[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

FILED
U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
MARCH 8, 2011
JOHN LEY
CLERK

No. 09-14342

D. C. Docket No. 08-00151-CV-T-17-TBM

LINDA WOLICKI-GABLES,
ROBERT GABLES,
her husband,

Plaintiffs-Appellants,

ARROW INTERNATIONAL, INC.,
CODMAN & SHURTLEFF, INC.,
JOHNSON & JOHNSON,
GREG NELSON,

Defendants-Appellees.

Appeal from the United States District Court
for the Middle District of Florida

(March 8, 2011)

Before EDMONDSON, HILL and ALARCÓN,[*] Circuit Judges.

ALARCÓN, Circuit Judge:

Robert Gables and Linda Wolicki-Gables appeal from the District Court's grant of summary judgment in favor of Arrow International ("Arrow"), Codman & Shurtleff ("Codman"), Johnson & Johnson, and Greg Nelson (collectively "Appellees"). The Gableses contend that the state law claims they brought against Appellees are not preempted by the Medical Device Amendments of 1976 ("MDA"). The Gableses also assert that the District Court erred in determining that she was not entitled to a presumption that the catheter connector for the Arrow pump implanted in Linda Wolicki-Gables was defective because it was destroyed by the manufacturer. We affirm because we conclude that the Gableses' claims are preempted, and the District Court did not err in determining that they were not entitled to a presumption that the catheter connector was defective.

I

A

During much of the 1990s, Linda Wolicki-Gables ("Wolicki-Gables") endured pain and physical limitations from two back injuries. On Apri1 30, 2002, Brian James, Wolicki-Gables's doctor, implanted an Arrow pump system in her

[*]Honorable Arthur L. Alarcón, United States Circuit Judge for the Ninth Circuit, sitting by designation

back to manage her pain. This pump system works by allowing the continuous delivery of pain medication into the intraspinal space to eliminate the peaks and valleys often experienced with traditional oral drug therapy. It also allows the doctor to inject a separate bolus (a single, large quantity) of medication directly into the intraspinal space. The system includes three components: a pump that releases pain medication, an intrathecal catheter through which the medicine is delivered into the spinal canal, and a metal connector that links the pump catheter to the intrathecal catheter. As with all inherently risky "Class III" medical devices on the market, the pump system had been approved by the Food and Drug Administration ("FDA") in a process called "premarket approval." 21 U.S.C. § 360c(a)(1)(C)(ii)(II).[1]

Venture Medical Devices, founded by Greg Nelson, distributed the pump for Arrow. In 2002, Codman, a subsidiary of Johnson & Johnson, acquired Arrow's pump division and assumed the distribution contract between Arrow and Venture. Nelson became a Codman employee in July 2003. In August 2002, at

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[1]Section 360c(a)(1)(C)(i-ii) of volume 21 of the United States Code reads as follows:

> [A Class III device is a] device which because it cannot be classified [under a less stringent classification], and is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury, is to be subject . . . to premarket approval to provide reasonable assurance of its safety and effectiveness.

Wolicki-Gables's request, Dr. James performed a dye injection test to assess whether the Arrow pump was working properly. Dr. James observed the dye spreading appropriately in the intraspinal space and saw no leaks in the system. On July 10, 2003, Dr. James performed a second test and found that the dye was not spreading appropriately. He hypothesized that the bolus feature of the pump was malfunctioning.

On July 15, 2003, Dr. James removed the Arrow pump, cut the pump catheter, and tested the bolus feature of the pump, which operated properly. Dr. James then removed the connector and sent a bolus through the intrathecal catheter, confirming that it too was functioning correctly. Having found nothing wrong, Dr. James replaced the connector between the pump and intrathecal catheters and reimplanted the pump into Wolicki-Gables. Nelson, who was present during the procedure, provided Dr. James with the new connector. Dr. James concluded in his postoperative report that the catheter "obviously had crimped."

Mr. Gables testified that Nelson approached him after the surgery and said he would return the catheter connector removed from Wolicki-Gables's back to the manufacturer. Mr. Gables also testified that Nelson later told him that the manufacturer had destroyed the catheter connector.

On July 29, 2003, Wolicki-Gables was taken to the hospital complaining of paralysis in her legs. After undergoing extensive testing, she was discharged with a diagnosis of transverse myelitis, the irritation or inflammation of the spinal cord. The neurologist who treated Wolicki-Gables during her hospitalization noted that there was no evidence of infection.

After she left the hospital, Wolicki-Gables entered HealthSouth, a rehabilitation facility. A few days later, HealthSouth noticed a purulent discharge around Walicki-Gables's incision site and transferred her back to the hospital. Dr. Raymon Priewe removed the entire pump system. Dr. Priewe's postoperative note stated that there was "no pus in pump pocket or dorsal spine, only superficial skin." Aside from a "superficial" infection at the incision site, the only other sign of bacteria was found in a culture taken from the incision site. Wolicki-Gables was discharged nine days after her readmission to the hospital with a diagnosis of suspected transverse myelitis. She has since lost her ability to walk and has become a partial paraplegic.

B

On July 24, 2007, the Gableses filed an action in the Florida State Circuit Court in Sarasota County alleging state law claims for product liability, negligence, vicarious liability, and loss of consortium against the Appellees. On

January 22, 2008, Codman and Johnson & Johnson filed a notice of removal to the Middle District of Florida based on diversity jurisdiction pursuant to 28 U.S.C. § 1332. Arrow and Nelson consented to the removal. The Gableses filed an amended complaint in the District Court on July 7, 2008. They alleged seventeen counts against the Appellees.

On July 24, 2008, Appellees filed two separate motions to dismiss the action pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. On December 10, 2008, the District Court granted in part and denied in part Appellees' motions. It dismissed three of the Gableses' negligence claims for failure to state a claim upon which relief can be granted. On March 12, 2009, the parties stipulated to the dismissal of a claim for vicarious liability as to Arrow and Nelson, and a claim for loss of consortium.

On March 12, 2009, Arrow filed a motion for summary judgment. It asserted that the Gableses' twelve remaining claims were preempted by the MDA. On March 12, 2010, Codman, Johnson & Johnson and Nelson filed their own motions for summary judgment and partial summary judgment and, on March 13, 2010, joined Arrow's motion for summary judgment.

The Gableses opposed the motions, arguing that the District Court should apply a presumption against preemption because Nelson participated in "off label"

use of the Arrow pump and its parts, which constitutes "performing a procedure for which there was no provision within the Instructions for Use." (Plaintiff's Response to Defendants' Motion for Summary Judgment at 16-17.) They asserted that Nelson should have advised Dr. James against replacement of only the catheter connector and should have recommended replacement of the entire pump. They also maintained that Nelson's failure to do so constituted violation of the PMA requirements for the pain pump. Further, the Gableses contended that the District Court should grant them a presumption that the destroyed catheter connector was defective.

The Gableses also moved for partial summary judgment based on their assertion that Codman, Johnson & Johnson, and Nelson were distributors of the Arrow pump.

In its July 22, 2009 order, *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270 (M.D. Fla. 2009), the District Court determined that each claim was "expressly preempted"[1] or was "derivative of"[2] a preempted claim. The District Court also articulated three alternative bases on which Appellees were entitled to summary judgment on several of the claims. As to the strict liability and negligence claims against Arrow, Codman and Johnson & Johnson, the District

[1] *Id.* at 1285, 1286, 1288, 1290, 1295, 1296.

[2] *Id.* at 1288, 1290, 1291, 1296.

Court stated that there was insufficient evidence to support the claims. Further, the District Court determined that there was no evidence that Nelson acted negligently or that he caused any injury to the Gableses. The District Court also concluded that there was no evidence to support an agency relationship between Nelson and Codman or Johnson & Johnson and that "undisputed record evidence further establishes that Defendant Arrow International, Inc. designed, manufactured, tested and sold the pump and catheter kit medical devices." (*Id.* at 1290.)

The Gableses have timely appealed. This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

II

The Gableses contend that the District Court erred in concluding that their state law claims are preempted. They argue that their claims survive preemption because they are parallel claims. The Gableses also assert that, because the manufacturer destroyed the catheter connecter, they are entitled to a presumption that the connector was not manufactured or designed in accordance with FDA regulations. They rely on *Cassisi v. Maytag*, 396 So.2d 1140 (Fla. Dist. Ct. App. 1981) for the presumption that "evidence of the nature of the accident itself may, under certain circumstances, give rise to a reasonable inference that the product

was defective . . . ." *Id.* at 1146. The Gableses rely on this alleged presumption, maintaining that they have presented a parallel claim because "the device was not designed or manufactured according to the pre-market approval or it would not have failed." (Appellants' Opening Br. at 18.)

We review a District Court's summary judgment ruling *de novo*. *Brooks v. Cnty. Comm'n of Jefferson Cnty.,* 446 F.3d 1160, 1161 (11th Cir. 2006). Summary judgment is appropriate where "there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c) (2).

A

"[T]he MDA expressly pre-empts only state requirements different from, or in addition to, any requirement applicable . . . to the device under federal law, § 360k(a)(1) . . . ." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321 (2008) (internal quotation marks omitted). Section 360k(a) reads as follows:

> 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).

In *Riegel*, the Supreme Court held that the MDA preemption clause does not apply to a parallel claim. *Id.* at 330. The Court defined a parallel claim as follows:

> State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements.

Id. (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

The Seventh Circuit explained the parallel claim principle as follows:

> In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show 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.

McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005), citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005).

The Supreme Court established a two-pronged test in *Riegel* for deciding whether state claims are preempted. First, a court must "determine whether the

Federal Government has established requirements applicable [to the device]." If so, "[the court] must then determine whether the [plaintiff's] common-law claims are based upon [state law] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Riegel*, 552 U.S. at 321-22 (citing § 360K(a)).

The Court noted in *Riegel* that, in accordance with it's holding in *Medtronic, Inc., v. Lohr*, 518 U.S. 470 (1996), "[p]remarket approval . . . imposes 'requirements' under the MDA" which are "specific to individual devices." *Riegel*, 552 U.S. at 323. The Arrow pump's pre-market approval imposes specific requirements on it that are sufficient to preempt a state law claim.

In this matter, the District Court explained at length the Florida state laws concerning (1) strict liability for manufacturing and design defect and failure to warn, and (2) concerning liability for negligent design, manufacture and assembly. *Wolicki-Gables*, 641 F. Supp. 2d at 1285-88. It determined that the Florida laws corresponding to each of those claims imposed requirements that were "different from, or in addition to" the federal requirements established for the Arrow pump. *Id.* Accordingly, the District Court concluded that a fact-finder could find liability even if the manufacturer had completely complied with the FDA regulations. *Id.*

In reviewing the District Court's decision, we must first consider whether

the Gableses have demonstrated that they have alleged a parallel claim. *Riegel*, 552 U.S. at 330. "Plaintiffs cannot simply incant the magic words '[Appellees] violated FDA regulations' in order to avoid preemption." *In re Medtronic Inc.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009). Parallel claims must be specifically stated in the initial pleadings. A plaintiff must allege that "[the] defendant violated a particular federal specification referring to the device at issue." *Ilarraza v. Medtronic, Inc.*, 677 F.Supp. 2d 582, 589 (E.D.N.Y. 2009). "To properly allege parallel claims, the complaint must set forth facts" pointing to specific PMA requirements that have been violated. *Parker v. Stryker Corp.*, 584 F.Supp. 2d 1298, 1301 (D. Colo. 2008). The trial court stated in *Parker* that an allegation that "the manufacturing processes for the device and certain of their . . . components did not satisfy the Food and Drug Administrations's Pre-Market Approval standards for the devices" is insufficient to satisfy the requisite elements of a parallel claim as set forth in *Riegel* if the complaint fails to "provide any factual detail to substantiate that crucial allegation." *Id.* at 1302.

The Gableses alleged in their complaint that Arrow, Codman and Johnson & Johnson:

> (a) fail[ed] to reasonably design the implantable drug delivery system in a manner which would have prevented injury to those like LINDA WOLICKI-GABLES;
> (b) fail[ed] to reasonably manufacture the implantable

> drug delivery systems in a reasonable manner; [and] (c) fail[ed] to reasonably provide adequate warnings regarding the defective and unreasonably dangerous implantable drug delivery system, having actual or constructive knowledge of the hazards associated with the product.

(Complaint at 12-13, 16, 20.[3]) These allegations do not "set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged." *Ilarraza*, 677 F.Supp. 2d at 589. Because the Gableses have failed to allege facts in their complaint demonstrating the presence of the elements of a parallel claim, we are persuaded that the District Court did not err in concluding that their state common law claims were preempted.

B

The Gableses also contend that the District Court erred in concluding that they are not "entitled to an inference that a defect existed within the pain pump." (Appellants' Opening Br. at 19.) They argue that they are entitled to such an inference because the malfunctioning connector was destroyed. In support of this argument, they rely on *Cassisi*. In *Cassisi*, the Florida Court of Appeal held that the evidence presented by the plaintiff was sufficient to create an inference "that the malfunction itself . . . is evidence of the product's defective condition at both the time of the injury and at the time of the sale." 396 So.2d at 1153.

[3]The same claim is repeated against each of the three Appellees.

In *Worsham v. A.H. Robins Co.,* 734 F.2d 676 (11th Cir. 1984), this Court stated that "the court in *Cassisi* held that absolute positive proof of product malfunction is not necessary where the product is destroyed; provided plaintiff can point to evidence that the cause of the accident most probably originated in the product." *Id.* at 683. "Evidence to so establish a defect can include facts that negate other causes of the accident and at the same time point to the product as the most logical cause." *Id.* Much like the concept of *res ipsa loquitur*, the inference of defect requires showing "more than a scintilla of evidence" that the device malfunctioned and that the malfunction was likely caused by a defect in the device's design or manufacture. *See Beauregard v. Cont'l Tire N. Am., Inc.*, 695 F. Supp. 2d 1344, 1354 (M.D. Fla. 2010) (declining to apply *Cassisi* where plaintiff's evidence of a tire belt separation could have happened due to normal wear rather than defect).

Cassisi is inapplicable because the Gableses have failed to demonstrate that a defect in the Arrow pump "most probably" caused her injuries and not some other malfunction or obstruction. Their experts, Dr. Michael Meriweather and Edward Reese, Ph.D.,[4] testified that though the catheter connector could have malfunctioned, they were unable to exclude alternate possible causes for a

[4]Dr. Meriweather is the Gableses' medical expert and Dr. Reese is their regulatory expert.

connecter to fail, such as an idiosyncratic complication with the patient, natural bodily rejection, or clogging. (District Court Order at 13-14, 43-44.) The District Court did not err in concluding that they were not entitled to a presumption that the Arrow pump was defectively manufactured.

III

Because the Gableses' claims are preempted, we do not address Arrow's assertion that private actions brought for violations of the FDA regulations are barred pursuant to 21 U.S.C. §337(a). Under 21 U.S.C. § 337(a), "[e]xcept as provided in subsection (b) [regarding actions brought by States], all such proceedings for the enforcement, or to restrain violations, of [the MDA] shall be by and in the name of the United States."

Similarly, because the claims are preempted, we also need not address the Gableses' contention that the District Court erred in finding that they failed to present sufficient evidence of an agency relationship between Nelson and Codman or Johnson & Johnson.

Conclusion

The Gableses have failed to allege a parallel claim in their complaint. Therefore their claims are preempted by the MDA. Further, they have not demonstrated that they are entitled to a presumption that the destroyed catheter

connecter was defective. Accordingly, the District Court's grant of summary judgment is **AFFIRMED.**