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NOT TO BE PUBLISHED IN THE OFFICIAL REPORTS

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION ONE

GRAYSON REED, Plaintiff and Appellant, v. MEDTRONIC, INC., Defendant and Respondent.	B245625 (Los Angeles County Super. Ct. No. SC116173)

APPEAL from a judgment of the Superior Court of Los Angeles County, Gerald Rosenberg, Judge. Reversed.

Hodes, Milman, Liebeck, Mosier, Daniel M. Hodes, Kevin Liebeck; Kenneth M. Sigelman and Associates, Kenneth M. Sigelman; Boudreau Williams and Jon R. Williams for Plaintiff and Appellant.

Reed Smith, Michael K. Brown, Lisa M. Baird, Mildred Segura and Kasey J. Curtis for Defendant and Appellant.

Grayson Reed appeals from a judgment entered in favor of Medtronic, Inc. after the trial court denied his motion for leave to file a second amended complaint, based on a failure to allege a permissible state law claim due to federal preemption. Reviewing de novo, we conclude the trial court erred in concluding that Reed failed to allege a permissible state law claim, and we reverse.

BACKGROUND

In February 2011, Reed filed suit in Alameda County Superior Court against Medtronic, Kevin Shannon, M.D., and The Regents of the University of California (the Regents). The initial complaint asserted medical negligence against the Regents and their employees and three causes of action against Medtronic related to Medtronic's manufacture and sale of an implantable cardiac defibrillator (the Secura ICD), which had been implanted in Reed during his 2009 surgery at UCLA Medical Center. In June, Reed amended the complaint, again asserting medical negligence against the Regents but altering the scope of his claim to assert a single cause of action against Medtronic, alleging that his Secura ICD contained a defect in the software that controlled its operation. Medtronic answered the amended complaint asserting federal preemption as an affirmative defense, among others.

In October 2011, Medtronic filed a motion for summary judgment, claiming that federal law preempted the claim for negligent manufacture. On December 5, 2011, Reed opposed the motion for summary judgment and requested a continuance under Code of Civil Procedure section 437c, subdivision (h). Reed argued that a continuance was needed to obtain necessary discovery related to the unresolved nature of the ICD's apparent failure, as it related to both Reed's negligent manufacture claim against Medtronic and Reed's medical negligence claim against the Regents.

On December 12, 2011, the trial court granted the Regents' unopposed motion to change venue and transferred the case to Los Angeles Superior Court. Following the transfer, Medtronic renoticed its motion for summary judgment on March 9, 2012, moving the hearing which had been scheduled for December 20, 2011 to July 10, 2012.

On June 22, 2012, Reed filed two motions. The first was a motion for leave to amend, with an attached declaration from Reed's counsel stating that he had received essential data from Reed's Secura ICD only eleven days earlier. The second motion opposed summary judgment on the basis of mootness, arguing that since Reed sought to amend his complaint to allege a different cause of action, the summary judgment motion was moot.

In the proposed second amended complaint submitted with the motion for leave to amend, Reed asserted a single cause of action: negligence against all defendants. The proposed complaint alleged that on October 23, 2009, Reed underwent surgery at UCLA Medical Center, where Dr. Shannon implanted in Reed a Secura DR implantable cardioverter-defibrillator model #D224DRG (the Secura ICD). Medtronic manufactured and supplied the Secura ICD. Medtronic held itself out as possessing the knowledge, training and skill necessary to instruct others in and/or determine the appropriate programming of the Secura ICD before Reed's 2009 surgery. ICD programming includes, but is not limited to, setting operating parameters, detection criteria, and therapeutic intervention modalities and thresholds for the specific patient. Medtronic "employed and made available in the field its employees to program and/or advise, instruct, and assist physicians in the programming" of the Secura ICD, and thus had a duty to Reed to exercise the degree of care necessary to correctly program the device to function as intended. Reed alleged that Medtronic failed to exercise the necessary degree of care, and as a result of the negligence of all the defendants, on November 16, 2009, Reed sustained serious injuries.

A hearing on Reed's motion for leave to amend was set for October 4, 2012. On July 10, 2012, before the hearing on Reed's motion for leave to amend, the trial court granted Medtronic's motion for summary judgment on the first amended complaint. During the summary judgment hearing, Reed's counsel stated that Reed no longer intended to pursue a claim for negligent manufacture, and asserted that the motion for leave to amend was to "bring in a general negligence claim against Medtronic on behalf of the conduct of its employee." In response, the trial court acknowledged "that's

separate," and made clear that it was ruling solely on the operative complaint: "I'll get to [the motion for leave to amend] when it comes up for hearing. I'm just staying with this. I've got an operative complaint. [Medtronic has] made a motion for summary judgment. I am going to grant it. [¶] . . . [¶] I have not even read [Reed's] motion yet." The court granted summary judgment in favor of Medtronic, stating that Reed's "claim for negligent manufacture is federally preempted and barred."

On October 4, 2012, the trial court conducted a hearing on Reed's motion for leave to amend. The court heard arguments regarding the scope of federal preemption, whether there was a legal basis for holding Medtronic liable, and Medtronic's claim that Reed had engaged in undue delay in moving for leave to amend. The trial court indicated, based on the grant of summary judgment, that "we're dealing in an area that has been preempted by federal law." Following the hearing, the trial court adopted its tentative ruling and denied Reed's motion for leave to amend on the grounds that the second amended complaint "fails to allege a permissible state law claim." The trial court held that since Reed "fail[ed] to allege that the programming of the device is not part of a products claim . . . the claim for improper programming may be preempted [and] is barred by *Riegel v. Medtronic, Inc*. (2008) 552 US 312, 315."

Medtronic served Notice of Entry of Judgment. Reed followed that notice with a timely appeal.

DISCUSSION

Reed's sole contention on appeal is that the trial court erred in denying the motion for leave to amend. We agree.

As a preliminary matter, this appeal arises from an unusual procedural situation. The trial court ruled on Medtronic's motion for summary judgment while Reed's motion to amend was still pending. Reed filed an ex parte application to modify the summary judgment to summary adjudication or in the alternative to stay entry of the judgment until the motion for leave to amend was decided. The trial court declined to modify the judgment, but "indicat[ed] that the judgment [would] not be signed pending the hearing on October 4, 2012 [on Reed's motion for leave to amend]." However, on September 28,

2012, the trial court signed the proposed judgment submitted by Medtronic. Medtronic served notice of entry of judgment based on the erroneously entered September 28 judgment. Reed submitted his notice of appeal in response. Ultimately the trial court corrected the error, ordering nunc pro tunc that its judgment, entered September 28, 2012, would be dated instead October 5, 2012. The trial court ordered that Medtronic's notice of entry of judgment did not need to be re-served. Reed appeals only the trial court's decision to deny Reed's motion for leave to amend.

A trial court's decision to deny a motion for leave to amend is typically reviewed for abuse of discretion. (*Levy v. Skywalker Sound* (2003) 108 Cal.App.4th 753, 770.) However, the legal sufficiency of a proposed amended complaint is a question of law reviewed de novo. (*McCall v. PacifiCare of California, Inc.* (2001) 25 Cal.4th 412, 415.) Additionally, preemption is a legal issue involving statutory construction and the ascertainment of legislative intent, which we also review de novo. (*Bravo Vending v. City of Rancho Mirage* (1993) 16 Cal.App.4th 383, 391–392.) Therefore, where, as here, the trial court denies a motion for leave to amend on the grounds that the proposed amended complaint failed to allege a permissible state law claim due to federal preemption, this court reviews the decision *de novo*. (*Washington Mutual Bank v. Superior Court* (2002) 95 Cal.App.4th 606, 612; *Stengel v. Medtronic, Inc.* (9th Cir. 2013) 704 F.3d 1224, 1227 (*Stengel*).)

Additionally, we must accept as true all facts that may be implied or inferred from those expressly alleged in the proposed amended complaint. (*Traders Sports, Inc. v. City of San Leandro* (2001) 93 Cal.App.4th 37, 43)

I. Federal Preemption under the MDA and *Riegel*

The Medical Device Amendments of 1976 (MDA) (21 U.S.C. § 360c et seq.) amended the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.). According to the statute's preamble, Congress enacted the MDA "'to provide for the safety and effectiveness of medical devices intended for human use.'" (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 474 [116 S.Ct. 2240, 135 L.Ed.2d 700 (*Lohr*).) The MDA established three classifications of medical devices: Class I, Class II, and Class III. The

classifications are based on the risk the device poses to the public; the higher the risk the more extensive the oversight. Class III devices, like the ICD at issue here, receive the most federal oversight and require premarket approval by the FDA. (*Riegel v. Medtronic, Inc.*, *supra*, 552 U.S. at pp. 315–319 [128 S.Ct. 999, 169 L.Ed.2d 892] (*Riegel*).)

The MDA includes an explicit preemption provision, stating in relevant part: "[N]o 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), italics added.) The United States Supreme Court has considered the scope of this preemption provision in three cases. (*Lohr*, *supra*, 518 U.S. 470; *Riegel*, *supra*, 552 U.S. 312; *Buckman Co. v. Plaintiffs' Legal Comm.* (2001) 531 U.S. 341 [121 S.Ct. 1012, 148 L.Ed.2d 854] (*Buckman*).)

In the most recent case, the United States Supreme Court set out a two-part test to determine whether a state law cause of action related to a medical device is preempted by the MDA. (*Riegel*, *supra*, 552 U.S. at pp. 321–323.) First, the court must determine "whether the Federal Government has established requirements applicable to [the device]." (*Id.* at p. 321.) If so, second, the court must determine whether the "common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." (*Id.* at pp. 321–322.) This two-part test has been recognized in California courts. (See *McGuan v. Endovascular Technologies, Inc.* (2010) 182 Cal.App.4th 974, 982.)

In *Riegel*, *supra*, 552 U.S. 312, the plaintiffs alleged that the defendant's catheter, a Class III device, was "designed, labeled, and manufactured in a manner that violated" state common law, and that these defects caused severe injuries. (*Id*. at p. 320.) Applying the test, the court first determined that "[p]remarket approval . . . imposes 'requirements' under the MDA." (*Id*. at p. 322.) After determining that the federal

government had established requirements applicable to the catheter, the Supreme Court turned to the second part of the test, which examines the state requirements. As a preliminary matter, the court determined that "[s]afety and effectiveness are the very subjects of the plaintiffs' common-law claims [that the device was designed, labeled and manufactured in violation of New York law]." (*Id*. at p. 323.) Next, the court examined whether the New York law at issue imposed a "requirement with respect to the device." The court determined that state common law legal duties are "requirements" under the MDA. (*Id.* at pp. 323–324.) The court concluded that New York's general tort duties regarding design, manufacture and labeling were requirements "'with respect to'" the catheter. (*Id*. at p. 328.) Finally, the Supreme Court addressed whether the requirements were "different from, or in addition to the federal ones." (*Ibid*.) The court reasoned that title 21 United States Code section 360k does *not* preempt claims based on state duties that are "'parallel'" to federal requirements. (*Id.* at p. 330.) A claim is parallel if it is premised on a violation of FDA regulations, since it does not "add to" the requirements imposed on the device. (*Id.* at p. 330.) The court relied on the district court's interpretation that the plaintiffs' claims asserted that the catheter violated state tort law notwithstanding compliance with the relevant federal requirements, and were therefore *not* parallel. (*Ibid*.) The court affirmed the court of appeals' conclusion that the state requirements were preempted. (*Ibid.*)

II. Application of the *Riegel* Test for Federal Preemption under the MDA

First, this court must determine whether the federal government has established requirements applicable to the device. The Secura ICD is a Class III device under the MDA, subject to premarket approval. The Supreme Court has instructed that premarket approval constitutes a requirement. (*Riegel*, *supra*, 552 U.S. at p. 322.) Furthermore, Reed has conceded that the federal government has established requirements applicable to the Secura ICD. Therefore, the critical inquiry in this case is whether Reed's negligence claim is based on California state law requirements preempted by the MDA.

Under the second part of the *Riegel* test, courts must determine whether the claim is based on "[1] requirements with respect to the device that are [2] 'different from, or in

addition to' the federal ones, *and* [3] that relate to safety and effectiveness." (*Riegel, supra*, 552 U.S. at p. 322, italics added.) We conclude that Reed's negligence claim in the Second Amended Complaint—incorrect programming by a Medtronic employee in the field—is not preempted. The claim asserts common law tort duties which are requirements different from, or in addition to the federal requirements. However, Reed's negligence claim is not based on California law that imposes requirements with respect to the device and the requirements do not relate to safety and effectiveness.

A. Requirements with respect to a device

Reed's negligence claim against Medtronic does not impose requirements *with respect to a device*. The Supreme Court has recognized that state law duties constitute requirements. (*Riegel, supra*, 552 U.S. at pp. 324–325.) However, the fact that a state law duty is a requirement is not sufficient to satisfy the *Riegel* test. The requirement must be *with respect to a device*. Here the duty of care alleged in the second amended complaint is a requirement with respect to the actions of an individual employed by Medtronic, not a duty with respect to design, manufacture, or labeling of a device—as was the case in *Riegel*.

Medtronic argues that the preemption clause of the MDA should be interpreted more broadly, applying to duties imposed on device manufacturers. According to Medtronic's interpretation, "if a common law claim would impose a duty *on a device manufacturer* that is 'different from, or in addition to' those imposed by the FDA in granting premarket approval of a device, the claim is preempted . . . ." (Italics added.) This is a misinterpretation of the scope of the MDA's preemption clause, which Medtronic previously raised before the United States Supreme Court, where it was rejected. In *Lohr*, the Supreme Court stated that "[Medtronic] argues that the plain language of the statute pre-empts any and all common-law claims brought by an injured plaintiff against a manufacturer of medical devices. [¶] Medtronic's argument is not only unpersuasive, it is implausible." (*Lohr, supra*, 518 U.S. at pp. 486–487 [part IV of the plurality opinion, four justices concurring].)

Thus, in determining whether a state law claim is preempted the focus is on requirements applicable *to the device*, not duties imposed *on a device manufacturer*.

B. Safety and Effectiveness

Reed argues that the negligence claim did not seek to challenge the safety and effectiveness of the ICD. Reed argues that since there is "no assertion 'challenging the safety and effectiveness of a medical device'" the claim is necessarily not preempted. We agree.

Unlike the claims in *Riegel*, *supra*, 552 U.S. 312, the safety and effectiveness of the device is not the crux of Reed's proposed negligence claim. In *Riegel*, the plaintiff had claimed that the device was designed, labeled, and manufactured in a way that violated state law. (*Id*. at p. 320.) The Supreme Court noted that "[s]afety and effectiveness are the very subjects of [these claims]." (*Id.* at p. 323.) In contrast, Reed's proposed second amended complaint did *not* allege any fault in the ICD as designed, manufactured, or labeled by Medtronic. Reed argues that the proposed second amended complaint only "sought to hold Medtronic vicariously liable for the conduct of one of its employees . . . ." Reed alleged in the proposed second amended complaint that Medtronic's product representative either negligently provided technical assistance to Reed's physicians in the programming of the ICD or in "advising, instructing or assisting" the physician in programming the device. While the product representative's alleged negligence may have prevented the ICD from functioning safely and effectively after it was implanted in Reed, safety and effectiveness are not "the very subjects" of Reed's proposed complaint. The subject of Reed's proposed complaint is the negligent action of a Medtronic employee, not the safety or effectiveness of the ICD.

Medtronic argues that Reed's negligence claim imposes requirements relating to the safety and effectiveness of the ICD, imposing a duty on Medtronic to ensure that physicians program ICD's properly. However, Medtronic mischaracterizes Reed's complaint. Reed's proposed negligence claim does *not* allege that Medtronic has a duty to ensure that physicians properly use and program ICD's. Reed merely alleges that Medtronic's employee improperly programmed or aided in programming the device. In

arguing otherwise, Medtronic appears to rely on Reed's argument that a claim of negligent programming parallels the federal requirement that ICD's must be programmed within acceptable parameters in order to meet premarket approval. It is true that, as a Class III medical device, Medtronic's ICD must be properly programmed within acceptable parameters in order to function as intended and as approved by the FDA. This does not mean, however, that any claim related to a subsequent act of programming a device—for instance, the setting of a device's operating parameters for an individual patient—is related to the safety and effectiveness of that device.

C. Different from, or in addition to the federal requirements

Reed argues that the proposed negligence claim does not impose requirements that are "'different from, or in addition to'" federal requirements, but "'parallel'" those instead. We disagree.

A claim is parallel if it is premised on a violation of FDA regulations. (*Riegel*, *supra*, 552 U.S. at p. 330.) Reed argues that the claim asserting that Medtronic's employee did not exercise due care when entering the programming values into the ICD is "parallel" to the premarket approvals by the FDA that require Medtronic's ICD be programmed within acceptable parameters in order to function as intended. This argument is not persuasive. Reed's argument conflates requirements placed by the FDA on the device's underlying software with the specific act of entering the individualized settings for a particular patient.

Reed argues that Reed's proposed negligence claim is like the general negligence claim alleged in *Stengel*, *supra*, 704 F.3d 1224, as it too seeks to impose a general duty of reasonable care and prudence under state law to prevent causing harm to others. (*Id*. at pp. 1232–1234.) However, as Medtronic argues, *Stengel* is distinguishable because it dealt with a situation where the plaintiff was able to identify a *specific federal requirement* that the manufacturer had allegedly violated. (*Id.* at p. 1233.)

III. Implied Preemption under the MDA and *Buckman*

Medtronic argues that even if Reed's proposed claim is not expressly preempted under *Riegel*, *supra*, 552 U.S. 312, it is impliedly preempted under *Buckman*, *supra*, 531

U.S. 341. In *Buckman*, the plaintiffs suffered injuries related to the implantation of orthopedic bone screws in their spines. (*Buckman*, at p. 343.) The bone screws were Class III medical devices under the MDA. The plaintiffs brought state tort law claims alleging that the bone screw manufacturer made fraudulent representations to the FDA in obtaining approval to market the screws, and that they would not have been injured if these representations had not been made. (*Ibid.*) The Supreme Court held that the state law fraud-on-the-FDA claims conflicted with, and thus, were impliedly preempted by federal law. (*Id.* at p. 348.) The court based this conclusion on the principle that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." (*Id.* at p. 347.)

Medtronic argues that Reed's claim is premised upon allegations that Medtronic violated the terms of its premarket approval by failing to ensure that Dr. Shannon properly programmed the ICD, and is therefore in preempted by *Buckman*, *supra*, 531 U.S. 341. Medtronic's argument fails for three reasons. First, Medtronic mischaracterizes Reed's claim. Reed alleges that Medtronic's employee negligently programmed the ICD. Reed does not allege any violation of the FDA premarket approval. Second, Medtronic's argument fails to recognize the gap between express preemption under *Riegel*, *supra*, 552 U.S. 312 and implied preemption under *Buckman*. "[T]he plaintiff 'must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).'" (*Eidson v. Medtronic, Inc.* (N.D.Cal. Oct. 3, 2013) 13-CV-02049-LHK, 2013 WL 5533081, *7.) Here, Reed's claim that Medtronic's employee negligently programmed or assisted in programming the ICD is not premised on a violation of the FDCA. Third, Medtronic's argument for implied preemption fails to recognize that the "parallel" requirement is only one component of the *Riegel* test. It is possible, as here, for a claim *not* to be parallel and still fall outside of the MDA's preemption provision because it does not impose

requirements on the device related to safety and effectiveness. Therefore, Reed's proposed claim is not impliedly preempted under *Buckman*.

IV. Legal Duty of Device Manufacturer

Medtronic argues that Reed failed to state a viable negligence claim. "[T]he existence of a duty to use due care" is a "threshold element" of negligence. (*Artiglio v. Corning Inc.* (1998) 18 Cal.4th 604, 614.) Medtronic argues that Medtronic did not owe Reed a duty of care to ensure the ICD was programmed correctly. Medtronic's argument is two-fold. First, Medtronic argues that device manufacturers do not owe a duty of care to patients. Second, Medtronic argues that Reed's surgeon, and only Reed's surgeon, owed a legal duty of care to ensure that the ICD was programmed correctly. Medtronic is incorrect on both points.

First, Medtronic relies on *Smith v. St. Jude Medical, Inc.* (2013) 217 Cal.App.4th 313 (*Smith*) to argue that California courts have rejected attempts to impose liability on medical device manufacturers. Medtronic's reliance on *Smith* is misplaced. *Smith* merely held that a duty of care did not exist under the specific facts at issue in that case, affirming the trial court's holding that the medical device manufacturer's employee "did not owe [the plaintiff] a duty of care 'with respect to the acts or omissions that allegedly caused her injury and death.'" (*Id.* at p. 314.) *Smith* does not foreclose the possibility that a device manufacturer may owe a duty of care to the patient as a matter of law, as is at issue in this case.

In *Smith*, *supra*, 217 Cal.App.4th 313, the First District of the California Court of Appeal addressed the question of whether there was a triable issue of material fact regarding whether a device manufacturer had a duty under a "negligent undertaking" theory of liability. (*Id.* at p. 323.) The court acknowledged that while the existence of an actionable duty of care stemming from an "'"undertaking"'" is a question of law, "'[i]n some cases . . . there may be fact questions "about precisely what it was the defendant undertook to do."'" (*Ibid.*, citing *Artiglio v. Corning Inc.*, *supra*, 18 Cal.4th at p. 615 ["if the record can support competing inferences [citation], or if the facts are not yet sufficiently developed [citation], "'an ultimate finding on the existence of a duty cannot

be made prior to a hearing on the merits'" [citation], and summary judgment is precluded"].) Ultimately, the court in *Smith* affirmed the trial court's grant of summary judgment based on the finding that the "defendants satisfied their burden 'of showing that Plaintiffs lack evidence to establish that Defendants had a duty of care . . . [and] that Plaintiffs lack evidence that any acts or omissions by [the product representative] breached his duty of care under the circumstances.'" (*Smith*, at p. 319.) Notably, the court did *not* reject the attempt to impose liability on the basis of a legal insufficiency of the claim. Instead, the court held that under the specific facts presented in that case the product representative did not owe a duty of care to the patient.

The facts in *Smith*, *supra*, 217 Cal.App.4th 313 are distinguishable from the facts alleged in Reed's amended complaint. The injury in *Smith* stemmed from the alleged negligent implantation of a pacemaker's lead. A sales representative for a medical device supplier was present during the surgical implantation of the pacemaker. However, the representative did not implant the leads, nor did he direct or instruct the surgeon how or where to implant them. According to the defendants in *Smith*, the representative was added as a doe defendant "'solely because [the representative] was in the operating room during [the patient's] surgery.'" (*Id*. at p. 316.) In contrast, Reed alleges that the Medtronic representative was an active participant, and his injury was allegedly caused by the employee's negligent programming of the specific ICD implanted in Reed. Reed alleges that Medtronic made available its employees to program ICD's. Reed also alleges that the Medtronic product representative "failed to exercise the degree of care necessary to ensure that the device was correctly programmed and would function as intended." Finally, Reed alleges that as a direct and proximate cause of this failure he sustained serious and severe injury. These allegations, which we take as true, support the existence of a duty of care under the Restatement (Second) of Tort's test for negligent undertakings[1] and for respondeat superior. The Medtronic employee rendered services to

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[1] "One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his

Dr. Shannon which the employee should recognize as necessary for the protection of a third person, since the ICD directly protected Reed's health. The incorrect values entered into the ICD increased the risk of harm to Reed. Therefore, based on the allegations in Reed's second amended complaint, Medtronic owed a duty of care to Reed under the doctrines of negligent undertaking and respondeat superior.

Second, Medtronic argues that imposing a legal duty on device manufacturers is nonsensical and unnecessary because physicians already bear the responsibility for programming the medical devices. Medtronic argues that a physician is the "captain of the ship," owes his or her patients nondelegable duties regarding patient care, and since physicians have a nondelegable duty they are the sole party responsible for negligence in the surgical theater. Medtronic relies on *Baumgardner v. Yusuf* (2006) 144 Cal.App.4th 1381 (*Baumgardner*) for this proposition. Medtronic's reliance is misplaced. The court in *Baumgardner* held that the trial court committed prejudicial error when it failed to instruct the jury that the defendant surgeon had a nondelegable duty: "'[I]t is the law in California that the surgeon's duty to remove all sponges and other foreign objects from the patient's body is nondelegable.'" (*Id.* at p. 1393.) The court in *Baumgardner* did *not* hold that the surgeon's nondelegable duty absolved other parties of a duty of care to the patient. Reed argues that even if the doctor cannot disclaim his own liability, Medtronic also remains liable if its product representative performed the task. We agree. The court in *Baumgardner* relied on *Truhitte v. French Hospital* (1982) 128 Cal.App.3d 332 (*Truhitte*) for the "captain of the ship" doctrine. In *Truhitte*, the trial court held the defendant surgeon solely liable for leaving a sponge in the patient after an operation. The appellate court reversed. The appellate court concluded that, while the surgeon had a nondelegable duty, "it does not follow that the hospital may escape liability for its

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things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if [¶] (a) his failure to exercise reasonable care increases the risk of such harm, or [¶] (b) he has undertaken to perform a duty owed by the other to the third person, or [¶] (c) the harm is suffered because of reliance of the other or the third person upon the undertaking." (Restatement (Second) of Torts § 324A (1965).)

independent negligence . . . ." (*Id.* at p. 349.) Thus, even where a surgeon is liable on a "captain of the ship" theory, other parties are not necessarily absolved of all liability. The existence of a physician's nondelegable duty to a patient does not necessarily mean that no other parties owe a duty of care to the patient as well.

V. Undue Delay

Medtronic argues that the trial court did not err in denying the motion for leave to amend because Reed had committed unjustifiable delay, and the proposed amendment constituted an "impermissible shift in the theory of the case." California courts have held that delay alone can be a valid reason for denying a motion to amend. (*Huff v. Wilkins* (2006) 138 Cal.App.4th 732, 746; see also *Leader v. Health Industries of America, Inc.* (2001) 89 Cal.App.4th 603, 613.) California courts have also held that it is "patently unfair to allow [a plaintiff] to defeat [a] summary judgment motion by allowing [him or her] to present a 'moving target' unbounded by the pleadings." (*Melican v. Regents of University of California* (2007) 151 Cal.App.4th 168, 176.)

The trial court, however, did not exercise its discretion to find undue delay or a "moving target." Federal preemption and failure to state a permissible state law claim were the sole grounds for denying leave to amend.

Medtronic argues that the trial court "cited [Reed's delay] as one of the bases for its ruling." Medtronic mischaracterizes the record. Prior to the hearing, the trial court issued a tentative ruling denying Reed's motion for leave to amend based on federal preemption and failure to state a permissible state law claim. During the hearing on Reed's motion for leave to amend, Medtronic raised the issue of Reed's delay as a ground for denying the motion. Reed's counsel argued (consistent with his declaration) that Reed received the data showing that the device "had actually functioned correctly but had been programmed incorrectly" not long before filing the motion for leave to amend. The trial court acknowledged that Reed's delay was "certainly a point in this case" and questioned whether Reed had a "good reason" for the delay. Following the hearing, the trial court clearly chose *not* to deny the motion based on delay, adopting its tentative ruling without modification and denying leave to amend on preemption grounds. The

trial court exercised its discretion in deciding not to deny on the basis of delay, and we see no abuse of that discretion.

DISPOSITION

The judgment is reversed. Grayson Reed is to recover his costs on appeal.

NOT TO BE PUBLISHED.

JOHNSON, J.

We concur:

ROTHSCHILD, Acting P. J.

MILLER, J.*

* Judge of the Los Angeles Superior Court, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.