RENDERED: January 30, 1998; 10:00 a.m.
TO BE PUBLISHED

96-CA-1753-MR

DIXIE LESLIE, Administratrix of the Estate of Isabelle Stanley, Deceased — APPELLANT

v.

APPEAL FROM FAYETTE CIRCUIT COURT
HONORABLE GARY D. PAYNE, JUDGE
CIVIL ACTION NO. 91-CI-2513

CINCINNATI SUB-ZERO PRODUCTS, INC. — APPELLEE

OPINION

REVERSING AND REMANDING

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BEFORE: BUCKINGHAM, COMBS, and EMBERTON, Judges.

BUCKINGHAM, JUDGE. Dixie Leslie (Leslie), administratrix of the estate of Isabelle Stanley (Stanley), appeals from an order of the Fayette Circuit Court granting summary judgment to Cincinnati Sub-Zero Products, Inc. (CSZ). For the reasons set forth hereinafter, we reverse and remand.

Stanley underwent coronary bypass surgery at Central Baptist Hospital in Lexington in 1990. During the operation, a heating/cooling blanket, commonly known as a thermal unit, was utilized to regulate Stanley's body temperature. The thermal unit was manufactured by CSZ and sold under the brand name

"Blanketrol Hypo-Hyperthermia System, Model 200." The unit is designed so that it can be used in either automatic or manual mode. If the automatic mode is selected, a temperature probe must be placed in or near the patient's body so that the unit can adjust its temperature level in correlation to the patient's body temperature.

The unit was placed in the automatic mode during Stanley's surgery, but no temperature probe was utilized. Two safety switches designed to prevent the unit from reaching unsafe temperatures failed to do so, causing Stanley to suffer severe burns over approximately thirty-five percent of her body. She died of complications related to the burns eleven days later.

Suit was filed on behalf of Stanley's estate in 1991, in which it was alleged that the thermal unit was in a defective condition and unreasonably dangerous at the time of its manufacture. The complaint also alleged that the safety switches were improperly designed and that CSZ failed to post adequate warnings of reasonably foreseeable dangers that might arise from the use or misuse of the unit and which were not apparent to those who used it. Following extensive discovery, the trial court entered an order granting CSZ's summary judgment motion, and this appeal resulted.[1]

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[1] **Suit was also filed against Central Baptist Hospital, Good Samaritan Hospital, and PSICOR (whose employee operated the thermal unit). The claims against those defendants were settled**

(continued...)

In the order granting summary judgment in favor of CSZ on Leslie's claims, the circuit court ruled that the claims are preempted by the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act and that even if the claims are not preempted, the Kentucky Product Liability Act bars the claims. Leslie contends that the circuit court erred with both rulings, and we agree.[2]

In 1976, Congress enacted the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug and Cosmetic Act of 1938[3] in response to consumer and regulatory concern. Medtronic, Inc. v. Lohr, 116 S.Ct. 2240, 2246 (1996). The MDA classifies medical devices into three categories based on the device's risk to the public. Class I devices are deemed to have the least risk factor and thus are subject to minimal regulation. Lohr, supra, at 2246. Class III devices pose a far greater risk or are used to support or sustain human life and thus are widely regulated. Id. Class II devices are not subject to the more stringent standards of Class III devices but are required to comply with federal

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[1](...continued)
by the parties.

[2] **Other than to rule in the manner stated above, the circuit court did not further explain or elaborate on its ruling. It is not required to make specific findings, however. Rule of Civil Procedure (CR) 52.01**; Wilson v. Southward Inv. Co. #1, Ky. App., 675 S.W.2d 10, 13 (1984).

[3] **21 U.S.C. § 301-395.**

performance regulations known as "special controls." Id. The thermal unit has been classified as a Class II device. 21 C.F.R. § 870.5900 (1997).

The section of MDA which is at the root of the preemption question is 21 U.S.C. § 360k(a) (1994 ed.). That statute states:

> 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
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> (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.

The interpretation of this statute varied widely from court to court (see Lohr, supra, at 2250 n.6), which caused the U.S. Supreme Court to take up the issue of interpreting the level of preemption afforded by § 360k(a). The Kentucky Supreme Court has also recently taken up the preemption issue in Niehoff v. Surgidev Corp., Ky., 950 S.W.2d 816 (1997). We must, therefore, determine whether Leslie's claims are preempted using the guidance of Lohr and Niehoff, neither of which had been rendered when the trial court entered its summary judgment in favor of CSZ.

Lohr involved the preemption of a claim under Florida law involving a Class III device (pacemaker). The U.S. Supreme Court was deeply divided on the issue, with the end result being that only parts I, II, III, V, and VII of the majority opinion gained the requisite five votes. The Court did not rule out the possibility that state tort claims would ever be preempted by the MDA. Lohr, supra, at 2257. However, the Court stated that the MDA's "overarching concern [is] that preemption occur only where a particular state requirement threatens to interfere with a specific federal interest. State requirements must be 'with respect to' medical devices and 'different from, or in addition to' federal requirements." Id. In addition, relying upon administrative regulations promulgated by the Food and Drug Administration (FDA), the Court ruled that "state requirements of 'general applicability' are not pre-empted except where they have 'the effect of establishing a substantive requirement for a specific device.'" Id.[4]

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[4] The regulation upon which the Court relied is 21 C.F.R. § 808.1(d) (1997), which states in part that

> **(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration**

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Underpinning the Court's rationale were the FDA regulations providing that state requirements would be preempted "'only' when the FDA has established 'specific counterpart regulations or . . . other specific requirements applicable to a particular device.' 21 C.F.R. § 808.1(d)(1)." Lohr, supra, at 2258. The Court concluded, therefore, that federal requirements and the allegedly preempted state requirements must be carefully compared "to determine whether they fall within the intended pre-emptive scope of the statute and regulations." Id. at 2257-58. The Court went on to rule that the general state common-law requirements in question were not preempted by the MDA. Id. at 2254-59. It classified the federal labeling and manufacturing requirements as "reflect[ing] important but entirely generic concerns about device regulation generally, not the sorts of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." Id. at 2258.

The Niehoff case involved a preemption claim concerning an artificial lens placed in an eye following cataract surgery.

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[4](...continued)

requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act.

The Kentucky Supreme Court stated in that case that it was "highly influenced by the decision of Lohr and the analysis we give it." Niehoff, supra, at 819. It interpreted the Lohr case to stand for the proposition that the "medical device amendments of 1976 do not preempt state law unless a specific state requirement contravenes a specific [federal] regulation." Id. The court also made clear that "[t]here is a presumption against preemption and a deference to the FDA determination of preemption." Id. at 820.

Classifying Justice Breyer's concurring opinion in Lohr as "critical[,]" the court in Niehoff apparently endorsed Breyer's view that § 360k(a) "would not preempt a state court decision based on a finding by a jury under the common law, unless it directly contravened a specific federal regulation applicable to a specific device." Id. at 821. The court further stated that the MDA did not preempt the plaintiff's strict liability claim (including failure to warn) as "Kentucky's strict liability case law and statutes are laws of general applicability to all products and fall beyond the scope of the federal preemption under § 360k." Id. at 822.

CSZ argues that the specificity requirements set forth by the FDA at 21 C.F.R. § 808.1(d) are "unwarranted attempt[s] to narrow the federal statute." (CSZ's brief, p. 8.) CSZ further argues that the regulations imposed on it by the MDA, such as good manufacturing requirements and "highly detailed labeling

requirements,"[5] are specific enough so that any common-law products liability decision against it would "serve to add to the requirements imposed by the FDA." (CSZ's brief, pp. 9-14).[6]

In Oja v. Howmedica, Inc., 111 F.3d 782 (10th Cir. 1997), the Tenth Circuit interpreted the Lohr decision to mean that a court "must first determine whether the FDA imposed any specific federal . . . requirement applicable to the [device]." Oja, supra, at 789. As CSZ has not pointed to any federal regulation which pertains specifically to the thermal unit, it has failed to meet the first half of the two-pronged preemption test of the Lohr case as interpreted by the court in Oja.

The second part of the two-pronged test as stated in Oja is whether the state requirement with respect to the medical device is different from, or in addition to, the federal requirement. Id. at 789. CSZ's argument also fails under this test. To prevail under a common-law strict liability claim in Kentucky, one must meet the requirements of § 402A of the

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[5] The "detailed" label required by the FDA is, in its entirety, "Caution: Federal law restricts this device to sale by or on the order of a _____ [physician]." 21 C.F.R. § 801.109(b)(1) (1997).

[6] CSZ's claim that the good manufacturing requirements promulgated by the FDA are sufficient to preempt state law claims is erroneous under Duvall v. Bristol-Myers-Squibb Co., 103 F.3d 324 (4th Cir. 1996). ("[S]tate-law claims pertaining to medical devices subject only to the general controls imposed by the . . . GMP's [good manufacturing practices], or labeling requirements are not preempted.") Id. at 330.

Restatement (Second) of Torts (1965), "which imposes strict liability on one who sells any product in a defective condition unreasonably dangerous to the user or consumer, even though the seller has exercised all possible care in the preparation and sale of the products." Niehoff, supra, at 822. These requirements are in no way specifically directed to the thermal unit, but rather are applicable to manufacturers of virtually any product.[7] Thus, the state requirements are not preempted according to 21 C.F.R. § 808.1(d)(1), which excepts state "requirements of general applicability" from federal preemption. Furthermore, CSZ has not demonstrated a "careful comparison" of how these general requirements are preempted by specific federal requirements as required by Lohr, supra, at 2257-58.

In short, given the holdings of Lohr and Niehoff and the fact that CSZ has not met its burden of showing which specific federal requirement would preempt the general state common-law requirements, the circuit court's ruling that state law is preempted by the MDA is erroneous.

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[7] **In addition, it appears that negligent design claims would also not be preempted under** Niehoff. ("A judgment by a Kentucky court or a potential jury verdict that Surgidev [the manufacturer of the device in question] failed to use ordinary care in its design . . . would not diverge from any specific federal regulation." Niehoff at 822.) See also Oja, supra, at 789 ("the standard of care governing [a plaintiff's] failure to warn claim is not the type of device-specific requirement that would threaten the MDA's federal interests[.]")

The remaining issue is whether or not the circuit court's alternative ground for granting summary judgment is correct. In addition to determining that Leslie's claims against CSZ were preempted by federal law, the circuit court also determined that CSZ was nonetheless entitled to summary judgment on the claims even if the state law claims were not preempted.

The statute upon which CSZ relies for its contention that Leslie's claims are barred by the Kentucky Product Liability Act is Kentucky Revised Statute (KRS) 411.310. That statute states in its entirety:

> (1) In any product liability action, it shall be presumed, until rebutted by a preponderance of the evidence to the contrary, that the subject product was not defective if the injury, death or property damage occurred either more than five (5) years after the date of sale to the first consumer or more than eight (8) years after the date of manufacture.
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> (2) In any product liability action, it shall be presumed, until rebutted by a preponderance of the evidence to the contrary, that the product was not defective if the design, methods of manufacture, and testing conformed to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared, and the product was manufactured.

The statute clearly sets forth two presumptions that the product was not defective which exist "until rebutted by a preponderance of the evidence to the contrary[.]" To overcome these presumptions and have his or her strict liability claim submitted to a jury, a plaintiff must "present something more than a

conclusion that it was theoretically probable that a different design would have been feasible and would have prevented his injury . . . ." Ingersoll Rand Co. v. Rice, Ky. App., 775 S.W.2d 924, 929 (1988).

The statutory presumptions of KRS 411.310 do no more than leave the burden of proof with Leslie to prove that the thermal unit was defective.[8] Contrary to what CSZ has suggested, Leslie does not have to prove that the unit was not designed in accordance with the 1980 "state of the art." The "sole question in a products liability case," regardless of whether the case involves failure to adequately warn, defective design, or other products liability theories, is whether the product is defective. Montgomery Elevator Co. v. McCullough, Ky., 676 S.W.2d 776, 782 (1984).

To attempt to prove that the thermal unit was defective and to overcome the statutory presumptions of KRS 411.310, Leslie relies on the deposition testimony of her expert witness, Dr. William Campbell, who testified that the thermal unit's "first deficiency" was its ability "to operate in any mode that could

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[8] See Rice, supra, at 928 (stating that the presumptions in KRS 411.310 may "do nothing more than codify what the law has always been" and that "the plaintiff must still prove by a preponderance of the evidence that the product in question is defective"); 2 Palmore, Kentucky Instructions to Juries, § 49.01 (1989), (the presumptions do "no more than to leave the burden of proof, and the quantum of proof necessary to sustain it, exactly where it was in the first place--with the plaintiff."). See also Kentucky Rule of Evidence (KRE) 301.

produce injury to the patient" (i.e., usage in automatic mode without a probe). (Campbell deposition, p. 41.) The heart of Campbell's testimony is his assertion that the two safety switches installed on the thermal unit were "redundant," meaning that they would age and eventually fail at the same rate. Campbell further testified that "fail-safe" technology regarding different circuitry for the machine, which would have prevented the thermal unit from overheating and burning Stanley, had existed for over 60 years.

Campbell also testified that "[i]t doesn't matter whether it [the thermal unit] was [properly] maintained or not" because the thermal unit was "a product that had a built-in time bomb [the redundant safety switches]." According to Leslie, therefore, the presumption in KRS 411.310 that the product was not defective was overcome by Campbell's testimony that the product was, in fact, defective and that standard circuitry technology existed when the thermal unit in question was manufactured which would have prevented Stanley's injuries and death.

CSZ argues that Campbell was unable to state authoritatively whether or not any medical devices manufactured in 1980 used the valve/circuitry which Campbell alleges would have prevented the accident. Campbell did testify, however, that at least one medical device (cystoscope) contains the safety valves which he asserts should have been installed on the thermal

unit. CSZ also asserts that Campbell admitted that he would not be testifying at trial as to the state of the art for thermal units in 1980. Campbell stated in a deposition, however, that he would testify as to the state of the art of the switches and instruments in the thermal unit.

CSZ also contends that Leslie admitted that the thermal unit was not maintained in accordance with CSZ's recommendations by Central Baptist Hospital. Campbell testified, however, that proper use and maintenance would not have prevented Stanley's injuries. Furthermore, KRS 411.320(1), which stated that a manufacturer would be held liable only for injury which would have occurred if the product had been properly maintained, was deemed to be repealed by the enactment of the comparative fault statute (KRS 411.182) in Caterpillar, Inc. v. Brock, Ky., 915 S.W.2d 751, 753 (1996). CSZ's argument that KRS 411.320(1) is still in effect if product misuse is the sole cause of the injury is irrelevant, as Campbell testified that Stanley's injuries would have occurred whether or not the thermal unit was properly maintained.

"The standard of review on appeal of a summary judgment is whether the trial court correctly found that there were no genuine issues as to any material fact and that the moving party was entitled to judgment as a matter of law." Scifres v. Kraft, Ky. App., 916 S.W.2d 779, 781 (1996). Furthermore, the trial court must view the evidence in a light most favorable to the

party opposing the summary judgment motion, and summary judgment should be granted only if it "appears impossible for the nonmoving party to produce evidence at trial warranting a judgment in his favor." Steelvest, Inc. v. Scansteel Service Center, Inc., Ky., 807 S.W.2d 476, 480-482 (1991). Leslie presented sufficient evidence through Campbell's testimony to overcome CSZ's summary judgment motion.[9]

As Kentucky product liability law is not preempted by the MDA, and as Leslie has presented sufficient evidence to withstand CSZ's summary judgment motion, we conclude that the trial court erred in granting summary judgment to CSZ. The judgment of the Fayette Circuit Court is reversed, and the case is remanded for a jury trial.

ALL CONCUR.

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[9] **This court is not required to defer to the determinations of the trial court since factual findings are not at issue.** Scifres, supra, at 781.

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