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SUPREME COURT OF THE STATE OF NEW YORK — NEW YORK COUNTY

PRESENT: LOBIS Justice PART 6

INDEX NO. 108815/10

JOAN DELGADO

- v -

MOTION DATE 12/6/11

MOTION SEQ. NO. 3

NEW YORK PRESBYTERIAN HEALTHCARE SYSTEM

MOTION CAL. NO.

The following papers, numbered 1 to 17 were read on this motion to/for summary judgment

	PAPERS NUMBERED
Notice of Motion/ Order to Show Cause — Affidavits — Exhibits ...	1-9
Answering Affidavits — Exhibits	10-12
Replying Affidavits	13-17

Cross-Motion: ☐ Yes ☑ No

Upon the foregoing papers, it is ordered that this motion is decided in accordance with the accompanying decision and order.

FILED

FEB 27 2012

NEW YORK COUNTY CLERK'S OFFICE

Dated: 2/24/12

JOAN B. LOBIS J.S.C.

Check one: ☐ FINAL DISPOSITION ☑ NON-FINAL DISPOSITION

Check if appropriate: ☐ DO NOT POST ☐ REFERENCE

☐ SUBMIT ORDER/ JUDG. ☐ SETTLE ORDER/ JUDG.

MOTION/CASE IS RESPECTFULLY REFERRED TO JUSTICE FOR THE FOLLOWING REASON(S):

SUPREME COURT OF THE STATE OF NEW YORK
NEW YORK COUNTY: IAS PART 6

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JOAN DELANGO and DENIS DELANGO as Administrators of The Estate of DANIELLE M. DELANGO, deceased; and ANDREW DENIS DELANGO, an infant under the age of 14 years, by his Guardians, Denis Delango and Joan Delango,

Plaintiffs,

-against-

NEW YORK-PRESBYTERIAN HEALTHCARE SYSTEM, LAWRENCE HOSPITAL CENTER, DANIEL GEOFFREY DAVIS, D.O., ALLERGAN, INC., INAMED HEALTH (a wholly owned subsidiary of Allergan, Inc.), BIOENTERICS CORPORATION and JOHN DOES 1-5,

Defendants.

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Index No. 106815/10

Decision and Order

JOAN B. LOBIS, J.S.C.:

Motion Sequence Numbers 003 and 004 are consolidated for disposition. In Motion Sequence Number 003, defendants Allergan, Inc. ("Allergan"), Inamed Health ("Inamed"), and BioEnterics Corporation ("BioEnterics") (collectively the "Moving Defendants") seek summary judgment and dismissal of the causes of action against them based on federal preemption. In Motion Sequence Number 004, plaintiffs Joan and Denis Delango, as co-administrators of Danielle M. Delango's estate and as guardians of her son, Andrew Denis Delango, seek leave to amend their complaint to assert a viable state claim against the Moving Defendants.[1]

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[1] The court notes that neither the Moving Defendants nor plaintiffs annexed copies of the original pleadings to their papers. All references to the original pleadings in this decision and order refer to the summons and attorney-verified complaint dated May 24, 2010, and the answer on behalf of Allergan dated July 9, 2010, as contained in the Supreme Court Records On-Line Library ("SCROLL"), available at http://iapps.courts.state.ny.us/iscroll (enter index number 106815/2010 and follow hyperlinks to "Summons and Complaint" and "Answer").

In this lawsuit, the allegations of medical malpractice, products liability, and wrongful death stem from decedent Danielle M. Delango's laparoscopic gastric band surgery on January 15, 2008, during which a LAP-BAND Adjustable Gastric Banding System ("Lap Band") was surgically implanted in Ms. Delango's abdomen. Ms. Delango subsequently died on March 3, 2008. The autopsy report indicated that the cause of death was cardiac arrest with fever of unknown etiology. The Lap Band is a Class III medical device currently manufactured and sold by Allergan. In 2001, BioEnterics, then a subsidiary of Inamed, obtained premarket approval ("PMA") of the Lap Band from the Food and Drug Administration ("FDA"). Allergan is the successor-in-interest of BioEnterics and Inamed, having acquired these entities in 2006.

Plaintiffs' complaint contains seven causes of action alleged against the Moving Defendants: negligence; strict products liability; strict products liability for defective design; breach of implied warranty; breach of express warranty; loss of consortium; and wrongful death. The Moving Defendants seek dismissal of these causes of action on the grounds that the state tort claims are preempted under the express preemption provision of the Medical Device Amendments ("MDA") (21 U.S.C. § 360k) to the Federal Food, Drug & Cosmetic Act ("FFDCA") (21 U.S.C. § 301 et seq). Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).

In opposition, plaintiffs ask the court to deny summary judgment and permit further discovery. Plaintiffs assert that state tort claims against manufacturers of Class III medical devices are permitted where it is alleged that the manufacturer failed to adhere to the specifications imposed by the device's PMA. However, plaintiffs essentially concede that their claims against the Moving

Defendants as set forth in the initial complaint are preempted by federal law. Thus, plaintiffs move separately to amend their complaint. The proposed amended complaint contains none of the tort claims originally asserted against the Moving Defendants, but adds a claim sounding in negligence, by which plaintiffs allege that the Lap Band was defective and was manufactured in violation of the FFDCA; Section 360k(a) of the MDA; and the PMA. Plaintiffs further allege that the Lap Band was adulterated in violation of 21 U.S.C. § 351, in that it failed to meet established performance standards and that the methods of manufacturing violated federal requirements. Plaintiffs also allege that the first application for PMA of the Lap Band was rejected by the FDA, and that the model of Lap Band implanted in Ms. Delango was part of a Class 2 recall initiated on September 16, 2010. Based on the aforementioned claims, plaintiffs allege that the Moving Defendants breached their duty to use reasonable care, thereby causing Ms. Delango's injury and death. Plaintiffs annex an affidavit from William A. Hyman, Sc.D., an engineer, who asserts that without further discovery of documents only within the Moving Defendants' possession, it is impossible for him to determine whether the device was changed without FDA approval. Mr. Hyman maintains that he is prepared to review these materials once they are available and offer his opinion on the case.

In opposition to plaintiffs' motion to amend the complaint, the Moving Defendants argue that plaintiffs' new cause of action is so broad and boilerplate that it could not withstand a motion to dismiss. They contend that plaintiffs fail to assert a true parallel state claim because they have not shown a malfunction of the device and a causal connection between the regulatory non-compliance and the alleged injury. They argue that plaintiffs' allegations that the FDA initially rejected the Lap Band for PMA and that there has been a Class 2 recall of model of the Lap Band

implanted in the decedent are irrelevant and fail to establish either a device malfunction or causation. Additionally, they assert that permitting plaintiffs to add this claim and requiring them to defend it is unduly prejudicial and unfair to them on a case that has been pending for seventeen months.

Under C.P.L.R. Rule 3025, leave to amend a pleading "shall be freely given upon such terms as may be just . . . ." In New York, it is well established that, absent prejudice or surprise resulting from the delay, leave to amend should be granted. Fahey v. County of Ontario, 44 N.Y.2d 934, 935 (1978); Anoun v. City of New York, 85 A.D.3d 694, 694 (1st Dep't 2011). The party seeking to amend must "show that the proffered amendment is not palpably insufficient or clearly devoid of merit." MBIA Ins. Corp. v. Greystone & Co., Inc., 74 A.D.3d 499, 500 (1st Dep't 2010) (citation omitted). Absent palpable insufficiency or a patent lack of merit, "[t]he sufficiency or underlying merit of the proposed amendment is to be examined no further." Maldonado v Newport Gardens, Inc., ___ A.D.3d ___, 2012 N.Y. Slip Op. 341 (2d Dep't 2012). See also MBIA Ins. Corp., 74 A.D.3d at 500 (in seeking leave to amend a pleading, "plaintiff need not establish the merit of its proposed new allegations"), citing Lucido v. Mancuso, 49 A.D.3d 220, 227 (2d Dep't 2008).

The amended pleading meets the basic pleading requirements set forth above. Additionally, the Moving Defendants have failed to articulate that the proposed amended complaint prejudices them to any extent beyond their complaint that this case is seventeen months old. At this stage of the litigation and under the circumstances of this case, plaintiffs' proposed amended complaint is sufficient to permit the proposed amendment and permit further discovery. Accordingly, it is hereby

ORDERED that the Moving Defendants' motion (Sequence 003) for summary judgment is partially granted to the extent that they are granted summary judgment on the third, fourth, fifth, sixth, and seventh causes of action in the initial complaint dated May 24, 2010, and those causes of action are dismissed; and it is further

ORDERED that the remainder of the Moving Defendants' motion (Sequence 003) is denied; and it is further

ORDERED that plaintiffs' motion (Sequence 004) for leave to amend the complaint is granted, and the amended complaint in the proposed form annexed to the moving papers shall be deemed served upon service of a copy of this order with notice of entry thereof; and it is further

ORDERED that defendants shall serve answers to the amended complaint or otherwise respond thereto within twenty (20) days from the date of said service; and it is further

ORDERED that counsel are directed to appear for a previously scheduled status conference on May 22, 2012, at 10:00 a.m.

Dated: Feb. 24, 2012

FILED

ENTER:

FEB 27 2012

NEW YORK
COUNTY CLERK'S OFFICE

JOAN B. LOBIS, J.S.C.