STATE OF NEW YORK
SUPREME COURT COUNTY OF MONROE

JOSEPH BARONE,

Plaintiff,

-vs-

BAUSCH & LOMB, INC.
MORCHER GmbH, and
FCI OPHTHALMICS, INC.,

Defendants.

DECISION AND ORDER

Index No.: E2017000711

PIAMPIANO, J.

Before the Court are three Motions to Dismiss the Plaintiff's Amended Complaint, with each Defendant having made a separate application.

The Plaintiff alleged, in his Amended Complaint, that he sustained injuries as a direct result of the failure of Defendant Bausch & Lomb Inc.'s Crystalens AO Lens product (Crystalens) and Defendants Morcher GmbH's and FCI Ophthalmics, Inc.'s Capsular Tension Ring (CTR) product.

As set forth in the Amended Complaint, Defendant Bausch & Lomb (B&L), a New York corporation, was the manufacturer and distributor of the Crystalens, an implantable medical device indicated to treat cataracts and presbyopia. Defendant Morcher GmbH (Morcher), a German company, was the manufacturer of the CTR, a prosthetic device designed to stabilize the Crystalens lens capsule. Defendant FCI Ophthalmics (FCI), a Massachusetts corporation, was the United States distributor of the CTR.

As further alleged in the Amended Complaint, the Crystalens is a Class III medical device which received Premarket Approval (PMA) by the Federal Drug Administration in 2003. The FDA's PMA required B&L, as a condition of continued approval to distribute the Crystalens, to provide the FDA with Adverse Reaction Reports within ten days after B&L received, or had knowledge concerning any injury that was attributable to the device; and that had not been addressed by the device's labeling, or that had been addressed by the device's labeling but was occurring with unexpected severity or frequency. The FDA maintains a MAUDE database on reported adverse events, which is a public database known to, and discussed by, the medical community.

The Crystalens allegedly is subject to a unique complication known as Z Syndrome, which occurs when one of the Crystalens' arms that attaches to the eye muscle detaches and folds forward inside of the eye, causing the Crystalens to assume a "Z" shape and to stop functioning.

The Plaintiff further alleged, in his Amended Complaint, that B&L was aware of Z Syndrome as early as April of 2009, when B&L forwarded the FDA a report that Z Syndrome had occurred, more than six years prior to the Plaintiff's implantation. However, upon the Plaintiff's information and belief, B&L failed to file Adverse Reaction Reports for all known incidents of Z Syndrome with B&L's Crystalens. Those alleged reporting failures allegedly violated 21 C.F.R. § 803.50 (a) and the conditions set by the FDA's initial approval for the Crystalens.

The Crystalens and CTR were implanted in the Plaintiff's right eye on or about August 20, 2015 in order to improve the Plaintiff's eyesight. The Plaintiff alleged that both

the Crystalens and the CTR failed within a matter of weeks after implantation. The product failures allegedly resulted in, among other things, multiple follow-up surgeries, extreme pain and discomfort, an inability to see, and permanent injuries. Upon the Plaintiff's information and belief, the failure of the Plaintiff's Crystalens may have been the result of Z Syndrome. In sum and substance, the Plaintiff alleged that, if he had known the true frequency of the occurrence of Z Syndrome associated with the Crystalens, he would not have agreed to the implantation of the Crystalens. As such, B&L's under-reporting of the incidents of Z Syndrome to the FDA via the Adverse Reaction Reports may have been a direct and proximate cause of the Plaintiff's personal and financial injuries. Further, as a result of defects and/or malfunctions in both the Crystalens and CTR products, the Plaintiff allegedly was caused to suffer and sustain injuries, necessitating multiple surgeries and medical treatments.

On May 9, 2017, the action was commenced by the filing of a Summons and Complaint. On November 28, 2017, an Amended Complaint was filed.

The Amended Complaint set forth seven Causes of Action:

First Cause of Action:	Strict Liability – Defective Design and Manufacture *As to Defendants Morcher and FCI.*
Second Cause of Action:	Strict Liability – Failure to Warn *As to Defendants Morcher and FCI.*
Third Cause of Action:	Negligence *As to Defendants Morcher and FCI.*
Fourth Cause of Action:	Breach of Implied Warranties *As to Defendants Morcher and FCI.*
Fifth Cause of Action:	Breach of Express Warranty *As to Defendants Morcher and FCI.*

Sixth Cause of Action: Strict Liability – Failure to Warn
As to Defendant B&L.

Seventh Cause of Action: Negligent Failure to Warn
As to Defendant B&L.

On December 20, 2017, Defendant B&L removed the case to the United States District Court (WDNY), alleging federal question jurisdiction. B&L subsequently filed a motion to dismiss the Amended Complaint on preemption grounds.

On August 27, 2018, the Federal Court (Elizabeth A. Wolford, United States District Court Judge) held oral argument on B&L's motion to dismiss. During the motion argument, the Federal Court raised, *sua sponte*, the issue of subject matter jurisdiction and required additional briefing on the issue. The Federal Court held further oral argument on February 26, 2019, to address the issue of its subject matter jurisdiction, and the Court reserved decision. Thereafter, the Federal Court, by Decision and Order entered on March 12, 2019, concluded that it did *not* have subject matter jurisdiction over the action, and the case was remanded to the New York Supreme Court, County of Monroe.

Addressing the motions now pending before this Court, Defendant Bausch & Lomb moved the Court, for an Order dismissing the Amended Complaint, pursuant to CPLR 3211 (a) (2) and CPLR 3211 (a) (7). Defendant Morcher moved the Court, for an Order dismissing the Amended Complaint, pursuant to CPLR 3211 (a) (7) and CPLR 3211 (a) (8). Defendant FCI moved the Court, for an Order dismissing the Amended Complaint, pursuant to CPLR 3211 (a) (7).

On a CPLR 3211 motion to dismiss, the Court must give the complaint a liberal construction, accept the allegations as true, and provide the plaintiff with the benefit of

every favorable inference. Indeed, the question of whether a plaintiff can ultimately establish its allegations is not part of the calculus in determining a motion to dismiss. (*See Roni LLC v Arfa*, 18 NY3d 846 [2011]).

Defendant Bausch and Lomb, in support of its motion, asserted that the Plaintiff's claim against B&L for an alleged failure to warn, whether pled under the theory of negligence or strict liability, was predicated entirely and exclusively, on the contention that B&L failed to submit adverse inference reports to the United States Food and Drug Administration. That claim, B&L argued, was expressly and/or impliedly preempted by federal law. To the extent that the Plaintiff contended that B&L failed to provide adequate warnings to the Plaintiff, as opposed to the Plaintiff's physician, B&L argued that such claim was barred by the informed intermediary doctrine.

The Plaintiff, in opposition to B&L's motion to dismiss, argued that the Plaintiff's claims were neither expressly, nor impliedly preempted by federal law. Addressing the preemption issues, the Court hereby determines that the Plaintiff's Amended Complaint pleaded parallel claims for a failure to warn under New York State law, which did not impose any requirements that were different from, or in addition to, Bausch and Lomb's duties to report incidents of Z Syndrome under federal law. (*See Riegel v Medtronic, Inc.*, 552 US312 [2008]). Furthermore, in this case, the Plaintiff has not sought to enforce any provision of the Food, Drug and Cosmetic Act (FDCA), nor has the Plaintiff sought to compel B&L to comply with FDCA regulations. Rather, the Plaintiff's failure to warn claims were based on B&L's failure to comply with its parallel State and federal duties to report adverse events to the FDA.

Additionally, the Plaintiff, rather than alleging that B&L had a duty to warn the Plaintiff, himself, regarding the dangers of the Crystalens, instead alleged that B&L had a duty to provide physicians with sufficient information concerning the risks of the Crystalens. B&L arguably breached that duty, by failing to adequately report the occurrences of Z Syndrome to physicians, including the Plaintiff's doctor, so that the Plaintiff would thereby have been able to make an informed decision regarding the risks and benefits of the device.

Upon consideration of Defendant B&L's motion to dismiss, and the Plaintiff's response thereto, as well as affording the Amended Complaint a liberal construction, accepting the allegations as true, and providing the Plaintiff with the benefit of every favorable inference, the Court determines that Defendant B&L's motion to dismiss is hereby denied, in all respects.

Addressing Defendant Morcher's motion to dismiss the Amended Complaint, pursuant to CPLR 3211 (a) (8), Morcher argued that the Court lacks personal jurisdiction over Morcher on the grounds that Morcher is a German company, based in Germany, with no relevant contacts with the State of New York. The Plaintiff argued that the Court has specific personal jurisdiction over Morcher.

As more fully set forth in the Plaintiff's submissions, the Court finds that the Plaintiff sufficiently alleged that Defendant Morcher's tortious acts were committed outside of New York State; that the causes of action arose from those acts; that the tortious acts caused an injury to a person or property in New York; that Defendant Morcher expected, or should reasonably have expected, that its actions would have consequences in New York;

and that Morcher derived substantial revenue from interstate or international commerce. The Court, therefore, determines that the Plaintiff sufficiently alleged that the Court has personal jurisdiction over Morcher, pursuant to CPLR 302 (a) (3) (ii). (*See LaMarca v Pak-Mor Mfg. Co.*, 95 NY2d 210 [2000].)

The Court also determines that the Plaintiff sufficiently alleged the Court has personal jurisdiction over Morcher, pursuant to CPLR 302 (a) (1), which provides jurisdiction over any non-domiciliary who, in person, or through an agent, transacts any business within the State, or contracts anywhere to supply goods or services in the State; and that the causes of action arose from such a business transaction.

The Court further determines, contrary to Morcher's argument, that it does not offend traditional notions of fair play and substantial justice for the Court to exercise personal jurisdiction over Morcher. Accordingly, the Court hereby denies Defendant Morchers's motion to dismiss, based upon a lack of personal jurisdiction.

Given that the Court has denied Defendant Morcher's motion to dismiss, pursuant to CPLR 3211 (a) (8), a determination must be made relative to Morcher's motion to dismiss, pursuant to CPLR 3211 (a) (7). While Morcher joined in, and incorporated by reference, the concurrently-filed motion to dismiss of Defendant Bausch & Lomb, Morcher argued that its entitlement to dismissal based on preemption was even more straightforward, on the ground that the Plaintiff did not allege that Morcher violated any federal regulations. As noted by Morcher, the Plaintiff's product liability claims against Morcher and its United States distributor, FCI Ophthalmics, were related to Morcher's Capsular Tension Ring

("CTR") medical device. Like B&L's Crystalens medical device, Morcher's CTR was approved by the FDA for sale in the United States through the Premarket Approval process.

The Plaintiff, in opposition to Defendant Morcher's motion, incorporated all of its arguments regarding preemption from its concurrently-filed opposition to Defendant B&L's motion to dismiss. In that regard, the Plaintiff argued that the Plaintiff's failure to warn claims, as pleaded in the Amended Complaint, were based on Morcher's failure to comply with its parallel State and federal duties to report adverse events to the FDA, and that such breach was a direct and proximate cause of the Plaintiff's injuries.

Upon consideration of Defendant Morcher's motion to dismiss, and the Plaintiff's response thereto, as well as affording the Amended Complaint a liberal construction, accepting the allegations as true, and providing the Plaintiff with the benefit of every favorable inference, the Court determines that Morcher's motion to dismiss is hereby denied, in all respects.

Addressing Defendant FCI's motion to dismiss the Amended Complaint, FCI joined in, and incorporated by reference, the concurrently-filed motions to dismiss of Defendant Bausch & Lomb and Defendant Morcher. FCI argued that it was entitled to dismissal, pursuant to CPLR 3211 (a) (7). Specifically, FCI argued that it was entitled to dismissal, based on federal preemption, given that the Plaintiff did not allege that Morcher or FCI violated any federal regulations. Additionally, FCI argued that the Plaintiff's claims against said Defendant, the Capsular Tension Ring distributor, were further preempted, on the ground that, where federal law makes it impossible for a defendant to do, under federal law, what state law would compel, the state law is impliedly preempted. As applied to this

case, the Defendant, as the CTR distributor, lacked the power to unilaterally change the device's relevant features. Rather, it was the FDA that mandated the design, manufacturing process, and labeling for the device. (*See Riegel v Medtronic, Inc.*, 552 US 312 [2008]).

In opposition to FCI's motion to dismiss, the Plaintiff asserted that the arguments made in its concurrently-filed opposition to Defendant Morcher's motion to dismiss applied with equal force to FCI, and required the denial of FCI's motion. In response to FCI's independent argument, that the Plaintiff's claims against FCI were impliedly preempted because FCI was a distributor of the CTR, rather than the manufacturer, the Plaintiff argued that FCI did not identify any federal regulation that applied to medical devices, which would preclude compliance with both State and federal law.

Upon consideration of Defendant FCI's motion to dismiss, and the Plaintiff's response thereto, as well as affording the Amended Complaint a liberal construction, accepting the allegations as true, and providing the plaintiff with the benefit of every favorable inference, the Court determines that FCI's motion to dismiss is hereby denied, in all respects.

In light thereof, it is

ORDERED, that the motion to dismiss of Defendant Baush & Lomb, Inc., is hereby DENIED; and it is further

ORDERED, that the motion to dismiss of Defendant Morcher GmbH, is hereby DENIED; and it is further

ORDERED, that the motion to dismiss of Defendant FCI Ophthalmics, Inc., is hereby DENIED; and it is further

ORDERED, that any relief requested by the Defendants' respective motions, but not specifically addressed herein, is hereby DENIED.

The above constitutes the Decision and Order of this Court.

Dated: December 6, 2019
Rochester, New York

HON. JAMES J. PIAMPIANO
SUPREME COURT JUSTICE

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