safety dictated by Federal law, which was completely violated in my case." Doc. 28 at 2.

Instead of answering, Mentor Worldwide once again moved to dismiss for failure to state a claim. Doc. 30. At the outset, rather than affording the *pro se* amended complaint's allegations the liberal construction to which they were entitled, Mentor Worldwide initially asserted they raised no manufacturing defect claim. *See* Doc. 30 at 5 (misdescribing amended complaint's claims). Later, however, Mentor Worldwide conceded the breach of implied warranty claim was "more appropriately characterized as a manufacturing defect claim." Doc. 30 at 10.

As before, Mentor Worldwide disclosed but didn't emphasize this Court's decisions in *Mink*, 860 F.3d at 1331, and *Godelia*, 881 F.3d at 1318. *See* Doc. 30 at 11. Instead, notwithstanding the *pro se* amended complaint's *factual* allegations, Mentor Worldwide asserted Dr. Jacob had failed to identify with particularity the parallel state and federal *legal* duties it had breached. Doc. 30 at 11 (comparing *Wolicki-Gables* v. *Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-02 (11th Cir. 2011) (summary judgment), with *Mink*, 860 F.3d at 1331 (dismissal), and *Godelia*, 881 F.3d at 1318 (dismissal)). Mentor Worldwide didn't discuss whether pleading with particularity is required only for fraud or mistake claims or whether notice pleading requires only allegations about facts, not legal theories. *See* Doc. 30 at 1-16 (never mentioning Federal Rule of Civil Procedure 9(b) or case law regarding necessity to allege legal theories); *see also infra* note 10.

Additionally, relying on a district court's summary judgment order, Mentor Worldwide argued Dr. Jacob "cannot premise her manufacturing defect claims on the alleged fact that her implant ruptured" because "Florida law rejects the proposition that an unfortunate result with an implanted medical device is evidence of a defect." Doc. 30 at 11-12 (citing

Savage v. *Danek Med., Inc.*, 31 F. Supp. 2d 980, 983 (M.D. Fla. 1999)). To buttress that point, Mentor Worldwide cited a series of other summary judgment opinions and orders from other jurisdictions. *See* Doc. 30 at 11 (citing *Walker* v. *Medtronic, Inc.*, 670 F.3d 569, 580-81 (4th Cir. 2012), *Hughes* v. *Cook*, 452 F. Supp. 2d 832, 842 (W.D. Tenn. 2006), *Rankin* v. *Boston Sci. Corp.*, 2010 WL 672135, at *4 (E.D. Ky. Feb. 19, 2010), and *Clark* v. *Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1094 (D. Minn. 2008)). But Mentor Worldwide didn't mention the procedural difference between those Rule 56 summary judgment decisions and its own Rule 12(b)(6) motion to dismiss. *See* Doc. 30 at 11-12.

After Dr. Jacob once again filed more *pro se* supplemental papers (Docs. 31; 33; 36; 37; 38; 39), the district court granted the motion to dismiss (Doc. 41). This time, however, despite Dr. Jacob's *pro se* status, the district court didn't afford her any more chances. Doc. 41 at 2. Instead of allowing discovery and waiting for the record to develop at summary judgment, it dismissed the *pro se* amended complaint and lawsuit with prejudice. Doc. 41 at 2.

As before, the dismissal was based on purported federal preemption problems. Doc. 41 at 1-2 (ruling *pro se* complaint was "previously"

dismissed because Dr. Jacob's claims were "expressly preempted under *Riegel*," "impliedly preempted under *Buckman*," and "otherwise failed to comply with Rules 8 and 10"). But still the district never mentioned this Court's decisions in *Mink*, 860 F.3d at 1331, or *Godelia*, 881 F.3d at 1318. In fact, notwithstanding its obligation to afford the *pro se* amended complaint a liberal construction, the district court never even contemplated the possibility that her breach of implied warranty claim might actually have been a manufacturing defect claim. *See* Doc. 41 at 6-7.

Dr. Jacob appealed. Doc. 42. While the appeal was pending, this Court appointed undersigned *pro bono* counsel.

Statement of facts

A. The *pro se* complaint's allegations

Dr. Jacob initiated this lawsuit by filing a basic *pro se* "Complaint for a Civil Case Alleging Negligence." Doc. 1 at 1-5. In a supplement, that document referenced and incorporated a much more detailed, typed 38-page complaint. Doc. 1.1 at 1-38. It asserted claims for negligent failure to warn and negligent manufacturing (count one), strict liability failure to warn (count two), and strict liability manufacturing defect (count three). Docs. 1 at 4; 1.1 at 15, 21, 24 and 35.

Dr. Jacob's negligent manufacturing claim (count one) alleged Mentor Worldwide had a duty under federal law, and a "parallel" duty under Florida tort law, to exercise reasonable care in the development, manufacturing, testing, inspecting, and selling of the MemoryGel implants to ensure that they were safe and made in conformity with the manufacturing and design specifications "mandated by the FDA as part of Mentor's PMA." Doc. 1.1 at 21. She alleged her left implant ruptured because the shell wasn't properly manufactured according to FDA specifications, which permitted the implant's contents to bleed into her body and caused "severe systemic chemical and heavy metal toxicity." Doc. 1.1 at 2.

More specifically, she alleged Mentor Worldwide manufactured the implants using different processes and materials than those required and approved by the FDA. Doc. 1.1 at 21-22. For instance, she alleged Mentor Worldwide failed to properly complete the post-approval studies required by its premarket approval[6] and failed to comply with 21 C.F.R. § 820.30,

[6] As a condition of approval, the FDA required Mentor Worldwide to conduct postmarket surveillance, including "six post-approval studies to characterize the long-term performance and safety of the devices." Doc. 11.1 at 2-5. According to the FDA, "data from these long-term, post-approval studies will provide important information for women, their families and friends, and health care providers, and may lead to improvements in implant design and labeling." Doc. 11.3 at 5.

which requires manufacturers to put procedures in place to ensure design requirements are met. Doc. 1.1 at 22. Because Mentor Worldwide failed to follow these FDA specifications and regulations, Dr. Jacob alleged, the MemoryGel implants she received were defectively manufactured under state and federal law, and those violations proximately caused her injuries. Doc. 1.1 at 23-24.

Similarly, Dr. Jacob's claim for strict products liability based on a manufacturing defect (count three) alleged Mentor Worldwide developed and manufactured the MemoryGel implants, that the implants contained a manufacturing defect in that the shell was porous, weak, and allowed leakage of silicone into Dr. Jacob's body in violation of federal regulations, and that this defect caused Dr. Jacob's health problems. Doc. 1.1 at 35-37. Specifically, Dr. Jacob alleged, again, that Mentor Worldwide failed to properly complete its post-approval studies and failed to comply

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Mentor Worldwide failed to properly complete these studies. Doc. 1.1 at 9-10. More specifically, Mentor Worldwide stopped following the Core post-approval study participants at 6 years instead of 10 years. Doc. 1.1 at 10. The follow up rate for the "Large" study was also very low. Doc. 1.1 at 11. Only 20.1% of participants were still being followed at seven years. Doc. 1.1 at 11-12. The "Adjunct" study, designed to follow-up with patients post-operatively, to assess local complications, also had a low follow-up rate. Doc. 1.1 at 14. By year 5, only 13.8% of participants were still being followed. Doc. 1.1 at 14.

with 21 C.F.R. § 820.30. She also alleged Mentor Worldwide violated 21 C.F.R. § 820.100(a)(6)(7), which requires manufacturers to "establish and maintain procedures for implementing corrective and preventative action." Doc. 1.1 at 23, 36.

B. The *pro se* amended complaint's allegations

After the original *pro se* complaint was dismissed, Dr. Jacob amended it, still proceeding *pro se*. Doc. 28. In the *pro se* amended complaint, perhaps confused as to which claims had specifically been found to be preempted, she brought claims for (1) violation of the PMA, (2) breach of implied warranty (which Mentor agreed would be more appropriately characterized as a manufacturing defect claim (Doc. 30 at 10)), and (3) lack of informed consent.[7] Doc. 28 at 1-6.

Dr. Jacob included some new facts in this complaint, including that she had been misinformed that she would be included in a post-approval study of patients with implants; in fact, she was excluded from that post-approval study. Doc. 28 at 1. She also alleged the MRI of her breasts showed an intracapsular rupture to the left side and that the contents on

[7] Dr. Jacob also alleged claims against new defendants (Doc. 28 at 4-5), but is not appealing the dismissal of those claims. *See supra* note 5.

both sides were of a thin oily consistency rather than the expected thick gummy gel. Doc. 28 at 2. The left side implant was "also a dark yellow in color instead of colorless as it should have been." The evidence of the implants' state was "indicative of the fact that the shells were defective or porous" and led to "gel bleed" or leakage of implant contents to the rest of Dr. Jacob's body resulting in her health problems. Doc. 28 at 2.

In support, she attached the report of Dr. Blais, who inspected her implants post-removal. Doc. 28.1 at 13-14. He provided a Failure Analysis Report and opined that the right implant "is deemed to have been defective from the outset":

> The left implant is ruptured with a large number of rupture sites ranging from submicroscopic to 60 mm in size. These rupture sites are distributed over two distinct pleat lines occupying opposite quadrants on the anterior side proximal to the equator. Id.

Doc. 28.1 at 13-14. Dr. Blais opined the left implant was "chronically leaky" and that both implants showed "abnormalities in composition and molecular structure, most probably as a result of errors in formulation or fabrication." Doc. 28.1 at 13-14. "Notwithstanding the foregoing, both implants failed clinically, the right one through excess effusion of gel

derivatives and the left through frank failure of the shell system at pleat lines." Doc. 28.1 at 14

She again alleged that Mentor Worldwide failed to properly conduct its post-approval studies and dropped patients from the studies that mentioned serious systemic symptoms. Doc. 28 at 2.

Standard of review

1. The dismissal of a complaint for failure to state a claim under Rule 12(b)(6) is reviewed de novo. *Godelia*, 881 F.3d at 1316. "[G]enerally, the existence of an affirmative defense will not support a rule 12(b)(6) motion to dismiss for failure to state a claim." *Fortner* v. *Thomas*, 983 F.2d 1024, 1028 (11th Cir. 1993). Nevertheless, district courts "may dismiss a complaint on a rule 12(b)(6) motion 'when its own allegations indicate the existence of an affirmative defense,'" but only when "'the defense clearly appears on the face of the complaint.'" *Id.* (citation omitted); *accord Godelia*, 881 F.3d at 1316 (reversing dismissal of manufacturing defect claims because complaint's allegations didn't conclusively indicate they were federally preempted); *Mink*, 860 F.3d at 1331 (same).

2. The *sua sponte* dismissal of a complaint for violation of Rules 8(a)(2), 8(d)(1), and 10(b) is reviewed for abuse of discretion. *See Weiland*

v. *Palm Beach County Sheriff's Office*, 792 F.3d 1313, 1319-26 (11th Cir. 2015) (reversing dismissal of complaint for purported violation of Rules 8(a)(2) and 10(b) because its allegations were "informative enough to permit a court to readily determine if they state a claim upon which relief can be granted"). "A district court abuses its discretion if it applies an incorrect legal standard, follows improper procedures in making the determination," "makes findings of fact that are clearly erroneous," or "appl[ies] the law in an unreasonable or incorrect manner." *Klay* v. *Utd. Healthgroup, Inc.*, 376 F.3d 1092, 1096 (11th Cir. 2004).

SUMMARY OF THE ARGUMENT

1. The district court erred when it dismissed for failure to state a claim Dr. Jacob's manufacturing defect claims. Under *Mink*, 860 F.3d at 1331, and *Godelia*, 881 F.3d at 1318, Dr. Jacob's pleadings stated actionable manufacturing defect claims—including the breach of parallel state and federal duties—that could survive a preemption challenge. The appellate remedy is to reverse the dismissal and remand for further proceedings. Alternatively, even if the allegations were technically inadequate in any way, Dr. Jacob's manufacturing defect claims weren't so "clearly" futile that they couldn't proceed if properly alleged. At a

minimum, therefore, the Court should vacate the dismissal and remand with instructions to allow Dr. Jacob to amend the complaint again.

2. The district court abused its discretion by dismissing the *pro se* complaint (Doc. 1) without prejudice for purported violations of Rules 8(a)(2), 8(d)(1), and 10(b). Those rules require complaints to set forth a "short and plain statement of the claim" in "simple, concise, and direct" language using "numbered paragraphs." But that's exactly what the supplement (Doc. 1.1) had already done. The district court's contrary ruling incorrectly and unreasonably applies those rules and ignores this Court's decision in *Weiland*, 792 F.3d at 1319-26. The appellate remedy is to reverse that ground for dismissal and remand for further proceedings.

ARGUMENT AND CITATIONS OF AUTHORITY

I. The district court erred when it dismissed the manufacturing defect claims with prejudice for failure to state a claim

The district court erred when it dismissed Dr. Jacob's manufacturing defect claims. Under this Court's precedent, *Godelia* v. *Doe 1*, 881 F.3d 1309, 1318 (11th Cir. 2018) (reversing dismissal of manufacturing defect claim because it wasn't federally preempted); *Mink* v. *Smith & Nephew, Inc.*, 860 F.3d 1319, 1331-32 (11th Cir. 2017) (same), they were sufficiently pleaded to survive a preemption challenge. At minimum, the

manufacturing defect claims weren't clearly futile, so Dr. Jacob should have been granted leave to amend.

A. Notice pleading isn't a game of skill in which one misstep is decisive to the outcome, *pro se* filings must be liberally construed, and *pro se* litigants must be granted leave to amend unless it would be futile

"The Federal Rules reject the approach that pleading is a game of skill in which one misstep by counsel may be decisive to the outcome." *Conley* v. *Gibson*, 355 U.S. 41, 48 (1957), *abrogated in part by Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544, 561-63 (2007) (retiring *Conley*'s "no set of facts" language as improvident dictum, but otherwise leaving its holding in place). Instead, they "accept the principle that the purpose of pleading is to facilitate a proper decision on the merits." *Id.*

Those mere notice concerns are heightened when the purported basis for dismissal rests upon an affirmative defense such as federal preemption; that's because, "generally, the existence of an affirmative defense will not support a rule 12(b)(6) motion to dismiss for failure to state a claim." *Fortner* v. *Thomas*, 983 F.2d 1024, 1028 (11th Cir. 1993). The only exception is when a complaint's "'own allegations indicate the existence of an affirmative defense" so "clearly" that they undeniably "appear[] on the face of the complaint.'" *Id.* (citation omitted); *accord*

Godelia, 881 F.3d at 1316 (reversing dismissal of manufacturing defect claims because complaint's allegations didn't conclusively indicate they were federally preempted); *Mink*, 860 F.3d at 1331 (same).

On top of the limited role of affirmative defenses in a motion to dismiss at the pleading stage, district courts are obligated to afford *pro se* filings a liberal construction: "*Pro se* pleadings are held to a less stringent standard than pleadings drafted by attorneys and will, therefore, be liberally construed." *Tannenbaum* v. *United States*, 148 F.3d 1262, 1263 (11th Cir. 1998).

In that regard, whenever it appears amendment of a *pro se* complaint would not clearly be futile, district courts should *sua sponte* grant *pro se* litigants leave to amend. At first, this Court had held district courts must *sua sponte* grant *all* plaintiffs "at least one chance to amend the complaint before the district court dismisses the action with prejudice." *Bank* v. *Pitt*, 928 F.2d 1108, 1112 (11th Cir. 1991). A decade later, however, this Court overruled *Bank* in part and held district courts need not grant *counseled* parties leave to amend *sua sponte* when they "never filed a motion to amend nor requested leave to amend before the district court." *Wagner* v. *Daewoo Heavy Indus. Am. Corp.*, 314 F.3d 541, 542

(11th Cir. 2002) (*en banc*). Importantly, however, *Wagner* left intact *Bank*'s holding with respect to *pro se* litigants, because it took pains to note it "decide[d] and intimate[d] nothing about a party proceeding *pro se*." *Id.* at 542 n.1. As such, district courts must still *sua sponte* grant *pro se* litigants leave to amend any claim that is not futile. *Clark* v. *Maldonado*, 288 Fed. App'x 645, 647 (11th Cir. 2008); *Spear* v. *Nix*, 215 Fed. App'x 896, 902 (11th Cir. 2007).[8]

B. Under *Mink* and *Godelia*, the liberally construed *pro se* manufacturing defect claims aren't clearly preempted

With these pleading principles in mind, *Mink* and *Godelia* explain how Dr. Jacob's liberally construed *pro se* manufacturing defect claims aren't clearly preempted. But first, it's helpful to have a general sense of the preemption landscape for tort claims about medical devices.

1. Medical devices are federally regulated

At first, the introduction of new medical devices was largely supervised by the states. *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008) (citing *Medtronic Inc.* v. *Lohr*, 518 U.S. 470, 475-76 (1996)). Many states adopted regulations to address the many failing complex medical devices

[8] Unpublished Eleventh Circuit opinions are "not binding precedent," *Bravo* v. *United States*, 532 F.3d 1154, 1164 n.5 (11th Cir. 2008), but "may be cited as persuasive authority," 11th Cir. R. 36-2.

that were entering the market. In 1976, Congress sought to clear up that regulatory patchwork by enacting the Medical Device Amendments ("MDA"), 21 U.S.C. § 360c *et seq*. *Id.* at 315-16; *Mink*, 860 F.3d at 1325.

The MDA amends the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and gives the FDA regulatory authority over these medical devices. *Riegel*, 552 U.S. at 315-16. Pursuant to the MDA, the FDA has the authority to evaluate the safety and effectiveness of medical devices and approve or deny their entry into the market. *Mink*, 860 F.3d at 1325. Medical devices subject to the MDA are classified into three categories, with Class III devices being those that pose the highest risk. *Riegel*, 552 U.S. at 317; *Mink*, 860 F.3d at 1325.

The MDA classifies the breast implants at issue here as Class III devices. Doc. 1.1 at 4. For a Class III medical device to be approved, it must undergo a "premarket approval" ("PMA") process. *Riegel*, 552 U.S. at 317; *Mink*, 860 F.3d at 1325.; *see also* 21 U.S.C. § 360e. This process involves the FDA reviewing data on the medical device and making a determination as to its safety and effectiveness. *Mink*, 860 F.3d at 1325. Even after a device is approved, however, there are continuing conditions that a manufacturer must adhere to, such as continuing to perform

studies on the device and refraining from making any changes to the device without approval. *Id.*; *Riegel*, 552 U.S. at 319. Further, distribution of a device that is not in compliance with approved conditions is a violation of the act. Doc. 11.1 at 4 (PMA approval letter). Here, the litigants agree the MemoryGel implants were approved through this PMA process. Doc. 1.1 at 9.

2. Consequently, some state tort remedies can be expressly preempted

Section 360k of the MDA expressly preempts any state from imposing a requirement on a Class III device that is "different from or in addition to" any federal requirement. Specifically, section 360k provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k; *see also Mink*, 860 F.3d at 1325.

The Supreme Court addressed this express preemption section in *Riegel*, 552 U.S. at 330. It found the plaintiff's claims for strict liability, breach of implied warranty, and negligence were preempted where the

district court interpreted the claims to assert that the defendant violated state tort law despite compliance with the federal requirements. *Id.* Because the plaintiff sought to impose state requirements that were "different" from the federal ones, it was preempted. *Id.*

Riegel set forth a two-pronged test to determine whether section 360k expressly preempts a plaintiff's claims. *Id.* at 321-22. First, a court must consider "whether the Federal Government has established requirements applicable" to the specific device at issue. *Id.* at 321. The PMA process involved in a Class III medical device case necessarily establishes such "requirements" so that only a review of the second prong is necessary in cases such as this one. *See id.* at 322; 21 U.S.C. § 360k(a). The second prong involves a review of whether a plaintiff's claims rely upon any "requirement" of law that is "different from or in addition to" the federal requirements. *Riegel*, 552 U.S. at 323.

In *Riegel*, the plaintiff was attempting to impose state regulations on a catheter manufacturer that were not required by the FDA. *Id.* at 320, 330. Thus, the state requirement was "different" from the federal requirement and the claim was preempted. *Id. Riegel* clarified that this preemption provision, however, "does not prevent a State from providing

a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330 (citing *Lohr*, 518 U.S. at 495).

3. Similarly, some state tort remedies can be impliedly preempted

Section 337(a) governs implied preemption and states "all such proceedings for the enforcement or to restrain violations of this chapter shall be by and in the name of the United States." *Mink*, 860 F.3d at 1327 (citing 21 U.S.C. § 337(a)). In *Buckman*, the Supreme Court interpreted section 337(a) to mean that a plaintiff cannot seek to privately enforce a duty that is owed to the FDA. *Mink*, 860 F.3d at 1327 (citing *Buckman*, 531 U.S. at 353).

Buckman is the seminal Supreme Court case addressing implied preemption. *Id.* There, the Supreme Court determined that a claim for fraud on the FDA, in which the plaintiff alleged a bone screw manufacturer had lied to the FDA to gain a 501(k) exception, was impliedly preempted where the plaintiff's action was not grounded in traditional state tort law but, rather, solely on the violation of the federal enactments. *Id.* at 346, 353. Because the plaintiff sought to recover for duties

that were owed to the FDA rather than to the plaintiff, the claim was impliedly preempted. *Mink*, 860 F.3d 1327.

4. But in *Mink* and *Godelia*, this Court held, notwithstanding *Riegel* and *Buckman*, that manufacturing defect claims aren't expressly or impliedly preempted when they involve parallel duties

This Court has since applied *Riegel* and *Buckman* and allowed both negligent and strict liability manufacturing defect claims to proceed in Class III medical device cases subject to the MDA. *See Mink*, 860 F.3d at 1331; *Godelia*, 881 F.3d 1309.

In conducting the implied preemption analysis, this Court held the common law duty to use care in manufacturing a medical device was already in existence prior to the MDA and is a duty that is owed to the plaintiff, not the FDA. *Mink*, 860 F.3d at 1330; *Godelia*, 881 F.3d at 1320. Accordingly, the traditional state tort law cause of action for a manufacturing defect isn't impliedly preempted. *Mink*, 860 F.3d at 1330.

In conducting the express preemption analysis, this Court held the Florida common law duty to use due care in manufacturing a medical device is "parallel to the federal requirement" that the medical device be manufactured "according to the approved specifications" and, thus, not "different." *Mink*, 860 F.3d at 1331. Further, "Florida law allows the

violation of a federal requirement to serve as *prima facie* evidence of negligence." *Id.* This Court went a step further in *Godelia* in holding a plaintiff's reference to a defendant's violation of a federal regulation that isn't device specific is acceptable, "of no moment," and doesn't render the claim preempted. 881 F.3d at 1319.

Since *Mink* and *Godelia*, district courts throughout this circuit have consistently allowed plaintiffs to proceed with state tort claims for strict liability and negligent manufacturing defect claims involving Class III medical devices subject to the MDA. *See, e.g.*, *Green* v. *Medtronic, Inc.*, 2020 WL 4577713 (N.D. Ga. May 1, 2020); *Rowe* v. *Mentor Worldwide, LLC*, 297 F. Supp. 3d 1288, 1299 (M.D. Fla. 2018); *Lewis* v. *Abbott Labs., Inc.*, 2020 WL 8254280, at *3 (M.D. Fla. Feb. 24, 2020); *Ramkelawan* v. *Globus Med. Inc.*, 2018 WL 8368675, at *3 (M.D. Fla. Aug. 8, 2018). And at least one district court has specifically instructed plaintiffs to follow *Mink* and *Godelia* carefully when given an opportunity to replead their case. *See, e.g.*, *Westerfield* v. *Corin Group, PLC*, 2019 WL 1233634, at *2 (M.D. Fla. Mar. 15, 2019) (instructing plaintiffs in "formulating their amended complaint" to "hew closely to the Eleventh Circuit's most recent teachings in *Mink* and *Godelia*").

In summary, as this Court held, preemption is not a silver bullet for the medical device industry:

> The Supreme Court made clear that the plain text of the Medical Device Amendments was not intended to 'have the perverse effect of granting complete immunity from [tort] liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order to provide for the safety and effectiveness of medical devices intended for human use.

Mink, 860 F.3d at 1331 (emphasis added) (citing *Lohr*, 518 U.S. at 487).

5. Per *Mink* and *Godelia*, Dr. Jacob's manufacturing defect claims aren't federally preempted because they implicate parallel state and federal duties

In light of the holdings of *Mink* and *Godelia*, Dr. Jacob's manufacturing defect claims aren't preempted because they allege state tort claims that implicate parallel federal duties.

When addressing a preemption challenge in a medical device case, courts should first look at the plaintiff's state law claims to see whether they're properly alleged and then analyze whether they're preempted either (1) expressly or (2) impliedly. *Mink*, 860 F.3d at 1327-28; *Godelia*, 881 F.3d at 1317. The district court addressed preemption based on *Riegel*, 552 U.S. 312, and *Buckman*, 531 U.S. 341, first and then, perfunctorily, stated that any claims that may "theoretically" be sustainable

suffered from procedural defects under Rules 8(a)(2), 8(d)(1), and 10(b). *See* Doc. 26 at 6.

Although the *pro se* complaint and amended complaint may not have been as artfully drafted as an attorney's pleadings, a review of the complaints from a step back reveals the forest from the trees. Dr. Jacob alleged Mentor Worldwide failed to follow through with the federal requirements placed on it by the FDA, namely performing the follow-up studies meant to ensure the implants' safety over time and putting procedures in place to establish compliance with the manufacturing requirements and utilization of the design specifications and materials approved by the FDA. Because of these failures, Dr. Jacob received defective implants that made her sick and ruined her life as she knew it. She now seeks (and deserves) her day in court.

a. Under Florida tort law, Dr. Jacob properly pleaded her claim for negligent manufacturing defect

Under Florida law, to maintain action for negligence, a plaintiff must establish that the defendant owed a duty, that the defendant breached that duty, and that this breach caused the plaintiff's damages. *Rowe*, 297 F. Supp. 3d at 1295 (citing *Chang* v. *JPMorgan Chase Bank,*

N.A., 845 F.3d 1087, 1094 (11th Cir. 2017), and *Fla. Dep't of Corr.* v. *Abril*, 969 So. 2d 201, 204 (Fla. 2007)). Florida common law recognizes negligence claims based on a theory of manufacturing defect. *Id.* (citing *Mink*, 860 F.3d at 1329). Further, in Florida, a manufacturer's duty to inspect and test is part and parcel of its duty to design a product with reasonable care. *Id.* (citing *Godelia*, 881 F.3d at 1318 (quoting *Adams* v. *G.D. Searle & Co.*, 576 So. 2d 728, 730-31 (Fla. 2d DCA 1991))).

Dr. Jacob sufficiently pleaded a negligence claim for a manufacturing defect because she alleged duty, breach and causation: "Upon information and belief, Plaintiff was implanted with Mentor MemoryGel Silicone Gel Breast Implants with manufacturing defects, manufactured with nonconforming materials and uncertified components, in violation of the FDA requirements, resulting in product failure and serious injury to her." Doc. 1-1 at 23-24. She alleged the manufacturing of the breast implants differed from the specifications agreed to by the FDA, that Mentor Worldwide used materials and components that differed from those approved by the FDA, and that Mentor negligently incorporated components and materials into its MemoryGel implants that could not stand up to normal usage. *See* Doc. 1.1 at 21-22. Factually, she alleged the

contents of both implants "were of a thin oily consistency rather than the thick gummy gel it was supposed to be," and the left implant was "also a dark yellow in color instead of colorless as it should have been." Doc. 28 at 2. She attached the report of Dr. Blais, who inspected her implants and opined that the right implant "is deemed to have been defective from the outset." Doc. 28.1 at 13-14.

In *Mink*, the plaintiff had hip surgery using a metal-on-metal hip replacement device manufactured by the defendant and alleged that he experienced health problems, including blood toxicity and eye problems, as a result of the device and eventually had the device removed. 860 F.3d at 1323-24. The plaintiff properly pleaded his negligent manufacturing defect claim where he alleged that "a properly manufactured BHR system would not cause immediate and toxic levels of chromium and cobalt in [his] blood from the date of surgery." *Id.* at 1329.

In *Godelia*, the plaintiff properly alleged both a negligence and strict liability claim for manufacturing defect where he pleaded that the defendant manufactured the device at issue, placed it into commerce, the device was defective and non-conforming and those defects caused his injuries. 881 F.3d at 1318; *see also Rowe*, 297 F. Supp. 3d at 1299 (plaintiff

sufficiently stated claim by alleging the manufacturing of the breast implant differed from the specifications set forth in the PMA, the breast implants were manufactured with nonconforming materials and the defendant negligently incorporated components into the breast implants that could not stand up to normal usage).

Under *Mink* and *Godelia*, Dr. Jacob sufficiently alleged a claim for negligence based on a manufacturing defect.

b. Under Florida tort law, Dr. Jacob properly pleaded her claim for strict liability manufacturing defect

To properly allege a strict liability claim in Florida, a plaintiff must include the manufacturer's "relationship to the product in question," the product's defective and unreasonably dangerous condition, and a causal connection between that condition and the plaintiff's injuries. *Godelia*, 881 F.3d at 1318 (citing *West* v. *Caterpillar Tractor Co.*, 336 So. 2d 80, 87 (Fla. 1976)). Here, Dr. Jacob again properly alleged all three elements.

She alleged: (1) Mentor Worldwide developed and manufactured the MemoryGel Silicone Gel Breast Implants; (2) the implants contained a manufacturing defect, specifically that the shell was porous and weak and allowed leakage of silicone into her body; and (3) this defect caused

her health problems. Doc. 1.1 at 35-37. Even in the *pro se* amended complaint, she still alleged the device at issue was the defendant's, it ruptured, and its shell was defective and caused her serious health problems. Doc. 28 at 1-2.

In *Godelia*, the plaintiff properly alleged a strict liability causes of action based on a manufacturing defect where he alleged that the defendant manufactured the LifeVest device at issue, placed it into commerce, the device was defective and non-conforming, and those defects caused his wife's injuries. 881 F.3d at 1319. This Court ruled it wasn't necessary for the plaintiff to allege the precise defect that caused the device to malfunction. *Id.*, *accord Dye* v. *Covidien LP*, 470 F. Supp. 3d 1329, 1336 (S.D. Fla. 2020) ("[i]t would be unreasonable for the Court to require Plaintiff to plead exactly how the implanted product is defective and how it caused his alleged injuries when Plaintiff has not yet been afforded discovery or the benefit of expert testimony"). These cases indicate Dr. Jacob's allegations sufficiently stated a claim for strict liability manufacturing defect.

c. Dr. Jacob's claims aren't preempted

Dr. Jacob's state common law claims also survive Mentor Worldwide's preemption challenge because (1) they seek to recover for duties

owed to Dr. Jacob, not the FDA, and (2) they seek to impose only parallel requirements, not any different requirements. *Mink*, 860 F.3d at 1327 (citing *Riegel*, 552 U.S. at 321-22, *Wolicki-Gables*, 634 F.3d at 1301-02, and *Buckman*, 531 U.S. at 348). In this respect, it's important to keep in mind that, under mere notice pleading, plaintiffs aren't required to plead the facts or legal theories of tort claims with particularity, *see* Fed. R. Civ. P. 9(b), nor are their complaints' allegations required to anticipate affirmative defenses like preemption, *see infra* note 10.

i. Her claims aren't impliedly preempted

Dr. Jacob's manufacturing defect claims aren't impliedly preempted because they seek to enforce duties owed directly to her, not to the FDA.

Both *Mink* and *Godelia* held the manufacturing defect claims weren't impliedly preempted because the duty sought to be enforced was "the traditional state tort duty of a manufacturer to use due care in manufacturing," which duty predates the MDA and includes the duty to inspect and test. *Mink*, 860 F.3d at 1331; *Godelia*, 881 F.3d at 1320. The traditional tort law duty Mentor Worldwide owed to Dr. Jacob to use due care in the manufacturing of the MemoryGel implants in accordance with the terms set by the FDA, including the duty to test the implants to

determine their safety over time, is not a duty owed to the FDA and, accordingly, it's not impliedly preempted. *See* Docs. 1; 1.1; 28; 30 at 12.

ii. Her claims aren't expressly preempted

Her claims aren't expressly preempted because they're grounded in traditional state tort claims and allege parallel federal duties.

This Court has made clear that properly pleaded negligence and strict liability claims based on a manufacturing defect also survive the express preemption analysis.[9] That's because the Florida common law duty to use due care in manufacturing medical devices is parallel to the federal requirement that they be manufactured according to federal specifications. *Mink*, 860 F.3d at 1331. In other words, it doesn't impose duties that are "different or in addition to" as prohibited by section 360k.

Here, Dr. Jacob specifically limited her manufacturing defect claims to include a breach of the parallel duties imposed on Mentor Worldwide by the federal government. *Mink* held the plaintiff had

[9] The original *pro se* complaint stated a claim for both negligent manufacturing defect (count one) and strict products liability for a manufacturing defect (count three). Doc. 1.1 at 21, 35. Although the amended *pro se* complaint labeled one of its claims as breach of implied warranty, Mentor Worldwide eventually agreed that claim would be more aptly characterized as a negligent manufacturing claim. *See* Doc. 30 at 10.

expressly limited his claim to "those that 'are parallel to and not different from or in addition to the requirements of federal law.'" 860 F.3d at 1329. Dr. Jacob similarly limited her manufacturing defect claims: "Mentor had a duty under Federal law, and a parallel duty under Florida law, to exercise reasonable care in developing, manufacturing, testing, inspecting and selling its product to ensure that it 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 PMA." Doc. 1.1 at 21.

Additionally, in identifying a parallel federal duty, it's sufficient for a plaintiff to cite either a specific or a more general federal regulation that a defendant failed to follow.[10] *Mink*, 860 F.3d at 1331; *Godelia*, 881 F.3d at 1318. In *Mink*, the plaintiff alleged the specific PMA approval of defendant's device included the requirement that the defendant conduct studies to continue to evaluate the efficiency of the device, but the

[10] Indeed, under notice pleading, a plaintiff must allege only facts, not legal theories. *E.g.*, *Donaldson* v. *Clark*, 819 F.2d 1551, 1561 (11th Cir. 1987) (notice pleading "does not require that pleadings allege all material facts or the exact articulation of the legal theories upon which the case will be based"); *accord Luckett* v. *Rent-A-Center, Inc.*, 53 F.3d 871, 873 (7th Cir. 1995) (Easterbrook, J.) (under notice pleading, complaints "need not anticipate defenses" and "need not plead legal theories").

defendant then failed to include him in such a study as had been promised. *Id.* at 1323-24.

Here, Dr. Jacob similarly alleged Mentor Worldwide failed to include her in a study and failed to properly follow through with the required post-approval studies by, among other things, failing to follow up with many of the participants and, thus, failing to obtain proper data. Docs. 1.1 at 42-77; 28 at 1-2. The FDA noted the data collected from these studies would provide important information for women and their families, friends, and health care providers, and it would lead to improved devices. *See* Doc. 11.3 at 5. Dr. Jacob's citation to this requirement is sufficient, as it was in *Mink*, 860 F.3d 1319. It's more than plausible that Mentor Worldwide's failure to include Dr. Jacob in a study or perform its follow-up studies resulted in a defect, discovered over time, persisting in its MemoryGel implant that made its way into Dr. Jacob's body.

Dr. Jacob also alleged that Mentor failed to comply with more general federal regulations like 21 C.F.R. § 820.309 ("Design Controls"),[11] 21

[11] 21 C.F.R. § 820.30 provides: "Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met."

C.F.R. § 812.5(a)10 ("Labeling of Investigational Devices"),[12] and 21 C.F.R. § 820.100(a)(6)(7). Doc. 1.1 at 22-23, 36. Citation to these types of more general federal regulations is perfectly acceptable under *Godelia*, 881 F.3d at 1318. *Godelia* held it was plausible that the alleged failure by the manufacturer to document and respond to complaints about its device in violation of 21 C.F.R. § 820.198(a) "could have resulted in a defect persisting" in their device thereby causing the death of the plaintiff's wife. *Id.* at 1320.

Similarly, it's also plausible that Dr. Jacob's allegation that Mentor Worldwide failed to establish and maintain procedures to ensure that specified design requirements were met in violation of 21 C.F.R. § 820.30 could have resulted in a defective implant reaching Dr. Jacob. Accordingly, even without citation to Mentor Worldwide's failure to abide by its

[12] 21 C.F.R. § 812.5(a) provides:

> a) Contents. An investigational device or its immediate package shall bear a label with the following information: the name and place of business of the manufacturer, packer, or distributor (in accordance with § 801.1), the quantity of contents, if appropriate, and the following statement: 'CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use.' The label or other labeling shall describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.

specific PMA requirements to conduct follow up studies, Dr. Jacob's more general federal regulation citations are also sufficient standing on their own. *Godelia*, 881 F.3d at 1320.

Here, similar to the defendant in *Mink*, Mentor Worldwide demands immunity "beyond what the Medical Device Amendments provide." 860 F.3d at 1329. This Court has allowed the very type of manufacturing defect claims that Dr. Jacob sought to bring to proceed beyond the pleadings. The district court's dismissal of Dr. Jacob's claims based on a manufacturing defect with prejudice was, therefore, erroneous. Docs. 26; 41. Dr. Jacob's negligent and strict liability causes of action based on a manufacturing defect were sufficiently pleaded, are not preempted, and should have been permitted to proceed to the discovery stage.

Lastly, Dr. Jacob alleged Mentor Worldwide didn't manufacture the breast implants according to the specifications or using the materials approved by the FDA. *E.g.*, Doc. 1.1 at 21, 24. Regardless whether Mentor Worldwide disputes the truth of those allegations, that's a matter to be determined only at summary judgment, not at the pleading stage.

iii. Even if there were any doubt about preemption, this issue would be better addressed at the summary judgment stage

Godelia noted it was possible, down the road, that a plaintiff's case might "show to extend beyond the purview of the federal requirements" that were alleged to have been violated but that at the pleadings stage, his claim was appropriate. 881 F.3d at 1319. *Godelia* also noted the plaintiff would not likely have an opportunity to "access documents describing all of the [device] specific regulatory requirements without discovery." *Id.* at 1320. "The specifications of the FDA's premarket approval documents, for example, are confidential, and there is no public access to complete versions of these documents." *Id.* (citing *Bausch* v. *Stryker Corp.*, 630 F.3d 546, 560 (7th Cir. 2010)).

Similarly, here, Dr. Jacob should at least have been given the opportunity to engage in discovery with regards to her negligence and strict liability claims based on a manufacturing defect. She doesn't have full access to all of the FDA's premarket approval documents with respect to the MemoryGel implants. Mentor Worldwide's motion to dismiss argued it had, in fact, completed the post-approval studies that Dr. Jacob alleged

they had not, which only serves to demonstrate a material issue of fact in dispute that requires discovery. *See* Doc. 11 at 5.

In that regard, Mentor Worldwide's heavy reliance (*see* Docs. 11 at 9, 10, 16, 21, 22, 23, 25; 30 at 11, 14) on this Court's earlier decision in *Wolicki-Gables* v. *Arrow Int'l, Inc.*, 634 F.3d 1296, 1297 (11th Cir. 2011), is misplaced. That decision involved summary judgment, not dismissal of a complaint.[13] *Id.* While the district court there had allowed 12 counts to proceed to the summary judgment stage, this Court upheld the finding that no facts supported the presence of the elements of a parallel claim. *Id.* at 1301-02.

Thus, because they are procedurally different, there is no prior-panel-precedent conflict between *Wolicki-Gables*'s summary judgment ruling on one hand and *Mink*'s and *Godelia*'s dismissal rulings on the other. As this Court has "pointed out many times," "regardless of what a court says in its opinion, the decision can hold nothing beyond the facts

[13] For the identical reason, Mentor Worldwide also misplaced reliance on cases like *Savage* v. *Danek Med., Inc.*, 31 F. Supp. 2d 980, 983 (M.D. Fla. 1999), *Walker* v. *Medtronic, Inc.*, 670 F.3d 569, 580-81 (4th Cir. 2012), *Hughes* v. *Cook*, 452 F. Supp. 2d 832, 842 (W.D. Tenn. 2006), *Rankin* v. *Boston Sci. Corp.*, 2010 WL 672135, at *4 (E.D. Ky. Feb. 19, 2010), and *Clark* v. *Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1094 (D. Minn. 2008).

of that case." *Edwards* v. *Prime, Inc.*, 602 F.3d 1276, 1298 (11th Cir. 2010); *see also United States* v. *Caraballo-Martinez*, 866 F.3d 1233, 1244-45 (11th Cir. 2017) (distinguishing *obiter dicta* from holdings).

C. Even if, as alleged in the pleadings, the *pro se* manufacturing defect claims were clearly preempted, the district court should have granted leave to amend

District courts should *sua sponte* grant *pro se* litigants leave to amend unless further amendment would be futile. *See Clark*, 288 Fed. App'x at 647; *Spear*, 215 Fed. App'x at 902.[14] Here, even if Dr. Jacob's allegations were insufficient in some hyper-technical fashion, she still should have been granted leave to amend because it's far from clear her manufacturing defect claims necessarily would have been futile.

Summary

Dr. Jacob, a *pro se* litigant, sufficiently alleged Mentor Worldwide failed to follow the requirements placed on it by the FDA, the duties of which parallel her state tort claims. As a result, she became very sick from their manufactured implants; implants that a physician has already opined were "defective from the outset." And even if her allegations were technically insufficient in any way, her claims were not clearly destined

[14] *See supra* note 8.

to be preempted if properly pleaded, and thus they couldn't be futile. At minimum, the district court should have granted her leave to amend.

II. The district court abused its discretion when it dismissed the *pro se* complaint without prejudice for purported violations of Rules 8(a)(2), 8(d)(1), and 10(b)

The district court abused its discretion when it dismissed the *pro se* complaint without prejudice for purported violations of Rules 8(a)(2), 8(d)(1), and 10(b).[15]

A. Rules 8(a)(2), 8(d)(1), and 10(b) require complaints to set forth a "short and plain statement of the claim" in "simple, concise, and direct" language using "numbered paragraphs"

Rule 8(a)(2) requires pleadings to include a "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Rule 8(d)(1) requires allegations to use language that is "simple, concise, and direct." *Id.* 8(d)(1). Rule 10(b) requires claims to be set forth in "numbered paragraphs." *Id.* 10(b).

[15] As the appellant, Dr. Jacob is obliged to challenge all grounds for a judgment, including this alternative basis for dismissing the original *pro se* complaint. *Sapuppo* v. *Allstate Floridian Ins. Co.*, 739 F.3d 678, 680 (11th Cir. 2014) ("To obtain reversal of a district court judgment that is based on multiple, independent grounds, an appellant must convince us that every stated ground for the judgment against him is incorrect.").

The leading case to consider a dismissal pursuant to those rules is *Weiland* v. *Palm Beach County Sheriff's Office*, 792 F.3d 1313, 1319-26 (11th Cir. 2015). There, this Court reversed the dismissal of a complaint for purported violations of Rules 8(a)(2) and 10(b) because its allegations were "informative enough to permit a court to readily determine if they state a claim upon which relief can be granted." *Id.* at 1326.

B. Per *Weiland*, the supplement was "informative enough" and properly set forth a "short and plain statement of the claim" in "simple, concise, and direct" language using "numbered paragraphs"

Here, the district court didn't even cite, never mind distinguish, *Weiland*. And its ruling that the original *pro se* complaint and its supplement (Docs. 1; 1.1) violated Rules 8(a)(2), 8(d)(1), and 10(b) is baffling.

Consistent with Rule 8(a)(2), the 38-page supplement contained "a short and plain statement of the claim showing that the pleader is entitled to relief." *See* Doc. 1.1 at 1-38. That is, the supplement carefully alleged facts in support of various tort theories, including negligent and strict liability manufacturing defect. *See* Doc. 1.1 at 21-24, 35-37.

Consistent with Rule 8(d)(1), the 38-page supplement used language that was "simple, concise, and direct." *See* Doc. 1.1 at 1-38. Like any well-drafted complaint drafted by a lawyer, never mind by a *pro se*

litigant like Dr. Jacob, the supplement told the plaintiff's factual and legal story in accessible and easily understood language.

Consistent with Rule 10(b), the 38-page supplement used numbered paragraphs. *See* Doc. 1.1 at 1-38. It also separated the legal theories into separate counts, despite the fact that wasn't even required. *See* Fed. R. Civ. P. 10(b) ("If doing so would promote clarity, each claim *founded on a separate transaction or occurrence*—and each defense other than a denial—must be stated in a separate count or defense." (emphasis added)).

For each of these reasons, the district court's ruling wasn't consistent with Rules 8(a)(2), 8(d)(1), and 10(b). And it certainly didn't heed the guidance of *Weiland*, which emphasized that the core question about those rules concerns nothing more than whether the allegations were "informative enough" to assess whether a claim has been stated and to allow the defendant to formulate an answer. 792 F.3d at 1326.

Some real world context is also helpful. Mentor Worldwide is not some legal naïf. Instead, it's a large and sophisticated company with extensive regulatory and litigation experience, and it's being represented by top drawer counsel in the district court and in this Court. Particularly when even Mentor Worldwide itself never found it necessary to complain

of purported violations of Rules 8(a)(2), 8(d)(1), and 10(b), there should be little doubt that the original *pro se* complaint and its supplement were, in *Weiland*'s language, "informative enough to permit a court to readily determine if they state a claim upon which relief can be granted." 792 F.3d at 1326. And they were certainly informative enough that Mentor Worldwide, if required, could have formulated an answer with appropriate admissions and denials. The Court should reverse this ground for dismissal of the *pro se* complaint.

CONCLUSION

This Court should vacate the judgment, reverse both orders of dismissal, and remand for further proceedings.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with Federal Rule of Appellate Procedure 32(a)(7)(B)'s type-volume requirement. As determined by Microsoft Word 2010's word-count function, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and 11th Circuit Rule 32-4, this brief contains 9,679 words.

2. This brief further complies with Federal Rule of Appellate Procedure 32(a)(5)'s typeface requirements and with Federal Rule of Appellate Procedure 32(a)(6)'s type-style requirements. Its text has been prepared in a proportionally spaced serif typeface in roman style using Microsoft Word 2010's 14-point Century Schoolbook font.

May 21, 2021

/s/ Thomas Burns
Thomas A. Burns

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I filed the original and six copies of the foregoing brief with the Clerk of Court via CM/ECF and regular mail on this 21st day of May, 2021, to:

David J. Smith, Clerk of Court
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ELEVENTH CIRCUIT
56 Forsyth Street N.W.
Atlanta, GA 30303

I FURTHER CERTIFY that I served a true and correct copy of the foregoing brief via CM/ECF on this 21st day of May, 2021, to:

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May 21, 2021

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