SENTINEL INSURANCE COMPANY, SENTINEL INSURANCE COMPANY, DR. JOHN W. MCGEHEE, JR., INC., Plaintiff v. DENTSPLY SIRONA, INC., Defendant

No. 2017-SU-000080

Preliminary Objections – Negligence - Strict Liability

1. The Court overruled Defendant's preliminary objection (Demurrer) as to Plaintiff's Count for Strict Liability.

2. The Court overruled Defendant's preliminary objection (insufficiency of the pleadings) as to Plaintiff's Count for Negligence.

IN THE COURT OF COMMON PLEAS OF YORK COUNTY, PENNSYLVANIA CIVIL DIVISION

SENTINEL INSURANCE COMPANY,	**:**	**No. 2017-SU-000080**
SENTINEL INSURANCE COMPANY,	**:**	
DR. JOHN W. MCGEHEE, JR., INC.	**:**	
Plaintiff	**:**	
	:	
v.	**:**	
	:	
DENTSPLY SIRONA, INC.,	**:**	**Civil Action – Law**
Defendant	**:**	

APPEARANCES:

For Plaintiff: Craig A. Cohen, Esquire
For Defendant: Jason A. Rosenberger, Esquire

MEMORANDUM OPINION OVERRULING DEFENDANT'S PRELIMINARY OBJECTION TO PLAINTIFF'S COMPLAINT

Before this Court are Defendant Dentsply Sirona, Inc.'s (hereinafter, "Defendant") Preliminary Objections to Plaintiff Sentinel Insurance Company, LTD's (hereinafter

"Plaintiff") Amended Complaint. For the following reasons, Defendant's Preliminary Objections to Plaintiff's Amended Complaint are **OVERRULED**.

FACTS

Plaintiff, as subrogee of Dr. John W. McGehee, Jr., Inc. (hereinafter, the "Insured"), filed a Complaint on January 12, 2017, asserting claims for strict products liability and negligence. Defendant is a corporation engaged in the business of designing, engineering, manufacturing, assembling, testing, inspecting, distributing, selling and/or otherwise placing into the stream of commerce dental devices and equipment, including Cavitron ultrasonic scaling units. Plaintiff alleges that on April 4, 2016, an employee working for the Insured allegedly discovered that a water supply-line filter (Dentsply Professional No. 90158) which had been connected to a Cavitron ultrasonic scaling device at the Insureds dental office had failed, causing a significant amount of water to discharge into the property. Plaintiff asserts that the repair technician who came to replace the water filter discussed recurring issues with this particular model filter and that he believed them to be defective. Additionally, Plaintiff avers that the technician informed Plaintiff that Defendant had recently changed the design of the filter.

Following the water leak, Plaintiff recovered the failed water filter and had it examined by an engineering laboratory which concluded that the water filter failed because of a design defect. Plaintiff asserts that as a result of the failure of the water filter, the Insured suffered damage to its real and business personal property, as well as an interruption of its ongoing business, totaling more than $154,978.39. Plaintiff has paid this

amount to the Insured, and, in accordance with the insurance policy, is now subrogated to the rights of the Insured. The claims asserted by Plaintiff sound in strict liability and negligence. Defendant's Preliminary Objections assert that as part of the Cavitron, a Class II Medical Device available only with a prescription, the water filter is a component of a medical device and therefore strict liability cannot be imposed. Additionally, Defendant asserts that Plaintiff's claim for negligence is insufficiently specific.

Plaintiff initiated the lawsuit by filing a Complaint on January 12, 2017. A Case Management Plan was ordered on January 31, 2017. Defendant filed Preliminary Objections to Plaintiff's Complaint on February 2, 2017. Plaintiff filed a First Amended Complaint on February 8, 2017. On February 27, 2017 Defendant filed Preliminary Objections to Plaintiff's Amended Complaint as well as a Brief in Support thereof. Plaintiff Filed an Answer to Defendant's Preliminary Objections on March 16, 2017, along with a Memorandum of Law in Opposition to Defendant's Preliminary Objections. Defendant filed a reply brief on March 23, 2017. The case was listed for one-judge disposition on March 27, 2017 and assigned to this Court on April 12, 2017. Oral argument on Defendant's Preliminary Objections was held on May 31, 2017.

DISCUSSION

Preliminary objections, if sustained, would result in the dismissal of a cause of action, and "should be sustained only in cases that are clear and free from doubt." *Bower v. Bower*, 531 Pa. 54, 611 A.2d 181, 182 (1992). When considering preliminary objections, "all material facts set forth in the challenged pleadings are admitted as true, as well as all

inferences reasonably deducible therefrom. *Feingold v. Hendrzak,* 2011 Pa. Super. 34, 15 A.3d 937, 941 (2011). In ruling on preliminary objections, "the court must consider the evidence in the light most favorable to the non-moving party." *Maleski by Taylor v. DP Realty Trust*, 653 A.2d 54, 61 (Pa. Commw. Ct. 1994).

I. Defendant's First Preliminary Objection, Pursuant to Pa. R. Civ. P. 1028(a)(4).

Defendant's first Preliminary Objection is that Count I of Plaintiff's Amended Complaint, which alleges strict liability for design defect, is legally insufficient (a demurrer) pursuant to Pa. R. Civ. P. 1028(a)(4). Defendant asserts that, under Pennsylvania jurisprudence, strict liability claims are not permitted where the allegedly defectively designed product is a medical device.

A demurrer admits all relevant facts set forth in the pleadings and all inferences fairly deductible therefrom, but not conclusions of law. *Chorba v. Davlisa Enterprises, Inc.* 303 Pa.Super 497, 500, 450 A.2d 36, 37 (1982). A demurrer will be sustained when the complaint evidences on its face that the claim cannot be sustained because the law will not permit recovery. *Id.* "If there is any doubt, the doubt should be resolved in favor of overruling the demurrer." *Id.* "In ruling on a demurrer, the court may consider only such matters as arise out of the complaint itself; it cannot supply a fact missing in the complaint."

Lerner v. Lerner, 954 A.2d 1229, 1234–35 (Pa. Super. Ct. 2008) (*citing Binswanger v. Levy*, 457 A.2d 103, 104 (Pa. Super. Ct. 1983)).

"Strict liability allows a plaintiff to recover where a product in 'a defective condition unreasonably dangerous to the user or consumer' causes harm to the plaintiff." *Phillips v. A-Best Products Co.*, 665 A.2d 1167, 1170 (Pa. 1995) (*citing* Restatement (Second) of Torts, § 402A (1965)). However, "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) of Torts, § 402A, cmt. k (1965).

> The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Id.

Recognizing that Comment k expressly discussed prescription drugs, the Pennsylvania Supreme Court adopted Comment k's application in *Hahn v. Richter*, 673 A.2d 888, 889-91 (Pa. 1996). Ten years later, the Superior Court addressed the issue of whether Comment k could be applied to preclude strict liability for claims arising out of a defective medical device. *Creazzo v. Medtronic, Inc.*, 903 A.2d 24 (Pa. Super. 2006).

The matter in *Creazzo* arose when a Model 7425 Itrel 3 Implantable Neurological Electrical Pulse Generator (hereinafter, the "Itrel 3") which was implanted into the body of the Plaintiff malfunctioned. *Id.*, at 25. The device "was designed to alleviate chronic pain by passing an electrical stimulus through nerve structures in the dorsal aspect of the

patient's spinal cord by way of a stimulation lead." *Id.* The lower court applied Comment k, concluding that "given the potential utility of the Itrel 3, no significant distinction can be drawn between the device and the drug upon with the Supreme Court Based its decision in *Hahn*." *Id.,* at 31 (*citing Hahn v. Richter,* supra.). The lower court accordingly denied the application of strict liability.

On appeal the Creazzos argued that medical devices did not fall within the purview of Comment k because they were not mentioned therein. *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. 2006). The Superior Court, affirming the lower court's decision, stated "[w]e find no reason why the same rational[*sic*] applicable to prescription drugs may not be applied to medical devices." *Creazzo*, supra, at 31.

In this case, Defendant is a seller of prescription medical devices for use in dental offices. The product at issue, the Cavitron Ultrasonic Scaler, is a Class II Medical Device as classified by the FDA and therefore requires a prescription. Defendant asks this Court to apply Comment k to Plaintiff's claim on this basis. Plaintiff distinguishes *Creazzo*, supra, by arguing that the product it is alleging is defective is not the Cavitron as a whole, but rather the water supply-line filter through which water is supplied to the device. Additionally, Plaintiff asserts that *Creazzo*'s application of Comment k to medical devices is distinguishable as the implantable device at issue there required surgery to be removed and therefore caused physical harm. In the instant case, the malfunction by the water filter in the Cavitron caused property damage, which is not the type of harm contemplated by Comment k and the doctrine of unavoidably unsafe products.

The Court believes that the type of harm contemplated by Comment k is personal injury. This belief is also supported by subsequent case law which declined to extend strict liability to medical devices which resulted in personal injury to the Plaintiff. There is no case in which the appellate courts applied Comment k to a property damage claim. The reasoning of the lower court in *Creazzo*, which stated that "no significant distinction can be drawn between the device and the drug upon which the Supreme Court based its decision in *Hahn*" is therefore inapplicable to the instant case. *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. 2006). Furthermore, the Court notes that although the Superior Court applied Comment k to the Itrel 3, it did not adopt a blanket prohibition on strict liability claims against sellers of medical devices.

Defendant cites to numerous federal cases which accord the *Creazzo* rationale the narrow interpretation argued by Defendant. However, those cases are not controlling in that they do not involve a property damage claim. Therefore, the Court finds that Plaintiff's claim for strict liability against Defendant is not prohibited by Comment k or by the Superior Court's holding in *Creazzo*. Accordingly, Defendant's first Preliminary Objection is **OVERRULED**.

II. Defendant's Second Preliminary Objection, Pursuant to Pa. R. Civ. P. 1028(a)(3).

Defendant's second Preliminary Objection asserts that Count II of Plaintiff's Amended Complaint, which states a claim for negligence, is insufficiently specific pursuant to Pa. R. Civ. P. 1028(a)(3).

> The pertinent question under Rule 1028(a)(3) is "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."

Rambo v. Greene, 906 A.2d 1232, 1236 (Pa. Super. 2006) (*quoting Ammlung v. City of Chester*, 302 A.2d 491, 498 n. 36 (Pa. Super. 1973)).

The specific paragraphs of Plaintiff's Amended Complaint which are the subjects of Defendant's Preliminary Objection are:

> a. Failing to exercise the requisite degree of care and caution in designing, engineering, manufacturing, assembling, distributing, selling and/or otherwise placing into the stream of commerce the Water Filter;
> b. Failing to properly inspect, examine, and/or test the design and construction of the Water Filter before distributing it;
> . . .
> e. Distributing, selling and/or otherwise placing into the stream of commerce a defective Water Filter, that Dentsply knew, or reasonably should have known, or with reasonable diligence would have known existed;
> f. Failing to design, engineer, manufacture, assemble, test, inspect, distribute, sell and/or otherwise place into the stream of commerce a properly functioning Water Filter;
> g. Designing, engineering, manufacturing, assembling, distributing, selling and/or otherwise placing into the stream of commerce a Water Filter that does not conform with prevailing industry specifications and standards;
> h. Designing, manufacturing, assembling and distributing and dental device with inadequate or defective component parts, including the Water Filter, which Dentsply knew or reasonably should have known created an unreasonable risk of harm; and
> i. Failing to exercise reasonable care in the design, assembly, construction, manufacture, fabrication and/or selection of the dental device's component parts, including the Water Filter.

Amended Complaint, pp. 8-9, paras. 39(a), 39(b), 39(e), 39(f), 39(g), 39(h), 39(i).

Defendants allege that the Amended Complaint is deficient because

> no facts are pled in the Amended Complaint which indicate: (1) what care and caution purportedly should have been exercised by Dentsply in the design, manufacture or distribution of the Cavitron water filter that supposedly was not; (2) how Dentsply allegedly failed to properly inspect, examine or test the construction of the Cavitron water filter before allegedly distributing it; (3) anything about the warnings that Dentsply allegedly provided or failed to provide regarding the Cavitron water filter; (4) how or why the Cavitron water filter allegedly did not properly function before or at the time it was placed into the stream of commerce; (5) how Dentsply allegedly knew or should have known that the Cavitron water filter purportedly failed to properly function before or at the time it was placed into the stream of commerce; (6) what applicable specifications and standards within the industry allegedly were violated by Dentsply and how it purportedly violated them; or (7) what Cavitron component parts (beyond the Cavitron water filter) allegedly are inadequate or defective and how Dentsply allegedly knew or should have known that they too supposedly created an unreasonable risk of harm.

Defendants Brief in Support of Preliminary Objections, p. 10.

In the instant case, Plaintiff alleges that Defendant was in the business of designing, engineering, manufacturing, assembling, testing, inspecting, distributing, selling, and/or otherwise placing into the stream of commerce dental devices and equipment, including the water filter at issue; that Defendant placed the water filter into the stream of commerce; that Defendant knew or reasonably should have known that the water filter was defective; and that the water filter failed and directly and proximately caused Plaintiff's injuries. Plaintiff asserts that the factual averments of the paragraphs Defendant complains of go to support the averments above and do not state separate instances of negligence. Accordingly, Plaintiff argues that it has pled with sufficient specificity.

Viewing the Complaint as a whole, the Court finds that the Amended Complaint "is sufficiently clear to enable the defendant to prepare [their] defense," and "informs the

defendant with accuracy and completeness of the specific basis on which recovery is sought so that [they] may know without question upon what grounds to make [their] defense." *Ammlung v. City of Chester*, 302 A.2d 491, 498 n. 36 (Pa. Super. 1973). Accordingly, Defendant's Second Preliminary Objection is **OVERRULED**.

CONCLUSION

Plaintiff's claim for strict liability is not barred by the doctrine of unavoidably unsafe products espoused in the Restatement (Second) of Torts, § 402A, cmt. k (1965), nor is it barred by the Superior Court's holding in *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. 2006). Additionally, taken as a whole, Plaintiff's Amended Complaint is sufficiently specific with respect to its claim for negligence as it informs Defendant with such accuracy and completeness of the specific facts on which it relied that Defendant is able to prepare a defense. Accordingly, Defendant's Preliminary Objections to Plaintiff's Amended Complaint are **OVERRULED**.

BY THE COURT,

JOSEPH C. ADAMS, PRESIDENT JUDGE

Dated: June 7, 2017

IN THE COURT OF COMMON PLEAS OF YORK COUNTY, PENNSYLVANIA
CIVIL DIVISION

SENTINEL INSURANCE COMPANY, LTD, as subrogee of DR. JOHN W. MCGEHEE, JR., INC.	:	**No. 2017-SU-000080**
Plaintiff	:	
	:	
v.	:	
	:	
DENTSPLY SIRONA, INC.,	:	**Civil Action – Law**
Defendant	:	

APPEARANCES:

For Plaintiff: Craig A. Cohen, Esquire
For Defendant: Jason A. Rosenberger, Esquire

ORDER OVERRULING DEFENDANT'S PRELIMINARY OBJECTIONS TO PLAINTIFF'S AMENDED COMPLAINT

AND NOW, this 7th day of June 2017, for the reasons set forth in the Memorandum Opinion of this date, Defendant's Preliminary Objections to Plaintiff's Amended Complaint are **OVERRULED**.

BY THE COURT,

JOSEPH C. ADAMS, PRESIDENT JUDGE