RENDERED: OCTOBER 29, 2020
TO BE PUBLISHED

Supreme Court of Kentucky

2019-SC-0118-DG

CLIFFORD RUSSELL, SR. AND JEANENE RUSSELL — APPELLANTS

V.

ON REVIEW FROM COURT OF APPEALS
NOS. 2017-CA-0866 AND 2018-CA-0195
FAYETTE CIRCUIT COURT NO. 16-CI-02180

JOHNSON & JOHNSON, INC., BIOSENSE WEBSTER, INC., JOHNSON & JOHNSON CONSUMER COMPANIES, INC., JOHNSON & JOHNSON INNOVATION JJDC, INC. F/K/A JOHNSON & JOHNSON DEVELOPMENT CORPORATION, AND BAPTIST HEALTH LEXINGTON ASC OF BAPTIST HEALTHCARE SYSTEM, INC. — APPELLEES

OPINION OF THE COURT BY JUSTICE WRIGHT

REVERSING AND REMANDING

Appellants, Clifford Russell and his wife Jeanene, filed suit against Appellees, Biosense,[1] alleging state tort claims due to injuries caused by a Class III medical device. Biosense moved for judgment on the pleadings based on federal preemption of all claims. The trial court granted the motion, and Court of Appeals affirmed. We reverse due to the Kentucky Rules of Civil Procedure as detailed below.

[1] "Biosense" collectively refers to Johnson & Johnson, Inc.; Biosense Webster, Inc.; Johnson & Johnson Consumer Companies, Inc.; and Johnson & Johnson Innovation JJDC, Inc.

I. BACKGROUND

The Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act classifies medical devices among three categories depending on their risk levels. 21 U.S.C. § 360(a)(1). Of relevance to this appeal, a Class III medical device has the most potential for danger and "(I) 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 (II) presents a potential unreasonable risk of illness or injury." *Id.* § 360(a)(1)(C)(ii).

Class III medical devices have the most oversight and must generally receive premarket approval from the Food & Drug Administration ("FDA"), which is a rigorous process. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-17 (2008). "Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). Importantly, the MDA contains a limited preemption[2] clause:

> Except as provided in subsection (b), 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 Act 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 Act**.

[2] "Preemption" is correctly spelled both with and without a hyphen. We have chosen the unhyphenated version of the word in our opinion, however quotes herein from other courts often use the hyphenated version. Both are equally correct.

21 U.S.C. § 360(k)(a) (emphasis added).

This limited preemption clause only applies to state "requirements," meaning state standards and regulations—**not** state claims and causes of action. The definition of "preemption" provides further guidance: "The principle (derived from the Supremacy Clause) that a federal law can supersede or supplant any inconsistent state law or regulation." PREEMPTION, Black's Law Dictionary (11th ed. 2019).

Therefore, when this preemption clause applies, it only preempts the state regulations that apply to the medical device. This preemption is not a blanket federal preemption of state causes of action; rather, it allows state claims that seek to impose parallel standards on the medical device. Those state standards cannot be more stringent than the federal standards that are "applicable to the [specific medical] device." The federal regulations must be specific to the device in order to preempt state standards that are the basis for state causes of action.

There are exceptions to the premarket approval process, such as the investigational device exemption at issue in this case. 21 U.S.C. § 360j(g). The investigational device exemption "permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device." 21 C.F.R. § 812.1. Its purpose is to allow medical devices without premarket approval—"to the extent consistent with the protection of public

health and safety and with ethical standards," *Id.*,—to be used in human trials "as early in the device development process as possible." 21 C.F.R. § 812.36(a).

The FDA approved the ThermoCool SmartTouch SF Catheter ("SF Catheter"), a Class III medical device, under the investigational device exemption for human trials. The SF Catheter was developed, manufactured, and marketed by Biosense. Less than a month after approval, Mr. Russell underwent a cardiac ablation procedure to treat his heart condition, and the SF Catheter was used. During the ablation procedure, electrical energy was delivered through the SF Catheter to the heart tissue, which resulted in burning and destroying heart tissue to achieve the desired result. If the device were to burn the heart or vein in the wrong location or deeper than intended, then it could result in severe damage to the heart or vein.

Unfortunately, the SF Catheter perforated Mr. Russell's pulmonary vein, which resulted in numerous life-threatening events. Approximately fourteen-months after Mr. Russell's surgery, the SF Catheter received full premarket approval, but importantly the SF Catheter was only at the investigational device exemption stage at the time of the surgery.

Mr. Russell and his wife Jeanene, filed suit against Biosense, asserting claims for strict liability, negligence, lack of informed consent, failure to warn, breach of express and implied warranties, fraud, unjust enrichment, and violation of Kentucky's Consumer Protection Act. Biosense answered and moved for judgment on the pleadings based upon federal preemption of all claims.

The trial court held a hearing on the motion and granted Biosense's motion for judgment on the pleadings, which dismissed all Appellants' claims; the Court of Appeals affirmed. Appellants then filed a motion for discretionary review to this Court, which we granted. We now reverse the Court of Appeals.

A. Standard of Review

Judgment on the pleadings is a question "of law and requires an examination of the pleadings." *Archer v. Citizens Fidelity Bank & Trust Co.*, 365 S.W.2d 727, 729 (Ky. 1962). Therefore, we conduct a *de novo* review. *See Schultz v. Gen. Elec. Healthcare Fin. Servs., Inc.*, 360 S.W.3d 171, 177 (Ky. 2012).

B. Preemption and Parallel State Claims

From the outset, we note that even if a device has received FDA premarket approval and federal preemption applies, parallel state claims are allowed to proceed in state court. Specifically, the Supreme Court of the United States stated "the MDA expressly pre-empts only state requirements 'different from, or in addition to, any requirement applicable . . . to the device' under federal law." *Riegel*, 552 U.S. at 321 (quoting 21 U.S.C. § 360K(a)(1)).

Importantly, the first time the Riegels "argue[d] that their lawsuit raise[d] parallel claims" was at the United States Supreme Court, and "they made no such contention in their briefs before the Second Circuit, nor did they raise [the] argument in their petition for certiorari." *Id.* at 330. Therefore, the Supreme Court "decline[d] to address that argument" but noted the trial court "recognized that parallel claims would not be pre-empted." *Id.* at 330.

As the United States Court of Appeals for the Tenth Circuit clarified:

> To the extent the state law duty is narrower than or equal to the federal duty it survives, through what seems a sort of Venn diagram approach to preemption. Still, even if the state claim fails that test because it would impose a "broader" duty than can be found in federal law, it appears we may not find the claim preempted just because it conflicts with "any" federal requirement. Instead, we may find the state law claim preempted only if there exists a device-specific federal requirement

Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1340 (10th Cir. 2015).

In *Caplinger*, the medical device completed "the premarket approval process," so the Court held "[t]here's no dispute . . . **device specific federal requirements** apply." (emphasis added). Thus, the state claims were not preempted as long as the "federal requirements impose duties that are at least as broad as those [the plaintiff] seeks to vindicate through state law." *Id.* at 1340.

The United States "Supreme Court has twice addressed the **limited scope** of this preemption provision." *Bausch v. Stryker Corp.*, 630 F.3d 546, 550 (7th Cir. 2010) (emphasis added). The Seventh Circuit analyzed both cases—*Riegel* and *Lohr*—and clarified "[n]either case held that state lawsuits premised on violations of federal law are preempted under section 360k(a). In fact, the Court's opinions in *Lohr* and *Riegel* expressly left the door open for state law claims based on violations of federal law." *Id.* at 550.

The Ninth Circuit has held "the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA." *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013). As to specific

parallel claims, the Fifth Circuit has held "claims for negligent failure to warn or negligent manufacturing of a device are not preempted, provided that such claims are premised entirely on violation of the applicable federal requirements." *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 770 (5th Cir. 2011). Further, *Hughes* "conclude[d] that invoking the negligence per se doctrine to support a negligence claim that is otherwise parallel to federal requirements is not expressly preempted." *Id.* at 772.

Here, in contrast to the above cases, the SF Catheter had not received FDA premarket approval and only had investigational device exemption status. Although the SF Catheter ultimately received FDA premarket approval, it was approximately fourteen-months after Mr. Russell's surgery. Even if we assume medical devices with the investigational device exemption are able to qualify for federal preemption, Kentucky's parallel tort claims are allowed; the federal preemption would only restrict the state standard that applies to the device.

None of the above-cited cases stand for the proposition that parallel tort claims cannot be filed in state courts. Instead, the cases make clear the limited federal preemption **only applies** to the extent Kentucky's parallel tort claims seek to impose a higher standard than federal law; our claims must be in harmony with the federal regulations.

Justice Ginsburg's *Riegel* dissent provides insight; she quoted "the former chief counsel to the FDA" as stating "that FDA product approval and state tort liability usually operate independently, **each providing a significant, yet distinct, layer of consumer protection**. . . . . Preemption of all such

claims would result in the loss of a significant layer of consumer protection . . . ." 552 U.S. at 337-38 (emphasis added). We agree and reiterate that Kentucky's parallel tort claims are not preempted by federal law.

If a state tort standard imposes a higher duty than federal regulations, the state standard is only preempted to the extent it imposes a more stringent duty; as long as the state cause of action seeks to vindicate a claim within the boundaries of the federal regulation, it survives. Further, even with a fully premarket approved device, if a state claim is premised on a violation of a federal regulation, it is not a federally preempted claim. Last, we note "[t]he medical device amendments does not preempt state punitive damage remedies." *Niehoff v. Surgidev Corp.*, 950 S.W.2d 816, 822 (Ky. 1997).

As a precursor, it was necessary for us to clarify these principles. We now turn to the Kentucky Rules of Civil Procedure, upon which the outcome of this case turns.

C. Judgment on the Pleadings

Under Kentucky Civil Rule 12.03, "[a]fter the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings." The moving party "admits for the purposes of his motion not only the truth of all his adversary's well-pleaded allegations of fact and fair inferences therefrom, but also the untruth of all his own allegations which have been denied by his adversary." *Pioneer Vill. v. Bullitt Cnty.*, 104 S.W.3d 757, 759 (Ky. 2003) (citing *Archer*, 365 S.W.2d 727). Importantly, a motion for judgment on the pleadings should never be granted unless "it appears beyond

doubt that the nonmoving party cannot prove any set of facts that would entitle him/her to relief." *Id.* (citing *Spencer v. Woods*, 282 S.W.2d 851 (Ky. 1955)). Furthermore, as our predecessor Court stated, if "the pleadings raise any issue of material fact," then a judgment on the pleadings "should be denied." *La Vielle v. Seay*, 412 S.W.2d 587, 590 (Ky. 1966).

1. Kentucky Pleading Standard

"Kentucky is a notice pleading jurisdiction, where the 'central purpose of pleadings remains notice of claims and defenses.'" *Pete v. Anderson*, 413 S.W.3d 291, 301 (Ky. 2013) (citing *Hoke v. Cullinan*, 914 S.W.2d 335, 339 (Ky. 1995)). In accordance with Kentucky Civil Rule 8.01(1), "[a] pleading which sets forth a claim for relief . . . shall contain (a) a short and plain statement of the claim showing that the pleader is entitled to relief and (b) a demand for judgment for the relief to which he deems himself entitled." As interpreted by this Court, "[i]t is not necessary to state a claim with technical precision under this rule, as long as a complaint gives a defendant fair notice and identifies the claim." *Grand Aerie Fraternal Order of Eagles v. Carneyhan*, 169 S.W. 3d 840, 844 (Ky. 2005) (citing *Cincinnati, Newport, & Covington Transp. Co. v. Fischer*, 357 S.W.2d 870, 872 (Ky. 1962)).

Importantly, "[w]e no longer approach pleadings searching for a flaw, a technicality upon which to strike down a claim or defense, as was formerly the case at common law." *Smith v. Isaacs*, 777 S.W.2d 912, 915 (Ky. 1989). When reviewing a complaint to determine whether it states a cause of action, it "should be liberally construed." *Morgan v. O'Neil*, 652 S.W.2d 83, 85 (Ky.

1983). Our liberal pleading standard was recently demonstrated when we held that a complaint "couched in general and conclusory terms, complied with CR 8.01(1)." *KentuckyOne Health, Inc. v. Reid*, 522 S.W.3d 193, 197 (Ky. 2017).

Applying Kentucky's well-established notice pleading principles, we hold Appellant's complaint alleged a sufficient cause of action to survive a motion for judgment on the pleadings. We refuse to mandate a heightened pleading standard and, therefore, reiterate Kentucky's requirement of bare-bones, notice pleading.

Here, Biosense asserts a complaint must include the specific federal regulations violated in order to survive a judgment on the pleadings; we disagree. Although Biosense appears to cite federal cases supporting this position, those cases were evaluated under the more stringent, federal pleading standard. Biosense does not cite any Kentucky cases on our pleading standard; and notably, Kentucky's pleading standard is more lenient. *See Combs v. ICG Hazard, LLC*, 934 F. Supp. 2d 915, 923 (E.D. Ky. 2013). *Combs* clarified "the [United States Supreme Court] altered the federal pleading standard by making it more stringent for plaintiffs," and held "Kentucky's pleading standard is more lenient than the federal rules." *Id.*

As we have held, "[t]he federal rules of procedure . . . are applicable to the proceedings in federal court and are not to be applied to practice or procedure in state courts." *Steelvest, Inc. v. Scansteel Serv. Ctr., Inc.*, 807 S.W.2d 476, 483 (Ky. 1991). In Kentucky, "[i]t is vital that we not sever

litigants from their right of trial, if they do in fact have valid issues to try, just for the sake of efficiency and expediency." *Id.*

Biosense's counsel asserted the Russells conceded they were not alleging parallel claims to the trial court. However, that assertion is inaccurate. At the hearing on the motion for judgment on the pleadings, the Russells **repeatedly** informed the trial court they were alleging parallel claims under Kentucky law. At first, the Russells stated they alleged parallel claims but not a violation of FDA regulations, then the Russells clarified they were alleging Biosense "violated FDA regulations" and "those violations under federal laws parallel recognized claims under state law." The Russells also informed the trial court about their absence of FDA regulations due to lack of discovery; they attempted to conduct discovery to gather more information. Biosense objected, refused to answer every question, refused to produce documents, and then attempted to block further discovery by filing a motion for judgment on the pleadings.

In Kentucky, our high standard necessary for granting a judgment on the pleadings requires there be no possible way the opposing party can prevail. This mitigates the concern of a party being shut out before resolving legitimate claims in court. The denial of a judgment on the pleadings allows for discovery on legitimate claims. We also find guidance from the Seventh Circuit, which stated "courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. **Formal discovery is necessary** before a plaintiff can fairly be expected to provide a detailed statement of the specific

bases for her claim." *Bausch*, 630 F.3d at 558 (emphasis added). We agree with the Seventh Circuit and believe discovery is necessary. Before discovery, plaintiffs simply don't know what they don't know.

Biosense asks this Court to determine whether "Plaintiffs have stated a non-preempted cause of action." This very question demonstrates the depth of misunderstanding of this federal preemption issue. As noted, state claims and causes of action are not federally preempted; only state standards that are more stringent than device-specific federal regulations are federally preempted. Further, a state claim based upon a violation of an applicable federal regulation or parallel state standard can proceed in state court. Confusion can easily result if the parties fail to differentiate between more stringent state standards, which are preempted, and parallel state causes of action, which may proceed in state court.

Among other viable claims, the Russells pleaded both negligence in manufacturing and failing to inform/warn. As the Seventh Circuit already clarified, those claims are not preempted as long as they are being used within the boundaries of the applicable federal regulations. This Court agrees. Further, the Russells expanded upon their claims by notifying the trial court they were asserting parallel claims under Kentucky law because our claims parallel "those violations under federal laws." Therefore, under Kentucky's notice pleading standard, the Russells' complaint sufficiently put Biosense on notice of parallel claims that may not be preempted.

II. CONCLUSION

Under Kentucky's notice pleading standards, the motion for judgment on the pleadings should have been denied. Even if investigational medical devices (such as the SF Catheter at the time it was used with Mr. Russell) qualify for federal preemption, a party may pursue parallel state tort claims, and those claims are not preempted under federal law. Here, under Kentucky's notice pleading standard, Biosense was properly put on notice of parallel claims. We reverse the Court of Appeals, and this case is remanded to the trial court for proceedings consistent with this opinion.

Minton, C.J.; Hughes, Keller, Lambert, and VanMeter, JJ., sitting. All concur. Nickell, J., not sitting.

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