FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CHRISTINA MCCLELLAN, *Plaintiff-Appellant*, v. I-FLOW CORPORATION, a Delaware corporation; DJO, L.L.C., a Delaware corporation; DJO INCORPORATED, a Delaware corporation; PACIFIC MEDICAL, INC., a California corporation, *Defendants-Appellees*.	No. 11-35109 D.C. No. 6:07-cv-01309-AA
CHRISTINA MCCLELLAN, *Plaintiff-Appellee*, v. I-FLOW CORPORATION, a Delaware corporation, *Defendant-Appellant*, and DJO, L.L.C., a Delaware corporation; DJO INCORPORATED, a Delaware corporation; PACIFIC	No. 11-35134 D.C. No. 6:07-cv-01309-AA OPINION

MEDICAL, INC., a California corporation,

Defendants.

Appeal from the United States District Court
for the District of Oregon
Ann L. Aiken, Chief District Judge, Presiding

Argued July 10, 2012
Submission Deferred July 12, 2012
Resubmitted January 13, 2015
Portland, Oregon

Filed January 23, 2015

Before: Alfred T. Goodwin, Harry Pregerson, and Morgan Christen, Circuit Judges.

Opinion by Judge Goodwin

SUMMARY*

Preemption

The panel vacated the district court's judgment, and remanded for a new trial, in a diversity action alleging common law claims for negligence and strict products liability. The panel dismissed, as moot, the cross appeal challenging the district court's denial of costs.

Christina McClellan alleged she suffered injuries after she was prescribed continuous infusion of a painkiller, delivered through a PainBuster infusion pump device, I-Flow. The PainBuster is regulated under the Medical Device Amendments of 1976 (MDA) to the Food, Drug & Cosmetics Act. The district court declined to give some of McClellan's requested jury instructions under Oregon law based on the court's conclusion that they were preempted by federal law.

The panel held that there was appellate jurisdiction because judgment was entered as to all the defendants. The panel held that the presumption against federal preemption of state law applied to this case. The panel held that McClellan's case was not controlled by *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (holding that the state law claims were preempted because the state law claims enjoyed no presumption against preemption and were in conflict with the MDA). The panel further held that McClellan's requested jury instructions did not conflict with the congressional intent behind the MDA, and would not

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

usurp the exclusive federal enforcement power over the MDA. The panel concluded that no federal preemption applied, and the district court's refusal to give the requested jury instruction was not harmless error. The panel remanded for a new trial due to the instructional error with leave to the district court to determine in the first instance whether the requested instructions were otherwise appropriate under Oregon law.

COUNSEL

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OPINION

GOODWIN, Circuit Judge:

Christina McClellan appeals the judgment entered in favor of defendant-appellees after a jury trial. Defendant I-Flow Corporation cross-appeals the district court's denial of costs. We vacate and remand for a new trial, and dismiss I-Flow's cross-appeal as moot.

I. BACKGROUND

McClellan underwent two surgeries to repair her anterior labrum, located in the shoulder. After each surgery, she was prescribed continuous infusion of a painkiller, delivered through a PainBuster continuous infusion pump device. I-Flow manufactured the PainBuster and defendants DJO, LLC and DJO Incorporated (collectively, DJO) distributed and sold the PainBuster.[1] A continuous infusion pump contains a portable medication reservoir attached to a catheter that delivers the medication to the site—here, to the shoulder joint.

During her recovery from the second surgery, McClellan's physician diagnosed her with chondrolysis of the shoulder. This condition meant that McClellan suffered the loss of articular cartilage in her main shoulder joint (the glenohumeral joint). Articular cartilage provides a slick surface allowing bones to move easily. In McClellan's case, it specifically allows the "ball-and-socket" of the

[1] DJO, Inc. is DJO, LLC's parent company. The district court severed the claims against DJO, Inc. The fourth defendant, Pacific Medical, Inc., was dismissed prior to trial.

glenohumeral joint to move properly. She suffered a complete loss of articular cartilage, resulting in a spontaneous fusion of her shoulder due to the ball and socket growing together into a single bone. She has no motion in the joint and can move her shoulder only a few degrees. McClellan's condition is not treatable.

McClellan filed suit, alleging state common law claims for negligence and strict products liability. She advanced two theories of liability: (1) I-Flow negligently failed to warn that its pain pump should not be used in intra-articular spaces such as the glenohumeral joint; and (2) I-Flow was strictly liable for selling a product that was unreasonably dangerous due to a lack of adequate warnings. Prior to submission of the case to the jury and in denying McClellan's motion for a new trial, the district court declined to give certain requested instructions, reasoning that they were preempted by federal law.

II. REGULATORY REGIME

The PainBuster is regulated under the Medical Device Amendments of 1976 (MDA) to the Food, Drug & Cosmetics Act (FDCA).[2] The MDA requires that manufacturers provide the U.S. Food and Drug Administration with "reasonable assurance of the safety and effectiveness" of a device prior to marketing and sale. 21 U.S.C. § 360c(a)(1)(A)(i), (B), (C)(i). This reasonable assurance process is known as "premarket approval." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). However, devices already on the market prior to

[2] For the sake of simplicity, we will refer to the FDCA as amended as the MDA.

1976 are allowed to remain on the market without approval until the FDA completes an evaluation. *Id.* at 478.

In addition to this "grandfathering provision," Congress also included a provision to increase competition and "to prevent manufacturers of grandfathered devices from monopolizing the market" while other manufacturers of similar devices are undergoing the process of providing the FDA with safety assurances. *Id.* This provision exempts a device from the "reasonable assurance of safety" requirement if the manufacturer shows that the device is "substantially equivalent" to a grandfathered device. 21 U.S.C. § 360e(b)(1)(B); *Lohr*, 518 U.S. at 478.

This process is known as the 510(k) process (after the original section number). *Lohr*, 518 U.S. at 478. The 510(k) process requires the manufacturer to submit a "premarket notification" to the FDA. 21 U.S.C. § 360(k); *Lohr*, 518 U.S. at 478. The FDA then uses the "premarket notification" to verify that the device is "substantially equivalent" to a grandfathered device. *Lohr*, 518 U.S. at 478. Once a manufacturer submits a 510(k) notification and the FDA finds the device to be substantially equivalent to a pre-1976 device, the device can be marketed without the manufacturer having made any additional showing regarding the safety and effectiveness of the device. *Id.*

III. DISCUSSION

In the discussion below, we first address and reject I-Flow's argument that we lack jurisdiction to hear this appeal. We then turn to McClellan's contentions. McClellan assigns four errors to the district court: (1) it wrongly refused to give jury instructions regarding negligence and federal standards

because it incorrectly concluded they were preempted; (2) it improperly barred expert testimony as to safety standards; (3) it improperly barred expert testimony as to an association between pain pump use and chondrolysis; and (4) it improperly excluded certain documentary evidence as hearsay. Because we hold that the requested instructions were not preempted by the MDA and remand for a new trial, we decline to reach the evidentiary issues.

A. Jurisdiction

We have appellate jurisdiction. This court has a duty to ensure subject matter jurisdiction exists over an appeal. *See, e.g.*, *D'Lil v. Best W. Encina Lodge & Suites*, 538 F.3d 1031, 1035 (9th Cir. 2008). I-Flow argues that no final, appealable judgment exists in this case, 28 U.S.C. § 1291, because a judgment as to fewer than all parties may be appealed "only if the [district] court expressly determines that there is no just reason for delay," Fed. R. Civ. P. 54(b). The judgment in this case did not so state. There was no need to do so.

The district court severed the claims against DJO, Inc. as its alleged liability would be wholly derivative of DJO, LLC's liability. I-Flow argues that this severance somehow left the claims against DJO, Inc. unresolved, thereby requiring the district court to expressly state that the judgment was appealable. But as McClellan points out, the judgment identifies I-Flow, DJO, LLC, and DJO, Inc. as defendants, and states that judgment was entered in favor of the defendants. That alone settles the issue, as judgment was entered as to all defendants. And even if it was not, given the alleged derivative liability of DJO, Inc., there can be no serious argument that judgment in favor of DJO, LLC and

dismissal of the action could preserve DJO, Inc.'s alleged liability. We therefore proceed to the merits of the appeal.

B. Preemption

McClellan challenges the district court's refusal to give a negligence per se instruction,[3] an instruction as to considering statutes and regulations in determining reasonable care,[4] and nine special instructions related to federal law.

The Supremacy Clause of the Constitution makes evident that "state laws that conflict with federal law are 'without effect,'" *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (citation omitted). There are three types of preemption: (1) express preemption, (2) field preemption, and (3) conflict preemption. *Id.* at 76–77; *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985). The district court relied upon, and the parties discuss, only conflict preemption.

Conflict preemption is implicit preemption of state law that occurs where "there is an actual conflict between state and federal law." *Altria Grp.*, 555 U.S. at 76–77. Conflict preemption "arises when [1] 'compliance with both federal and state regulations is a physical impossibility,' . . . or [2] when state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Hillsborough Cnty.*, 471 U.S. at 713 (citations omitted). Only the latter flavor of conflict, obstacle preemption, is at issue here.

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[3] Oregon Uniform Civil Jury Instruction 20.03.

[4] Oregon Uniform Civil Jury Instruction 20.04.

In evaluating whether federal law has preempted state law, we must (1) look to "the purpose of Congress [as] the ultimate touchstone," while also (2) "start[ing] with the assumption that the historic police powers of the States were not to be superseded . . . unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). The presumption against preemption "applies with particular force when Congress has legislated in a field traditionally occupied by the States." *Altria Grp.*, 555 U.S. at 77. With respect to express preemption, "when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption.'" *Id.* (citation omitted). This presumption against preemption applies with equal force to conflict preemption. *Wyeth*, 555 U.S. at 565 n.3.

In holding that McClellan's requested instructions would run afoul of MDA preemption, the district court relied upon the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). That case involved state-law claims that the defendant made fraudulent representations to the FDA, resulting in improper market clearance for bone screws, and harm to patients through their use. *Id.* at 346–47. The Court held that the claims enjoyed no presumption against preemption, were in conflict with the MDA, and were therefore preempted. *Id.* at 347–48.

In *Buckman*, the Supreme Court described the plaintiffs' claims as "state-law fraud-on-the-FDA claims" and held that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' such as to warrant a presumption" against preemption. *Id.* at 347–48 (internal citation omitted). Despite I-Flow's and DJO's urging for application of *Buckman*'s ultimate result, there is

no reason not to apply the presumption against preemption here. Unlike the plaintiff in *Buckman*, McClellan has not alleged any fraud on the FDA. Instead, McClellan has alleged failure-to-warn theories that are clearly concerned with the labeling and regulation of medical devices. The regulation of medical devices prior to the MDA "was left largely to the States to supervise as they saw fit." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). Thus, we apply the presumption against preemption in this case.

With that presumption in mind, we conclude this case is not controlled by *Buckman*. There, the Court wrote that "fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." 531 U.S. at 350. The claims in *Buckman* failed in part because there was "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." *Id.* at 352. The Court discussed its earlier decision in *Medtronic, Inc. v. Lohr*, noting that the non-preempted claims in *Lohr* "arose from the manufacturer's alleged failure to use reasonable care in the production of the product, *not solely* from the violation of FDCA requirements." *Buckman*, 531 U.S. at 352 (citing *Lohr*, 518 U.S. at 481) (emphasis added). On the other hand, the fraud claims in *Buckman* "exist[ed] *solely* by virtue of the FDCA disclosure requirements." 531 U.S. at 352–53 (emphasis added). The Court concluded that "were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in question. On the contrary, the existence of these federal enactments is a critical element in their case." *Id.* at 353. Additionally, as this court recently pointed out, *Buckman* occurred within the context of the

premarket approval process. *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc).

Further, *Buckman* recognized that *Lohr*, while dealing explicitly with only express preemption, left the door open to state-law claims "parallel" to federal requirements. 531 U.S. at 353; *see also Stengel*, 704 F.3d at 1228 ("The rule that emerges from these [three Supreme Court MDA preemption cases] is that the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA."). The Seventh Circuit recognized *Buckman*'s limitations in holding that manufacturing defect claims were not preempted even where they sought to borrow the definition of "adulterated" from the MDA. *Bausch v. Stryker Corp.*, 630 F.3d 546, 556–58 (7th Cir. 2010). The Fifth Circuit did likewise in holding that claims for failure to warn, premised on violation of FDA regulations, were not preempted under *Buckman*. *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 774–76 (5th Cir. 2011).

In this case, we perceive nothing about McClellan's requested instructions that conflicts with the congressional intent behind the MDA. McClellan's claims were not fraud-on-the-FDA claims. The failure-to-warn claims McClellan alleged did not arise solely by virtue of the MDA.[5] Further, there is no suggestion that Congress intended to displace traditional tort law by making all policing of medical labels and warnings the exclusive province of the FDA.

[5] In fact, if this were the case, McClellan's claims could not have been placed in front of a jury in the first instance, as there would have been no traditional tort-law claims left to advance.

More generally, McClellan's requested instructions would not usurp the exclusive federal enforcement power over the MDA. The allegations at issue occur outside the context of the regulatory process, unlike in *Buckman*. Where the plaintiff in Buckman alleged that the defendant made fraudulent representations *during* the market approval process, *to the FDA*, 531 U.S. at 346–47, McClellan's requested instructions here have little to do with direct regulatory interaction with the FDA. The appellees would have us conclude that any use of federal law to establish a standard of care is an attempt to enforce the underlying federal provisions, but we do not accept that proposition.[6]

Appellees' arguments fail to convince us that allowing a jury to look to the MDA to establish certain standards of care will create an obstacle to accomplishing the goals Congress envisioned in passing the MDA. I-Flow's and DJO's attempts to characterize McClellan's claims as torts in form only are poorly explained and unpersuasive.

Having concluded that no preemption applies, we disagree with I-Flow and DJO that refusal to give the requested instructions was harmless error. The instruction actually given by the district court—allowing the jury to consider federal law discussed during trial—is not equivalent to instructions specifically including reference to federal law.

[6] It is also telling that I-Flow and DJO fail to offer any concrete examples of FDA enforcement authority that McClellan would usurp if she were to receive the requested instructions.

Moreover, the instruction given was far weaker than the requested negligence per se instruction. We cannot say the error was more probably than not harmless. *See, e.g.*, *Head v. Glacier Nw., Inc.*, 413 F.3d 1053, 1063 (9th Cir. 2005). The appellees also argue that the error was harmless because the jury implicitly made two findings that would make the instructions irrelevant. Those arguments lack merit as they speculate regarding how the jury reached its verdict.

In sum, we vacate the judgment and remand for a new trial due to the instructional error. We leave it to the district court to determine in the first instance whether the requested instructions are otherwise appropriate under Oregon law.

C. Evidentiary Issues and I-Flow's Costs

Because we conclude a new trial is warranted, we need not reach the challenged evidentiary rulings, *see Transue v. Aesthetech Corp.*, 341 F.3d 911, 912–13 (9th Cir. 2003), leaving any future reconsideration of those rulings to the district court. The district court's denial of I-Flow's costs is moot and we dismiss the cross-appeal. *See, e.g.*, *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883, 917 (9th Cir. 2008); *Friedman & Friedman, Ltd. v. Tim McCandless, Inc.*, 606 F.3d 494, 503 (8th Cir. 2010).

IV. CONCLUSION

Because the district court erred in not giving McClellan's requested jury instructions, incorrectly believing that the MDA preempted such instructions, we vacate the judgment

and remand for a new trial. We dismiss I-Flow's cross-appeal as moot.

Each party shall bear its own costs on appeal.

VACATED AND REMANDED. Defendant-Appellant I-Flow Corporation's cross-appeal is DISMISSED as moot.