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

PRESENT: HON. SHEILA ABDUS-SALAAM PART 13
Justice

Madeline Sanchez

- v -

Heritage Worldwide, Inc., et al.

INDEX NO. 109155/04

MOTION DATE 2/15/07*

MOTION SEQ. NO. 005

MOTION CAL. NO.

* Held in abeyance until 6/28/07 for companion motion seq. 006

The following papers, numbered 1 to _____ were read on this motion to/for _____

	PAPERS NUMBERED
Notice of Motion/ Order to Show Cause — Affidavits — Exhibits ...	
Answering Affidavits — Exhibits	
Replying Affidavits	

Cross-Motion: ☐ Yes ☒ No

Upon the foregoing papers, it is ordered that this motion by defendant Poly Implant Prostheses, S.A. ("PIP") for summary judgment and the motion by defendants Eli Milch, M.D., his professional corporation and Park East Plastic Surgery Center for summary judgment is also denied.

Plaintiff Madeline Sanchez had bilateral saline breast implant surgery performed by defendant Dr. Milch on March 2, 2000. Plaintiff alleges that the implants were manufactured by defendant Heritage Worldwide and/or PIP, a subsidiary of Heritage and that they were distributed by defendant III Acquisition Corp. d/b/a PIP America. On or about April 2001, plaintiff's left breast deflated. On April 8, 2002, defendant Dr. Milch replaced plaintiff's left implant with what both plaintiff and Dr. Milch assert was a PIP implant (the delay in replacing the implant was caused by plaintiff's pregnancy). In April 2004, plaintiff's left breast again deflated and in November 2004, her

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

right breast deflated. Plaintiff alleges that as a result, she has suffered significant scarring, the need for reconstructive surgery, pain and suffering, and economic loss.

The complaint against PIP sounds in strict products liability and negligence. PIP has moved for summary judgment on the grounds that plaintiff's claims are preempted by the Medical Device Amendments ("MDA") to the federal Food, Drug and Cosmetics Act; that even if the claims are not preempted, they fail as a matter of law because plaintiff has not come forward with any evidence to support the claims or showing that she suffered any injury, and that plaintiff's claims must be dismissed based on defendant's theory that she has willfully spoliated the evidence (the implants) because she has not yet had them removed from her body so that they can be inspected by defendant.

Regarding the spoliation argument, the court rejects defendant's assertion that plaintiff has spoliated the evidence by failing to undergo surgery to have the implants removed. On the issue of whether there is any proof that the implants are PIP implants, Dr. Milch testified at his deposition that he used PIP implants for the 2000 procedure and a PIP implant for the 2002 procedure. His records also reflect that he used PIP implants for both surgeries. Dr. Milch's records also indicate the serial numbers for the implants and defendant has not come forward with any proof that these serial numbers do not correspond to PIP implants. Thus, there is proof in the record that PIP implants were used for plaintiff's surgeries.

Defendant has not shown that plaintiff's claims are preempted. The MDA, which was enacted in 1976 (21 USC § 360c *et seq*) contains a preemption clause that preempts state law as follows:

> Except as provided in subsection (b) of this section, no 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.

In Medtronic v. Lohr (518 U.S. 470, 116 S.Ct. 2240 [1996]), the Supreme Court addressed preemption in the context of a device that had been placed in the market pursuant to a "510(k)" process[1]. Noting that the federal regulation with respect to preemption provides that "[s]tate ... requirements are preempted only when ... there are ... *specific* [federal] requirements applicable to a particular device ... thereby making any existing *divergent* State ... requirements applicable to the device different from, or in addition to, the *specific* [federal] requirements" 21 CFR § 808.1(d) (1995) (emphasis added)" (id. at 506, concurring opinion of Justice Breyer), the Supreme Court concluded that preemption should occur only " . . . where a particular state requirement threatens to interfere with a specific federal interest."(Id. at 500.)

> State requirements must be "with respect to" medical devices and "different from, or in addition to," federal requirements. State requirements must also relate "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device," and the regulations provide that state requirements of "general applicability" are not pre-empted except where they have "the effect of establishing a substantive requirement for a specific device." Moreover, federal requirements must be "applicable to the device" in question, and,

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[1]The § 510(k) notification process permits a device that is "substantially equivalent" to a device that was on the market prior to the passage of the MDA to be marketed without undergoing the PMA process (21 U.S.C. § 360e(b)(1)(B))."A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by FDA (as opposed to 'approved' by the agency under a PMA)."(Thorn v. Thoratec Corp., 376 F.3d 163, 167 [3d Cir. 2004].)

> according to the regulations, pre-empt state law only if they are "specific counterpart regulations" or "specific" to a "particular device." The statute and regulations, therefore, require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations.

Id. at 500.

In Sowell v. Bausch & Lomb, Inc. (230 AD2d 77 [1997]), a decision issued after Medtronic, the First Department held that plaintiff's state law claims in negligence and strict products liability were not preempted by Federal law merely because the product (a class III medical device under the MDA, as are the breast implants in this case) had received a premarket approval ("PMA") by the FDA. As was noted by the court in Sowell, id., the MDA separated medical devices into three categories- - Class I devices, like tongue depressors, pose little or no threat to the public health and are subject only to general controls and Class II devices like tampons and oxygen may pose some risk of injury and are subject to special controls including performance standards and postmarket surveillance programs. A Class III device is one which presents a " 'potential[ly] unreasonable risk of illness or injury' or which 'is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health' (21 USC § 360c [a] [1] [C] [ii]; 21 CFR 860.3 [c] [3]." (Id. at 79.) The court explained:

> The general rule applicable to distributors of Class III medical devices requires them to obtain premarket approval (PMA) of the device before marketing it (21 USC , § 360e; 21 CFR 814.1 [c]; 860.3 [c] [3]). Before a PMA will be granted, the Federal Food and Drug Administration (FDA) conducts a rigorous review of the product, involving the submission by manufacturers of 'detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission' (Medtronic, Inc. v. Lohr, 518 U.S.

470, 116 S. Ct. 2240).

Id. at 79.

The Sowell court held that there was no preemption because "[t]here have been no steps taken by the FDA to issue regulations that are specific to this device and that will be universally applied to similar devices. Only that type of specific regulation by the Federal Government could constitute a requirement within the meaning of the MDA (citations omitted)." (id. at 84-85). Further, the court rejected defendant's argument that there should be preemption because the PMA review of their product had been "quite detailed, and the postmarket requirements that were imposed as part of their premarket approval were both elaborate and specific", finding that "this type of ad hoc specificity imposed as part of the individual review process is not enough to preempt State law (*see, Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459, *cert denied* __ US __, 116 S Ct 2579 ["The fact that the premarket approval process involves specific requirements, *see* 21 C.F.R. § 814, 820, must not be confused with the premarket approval requirement itself acting as a *specific* requirement"]."(id. at 84.)

In Riegel v. Medtronic, Inc. (451. F.3d 104 [2d Cir. 2006]), the court held that a cardiac patient's state law claims for strict liability, breach of implied warranty and negligent design and marketing regarding an angioplasty catheter were preempted under the MDA where there had been PMA approval of the catheter. The Second Circuit concluded that such approved devices are subject to the federal device-specific requirements that were discussed in Medtronic v. Lohr, (supra).[2] However, significantly, in the case of Ms. Sanchez, PIP had submitted the breast implants for the PMA process *but the implants were not approved*. The FDA disapproved PIP's PMA application on May 10, 2000 (one month after the bilateral implant surgery was performed by Dr. Mlich) and PIP ceased distributing the product

[2] The court also held that the breach of express warranty and negligent manufacture claims were not preempted.

(see affidavit of Robert Hanks, PIP/USA's President from December 1997 to April 1998)[3]. In contrast, the device before the court in Riegel had received PMA approval. Thus, defendant's reliance upon Riegel is misplaced. PIP argues that its product " . . . was subjected to the full PMA process, and, *ergo*, must be afforded the treatment of similar PMA products for determination of the issue of preemption." (Reply Memorandum of Law, p. 7). PIP has not cited to any authority that supports its position that plaintiff's claims are preempted merely because the PIP product underwent some portion of the PMA process. And subscribing to such an argument would lead to the untenable conclusion that state law claims are preempted for any medical device that initiates a PMA process, no matter how defective or dangerous that device might be, and despite the fact that the device did not receive PMA from the FDA.

The controlling law in the First Department, as enunciated in Sowell, supra, is that even where a product has received PMA approval, there is no preemption unless the FDA has issued regulations that are sufficiently device-specific to preempt State law.[4] Thus, defendant's argument that plaintiff's claims are preempted on the basis that the implants were merely submitted for PMA, is rejected.

Defendant also takes the position that plaintiff's state law claims are preempted because the implants were marketed under an investigational device exemption ("IDE") which is an experimental program that permits a

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[3]The record shows that PIP did not notify Dr. Milch until November 8, 2002 that it had decided to withdraw the implants from distribution. At that time it requested that he stop using all PIP implants and return them to the company.

[4] While the Second Circuit in Riegel, supra, found that there was preemption where a device had PMA, the Eleventh Circuit found to the contrary in Goodlin v. Medtronic, Inc., (167 F.3d 1367 [11th Cir. 1999]), which like Riegel, was issued after the Supreme Court issued its decision in Medtronic v. Lohr, supra. See also Heymach v. Cardiac Pacemakers, Inc., (183 Misc.2d 584) where the Supreme Court, Suffolk County found that state law claims were not preempted.

manufacturer to market a device that does not have PMA in order "to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use." (21 U.S.C. § 360J (g) (1)). As explained by defendant, an IDE allows a device to be used in a clinical study in order to collect safety and effectiveness data to support a PMA application. According to the affidavit of Mr. Hanks, on April 28, 2000, the FDA approved PIP's IDE study for "saline-filled breast implants for a limited number of augmentation, reconstruction and revision patients at a limited number of sites."(Hanks affidavit, ¶ 8). The record in this case shows that plaintiff was not enrolled in the study during either the March 2000 surgery performed by Dr. Milch (that procedure pre-dated the April 28, 2000 date that Mr. Hanks indicates was the date that the FDA approved the IDE study) or the 2002 surgery performed by Dr. Milch. According to the FDA's Breast Implant Handbook of 2004, a copy of which has been annexed as an exhibit to plaintiff's papers:

> Prior to August 1999, saline-filled breast implants were sold on the market either as preamendments [sic] devices (they were on the market prior to May 1976) or as 510-(k)-cleared devices. In August 1999, FDA issued a regulation that required that all saline-filled breast implants be PMA-approved to be sold on the market. However, those companies that had a preamendments or 510-(k)- cleared saline-filled breast implant and submitted their PMA within 90 days of the August 1999 regulation were allowed to keep their device on the market until the final decision/actions were made in May 2000. Since May 2000, a saline-filled breast implant must be approved to be sold on the market [footnote omitted].
>
> On May 10, 2000, FDA approved Mentor Corporation's and Inamed Corporation's (formerly McGhan Medical) saline-filled breast implant PMAs. As of the date of this handbook, these are the only two companies with PMA-approved saline-filled breast implants.

> ***Except for two PMA-approved saline-filled breast implants, all other saline-filled breast implants are considered investigational devices because they are not PMA-approved. For a woman to receive an investigational saline-filled breast implant in the U.S., she must enroll in an investigational device exemption (IDE) study.***
>
> An IDE study is a clinical study that must be reviewed and approved by FDA to help assure that the resulting data will be meaningful and that patients will not be exposed to unreasonable risks. IDE studies may include augmentation, reconstruction, and/or revision patients. The number of patients and the number of sites are limited in IDE studies. In addition, each woman who participates in an IDE study must give informed consent [see FN]. The safety and effectiveness data collected in an IDE study are used to support a future PMA.
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> [fn] Note that the informed consent document required for a patient to participate in an IDE study should not be confused with a standard surgical consent form that a hospital requires to be signed by any surgical patient.

Handbook, p.14-15, emphasis in original.

Defendant has cited some authority for the proposition that state law claims are preempted for such IDE devices. For example, in Martin v. Telectronic Pacing Systems (105 F.3d 1090 [6th Cir. 1997], cert denied 522 U.S. 1075 [1998]), the Sixth Circuit held that state law claims regarding a pacemaker that had been approved as an IDE were preempted under the MDA. In the decision, the court wrote that the plaintiff had signed a form consenting to implantation of the device, but there is no indication in the decision that the plaintiff was enrolled in the IDE study. The court noted that "[a]lthough investigational devices are not subject to the rigorous PMA process, they are subject to a different set of complex and comprehensive regulations which set forth detailed procedures for determining whether investigational devices are safe and effective. See 21 U.S.C. § 360j(g)(3); 21 C.F.R. §§ 812.20, 812.25, 812.27 (1996)." The Sixth Circuit reasoned as

follows:

> Unlike the general federal requirements discussed in Medtronic, the regulations governing investigational devices are essentially device specific. There are no specific regulations governing pacemakers like the one at issue; however, the application and approval process under the IDE is device specific. For example, the FDA requires information regarding "the methods, facilities, and controls used for manufacture ... of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device." 21 C.F.R. § 812.20(b)(3). The FDA then exempts the device, if approved, from the general requirements of good manufacturing practice that would ordinarily apply. 21 C.F.R. § 812.1(a). In reviewing the application, the FDA calculates the risks and benefits of the particular device and grants an exemption only if the risks are outweighed by the benefits to the subjects. 21 C.F.R. § 812.30(b)(4).

Id. at 1097.

Other courts have reached similar conclusions that some, if not all state claims are preempted for investigational devices (see e.g., Chambers v. Osteonics Corp., 109 F.3d 1243 [7th Cir. 1997]; Berish v. Richards Medical Co., 937 F.Supp 181 [N.D.N.Y. 1996]; Touchet v. Ace Medical Co., 1998 WL 531887 [E.D. La. Aug. 24, 1998]; Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp. 2d 1353 (M.D. Fla. 1999]). However, I do not believe that the approval of a device as an IDE is the type of device-specific regulation that was contemplated by the Supreme Court in Medtronic v. Lohr, (518 U.S. 470,.116 S. Ct. 2240 [1996]) or the First Department in Sowell v. Bausch & Lomb, Inc. (230 AD2d 77 [1997]). There is no preemption here because plaintiff's claims do not violate, or diverge from a federal regulation on the subject. Rather, I concur with the reasoning employed by the New Jersey Supreme Court in Baird v. American Medical Optics (155 NJ 54 [1998]) where a plaintiff brought state common law tort

claims alleging that she had been injured by an intraocular lens that had been used as an IDE:

> Our reading of Medtronic and the proposed FDA regulations leads us to conclude that the United States Supreme Court, Congress, and the FDA do not intend that claims such as plaintiff's should be preempted. Those authorities must speak more clearly if they wish to prevent consumers who have been injured by experimental medical devices from maintaining state-law claims to recover for their injuries. Because the MDA does not provide a federal remedy for injured consumers, preemption of state-law claims would eliminate any remedy for them and effectively immunize manufacturers of investigational devices from liability.

Id. at 76-77.

A similar conclusion has been reached by other courts that have held that some state law claims are not preempted where there is a claim involving an IDE (see e.g. Oja v. Howmedica, Inc., 111 F.3d 782 [10th Cir.1997]; Shea v. Oscor Medical Corp., 950 F.Supp. 246 [N.D.Ill.1996]; Niehoff v. Surgidev Corp., 950 S.W.2d 816 [Ky.1997], cert. denied, 523 U.S. 1005, 118 S. Ct. 1187 [1998]; Connelly v. Iolab Corp., 927 S.W.2d 848 [Mo.1996], cert. dismissed sub. nom. Iolab Corp. v. Hunter, 520 U.S. 1260, 117 S.Ct. 2429, [1997]).

And, as is stated in one practice guide, which notes that "[p]erhaps the most bizarre judicial treatment of the MDA occurs in cases concerning devices which are exempt from FDA safety requirements, because they are new experimental devices which show some promise for use on humans, but have not yet been clinically tested", an analysis that holds that state law tort claims are preempted for devices that have an IDE "appears to be directly contrary to the Supreme Court's decision in Freightliner Corp. v. Myrick [514 U.S. 280, 115 S.Ct 1483 [1995] holding that express preemption of state requirements only occurs when an actual federal standard is in effect."(15 N.Y. Prac., New York Law of Torts § 16.85).

Based upon the foregoing, I find that plaintiff's claims are not preempted.

Finally, defendant PIP's argument that plaintiff has not suffered any injuries and that she cannot sustain her burden of proof with respect to liability are rejected. As noted, plaintiff claims that she has deflated implants and she will need reconstructive surgery. Regarding defendant's application for summary judgment with respect to liability, plaintiff may prove that the implants were defective based upon circumstantial evidence (see e.g. Speller v. Sears, Roebuck and Co., 100 NY2d 38 [2003]). Defendant has not met its burden of making a prima facie showing of entitlement to summary judgment by establishing that there was no defect in the design or manufacture of the implants (see Ramos v. Howard Industries, 38 AD3d 1163 [2007]). Even under these circumstances, where the product is not available for inspection, it cannot be inferred from the evidence submitted by defendant that the product was not defective when it left defendant's control (see dissenting opinion in Ramos, id.).

The motion by Dr. Milch, his professional corporation and Park East Plastic Surgery Center for summary judgment is also denied. The competing experts' submissions raise triable issues including whether Dr. Milch departed from the standard of care by not informing plaintiff prior to the April 8, 2002 procedure that the FDA had disapproved PIP's PMA and by implanting a non-FDA approved device rather than removing both implants after the left implant had deflated. There is also a triable issue of fact as to whether there was a proper informed consent for the procedure. Plaintiff testified that she was told by Dr. Milch in April 2002 that he was going to replace the deflated implant with a different type of implant. Additionally, there is no informed consent form signed by plaintiff indicating that she was part of an IDE study or indicating that she was receiving PIP implants. The consent form signed by her in 2000 is a consent for a McGhan product.

Based upon the foregoing, the motions are denied.

A pre-trial conference is scheduled for September 27, 2007 at 11 A.M.

Dated: August 1, 2007

J.S.C.

Check one: ☐ FINAL DISPOSITION ☒ NON-FINAL DISPOSITION

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