Ortiz v. Allergan, Inc. Doc. 27

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

YOLANDA ORTIZ,

Plaintiff,

-against-

ALLERGAN, INC.,

Defendant.

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14 Civ. 8188 (PAC)

OPINION & ORDER

HONORABLE PAUL A. CROTTY, United States District Judge:

Plaintiff Yolanda Ortiz sues Defendant Allergan, Inc., for alleged injuries arising from a breast implant manufactured by Defendant that allegedly ruptured in Plaintiff's body and began leaking.

Defendant moves to dismiss the Complaint, pursuant to Fed. R. Civ. P. 12(b)(6), for failure to state a claim. Plaintiff moves to amend the Complaint, pursuant to Fed. R. Civ. P. 15(a).

For the reasons set forth below, Plaintiff's motion to amend the Complaint is GRANTED. The Court considers the Amended Complaint ("AC") as the operative pleading. Defendant's motion to dismiss the AC is GRANTED.

PROCEDURAL HISTORY

On August 20, 2014, Plaintiff sued Defendant in New York Supreme Court, alleging strict products liability, negligence, and breach of warranty. Defendant removed the case to federal court on the basis of diversity jurisdiction. On December 1, 2014, Defendant moved to dismiss the Complaint. Plaintiff moved for leave to amend the Complaint on December 12,

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2014, attaching to her motion the AC, which alleges two claims: strict liability for manufacturing defects, and breach of express and implied warranties.

Fed. R. Civ. P. 15(a)(1)(B) provides that "[a] party may amend its pleading once as a matter of course" within "21 days after service of a motion under Rule 12(b)." Since Plaintiff complied with Rule 15's requirements, leave to amend the Complaint is granted. *See Lalumia v. Sutton*, 2013 U.S. Dist. LEXIS 175498, at *5-6 (N.D.N.Y. Dec. 13, 2013). The Court will consider the AC as the operative pleading.[1] *See Emrit v. Viacom/MTV*, 2013 U.S. Dist. LEXIS 189636, at *3 n.1 (S.D.N.Y. Oct. 15, 2013); *Chevron Corp. v. Salazar*, 2011 U.S. Dist. LEXIS 92091, at *13-14 (S.D.N.Y. Aug. 17, 2011).

BACKGROUND[2]

On May 10, 2000, Defendant's predecessor-in-interest, McGhan Medical Corporation, was granted conditional approval by the Food and Drug Administration ("FDA") to design, manufacture, distribute, and sell saline-filled breast implants.[3] AC ¶ 17. Allergan, as successor-in-interest to McGhan, agreed to comply with all FDA requirements with respect to the design, manufacture, distribution, and sale of the implants. *Id.* ¶ 19.

In February 2007, Defendant sought approval from the FDA to change the trade name of its implants to Natrelle. *Id.* ¶ 20. The FDA granted the request in May 2007. *Id.* ¶ 21. Defendant agreed to continue to perform post-approval studies on the long-term clinical performance of Natrelle implants, and to perform "retrieval studies and mechanical testing of all

[1] The parties have fully briefed the allegations in the AC. Plaintiff's Opposition to the Motion to Dismiss sets forth arguments based on the allegations in the AC, rather than the original Complaint. *See* Opp. to Mtn. to Dismiss, at 1 ("The arguments made herein are supported by the allegations set forth in plaintiff's proposed amended complaint."). Defendant responds to those arguments in its Opposition to Plaintiff's Motion to Amend, and Plaintiff replies to Defendant's arguments in her Reply in Support of her Motion to Amend.

[2] The statements in the Background section are based on the allegations of the AC and are assumed to be true. *See Brod v. Omya, Inc.*, 653 F.3d 156, 164 (2d Cir. 2011).

[3] The AC states that conditional approval was granted on May 10, 2010. *Id.* ¶ 17. This appears to be a typographical error. *See* McGuirl Aff., Ex. B, C.

explanted implants to determine the mode of failure." *Id.* ¶ 22. Defendant also has an ongoing obligation to comply with FDA regulations regarding keeping records of explanted Natrelle implants that have been returned to the company. *Id.* ¶ 23.

On August 27, 2010, Plaintiff had two Natrelle implants placed in her body. *Id.* ¶ 28. "[A]t or about and/or before" Plaintiff received the implants, Defendant provided her "an express warranty and/or representations indicating the Natrelle implants were safe and effective and were of the quality required by the FDA." *Id.* ¶ 25. Also "on or about and/or before" she received the implants, Defendant "expressed and/or represented that said implants were in compliance with all manufacturing standards as set forth by the FDA." *Id.* ¶ 26; *see* Ortiz Aff. ¶ 4 (prior to August 27, 2010, Plaintiff "reviewed the warranties provided by [Defendant] and online," and relied on those warranties in choosing Defendant's implants).

Between December 2013 and January 2014, Plaintiff "became aware" that her "breast implant(s) were deflating and/or leaking and/or rupturing." AC ¶ 30. Plaintiff had the implants surgically removed on March 20, 2014. *Id.* ¶ 31.

The AC alleges that Defendant failed "to follow the proper plans and specifications to manufacture" the Natrelle implants, and that "the shells of [Plaintiff's] implants were not constructed correctly with the required medical grade silicone elastromers." *Id.* ¶¶ 33-34. The surface area of the shells was not "manufactured to the required thickness and required tensile strength, and did not perform in accordance with [American Society for Testing and Materials] and FDA regulations during the manufacturing process." *Id.* ¶ 35. In addition, the shell surface thickness was not "uniform," and the shell surface "had temperature discrepancies during the manufacturing process," causing the implants to lack "strength and uniformity." *Id.* ¶¶ 39, 41.

Plaintiff also alleges that the implant "valves and/or valve shell joints were defective as a result of valve delimination and/or shell breakage at the joint and/or patch shell joints," and "there was fatigue of the valves and/or val[v]e joint and/or patch shell joint and/or adjacent areas." *Id.* ¶¶ 37-38.

According to Plaintiff's affidavit, after having both implants removed, Plaintiff "saw photographs of them." Ortiz Aff. ¶ 6. Plaintiff also "spoke to [her] surgeon about the cause of the rupture" and was "informed that the leaks appeared to be in the area of the valves and that the thickness of the implant shell surfaces were not uniform and also may have caused leakage." *Id.* In addition, "[t]he areas of the shell surfaces appeared to have thinned out." *Id.*

When Plaintiff's explanted implants were returned to Defendant, Defendant "improperly disposed of the explanted implants and/or failed to properly test the causes of the rupture." *Id.* ¶ 47.

APPLICABLE LAW

I. Legal Standard

A motion to dismiss for failure to state a claim cannot be granted if the complaint "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible if it includes "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. The allegations in the complaint must be sufficient to "nudge[] [plaintiff's] claims across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570.

In ruling on a motion to dismiss, the court "merely . . . assess[es] the legal feasibility of the complaint"; it does not "assay the weight of the evidence which might be offered in support thereof." *Lopez v. Jet Blue Airways*, 662 F.3d 593, 596 (2d Cir. 2011) (citation omitted).

II. Medical Device Claims

Medical devices are classified into three categories under the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 360c. A Class III device, such as a breast implant, must undergo a premarket approval process, and be granted premarket approval ("PMA") by the FDA. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-18 (2008). Medical devices, including Class III devices, are subject to the FDA's current good manufacturing practice requirements ("CGMPs"). Compliance with these requirements requires manufacturers to "adopt a variety of procedures and controls relating to areas such as: (1) design control, (2) quality assurance, (3) manufacturing and processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action." *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 152 (S.D.N.Y. 2011).

The MDA allows for preemption of state law claims. *See* 21 U.S.C. § 360k(a). In considering whether a state law claim is preempted under the MDA, courts first "determine whether the Federal Government has established requirements applicable to [the device]," and if so, whether the state law claims are "based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Rigel*, 552 U.S. at 321-22 (quoting § 21 U.S.C. 360k(a)).

A plaintiff's claim that a defendant violated FDA regulations when manufacturing a device constitutes a "parallel" state claim that is not preempted under the MDA. *See id.* at 330. Such "parallel" claims include allegations that "the FDA-approved processes and procedures

were not followed, and the [plaintiff's] injury was caused by this deviation." *Bass v. Stryker Corp.*, 669 F.3d 501, 512 (5th Cir. 2012). "To properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated."[4] *Gelber*, 788 F. Supp. 2d at 155 (quoting *Wolicki-Gables v. Arrow, Int'l, Inc.*, 634 F.3d 1296, 1302 (11th Cir. 2011)). In addition, plaintiffs must "allege how the alleged violation is linked to the plaintiffs' injury." *Id.* Although it may be difficult for plaintiffs to identify "the precise defect or the specific federal regulatory requirements that were allegedly violated . . . because certain premarket approval documents are confidential," plaintiffs must still meet the pleading standards set forth in *Twombly* and *Iqbal*. *Id.* at 157 (citation omitted).

ANALYSIS

I. Manufacturing Defect Claim

Under New York law, "to plead and prove a manufacturing flaw under . . . strict liability," a plaintiff must show "that a specific product unit was defective as a result of some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction, and that the defect was the cause of plaintiff's injury." *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001) (citations omitted).

The AC fails to state a manufacturing defect claim, because its allegations are almost entirely conclusory. Plaintiff asserts that her implants "were not constructed correctly with the required medical grade silicone elastromers," and that they "were not manufactured to the required thickness and . . . strength." AC ¶¶ 34-35. Plaintiff provides no factual basis to support

[4] Courts "have disagreed as to whether a plaintiff can plead a parallel claim" by alleging that a defendant violated the CGMPs, which are general regulations that apply to all medical devices, or whether plaintiffs must allege a violation of a device-specific regulation. *Gelber*, 788 F. Supp. 2d at 158.

these claims, which are merely naked assertions that the proper silicone was not used and the correct manufacturing process not followed. Similarly, Plaintiff alleges that the "shell surface [of her implants] also had temperature discrepancies during the manufacturing process," *id.* ¶ 41, but does not provide any factual basis from which the Court could conclude that such discrepancies occurred.

The allegations that the "valves and/or valve shell joints were defective as a result of valve delimination and/or shell breakage at the joint and/or patch shell joints," and that "there was fatigue of the valves and/or val[v]e joint and/or patch shell joint and/or adjacent areas" are both vague and conclusory. *Id.* ¶¶ 37-38. A list of components that may have been defective, and the manner in which they may have malfunctioned, does not, without more, "nudge[] [plaintiff's] claims across the line from conceivable to plausible."[5] *See Twombly*, 550 U.S. at 570.

Nor does Plaintiff's affidavit provide the missing factual allegations. The affidavit simply states that Plaintiff "saw photographs" of the implants after they were removed, and "[t]he areas of the shell surfaces appeared to have thinned out." Ortiz Aff. ¶ 6. Plaintiff does not link the allegation that certain surfaces appeared "thinned out" to any particular manufacturing defect, or to her alleged injury.[6]

[5] Defendant also contends that the AC is "impermissibly vague with regard to specific laws and regulations" that were allegedly violated, and notes that the AC alleges violations of CGMP requirements, which some courts have held do not provide a basis for parallel claims. Opp. Mtn. to Amend, at 7, 9; *see Gelber*, 788 F. Supp. 2d at 158. Because this Court determines that the AC fails to sufficiently allege a manufacturing defect, it is unnecessary to reach that issue.

[6] The hearsay assertion that Plaintiff was "informed that the leaks appeared to be in the area of the valves and that the thickness of the implant shell surfaces were not uniform and also may have caused leakage" also fails to provide the requisite facts. *Id.* Even were the Court to consider this statement, it is too vague to support the allegations in the AC; moreover, the actual content of the alleged conversation suggests that Plaintiff's surgeon was offering mere speculation.

Unlike other cases where plaintiffs have alleged valid manufacturing defects, Plaintiff does not allege any FDA action pertaining to Natrelle implants, such as a warning letter, enforcement action, or recall. In *Gelber*, for example, Plaintiffs alleged that the manufacturer had issued a voluntary recall of its prosthetic hip devices, and that the FDA had issued a warning letter, identifying "breaks in the lubrication layer" that "could ultimately lead to the formation of a wear scar, or a stripe which is a located abraded area on the implant surface." 788 F. Supp. 2d at 157. Plaintiff's hip device was surgically removed after complications, and her surgeon noted a "stripe on the ceramic head component, as well as wear on the ceramic insert," which corresponded to the potential defects referenced in the FDA warning letter. *Id.* at 149; *see Tansey v. Cochlear Ltd.*, 2014 U.S. Dist. LEXIS 138250, at *3-4 (E.D.N.Y. Sept. 26, 2014) (manufacturer issued voluntary recall due to "loss of heremeticity"; device technician determined that plaintiff's device had "experience[d] a hermeticity failure as per the recall, requiring immediate removal").

While an FDA warning letter or recall is not *required* to state a manufacturing defect claim, the existence of such actions provides factual support for the claim that a defendant's manufacturing process is flawed, making a manufacturing defect claim significantly more plausible. Here, Plaintiff does not connect her allegations with any particular defect or flaw in the manufacturing process.

II. Breach of Express and Implied Warranties Claim

To state a claim for breach of express warranty, a plaintiff must allege: "(1) the existence of material statement amounting to a warranty, (2) the buyer's reliance on this warranty as a basis for the contract with the immediate seller, (3) breach of the warranty, and (4) injury to the

buyer caused by the breach." *Cordova v. Smith & Nephew, Inc.*, 2014 U.S. Dist. LEXIS 104956, at *20 (E.D.N.Y. July 30, 2014) (citation omitted).[7]

Breach of implied warranty requires a plaintiff to show "that the product was not reasonably fit for its intended purpose," and that the defendant's breach of implied warranty was "due to [defendant's] failure to comply with FDA requirements." *Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 259 (E.D.N.Y. Mar. 17, 2014) (citation omitted).

Plaintiff fails to plead sufficient facts to support her breach of express and implied warranty claims. The AC conclusorily states that "at or about and/or before the time Natrelle implants were implanted in the plaintiff," Defendant "provided to the plaintiff an express warranty and/or representations indicating the Natrelle implants were safe and effective and were of the quality required by the FDA." AC ¶ 25. The AC contains no allegations setting forth when the alleged representations were made, who made them, and what they entailed. Nor does Plaintiff's affirmation provide any such detail; it merely alleges that "prior to the dates [the Natrelle implants] were implanted I reviewed the warranties provided by [Defendant] and online." Ortiz Aff. ¶ 4. This falls far short of the pleading standard set forth in *Twombly* and *Iqbal*. Moreover, Plaintiff has failed to provide factual allegations supporting her claim that Defendant failed to comply with FDA requirements. *Bertini*, 8 F. Supp. 3d at 259.

[7] Although courts are split regarding whether express warranty claims are subject to MDA preemption, courts in this Circuit have held that "a breach of warranty claim is not preempted to the extent it relies on a manufacturing defect." *Id.* at *24.

CONCLUSION

Plaintiff's motion to amend the Complaint is GRANTED. Defendant's motion to dismiss the Amended Complaint is GRANTED. The Clerk is directed to enter judgment and close this case.

Dated: New York, New York
September 4, 2015

SO ORDERED

PAUL A. CROTTY
United States District Judge