IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

KATHLEEN SPIES and ALAN SPIES, Plaintiffs, v. ABDUL AMINE, M.D., individually, and ABDUL AMINE, M.S., a service corporation, EBBY JIDO, M.D., MARGARITA KOS, N.P., MIDWEST ANESTHESIOLOGISTS, LTD, BRANDON GAYNOR, M.D., JEFFREY CURTIN, D.O., JOSEPH KOWALCZYK, M.D., VINSON UYTANA, M.D., ADVOCATE HEALTH & HOSPITALS CORPORATION, MEDTRONIC, INC. Defendants.	)	No. 20 L 8663

MEMORANDUM OPINION AND ORDER

Illinois contract law recognizes the validity of private agreements tolling the statute of limitations. Two parties in this case previously entered such an agreement, resulting in the plaintiffs timely re-filing their lawsuit and this court denying the defendant's motion to dismiss. The defendant has, however, successfully argued that the plaintiffs' claim, as pleaded, appears expressly preempted by the Medical Device Amendment to the Food, Drug and Cosmetics Act as the plaintiffs have failed to plead sufficient facts to fit their claim in the narrow gap of permissible state law claims. The defendant's motion on this issue is, therefore, granted, but without prejudice to permit the plaintiffs to re-plead.

Facts

In August 2015, Kathleen Spies underwent a surgical procedure to implant an intrathecal pain pump—manufactured and distributed by Medtronic—to treat her ongoing back pain. In May 2017, the pump ceased functioning, leading Kathleen to seek treatment at Advocate Christ Medical Center. While at ACMC, Kathleen underwent medical treatment provided by, among others, defendant Dr. Abdul Amine. Amine, in consultation with Medtronic employees, determined that the pain pump was malfunctioning and needed to be removed and replaced.

On May 17, 2017, Amine performed surgery on Kathleen at ACMC to disconnect the first pain pump from its catheter and remove it from the subcutaneous pocket in which it had been implanted. Amine elected not to remove the preexisting catheter (Catheter 1), deciding instead to leave it inside Kathleen's body with one end still inserted into her thecal sac and the other end ligated to seal it. Amine implanted a new intrathecal pain pump, again manufactured and distributed by Medtronic, that he attached to a new catheter (Catheter 2) and inserted into Kathleen's thecal sac.

On May 25, 2017, Kathleen sought further treatment from Amine because of cerebral spinal fluid (CSF) leakage into the pocket. On May 27, Amine performed a second surgery on Kathleen at ACMC to investigate the cause of the spinal fluid leak and make any necessary revisions. During surgery, Amine determined that the CSF leak related to Catheter 1. Amine again ligated Catheter 1. Shortly after the surgery, Kathleen began experiencing painful headaches radiating into her scalp, upper neck, shoulders and back, as well as momentary blackouts.

On November 28, 2017, and at Kathleen's request, Dr. Brandon Gaynor conducted a surgery during which he disconnected the second pain pump from Catheter 2 and removed the pump, but left Catheter 2 inside Kathleen's body. Gaynor noted there was no CSF leakage. Kathleen's headaches and

radiating pain continued. She later received treatment from several defendant health care practitioners, none of whom determined the cause of her symptoms.

On May 16, 2019, Kathleen and Alan entered into a tolling agreement with Medtronic in which the parties agreed that "all applicable statutes of limitations and/or filing deadlines for the above-referenced claims, including the deadline in which to file a lawsuit . . . shall be tolled for 120 days, from May 14, 2019 to September 11, 2019." The next day, May 17, 2019, Kathleen and Alan filed a complaint in case number 19 L 5409. The Spies did not name Medtronic as a defendant in that complaint. On August 14, 2019, Kathleen and Alan filed their first amended complaint naming Medtronic as a defendant and alleging negligence on its part. The Spies never sought to serve Medtronic with that complaint; rather, the same day, Kathleen and Alan filed a motion for voluntary dismissal without prejudice pursuant to Code of Civil Procedure section 2-1009, 735 ILCS 5/2-1009, and with leave to refile. On August 15, 2019, this court granted the motion for voluntary dismissal with leave to refile within one year pursuant to section 13-212. 735 ILCS 5/13-212.

In May 2020, Dr. Ryan Trombley diagnosed Kathleen with an ongoing CSF leak. On May 12, 2020, Trombley performed surgery on Kathleen during which he determined that she had been experiencing an ongoing CSF leak in connection with Catheter 1.

On August 17, 2020, the Spies filed their current complaint in this lawsuit, 20 L 8663, pursuant to section 13-212. The Spies named Medtronic as a defendant and alleged its negligence. On October 5, 2020, Medtronic filed its appearance, jury demand, and motion to dismiss. On November 9, 2020, the Spies filed their response and exhibits. On November 30, 2020, Medtronic filed its reply and exhibits.

Analysis

Section 2-619.1 of the Illinois Code of Civil Procedure permits a combined motion under section 2-615 and section 2-619, and section 2-1005. 735 ILCS 5/2-619.1. A section 2-619.1 combined motion must be: (1) in parts; (2) with each part limited to and specifying that it is made under one of sections 2-615, 2-619, or 2-1005; and (3) with each part clearly showing the points or grounds relied on under the section on which it is based. *Id.* A court considering either motion must accept as true all well-pleaded facts and reasonable inferences arising from them, *Doe v. Chicago Bd. of Ed.*, 213 Ill. 2d 19, 23-24 (2004), but not conclusions unsupported by facts, *Pooh-Bah Enterps., Inc. v. County of Cook*, 232 Ill. 2d 463, 473 (2009). *See also Hanks v. Cotler*, 2011 IL App (1st) 101088, ¶ 17.

I. Medtronic's Section 2-615 Motion to Dismiss

Illinois Code of Civil Procedure section 2-615 allows a party to object to a pleading or portion of a pleading as "substantially insufficient in law[.]" 735 ILCS 5/2-615. A section 2-615 motion to dismiss challenges the legal sufficiency of a complaint based on facially apparent defects. *Marshall v. Burger King Corp.*, 222 Ill. 2d 422, 429 (2006). In reviewing the sufficiency of a complaint, courts accept all well-pleaded facts, and all reasonable inferences drawn from those facts, as true. *Id.* Courts also construe the allegations in the light most favorable to the plaintiff. *Id.* Thus, a court should not dismiss a cause of action unless it is "clearly apparent" that no set of proven facts would entitle recovery. *Id.*

Illinois is a fact-pleading jurisdiction, in which plaintiffs must allege sufficient facts to bring a claim within a legally recognized cause of action. *Id.* at 429-30. Plaintiffs need not prove their case, but rather allege sufficient facts to state all the elements of their causes of action. *Fox v. Seiden*, 382 Ill. App. 3d 288, 294 (1st Dist. 2008). Mere conclusions are insufficient. *Marshall*, 222 Ill. 2d at 430. "A complaint fails to state a cause of action if it does not contain factual allegations in support of each

element of the claim that the plaintiff must prove in order to sustain a judgment." *Grund v. Donegan*, 298 Ill. App. 3d 1034, 1037 (1st Dist. 1998).

The Spies' sole claim against Medtronic—count 26—sounds in negligence. To plead a negligence claim, a plaintiff must establish defendant's duty of care, a breach of that duty, proximate cause, and damages. *See Cangemi v. Advocate South Suburban Hosp.*, 364 Ill. App. 3d 446, 458-59 (1st Dist. 2006). Failure to do so is grounds for dismissal pursuant to Section 2-615.

In their complaint, the Spies have failed to allege that Medtronic owed Kathleen a duty of care. Indeed, nowhere in count 26—"Negligence Against Medtronic"—does the word "duty" appear. As the Spies have failed to allege an essential element of any negligence claim, they have failed to state a claim for which relief can be granted. Medtronic's motion to dismiss count 26 of the plaintiffs' complaint must be granted pursuant to section 2-615, but is without prejudice to replead. This court urges the plaintiffs in amending their complaint to consider Medtronic's other arguments as to pleading insufficiencies.

II. Medtronic's Section 2-619 Motion to Dismiss

A section 2-619 motion to dismiss admits the legal sufficiency of a complaint but raises defects, defenses, or some other affirmative matter appearing on the face or by external submissions that defeats the plaintiff's claim. 735 ILCS 5/2-619. The purpose of a section 2-619 motion to dismiss is to dispose of easily proven factual issues. *Kedzie & 103rd Currency Exch. v. Hodge*, 156 Ill. 2d 112, 115 (1993). When considering a section 2-619 motion, a court must construe all pleadings and supporting matter in the light most favorable to the non-movant. *Doe v. Univ. of Chi. Med. Ctr.*, 2015 IL App (1st) 133735, ¶ 35. Dismissal is appropriate only if no set of provable facts support a cause of action. *Id.*

A. Statute of limitations

Code of Civil Procedure section 2-619 authorizes the involuntary dismissal of a complaint if a plaintiff fails to commence an action within the applicable limitations period. 735 ILCS 5/2-619(a)(5). A section 2-619 motion to dismiss properly raises whether an applicable statute of limitations bars a claim. *Porter v. Decatur Mem. Hosp.*, 227 Ill. 2d 343, 352 (2008). The statute of limitations for a personal injury product liability action is two years from the accrual date. 735 ILCS 5/13-202.

The Illinois legislature has ensured, through section 13-217, that plaintiffs have the option of securing leave to reinstate a dismissed defendant at the time a voluntary dismissal is granted. 735 ILCS 5/13-217. Reinstatement of a case and bringing a defendant back into the lawsuit is authorized only if the court's dismissal order granted leave to reinstate. *See Mozer v. Kerth*, 224 Ill. App. 3d 525, 539 (1st Dist. 1992). Thus, section 13-217 "operates as a savings statute, with the purpose of facilitating the disposition of litigation on the merits and to avoid its frustration upon grounds unrelated to the merits." *S.C. Vaughan Oil Co. v. Caldwell, Troutt & Alexander*, 181 Ill. 2d 489, 497 (1998) (citing *Gendek v. Jehangir*, 119 Ill. 2d 338, 343-44 (1988)). A complaint is considered a refiling under section 13-217 if it contains "the same cause of action" as a previously filed complaint for purposes of *res judicata*. *D'Last Corp v. Ugent*, 288 Ill. App. 3d 216, 220 (1st Dist. 1997). Claims are identical if the parties are the same and the theories of relief arise out of a single core of operative facts. *First Midwest Bk. v. Cobo*, 2017 IL App (1st) 170872, ¶16.

Medtronic argues that the two-year statute of limitations bars the Spies' claim in the 20 L 8663 case. It is uncontested, however, that the Spies' first amended complaint in the 19 L 5409 case alleged Medtronic's intrathecal pain pump placed into Kathleen malfunctioned, causing her injuries and requiring additional surgical procedures. The Spies also previously alleged that Medtronic failed to warn Kathleen of potential malfunctions associated with the pump and injuries could occur from any

malfunction. The operative complaint at the time of the voluntary dismissal is the controlling complaint for purposes of relation back. While the 20 L 8663 complaint contains a more extensive factual background than the first amended complaint in the 19 L 5409 case, the allegations against Medtronic are identical and both complaints contain the same core of operative facts.

On August 15, 2019, this court granted the voluntary dismissal of the 19 L 5409 case and specifically allowed the Spies up to one year to re-file. As August 15, 2020 was a Saturday, the Spies had until Monday, August 17, 2020 to re-file what became the 20 L 8663 case. *See* 5 ILCS 70/1.11. Although this court never recommends filing a complaint on the last day of a statute of limitations, the Spies timely filed the 20 L 8663 case pursuant to section 13-217.

Medtronic also argues it was unaware of the 2019 case. That argument is specious because on May 14, 2019 Medtronic voluntarily executed a tolling agreement with the Spies. The agreement explicitly tolled the deadline for the Spies to file their complaint against Medtronic until September 11, 2019. As provided:

> The parties wish to undertake discussions to reach an amicable resolution of [Kathleen and Alan's] claims. To facilitate this process, the parties agree that all applicable statutes of limitations and/or filing deadlines for the above-referenced claims, including the deadline in which to file a lawsuit in federal or state court, shall be tolled for 120 days, from May 14, 2019 to September 11, 2019.

As a matter of law, "[i]n Illinois, tolling agreements are reviewed 'in accordance with well-established contract principles' with the primary goal of giving effect to the parties' intent." *Gruner v. Huron Consulting Group, Inc.*, 2019 U.S. Dist. LEXIS 134938, at *27-28 (N.D. Ill. Aug. 12, 2019) (quoting *Joyce v. DLA*

Piper Rudnick Gray Cary LLP, 382 Ill. App. 3d 632, 636 (1st Dist. 2008)).

It is indisputable that Medtronic and the Spies intended to toll the statute of limitations and allow the Spies to file a complaint before September 11, 2019. The Spies did just that. Even if Medtronic's current counsel was unaware of the tolling agreement, Medtronic plainly knew of the Spies' pending claims. To punish the Spies because of Medtronic's current attorneys' lack of knowledge would be patently unjust and contrary to the tolling agreement the parties voluntarily executed.

The record shows on August 14, 2019, the Spies filed their first amended complaint in the 19 L 5409 case. On August 17, 2020, the Spies re-filed the 20 L 8663 case, 25 days before the September 11, 2019 filing deadline agreed upon by Medtronic and the Spies in their tolling agreement. In sum, Medtronic's section 2-619 motion to dismiss as untimely count 26 of the Spies' complaint is denied with prejudice.

B. Preemption

Medtronic further argues that the plaintiffs' claim is expressly preempted by federal statute, *see* 21 U.S.C. § 360k(a), and impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) and 21 U.S.C. §337(a). The foundation for Medtronic's argument lies with the medical device amendments (MDA) Congress enacted in 1978 to the Federal Food, Drug and Cosmetics Act (FDCA). 21 U.S.C. § 360c *et seq.* The MDA gave the FDA exclusive authority to regulate medical devices and established a "regime of detailed federal oversight." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Up to that point, states had generally regulated the use of medical devices. *Id.* at 315. Congress adopted the MDA in response to the undue burden imposed by various state regulations. H.R. Rep. No. 94-853, at 45 (1976). The post-MDA statutory and administrative scheme created a comprehensive federal regulatory system for medical devices. *See Riegel,* 552 U.S. at 316-17.

In addition to the extensive regulatory framework provided by the MDA, Congress included an express preemption clause in the statute. That provision states, in part:

> 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(a); *see Riegel*, 552 U.S. at 316 (observing section 360k(a) is an express preemption provision). In addition to the statute's express preemption provision, state causes of action are impliedly preempted under the FDCA "no private right of action" provision. 21 U.S.C. § 337(a). That section directs all actions to enforce the FDCA "shall be made in the name of the United States. . . ." *Buckman*, 531 U.S. at 349 n.4.

Under the MDA, innovative Class III devices "incur the FDA's strictest regulation" and must receive a pre-market approval (PMA) from the FDA before being marketed. *Id.* at 344. Class III devices cover a variety of products, including those that present "a potential unreasonable risk of illness or injury." 21 U.S.C. §360c(a)(1)(C)(ii). Such products include heart valves, cerebella stimulators, and pacemakers. *Riegel*, 552 U.S. at 317. It is undisputed the FDA reviewed Medtronic's intrathecal pain pump (Medtronic SynchroMed II Implantable Drug Infusion Pump) Kathleen received as a Class III product.

Class III approval is a rigorous process. *Riegel*, 552 U.S. at 317. The FDA reviews Class III devices first by determining whether the device may be classified as "substantially equivalent"

to another device exempt from the PMA process. *Id.* (referring to section 510(k) process). If the product is not substantially equivalent, the product must then go through the PMA process. *Id.* at 318. If a product receives a PMA, the manufacturer is prohibited from making any changes in specifications, manufacturing processes, or labeling that would affect the product's safety or effectiveness. *Id.* at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). All Class III products are also subject to extensive reporting requirements. *Id.* (citing 21 U.S.C. § 360i).

It is plain that *Riegel*, through its interpretation of express preemption in section 360k(a), and *Buckman*, through its finding of implied preemption in section 337(a), "create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010); *see also Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013). To avoid preemption, a plaintiff bringing a state common law tort claim must allege the state law duty at issue parallels a federal requirement. *Riegel*, 552 U.S. at 330.

The court in *Riegel* thus established a two-part test for determining if a state law claim is expressly preempted by the MDA: (1) determine if the federal government has established requirements applicable to the medical device; and (2) if so, determine whether the state law claims are based on requirements with respect to the device that are different from, or in addition to, the federal ones, and relate to safety and effectiveness. *Riegel*, 552 U.S. at 321-22; *Raleigh v. Alcon Labs., Inc.*, 403 Ill. App. 3d 863, 873 (1st Dist. 2010). If, for example, a plaintiff can show a medical device manufacturer failed to follow FDA-approved processes and procedures and the plaintiff's injury resulted from those deviations, the plaintiff's claim is parallel and may proceed. *See Bass v. Stryker Corp.*, 669 F.3d 501, 510 (5th Cir. 2012). In contrast, if a plaintiff challenges the suitability of the manufacturer's precise processes or procedures approved by the FDA, such a claim is not parallel and may not proceed. *Id.* at 512.

In this instance, even if this court were to assume the Spies' claim against Medtronic properly alleged a state common law tort, the complaint does not allege a state law duty that parallels a federal requirement. *See Riegel*, 552 U.S. at 330. Also absent are allegations that, if there were a proper state law claim, it would be based on requirements with respect to the device that are different from, or in addition to, the federal ones. The Spies have not, therefore, submitted a state law claim that fits in the narrow gap through which it may escape express or implied preemption.

Medtronic has successfully argued the MDA gives the FDA exclusive authority to regulate medical devices such as the intrathecal pain pump. Yet the paucity of details in the current pleading makes it impossible for this court to find that Spies' claim against Medtronic overcomes the two-part test established in *Riegel*. Medtronic's section 2-619 motion to dismiss count 26 of the plaintiffs' complaint as preempted by the MDA is, therefore, granted, but without prejudice for the Spies to re-plead.

Conclusion

For the reasons presented above, it is ordered that:

1. Medtronic's section 2-615 motion to dismiss count 26 as to duty is granted without prejudice;
2. Medtronic's section 2-619 motion to dismiss count 26 as untimely is denied with prejudice;
3. Medtronic's section 2-619 motion to dismiss count 26 as preempted by the MDA is granted without prejudice; and
4. The Spies have until January 29, 2021 to file an amended complaint.

Judge John H. Ehrlich

DEC 28 2020

Circuit Court 2075

John H. Ehrlich, Circuit Court Judge