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UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

BRIAN C. HOWARD, Plaintiff-Appellant, v. SULZER ORTHOPEDICS, INC., fka Centerpulse Orthopedics, Inc., nka Zimmer Austin, Inc.; SULZER MEDICA USA HOLDING CO.; SULZER MEDICA USA INC., Defendants-Appellees.	)	ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO

Before: GUY, CLAY, and KETHLEDGE, Circuit Judges.

KETHLEDGE, Circuit Judge. Plaintiff Brian C. Howard, M.D. appeals the district court's order granting summary judgment, on preemption grounds, in favor of defendant Sulzer Orthopedics, Inc. (Sulzer) on their negligence per se claim. Howard argues that Sulzer failed to comply with certain Food and Drug Administration (FDA) regulations when it manufactured a knee implant that failed in Howard's body. Howard also argues that the court erred when it refused to transfer his case back to the Northern District of Oklahoma—which is where he filed it—because in his view the Ohio district court lacked personal jurisdiction over him. Although Howard's jurisdictional claim is meritless, we conclude that the district court erred when it found that Howard's negligence per se claim was preempted. We therefore vacate and remand for further proceedings on Sulzer's summary-judgment motion.

I.

Sulzer designs, manufactures, and distributes orthopedic joint implants. For one such device, the "Inter-Op acetabular shell" (Inter-Op) hip implant, originally the company first machined the metal implant parts, and then applied a porous coating to assist bonding between the device and the patient's bone. Sulzer thereafter switched these steps, applying the porous coating first, and then machining the parts. Unbeknownst to Sulzer, however, this new process left lubricating machine oil on the implants. Although Sulzer used an FDA-approved cleaning process for each device, the process failed to remove the oily residue that the new manufacturing process left behind. As a result, thousands of patients' Inter-Op shells failed to bond with the bone. Sulzer discovered the problem and voluntarily recalled about 40,000 of the implants.

The problem was not limited to the Inter-Op shell. Sulzer discovered that it had also used the new manufacturing process for some "Natural Knee II Tibial Baseplate" (NK-II) implants. Consequently, Sulzer instituted another recall. For both the Inter-Op shell and the NK-II, thousands of patients underwent "revision surgery" to replace the defective implants.

Litigation followed. As a patient whose NK-II failed, Howard sued Sulzer in the United States District Court for the Northern District of Oklahoma. The Judicial Panel on Multidistrict Litigation thereafter transferred all the federal cases, including Howard's, to the Northern District of Ohio for multi-district-litigation (MDL) pre-trial proceedings. After identifying which implants had been manufactured with the new process (the "affected lots"), Sulzer entered into a settlement agreement with patients who had received them. The district court approved the settlement.

Howard's case was excluded from the settlement because his device was not in an affected lot. He alleged nonetheless that oily residue caused his NK-II implant to fail. Sulzer responded with

a motion for summary judgment, which argued that Howard's claims were preempted. The motion was based upon the NK-II's Premarket Approval (PMA) application. For any Class III medical device, like a knee implant, the PMA prescribes the manufacturer's obligations in manufacturing and distributing the device. Sulzer contended that it met all those obligations with regard to Howard's device, which rendered his claims preempted.

The district court agreed with Sulzer as to most of Howard's claims: for strict liability, negligence, breach of implied and express warranty, and deceit. The court initially determined that there was no preemption for Howard's negligence per se claim, however, because that claim was based on allegations that Sulzer failed to comply with FDA manufacturing requirements that the PMA incorporated. *See In re Sulzer Hip Prosthesis and Knee Prosthesis Liab. Litig.*, 455 F. Supp. 2d 709, 716 (N.D. Ohio 2006).

Sulzer renewed its summary-judgment motion on the negligence per se claim after further discovery. It argued that Howard lacked evidence creating a genuine fact issue that Sulzer violated any FDA requirement. Howard presented several theories as to how Sulzer violated FDA requirements, including that his NK-II actually was part of an affected lot, and that Sulzer did not follow the manufacturing process outlined in the NK-II PMA when it made Howard's implant. To support these theories, Howard presented, in part, a chemical test on his implant that showed "at least two or more hydrocarbon components that are normally associated with mineral oil." Howard also submitted expert affidavits that purported to explain how Sulzer had deviated from the manufacturing steps outlined in the PMA. The court rejected most of these theories as unsupported by the evidence, finding no genuine issue as to whether Sulzer had followed (and documented) the processes mandated by the PMA when it made Howard's implant.

Howard's last theory presented a closer case. He argued that the NK-II PMA required Sulzer to follow not only the specific manufacturing steps it listed, but also the more general Good Manufacturing Practices (GMPs) that the PMA incorporated. The GMPs are FDA regulations based upon manufacturing standards that apply to all FDA-regulated medical devices. *See generally* 21 C.F.R. § 820. They require, among other things, a process to remove manufacturing materials like lubricating oil. Sulzer responded that the GMPs, although incorporated into the PMA, did not require it to take any steps beyond the specific steps outlined elsewhere in the PMA; and Sulzer said it followed those steps.

The district court agreed with Sulzer, finding that the GMPs imposed no additional obligations other than those otherwise spelled out in the PMA. That meant Howard's claim did impose obligations beyond those in the PMA, and was therefore preempted. So the court granted summary judgment on Howard's negligence per se claim. The court also denied Howard's motion to transfer his case back to the Northern District of Oklahoma.

This appeal followed.

II.

A.

1.

We review *de novo* a district court's grant of summary judgment, viewing the evidence in the light most favorable to the nonmoving party. *Upshaw v. Ford Motor Co.*, 576 F.3d 576, 584 (6th Cir. 2009). Summary judgment is appropriate when "the pleadings, the discovery and disclosure materials on file, and any affidavits show that 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).

The Medical Device Amendments of 1976 (MDA) to the Food, Drug and Cosmetic Act contain an express preemption clause:

> [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) (emphasis added).

The Supreme Court has interpreted § 360k(a) to preempt most common-law tort duties. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323-25 (2008). The Court's reasoning was that state-law tort suits would interfere with the requirements that the FDA imposed for a particular device through the extensive PMA process for Class III devices like knee implants. That holding applies, however, "only to the extent that [the state-law requirements] are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330 (quoting 21 U.S.C. § 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.*

Here, Howard argues that, even if Sulzer followed the specific manufacturing steps outlined in the PMA, the PMA itself incorporated the GMP standards, which in turn imposed additional requirements. Sulzer tries to head this argument off at the pass, arguing that the GMPs are "simply too generic, standing alone, to serve as the basis for Plaintiffs' manufacturing-defect claims." *See In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1157 (D. Minn.

2009).

The *Spring Fidelis* opinion—on which Sulzer relies—cites the FDA's final rulemaking for the GMPs, which states that, "[b]ecause this regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device." Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, 61 Fed. Reg. 52,602, 52,603 (Oct. 7, 1996). But the alleged violations in *Sprint Fidelis* were different from the ones here; and moreover the plaintiff there did not even identify a specific GMP that he thought had been violated. Howard, in contrast, has done that; and, as we explain below, the particular GMP that he cites is not so vague as to be incapable of enforcement. We thus reject Sulzer's argument that the relevant GMP is categorically unenforceable here.

We turn to that GMP. It provides:

> *Manufacturing material*. Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material *to ensure that it is removed or limited to an amount that does not adversely affect the device's quality*. The removal or reduction of such manufacturing material shall be documented.

21 C.F.R. § 820.70(h) (emphasis added).

It is undisputed that lubricating oil falls within the definition of manufacturing material. *See* 21 C.F.R. § 820.3(p). Howard argues that the presence of "hydrocarbon components that are normally associated with mineral oil" on his NK-II means that Sulzer failed to "ensure" that it had removed manufacturing material in compliance with § 820.70(h). Sulzer responds that it followed the PMA-prescribed process for removing machining oil, which in its view was all that § 820.70(h) required.

The question, then, is whether this subsection requires compliance with a validated cleaning *process*, or whether it also requires a specific *result*: namely, actual removal. The district court held that only compliance with the cleaning process was required.

Facially, at least, § 820.70(h) can be read either way. On the one hand, it states that "the manufacturer shall establish and maintain *procedures*" to clean the devices—which favors Sulzer's interpretation. On the other, it says that the procedures should "*ensure* that [manufacturing material] *is removed* or limited to an amount that does not adversely affect the device's quality." *See* 21 C.F.R. § 820.70(h) (emphasis added). That language suggests that actual removal is required.

An agency's interpretation of its own regulation controls unless "plainly erroneous or inconsistent with the regulation." *See Auer v. Robbins*, 519 U.S. 452, 461 (1997) (internal quotation marks and citation omitted). Neither of the proposed interpretations here would fall outside those bounds. But we do not have the benefit of the FDA's interpretation of these regulations. So we do the best we can with what we have.

What we have are the FDA's comments in its final rulemaking and some FDA "guidance documents" that generally discuss the GMPs. The comments imply that actual removal is required. One comment states: "[Section 820.70(h)] only requires that *the fact that manufacturing material was removed or reduced* be documented, not how much was removed." 61 Fed. Reg. at 52,629 (emphasis added). An illustration in the commentary agrees: "For example, some components, such as natural rubber latex, contain allergenic proteins that *must be* reduced or removed from the finished devices." *Id.* at 52,610 (emphasis added).

The guidance documents point the same way. Although they speak repeatedly of the need to establish processes, they include language implying that actual removal is necessary as well. For

example, one such document states:

> When manufacturing materials such as oils . . . are used on or in equipment, manufacturers should:
> - provide written procedures for the use and removal of materials; *and*
> - *remove the material* or limit it to a safe amount;
> - document the removal.

Medical Device Quality Systems Manual: A Small Entity Compliance Guide, HHS. Pub. FDA 97-4179, at 7-4 (Dec. 1996) (emphasis added).

In light of these materials, the better reading of this provision—so far as we can tell—is that it requires actual removal. Sulzer suggests, not unreasonably, that this reading renders it liable even in circumstances where it complied fully with the specific cleaning process approved by the FDA. But the risk of a defective device must fall somewhere. We would not think it irrational for the FDA to assign that risk to that party that actually can do something to minimize it—like preventing oil from getting on a device in the first place—rather than assign the risk to the party that cannot. And if the FDA may require a manufacturer to keep a device oil-free, a state may provide a damages remedy for violations of an identical state requirement. *See Riegel*, 552 U.S. at 330. So we adhere to our reading of this provision.

We do not suggest, however, that our reading is definitive. The provision, as we say and as the dissent illustrates, can reasonably be read either way. Our decision in this appeal, however, is to reverse the district court's preemption holding on the negligence per se claim because the GMPs required Sulzer to actually remove machine oil.

2.

We address several housekeeping concerns for purposes of remand. First, we agree with Sulzer that Howard's experts are not competent to testify to legal conclusions about what the GMPs

require. *See Berry v. City of Detroit*, 25 F.3d 1342, 1354 (6th Cir. 1994). We therefore do not rely on those conclusions in our analysis. Nor do we endorse the experts' suggestion that Sulzer was required to test Howard's implant (and everyone else's) using "destructive" testing that would have rendered the device useless.

Third, since the district court granted summary judgment on preemption grounds alone, it did not reach the question whether Howard had actually created a genuine issue that oil was left on his device. We likewise do not reach that issue in this appeal. We also leave it to the district court to consider Sulzer's alternative ground for summary judgment: namely, whether Oklahoma law recognizes a negligence per se action based on violations of FDA regulations. All that we decide today, rather, is that Howard's negligence per se claim for GMP violations is not preempted.

B.

Howard argues that the court's refusal to transfer the case back to the Oklahoma district court violated due process. In his view, the Ohio court lacked personal jurisdiction over him because he did not have sufficient "minimum contacts" with Ohio. He contends that due process requires that he have the opportunity to "opt out" of the MDL procedure, just as absent class plaintiffs can opt out of a class action suit under *Phillips v. Shutts*, 472 U.S. 797 (1985).

Howard's argument is meritless. As an initial matter, "Congress could provide for service of process anywhere in the United States." *Mississippi Publ'g Corp. v. Murphree*, 326 U.S. 438, 442 (1946). The MDL statute (28 U.S.C. § 1407) is, in fact, legislation "authorizing the federal courts to exercise nationwide personal jurisdiction." *In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d 145, 163 (2d Cir. 1987); *see also In re FMC Corp. Patent Litig.*, 422 F. Supp. 1163, 1165 (J.P.M.L. 1976) ("Transfers under Section 1407 are simply not encumbered by considerations of in personam

jurisdiction and venue. . . . Following a transfer, the transferee judge has all the jurisdiction and powers over pretrial proceedings in the actions transferred to him that the transferor judge would have had in the absence of transfer"). Contacts with the United States, and not a particular state, are what matters in federal court.

Here, the transferor court in the Northern District of Oklahoma had personal jurisdiction over Howard, and through § 1407 the Northern District of Ohio did as well. The district court did not err in refusing to transfer the case back to the Northern District of Oklahoma.

* * *

We reverse the district court's preemption holding on the negligence per se claim, vacate its grant of summary judgment, and remand the case for proceedings consistent with this opinion.

RALPH B. GUY, JR., Circuit Judge, dissenting. I depart from the majority because I believe the Good Manufacturing Practices (GMPs) set forth in 21 C.F.R. § 820.70(h) and incorporated into the FDA's Premarket Approval (PMA) for the NK-II implant should not be interpreted as establishing a "requirement" of "actual removal" upon which a negligence per se claim may be predicated. The Supreme Court in *Riegel* found that the FDA's premarket approval of a Class III medical device imposed device-specific requirements, and that such requirements would preempt state common-law claims to the extent that the state requirements "are 'different from, or in addition to' the requirements imposed by federal law." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (quoting 21 U.S.C. § 360k(a)). That also means that § 360k(a) will not bar a state-law remedy premised upon violation of federal regulation if "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id*. (citation omitted). Thus, plaintiff's remaining negligence per se theory premised upon an alleged violation of § 820.70(h), may escape preemption if it is based on duties that are "parallel" to the FDA's federal requirements for the NK-II implant.

The PMA for the NK-II implant imposed extensive device-specific requirements concerning design, manufacture, quality control, and marketing. Each step of the manufacturing process was detailed—including providing procedures and protocols for at least six different cleaning processes. As the district court found, the PMA application specified the cleaning procedures to be used for the removal of "manufacturing materials"

such as machine oil. Plaintiff was unable to show that Sulzer failed to comply with the PMA's procedures and protocols, and a common-law claim for failure to use a *different* cleaning method would be preempted. What remains is plaintiff's claim that, irrespective of whether Sulzer complied with the approved device-specific procedures for cleaning the NK-II implant, Sulzer's statement in the PMA application that it would comply with the GMPs for all medical devices established a federal requirement that it actually remove any manufacturing materials that "could reasonably be expected to have an adverse effect on product quality." 21 C.F.R § 820.70(h) ("Subpart G—Production and Process Controls").

The pertinent language from § 820.70(h), which bears repeating, states that "the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality." As the majority opinion illustrates, this language is susceptible to more than one interpretation. In my view, however, § 820.70(h) should not be interpreted to both require procedures *and* mandate outcomes. It would be another story if the regulation said "and ensure" rather than "to ensure"; but it does not. *See also Medical Device Quality Systems Manual*, HHS. Pub. No. 97-4179, at 7-4 ("Section 820.70(h) requires a written procedure for the use and removal of manufacturing materials that can have an adverse effect on devices."). Nor do the references to "removal" in the FDA's comments and guidance document persuade me otherwise because removal (or reduction) of such materials is plainly the object of the procedures which are explicitly required by § 820.70(h). This

view is also consistent with the requirements of other Quality System Regulations that make up the GMPs for a broad range of medical devices ("Part 820–Quality System Regulation"). In the absence of a more explicit indication that § 820.70(h) requires "actual removal," I would affirm the judgment of the district court.