UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

Rebecca A. Small and
Lawrence W. Small,

Plaintiffs,

v.

Amgen, Inc., Pfizer, Inc.,
and Wyeth, Inc.,

Defendants.

Civ. No. 2:12-476-Ftm29-CM

MEMORANDUM AND ORDER

This matter is before the Court on Defendants' Motion for Judgment on the Pleadings. For the reasons that follow, the Motion is denied.

BACKGROUND

Plaintiffs Rebecca Small and Lawrence Small allege that Defendants manufactured, designed, distributed, sold and/or supplied a defective drug, Enbrel. Rebecca Small's doctor prescribed Enbrel to treat her rheumatoid arthritis. She alleges that Enbrel caused her to suffer from multiple infections requiring hospitalization, several surgeries, and ongoing treatment. Lawrence Small, Rebecca's husband, alleges loss of consortium.

Plaintiffs' Fourth Amended Complaint (Docket No. 54) raises claims for strict liability/design defect, strict liability/failure to warn, breach of express warranty, negligence, and loss of consortium against Defendants Amgen Inc., Wyeth, LLC, and Pfizer Inc. In March 2014, the Hon. John E. Steele granted in part and denied in part Defendants' motion to dismiss that pleading, dismissing the negligence claim to the extent it asserted a negligent-

failure-to-test or -inspect claim and to the extent it asserted a negligence per se claim. (Docket No. 66.)

In December 2014, Defendants filed a motion for summary judgment based on the learned intermediary doctrine. (Docket No. 82.) The motion did not seek judgment on any other basis. And although the case had been pending for more than two years, the parties stipulated to stay all discovery until the court ruled on the motion for summary judgment. (Docket No. 88.) In September 2015, Judge Steele ruled that Plaintiffs' failure-to-warn claims were precluded by Florida's learned intermediary doctrine, and entered judgment on Count II in its entirety and on Count IV to the extent it raised a claim for negligent failure to warn. (Docket No. 97.) Thus, the claims remaining are design defect, breach of express warranty, negligent manufacture and design, and loss of consortium. The parties had not, as of the end of November 2015, engaged in any discovery. (See Docket No. 123 at 7 (Tr. of Nov. 30, 2015, hr'g).)

Despite previously bringing two dispositive motions, and more than three years into this litigation, Defendants now move for judgment on the pleadings. The Motion seeks dismissal of Plaintiffs' strict liability design-defect and negligent manufacture/design claims.

DISCUSSION

Judgment on the pleadings under Fed. R. Civ. P. 12(c) is appropriate where no issue of material fact remains unresolved and the moving party is entitled to judgment as a matter of law. Cunningham v. Dist. Attorney's Office for Escambia Cnty., 592 F.3d 1237, 1255 (11th Cir. 2010). The Court must accept the facts in the Complaint as true and view them

in the light most favorable to the nonmoving party. Id.

The procedural posture of this Motion warrants comment. It is unusual, to say the least, for a party to seek judgment on the pleadings after the denial of summary judgment. Logically, if there is sufficient evidence to preclude summary judgment on a claim, then that claim likewise is sufficient to withstand a motion under Rule 12(c). Because the motion fails on its merits, however, the Court will overlook the procedural irregularities.

A. Preemption

Defendants contend that Plaintiffs' design-defect claim is preempted by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. Preemption is an affirmative defense that usually must be raised in an answer or other responsive pleading and, if not so raised, the defense is considered waived. Latimer v. Roaring Toyz, Inc., 601 F.3d 1224, 1239 (11th Cir. 2010). Here, however, Defendants' preemption argument rests on a case that was decided only days before the completion of briefing on the motion to dismiss. Mutual Pharm. Co. v. Bartlett, 133 S. Ct. 2466 (2013). Defendants did not waive the defense by failing to raise it in the motion to dismiss. And preemption may be raised later in a litigation "if the plaintiff has suffered no prejudice from the failure to raise the defense in a timely fashion." Miranda De Villalba v. Coutts & Co., 250 F.3d 1351, 1353 (11th Cir. 2001); see also Kennan v. Dow Chem. Co., 717 F. Supp. 799, 810 (M.D. Fla. 1989) (holding that if the preemption defense presents a question of law and there are "no factual issues on which [the opposing party] could conduct discovery that would alter the Court's finding of preemption," the defense can be asserted later in the litigation)..

The application of Bartlett's holding to this case will require discovery into Enbrel's chemical formulation and whether that formulation is capable of redesign. Bartlett found that when a drug is "chemically incapable" of being redesigned, it is impossible for a drug manufacturer to make the drug safer and thus state-law design-defect claims are preempted. Bartlett, 133 S. Ct. at 2475. Defendants argue that Enbrel is a biologic and incapable of reformulation, but Plaintiffs dispute this contention and must be allowed to take discovery on the issue. Because in this case the preemption question is not one that is purely legal, judgment on the pleadings on the basis of preemption is not appropriate.

If, however, Defendants are correct that Enbrel is incapable of redesign, Bartlett would bar any design-defect claim based on an alleged failure to redesign Enbrel. Moreover, it is likely, even if Enbrel is capable of redesign, that any claim that Defendants should have changed Enbrel's design before seeking FDA approval would likewise be preempted. See Yates v. Ortho-McNeil-Janssen Pharm., Inc., 808 F.3d 281, 299-300 (6th Cir. 2015) (holding that a claim for breach of a pre-approval design duty was speculative and was preempted). These issues, however, are matters for post-discovery dispositive-motion practice, not a motion for judgment on the pleadings.

B. Manufacturing Defect

Defendants also contend that Count I does not adequately plead a claim for a manufacturing defect. This Count, titled "Strict Liability - Design Defect," mentions "manufacture" (4th Am. Compl. ¶ 48) and "formulation" (id. ¶ 46) in a laundry list of Enbrel's alleged defects. Plaintiffs argue that this language in Count I is sufficient to put Defendants on notice that they intended to raise a manufacturing-defect claim.

In the Order on Defendants' motion for summary judgment, Judge Steele denied the motion "as to plaintiffs' design and manufacturing defect claims." (Docket No. 97 at 27.) Thus, it is clear that the parties as well as the Court understood Plaintiffs to raise a manufacturing defect claim. The law of the case precludes Defendants from now arguing that the claim was insufficiently pled.

CONCLUSION

Defendants' Motion is procedurally improper and fails on the merits. Accordingly, **IT IS HEREBY ORDERED that** Defendants' Motion for Judgment on the Pleadings (Docket No. 107) is **DENIED**.

Dated: January 25, 2016

s/ Paul A. Magnuson
Paul A. Magnuson
United States District Court Judge