

OCT 23 2015

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

NICOLE WEBER,

Plaintiff - Appellant,

v.

ALLERGAN, INC.,

Defendant - Appellee.

No. 13-17017

D.C. No. 2:12-cv-02388-SRB

MEMORANDUM*

Appeal from the United States District Court
for the District of Arizona
Susan R. Bolton, District Judge, Presiding

Argued and Submitted September 18, 2015
San Francisco, California

Before: W. FLETCHER, BERZON, and BEA, Circuit Judges.

Nicole Weber appeals the district court's dismissal of her second amended complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).

* This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36-3.

Weber’s allegations, as they stand, are not sufficient to survive a motion to dismiss under Rule 12(b)(6), as they are not adequate to “nudge [her] claims across the line from conceivable to plausible.” *Eclectic Props. E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 997 (9th Cir. 2014) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (internal alteration omitted)); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). At oral argument, however, Weber identified additional facts she can plead that, if added to her complaint, would satisfy the *Twombly/Iqbal* standard. Also, Weber has identified, to the extent possible without discovery, the standards she believes the manufacture of her implants violated, thereby adequately stating parallel state-law claims under 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(d). *See* 21 C.F.R. § 820.1 *et seq.*; *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010). Accordingly, we conclude that amendment would not necessarily be futile, and an opportunity to amend should be allowed. *See Foman v. Davis*, 371 U.S. 178, 182 (1962).

Specifically, with the following additions, or similar amendments (if they are true to the best of Weber’s knowledge, of course), the complaint would meet the *Twombly/Iqbal* plausibility requirement:

1. At the time of their removal, Weber’s implants had lost approximately 2.8% of their mass and/or volume, whereas Allergan’s Directions for Use and

Patient Labeling documents disclose that only 1% of the silicone gel in Allergan's implants is expected to bleed from implants manufactured according to FDA-approved specifications.

2. Manganese is a chemical constituent of Allergan's silicone-gel implants and/or is present in the implants as a relic of the manufacturing process. Absent silicone gel bleed beyond that Allergan disclosed to the FDA, manganese at the levels present in Weber's body would not be found.

3. Weber's symptoms cannot be entirely explained by her idiosyncratic, severe generalized reaction to silicone. Rather, the severity of her symptoms indicates that a bleed occurred that exceeded the extremely low-level gel bleed of no clinical consequence that Allergan's implants are known to cause.

If Weber can and does amend her complaint to add these allegations, or other allegations at a similar level of specificity and relevance to the plausibility of her claims, the complaint will contain factual allegations that permit her complaint to survive a motion to dismiss brought pursuant to Rule 12(b)(6), as interpreted by *Iqbal* and *Twombly*. Accordingly, on remand the district court should entertain a motion for further leave to amend the complaint.

REVERSED AND REMANDED.

FILED

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W. Fletcher, J., concurring in the result:

I would hold that the allegations in the complaint, as they now stand, are sufficient to meet the particularity and plausibility standards of Federal Rule of Civil Procedure 8(a). *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).