

DISTRICT COURT OF APPEAL OF THE STATE OF FLORIDA
FOURTH DISTRICT
July Term 2009

**CORDIS CORPORATION and JOHNSON & JOHNSON OF NEW
JERSEY, INC., d/b/a JOHNSON & JOHNSON,**
Petitioners,

v.

SEAN O'SHEA,
Respondent.

No. 4D09-1597

[September 9, 2009]

PER CURIAM.

Petitioners Cordis Corporation and Johnson & Johnson of New Jersey, Inc. seek prohibition barring the circuit court from continuing to entertain a complaint against them alleging various claims involving the use of a Cypher brand cardiac drug-eluting stent. The petition follows a March 2, 2009 order which granted in part and denied in part their motion to dismiss the third amended complaint with prejudice.

Part of petitioners' defense is that federal law preempts state causes of action. The Cypher stent is considered a Class III medical device regulated by the Food and Drug Administration (FDA) pursuant to the 1976 Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399a. Class III devices are used for "supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C)(ii)(I). Before a manufacturer can market a Class III device, it must submit a Pre-Market Approval (PMA) application providing the FDA with "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). The FDA may deny the application, request additional information from the manufacturer, or grant approval. The manufacturer must comply with all design, manufacturing and labeling specifications set forth in a PMA approval order. 21 C.F.R. § 814.80. Petitioners advise that the FDA continues its oversight of the safety and effectiveness of PMA-approved devices after approval.

Petitioners contend that the Cypher brand stent was the first drug-

eluting stent of its kind. It was approved by the FDA through a PMA in April, 2003 for use by physicians in patients with atherosclerotic obstructive coronary disease. The conditions of approval call for continuing supervision by the FDA. Petitioners' argument is that the FDA's extensive oversight of the Cypher brand stent's safety and effectiveness leads to federal preemption of any state claim that challenges the FDA's determination that the stent is safe.

In a thoughtful series of orders, the circuit court dismissed some claims, allowed others to proceed, and considered the application of *Riegel v. Medtronic, Inc.*, 552 U.S. ___, 128 S. Ct. 999 (2008), where the Supreme Court wrote:

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. Section 360k(a)(1). Thus, Section 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. at 1011 (citations omitted).

We reject petitioners' assertion that this case is controlled by *American Maritime Officers Union v. Merriken*, 981 So. 2d 544 (Fla. 4th DCA 2008). In *American Maritime*, we held that a petition for prohibition would lie where a complaint against a benefits plan alleging whistleblower claims was completely preempted by federal ERISA law. However, that holding was based upon ERISA's grant of exclusive jurisdiction to federal district courts for violations under its laws. See 29 U.S.C. § 1132(e). No similar statute grants exclusive jurisdiction over the subject matter of this case.

We agree with respondent that this is a case of defensive, and not complete, preemption. Further, the issues presented are more properly characterized as a "choice of law" issue rather than "choice of forum" preemption, which would provide exclusive jurisdiction in the federal courts. See *Bertoni v. Stock Bldg. Supply*, 989 So. 2d 670, 674 (Fla. 4th DCA 2008) (in which the court contrasted defensive preemption with complete preemption); *Days Inn Acquisition Corp. v. Hutchinson*, 707 So. 2d 747, 749 n.1 (Fla. 4th DCA 1997) (where court recognized that a question of whether federal law governed the substance of a dispute was not a question of subject matter jurisdiction); *Cent. Nat'l Bank of Miami v. Cent. Bancorp, Inc.*, 411 So. 2d 358 (Fla. 3d DCA 1982). We agree with

the analysis of *Gonzales v. Surgidev Corp.*, 899 P.2d 576, 582 (N.M. 1995):

In considering whether federal preemption affects subject matter jurisdiction, the issue is not whether Congress intended to replace state law with a federal regulatory scheme but “whether jurisdiction provided by state law is itself pre-empted by *federal* law vesting exclusive jurisdiction over that controversy in another body.” *International Longshoremen’s Ass’n v. Davis*, 476 U.S. 380, 387-88 (1986). The *Davis* Court labeled this distinction choice-of-forum preemption, which deprives the state court of subject matter jurisdiction, as opposed to choice-of-law preemption, which limits the court’s ability to grant relief on a state law claim. *Id.* at 391. Under choice-of-law preemption, a state court has jurisdiction to entertain the claim, but it must apply federal law in deciding the claim on the merits. In contrast, under choice-of-forum preemption, the state court lacks jurisdiction even to entertain the claim, which can then only be raised in federal court. The *Davis* Court noted that choice of forum preemption “does not apply to preemption claims generally but only to those preemption claims that go to the State’s actual adjudicatory or regulatory power as opposed to the State’s substantive laws.” *Id.* at 391 n.9.

(Some internal citations omitted).

We dismiss the petition for writ of prohibition without prejudice to petitioners’ right to raise their challenges on final appeal.

GROSS, C.J., DAMOORGIAN and GERBER, JJ., concur.

* * *

Petition for writ of prohibition to the Circuit Court for the Fifteenth Judicial Circuit, Palm Beach County; Glenn D. Kelley, Judge; L.T. Case No. 502006CA013019XXXXMB.

Jeffrey B. Shapiro and Andrea Cox of Arnstein & Lehr LLP, Miami, for petitioners.

Jane Kreuzler-Walsh and Rebecca Mercier Vargas of Kreuzler-Walsh, Compiani & Vargas, P.A., West Palm Beach, and Theodore Babbitt of Babbitt, Johnson, Osborne & LeClainche, P.A., West Palm Beach, for

respondent.

Not final until disposition of timely filed motion for rehearing.