IN THE COURT OF COMMON PLEAS
OF CLARION COUNTY, PENNSYLVANIA

AMY J. HIGHFIELD and MICHAEL W. HIGHFIELD, her husband, Plaintiffs	:	
v.	:	529 CD 2013
ANIE PERARD, M.D.; WOMEN's HEALTHCARE OF CLARION, INC.; and CLARION HOSPITAL, Defendants	:	
v.	:	
BOSTON SCIENTIFIC CORPORATION, Additional Defendant	:	

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JEFFREY A. HIMES
CLARION CO.

OPINION AND ORDER OF COURT

Arner, J. July 16, 2014

I. Background

On August 1, 2013, Defendant Anie Perard, M.D. filed a Praecipe for Writ to Join Additional Defendant Boston Scientific Corporation (BSC). Soon thereafter, Dr. Perard filed her Original Complaint to Join Additional Defendant BSC. BSC filed Preliminary Objections to the Original Complaint on December 16, 2013. Dr. Perard filed her opposition to those Preliminary Objections on January 3, 2014. This court heard oral arguments on BSC's Motion on March 10, 2014. After careful consideration of the issues, this Court granted BSC's Preliminary Objections to the Original Complaint and directed Dr. Perard file an Amended Complaint to Join Additional Defendant.

Dr. Perard filed her Amended Complaint on May 2, 2014. BSC once again filed Preliminary Objections on May 27, 2014. This time, BSC argues that Dr. Perard's Amended Complaint is "substantively identical" to the one dismissed by this Court on April 2 of this year. Dr. Perard disagrees, noting that her Amended Complaint includes specific violations of "Current Good Manufacturing Practices" (CGMP). In this case, Dr. Perard alleges that BSC violated three CGMPs: failing to ensure that the equipment conformed to its specifications (21 C.F.R. § 820.70(a)), failing to implement procedures to ensure that damage, deterioration, contamination or other adverse effects did not occur during the handling of the equipment (21 C.F.R. § 820.140), and/or failing to implement procedures to prevent damage, deterioration, contamination or other adverse effects on the equipment (21 C.F.R. § 820.150). Dr. Perard also asserted a general claim of failing to maintain the equipment and insure such equipment was in good working order.

The original Plaintiffs in this action are not parties to the instant proceedings. Counsel for Clarion Hospital appeared alongside counsel for Dr. Perard during scheduled oral arguments, but only echoed her position during oral arguments.

II. Issues

1. Has Dr. Perard set forth causes of action and/or claims with sufficient specificity that allows her state law tort claim for failure to maintain move forward?

2. Has Dr. Perard set forth causes of action and/or claims with sufficient specificity that allows alleged violations of three sections of the CFR to move forward?

III. Analysis

The court has already defined the preliminary objection standard in previous orders. In general, a preliminary objection is properly granted where the contested

pleading is legally insufficient. *Cardenas v. Schober*, 783 A.2d 317, 321 (Pa. Super. 2001) (*citing* Pa.R.C.P. 1028(a)(4)). "Preliminary objections in the nature of a demurrer require the court to resolve the issues solely on the basis of the pleadings; no testimony or other evidence outside of the complaint may be considered to dispose of the legal issues presented by the demurrer." *Id.* at 321–22. Furthermore, "the standard of review for preliminary objections in the nature of a demurrer is limited; the question presented by the demurrer is whether, on the facts averred, the law says with certainty that no recovery is possible." *AM/PM Franchise v. Atlantic Richfield*, 584 A.2d 915, 921 (Pa. 1990). The pleadings submitted by the party against whom the preliminary objection is directed must be facially insufficient to mount a legal challenge. *Williams v. Nationwide Mutual Insurance Co.*, 750 A.2d 881, 883 (Pa. 2000).

Pennsylvania Rules also permit preliminary objections based on insufficient specificity within the pleading. Pa.R.C.P. 1028(a)(3). That Rule requires courts to consider "whether the complaint is sufficiently clear to enable the defendant to prepare his defense," or "whether the plaintiff's complaint informs the defendant with accuracy and completeness of the specific basis on which recovery is sought so that he may know without question upon what grounds to make his defense." *Ammlung v. City of Chester*, 302 A.2d 491, 498 n. 36 (Pa. Super. 1973) (citations omitted). This section does not require the party asserting the complaint to present evidence. *Podolak v. Tobyhanna Tp. Bd. of Supervisors*, 37 A.3d 1283, 1289 (Pa. Cmwlth. Ct. 2012). However, there must be enough information contained within the Complaint to allow defendants the opportunity to mount a defense against the allegations. *Id*; *cf. Unified*

Sportsmen of Pennsylvania v. Pennsylvania Game Commission, 950 A.2d 1120, 1134 (Pa. Cmwlth. 2008).

The Court's inquiries are essentially the same as they were during the first round of preliminary objections. Has Dr. Perard defined the issues presented? *See Santiago v. Pennsylvania Nat. Mut. Cas. Ins. Co.*, 613 A.2d 1235, 1238 (Pa. Super. 1992); *cf.* Pa.R.C.P. 1019, and if so, do such allegations rise above "blind suspicions?" *Feingold v. Hendrzak*, 15 A.3d 937, 942–43 (Pa. Super. 2011) *citing Feingold v. Hill*, 521 A.2d 33 (Pa. Super. 1987). Given the nature of federal preemption and the case law supporting these complex medical device claims, the court finds she has not.

A brief summary of the medical device, and the appropriate standards of review, is necessary here. The HydroThermAblator ("HTA") at the crux of this action is a device designed to treat excessive uterine bleeding. This device, manufactured by Boston Scientific, is categorized by the Food and Drug Administration as a Class III Device. Such devices are used "in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). These devices may also present "a potential unreasonable risk of illness or injury." The FDA conducts a lengthy and meticulous pre-approval process for any Class III Devices. This process requires:

> The applicant must submit detailed information including full reports of all relevant information that is known by the applicant, samples of both labeling and the device itself, and a full description of the methods and facilities used for manufacturing and installation of the device. In its review, the agency must 'weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.' Once a device has received PMA approval, the manufacturer cannot make changes to any feature of the device without obtaining FDA permission.

Hughes v. Boston Scientific Corp., 631 F.3d 762, 764–65 (5th Cir. 2011) (citations omitted). Even after the premarket approval, companies must continue to comply with FDA requirements. *Id.* at 765 *citing* 21 U.S.C. § 360i(a)(1); 21 C.F.R. § 803.50(a).

Coloring this analysis is the fact that much of the law related to devices approved through the PMA process is preempted through legislation found in the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetics Act of 1938. *See* 21 U.S.C. § 301 *et seq.* Should the federal government wish to occupy and overrule state law claims, it may do so subject to certain restrictions. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). Here, Congress elected to preempt state law claims so "to prevent manufacturers from being subject to inconsistent laws and regulations." *Schouest v. Medtronic, Inc.*, 2014 WL 1213243 at *4 (S.D. Tex. 2014) *citing* 21 U.S.C. § 360k(a).

Framing the analysis of any preemption issue is the recent two-prong approach found in the decision by the United States Supreme Court in *Riegel v. Medtronic*, 552 U.S. 312 (2008). A court must first "determine whether the Federal Government has established requirements applicable to" the medical device. *Id.* at 321. As a Class III device subject to FDA regulations, the HTA was clearly subject to federal requirements. This first prong of the preemption analysis appears to be uncontested by the parties.

The second prong of the analysis asks if the state law creates a "requirement" related to the device's safety or effectiveness that is "different from or in addition to the federal requirement." *Id.* at 322. The Supreme Court categorized requirements as state law causes of action that cannot vary with the federal requirements established by §360k. *Id.* at 325. While that preempts many claims, that does not foreclose recovery if

a party asserts "parallel claims" against a device manufacturer. A state requirement is parallel to a federal one if the plaintiff shows "that the requirements are 'genuinely equivalent.' State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law." *Wolicki–Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir.2011). In *Riegel*, the Court found "state requirements" encompass negligence, strict liability, and breach of implied warranty. *Id.* at 324–28.

Issue One – State Law Claims

Congress's desire to preempt the states and block juries from assigning "extra" requirements to the PMA process dismisses the failure to maintain and inspect claim asserted by Dr. Perard. Allowing such a claim to go forward ignores Supreme Court guidance and invades a realm Congress sought to exclude the states from through its enactment of the MDA in 1976. As such, this claim immediately fails.

Issue Two – CFR Claims

Dr. Perard also cites to three sections of the Code of Federal Regulations which allege failings on the part of BSC. These include a failure to ensure that the equipment conformed to its specifications (21 C.F.R. § 820.70(a)), failure to implement procedures to ensure that damage, deterioration, contamination or other adverse effects did not occur during the handling of the equipment (21 C.F.R. § 820.140) and/or a failure to implement procedures to prevent damage, deterioration, contamination or other adverse effects on the equipment (21 C.F.R. §820.150). Plaintiff's Amended Complaint at 3. These cited sections are sometimes referred to as "Current Good Manufacturing Practices" (CGMPs).

Some federal courts in the United States have held that a citation to specific CGMPs may provide a basis for alleging a parallel complaint. *Gelber v. Stryker Corp.*, 788 F.Supp.2d 145, 159 (S.D.N.Y.2011); *Howard v. Sulzer Orthopedics, Inc.*, 382 Fed.Appx. 436, 440–41 (6th Cir. 2010); *Bausch v. Stryker Corp.*, 630 F.3d 546, 555–56 (7th Cir. 2010). Others have conceded that there is a "narrow gap" with which a party may assert parallel claims against another. *Riley v. Cordis Corporation*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009). There appears to be only two avenues for recovery via parallel claims: (1) "an adequately pleaded claim that a specific device was not manufactured in accordance with its PMA specifications;" and (2) "a claim brought under a state statute providing a remedy for a violation of the FDCA." *In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation*, 592 F. Supp. 2d 1147, 1161, n. 17 (D. Minn. 2009).

Under Pennsylvania law, there is no private cause of action for FDCA violations. *See Killen v. Stryker Spine*, 2012 WL 4482371 at *6 (W.D. Pa. Aug. 21, 2012). Thus, in order to move forward, Dr. Perard must have an adequately pleaded claim that a device was not manufactured according to the FDA's PMA specifications. This is the only avenue of recovery available to her. Though some courts have found a citation to CGMPs sufficient to move a claim forward, this court is not persuaded.

Writing in a 2012 decision in the Western District of Pennsylvania, Judge Nora Barry Fischer dismissed claims by a party who asserted CGMP violations. Judge Fischer makes two important observations in her rejection of CGMP violations as a basis for liability. First, "the PMA process *does not certify the absolute safety of medical devices*; rather, the process entails the balancing of risks and benefits by the FDA

throughout the approval process." *Gross v. Stryker Corp.*, 858 F.Supp 2d. 466, 496 (W.D. Pa. 2012) *citing Banner v. Cyberonics, Inc.,* No. 08–0741, 2010 WL 455286, at *4 (D.N.J. Feb. 4, 2010) (emphasis added). Judge Fischer also quotes from the *Banner* decision to note that "if the FDA approves a manufacturing process and the defendant-manufacturer conforms with it, a device thereby produced that nevertheless does not function as intended does not give rise to liability." *Banner*, 2010 WL 455286 at *4. Second, device makers must adhere to "device specific" requirements. *Gross*, 858 F.Supp.2d at 496 *citing Riegel*, 552 U.S. at 322–23. That is, what is a requirement for one device may not be a requirement for another. *Id.* ("Unlike general labeling duties, premarket approval is specific to individual devices.").

Just as the case in *Stryker*, the CGMPs cited by Dr. Perard apply to all Class III Devices, not just HTAs. *See* BSC Brief in Support of Second Preliminary Objections at 18–19. In order for such claims to move forward, Dr. Perard needed to point to specific, parallel violations in support of her complaint against Boston Scientific. CGMPs recognized by the FDA are "purposefully broad" and apply to all Class III medical devices. *See id.* at 19; *Ilarraza v. Medtronic, Inc.,* 677 F.Supp.2d 582, 588 (E.D.N.Y. 2009). These general violations do not support a causal nexus between a violation of federal standards and Mrs. Highfield's alleged injury at the hands of Dr. Perard. *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 281–82 (E.D.N.Y. 2009); *Parker v. Stryker Corp.*, 584 F.Supp.2d 1298, 1301 (D. Colo. 2008). Because of the general nature of these allegations, even after this court has given Dr. Perard leave to amend, preliminary objections on behalf of BSC must be granted.

Dr. Perard failed to narrow her claims against BSC in her amended complaint. True, she cited to specific sections alleging breaches of CGMPs, but did so by identifying general regulations that apply to Class III devices. An HTA is a device markedly different from other Class III devices. The FDA provides a database for Class III devices working their way through the PMA process. During the week of July 7th, 2014, replacement heart valves, glucose monitoring systems, and lip implants are Class III Devices reviewed for PMA approval. *See* Premarket Approvals (PMA) *available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. Without the requisite specificity required in these sorts of cases, Dr. Perard cannot claim BSC violated CGMPs that are used by devices across the health care spectrum.

Had Dr. Perard pointed out these specifics in her initial Complaint or her Amended Complaint to Join, this court could have moved the litigation forward and allowed for the taking of additional discovery and depositions. As such, it is pointless to allow Dr. Perard for leave to amend her Complaint to Join Additional Defendant again. The difference between the Initial and Amended Complaints to Join is, at best, minimal. Any specificity Dr. Perard may have added in her Amended Complaint is lost upon further investigation of the CGMPs and the FDA approval process generally. In addition, her brief to that Amended Complaint provides no law or legal authority to support this preemption issue. While much of BSC's brief focused on preemption and the relevant factors courts must consider, Dr. Perard all but ignored this issue which is ultimately fatal to her attempt to join BSC in this instant action. Because amending the complaint again would be futile, the court has no other recourse but to dismiss BSC from this matter. Hence, the following Order:

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ORDER OF COURT

AND NOW, this 16th day of July, 2014, it is ORDERED that Additional Defendant Boston Scientific's Preliminary Objections are granted. The Amended Complaint to Join Additional Defendant is dismissed with prejudice. Boston Scientific is hereby removed as a party to this action.

BY THE COURT:

JAMES G. ARNER, P.J.

7-16-2014
Opinion + order
to
A. Roy Esq
N. Rosen Esq
J. Macerelli Esq
M. Patcher