

CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA
FIFTH APPELLATE DISTRICT

CARLYNE MC KENNEY,

Plaintiff and Appellant,

v.

PUREPAC PHARMACEUTICAL COMPANY,

Defendant and Respondent.

F052606

(Super. Ct. No. 343927)

OPINION

APPEAL from a judgment of the Superior Court of Stanislaus County. William A. Mayhew, Judge.

Law Office of Laurence O. Masson, Laurence O. Mason; Medical Legal Consultants of Washington, Ralph D. Pittle; and Jones, Martin, Parris & Tessener, Gregory M. Martin, for Plaintiff and Appellant.

Tucker, Ellis & West, Michael C. Zellers, Richard A. Dean and Peter E. Schnaitman, for Defendant and Respondent.

Appellant Carlyne McKenney brought this civil action against respondent Purepac Pharmaceutical Company (Purepac) and other defendants. Appellant alleges that she was injured as a result of using the prescription drug metoclopramide manufactured by Purepac. The superior court sustained Purepac's demurrer to McKenney's fourth amended complaint and entered judgment in favor of Purepac. The pleading alleges that

metoclopramide is the active ingredient of the brand name drug Reglan, and that Purepac “distributed the generic drug metoclopramide.” It alleges that there were “false and/or misleading statements contained in” Purepac’s labeling of the drug, and that the labeling “substantially understated and downplayed the risks of tardive dyskinesia,” a condition McKenney contracted as a result of her treatment with metoclopramide. The superior court concluded: “All of Plaintiff’s causes against Purpac are pre-empted by federal law.... Defendant Purepac is not the original manufacturer of Reglan. It is a generic manufacturer of metoclopramide and, as such, must obtain approval by the FDA before issuing any label [on] metoclopramide which deviates from the labeling previously approved by the FDA.”

Appellant contends that the court erred in sustaining the demurrer to her fourth amended complaint. As we shall explain, we agree with appellant. We hold that the federal requirement that a generic drug have the same labeling as a reference listed drug does not necessarily result in federal preemption of a state tort action against the generic manufacturer for failure to adequately warn of the dangers of the drug. We will reverse the judgment.

STANDARD OF REVIEW

“The party against whom a complaint or cross-complaint has been filed may object, by demurrer or answer ..., to the pleading on any one or more of the following grounds: [¶] ... [¶] (e) The pleading does not state facts sufficient to constitute a cause of action.” (Code Civ. Proc., § 430.10.) “The familiar terms ‘general demurrer’ and ‘special demurrer’ do not appear in the statutes. The name ‘general demurrer’ is, however, universally applied to a demurrer raising the fundamental ground: ‘The pleading does not state facts sufficient to constitute a cause of action.’ (C.C.P. 430.10(e).)” (5 Witkin, Cal. Procedure (4th ed. 1997), Pleading, § 904(3); see also Weil & Brown, Cal. Practice Guide: Civil Procedure Before Trial (The Rutter Group 2007), §7:37 (Rev. #1 2007).) “The absence of any allegation essential to a cause of action

renders it vulnerable to a general demurrer. A ruling on a general demurrer is thus a method of deciding the merits of a cause of action on assumed facts without a trial.” (*Linder v. Thrifty Oil Co.* (2000) 23 Cal.4th 429, 437, fn. 4.) “Neither trial nor appellate courts should be distracted from the main issue, or rather, the only issue involved in a demurrer hearing, namely, whether the complaint, as it stands, unconnected with extraneous matters, states a cause of action.” (*Griffith v. Department of Public Works* (1956) 141 Cal.App.2d 376, 381.)

“On appeal from a judgment dismissing an action after sustaining a demurrer without leave to amend, the standard of review is well settled. We give the complaint a reasonable interpretation, reading it as a whole and its parts in their context. [Citation.] Further, we treat the demurrer as admitting all material facts properly pleaded, but do not assume the truth of contentions, deductions or conclusions of law. [Citations.] When a demurrer is sustained, we determine whether the complaint states facts sufficient to constitute a cause of action. [Citation.] And when it is sustained without leave to amend, we decide whether there is a reasonable possibility that the defect can be cured by amendment: if it can be, the trial court has abused its discretion and we reverse. [Citation.]” (*City of Dinuba v. County of Tulare* (2007) 41 Cal.4th 859, 865; in accord, see also *Reynolds v. Bement* (2005) 36 Cal.4th 1075, 1083, *Zelig v. County of Los Angeles* (2002) 27 Cal.4th 1112, 1126, *Aubrey v. Tri-City Hospital Dist.* (1992) 2 Cal.4th 962, 966-967, and *Blank v. Kirwan* (1985) 39 Cal.3d 311, 318.) Our review of the sufficiency of the complaint is de novo. (*McCall v. PacifiCare of Cal., Inc.* (2001) 25 Cal.4th 412, 415; *Zelig v. County of Los Angeles, supra*, 27 Cal.4th at 1126.) “We also consider matters that may be judicially noticed.” (*Reynolds v. Bement, supra*, 36 Cal.4th at p. 1083; *Zelig v. County of Los Angeles, supra*, 27 Cal.4th at p. 1126; *Serrano v. Priest* (1971) 5 Cal.3d 584, 591.) The burden of demonstrating a reasonable possibility that the defect can be cured by amendment “is squarely on the plaintiff.” (*Blank v. Kirwan, supra*, 39 Cal.3d at p. 318; *Zelig v. County of Los Angeles, supra*, 27 Cal.4th at p. 1126.)

Because a reviewing court will “assume the truth of all well-pleaded factual allegations of the complaint” (*Kearney v. Salomon Smith Barney, Inc.* (2006) 39 Cal.4th 95, 101), “the question of plaintiff’s ability to prove these allegations, or the possible difficulty in making such proof does not concern the reviewing court. [Citations.]” (*Alcorn v. Anbro Engineering, Inc.* (1970) 2 Cal.3d 493, 496.) “It is not the ordinary function of a demurrer to test the truth of the plaintiff’s allegations or the accuracy with which he describes the defendant’s conduct. A demurrer tests only the legal sufficiency of the pleading. [Citation.]” (*Committee on Children’s Television, Inc. v. General Foods Corp.* (1983) 35 Cal.3d 107, 213.) Thus “[w]hether the plaintiff will be able to prove the pleaded facts is irrelevant to ruling upon the demurrer.” (*Stevens v. Superior Court* (1986) 180 Cal.App.3d 605, 610.)

Particularly pertinent to the appeal presently before us is the principle that “[w]hen a complaint affirmatively alleges facts amounting to an affirmative defense, it is subject to a demurrer.” (*Halvorsen v. Aramark Uniform Services, Inc.* (1998) 65 Cal.App.4th 1383, 1391.) “A general demurrer will lie where the complaint ‘has included allegations that *clearly* disclose some defense or bar to recovery.’ [Citation.] Thus, a demurrer based on an affirmative defense will be sustained only where the face of the complaint discloses that the action is necessarily barred by the defense. [Citation.]” (*Casterson v. Superior Court* (2002) 101 Cal.App.4th 177, 183; in accord, see also *Cryolife, Inc. v. Superior Court* (2003) 110 Cal.App.4th 1145, 1152, and *Holiday Matinee, Inc. v. Rambus, Inc.* (2004) 118 Cal.App.4th 1413, 1421.) Purepac contends that the causes of action alleged in McKenney’s fourth amended complaint are barred by the defense of federal preemption. Thus the issue before us is whether the allegations of that pleading, in conjunction with other matters that may be judicially noticed (see *Holiday Matinee, Inc. v. Rambus, Inc.*, *supra*, 118 Cal.App.4th at p. 1421), demonstrate that all possible recovery by McKenney is barred by the defense of federal preemption. The parties

agree, however, that all of McKenney's causes of action are based upon the alleged inadequacy of the metoclopramide labeling in warning of the dangers of using the drug.

**THE FOURTH AMENDED COMPLAINT DOES NOT DISCLOSE
THAT THIS ACTION IS NECESSARILY BARRED BY THE
DEFENSE OF FEDERAL PRE-EMPTION**

Article VI, Clause 2 of the Constitution of the United States provides: "This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." This clause "invalidates state laws that 'interfere with, or are contrary to,' federal law." (*Hillsborough County Florida v. Automated Medical Laboratories, Inc.* (1985) 471 U.S. 707, 712 (*Hillsborough*), quoting from *Gibbons v. Ogden* (1824) 22 U.S. 1, 211, 6 L.Ed. 23.)

Federal Preemption Principles

The United States Supreme Court has described at least three different ways in which federal law may supersede or "pre-empt" state law. "First, when acting within constitutional limits, Congress is empowered to pre-empt state law by so stating in express terms." (*Hillsborough, supra*, 471 U.S. at p. 713.) This is commonly called "express pre-emption." Second: "In the absence of express pre-emptive language, Congress' intent to pre-empt all state law in a particular area may be inferred where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplemental state regulation. [Citation.] Pre-emption of a whole field also will be inferred where the field is one in which 'the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.' [Citations.]" (*Id.* at p. 713.) This is commonly called "field pre-emption." Third: "Even where Congress has not completely displaced state

regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law. Such a conflict arises when ‘compliance with both federal and state regulations is a physical impossibility,’ [citation], or when state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress’ [citations].” (*Hillsborough, supra*, 471 U.S. at p. 713.) This is commonly called “conflict pre-emption,” although we note that on this appeal Purepac refers to the second clause of this description of conflict pre-emption as “obstacle pre-emption.” Because field pre-emption and conflict pre-emption are not express, they are sometimes referred to as forms of “implied” or “implicit” pre-emption. (See *Geier v. American Honda Motor Co., Inc.* (2000) 529 U.S. 861, 884, and *Hillsborough, supra*, 471 U.S. at p. 716.) California state courts have repeatedly recognized and applied these same basic principles. (See, e.g., *Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, 923-924; *Bronco Wine Co. v. Jolly* (2004) 33 Cal.4th 943, 955; *Viva! Internat. Voice of Animals v. Adidas Promotional Retail Operations, Inc.* (2007) 41 Cal.4th 929, 935-936; and *People v. Edward D. Jones & Co.* (2007) 154 Cal.App.4th 627, 637.)

There is a “presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause.” (*Hillsborough, supra*, 471 U.S. at p. 715.) “‘Where ... the field that Congress is said to have pre-empted has been traditionally occupied by the States “we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.’” [Citations.]” (*Hillsborough, supra*, 471 U.S. at p. 715.) California courts have similarly recognized that “[c]ourts are reluctant to infer preemption, and it is the burden of the party claiming Congress intended to preempt state law to prove it.” (*Elsworth v. Beech Aircraft Corp.* (1984) 37 Cal.3d 540, 548; *Olszewski v. Scripps Health* (2003) 30 Cal.4th 798, 815; *Viva! Internat. Voice for Animals v. Adidas Promotional Retail Operations, Inc., supra*, 41 Cal.4th at p. 936.)

“Federal regulations have no less pre-emptive effect than federal statutes. Where Congress has directed an administrator to exercise his discretion, his judgments are subject to judicial review only to determine whether he has exceeded his statutory authority or acted arbitrarily. [Citation.] When the administrator promulgates regulations intended to pre-empt state law, the court’s inquiry is similarly limited: [¶] ‘If his choice represents a reasonable accommodation of conflicting policies that were committed to the agency’s care by the statute, we should not disturb it unless it appears from the statute or legislative history that the accommodation is not one that Congress would have sanctioned.’ [Citation.]” (*Fidelity Federal Savings & Loan Assn. v. De la Cuesta* (1982) 458 U.S. 141, 153-154; in accord, see also *Capital Cities Cable, Inc. v. Crisp* (1984) 467 U.S. 691, 699, and *United States v. Shimer* (1961) 367 U.S. 374, 381-382.) “We have held repeatedly that state laws can be pre-empted by federal regulations as well as by federal statutes.” (*Hillsborough, supra*, 471 U.S. at p. 713.)

Purepac’s successful argument in the superior court, and its argument once again to this court, goes like this. The United States Food and Drug Administration (“FDA”) “shall – (1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner” and “with respect to such products, protect the public health by ensuring that – ... human and veterinary drugs are safe and effective.” (21 U.S.C.A. §393, subds. (b)(1) & (b)(2)(B).) Pursuant to this congressional directive, the FDA has adopted regulations overseeing the labeling of drugs. (See, e.g., 21 C.F.R. §§ 201.56, 201.80 and 314.70.) Because Purepac was not free to deviate from the FDA-approved labeling for metoclopramide, any civil liability to McKenney under state law for failure to adequately warn of the dangers of taking the drug are pre-empted as impermissibly conflicting with the FDA’s authority over drug labeling. To put it a bit simpler, Purepac contends that its metoclopramide labeling was FDA-approved, that it could not have utilized any labeling that was not FDA-approved, and that therefore it cannot be held liable under state law for

failing to use whatever different labeling McKenney may contend Purepac should have used. Purepac argues that being held liable under state law for not utilizing unapproved labeling would “stand[] as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress” (*Hillsborough, supra*, 471 U.S. at p. 713.)

We see no contention from Purepac that all state civil liability for injury caused by mislabeled drugs is pre-empted – such as, for example, injury caused by a manufacturer mislabeling a drug and failing to utilize an FDA-approved label for that drug. The FDA itself has said: “FDA recognizes that FDA’s regulation of drug labeling will not preempt all State law actions. The Supreme Court has held that certain State law requirements that parallel FDA requirements may not be preempted [citation]” (71 Fed.Reg. 3922, 3936 (an FDA document referred to by the parties as the “Final Rules Preamble” or the “Preemption Preamble”).) In considering the preemptive effect of another federal statute involving medical devices, the U.S. Supreme Court has said: “Nothing in [the statute] denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.... The presence of a damages remedy does not amount to the additional or different ‘requirement’ that is necessary [for pre-emption] under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing ‘requirements’ under federal law.” (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 495.)

Purepac persuaded the superior court that Purepac’s status as a generic manufacturer of metoclopramide required preemption of McKenney’s action because Purepac was required, as a generic manufacturer, to use the same labeling used on the originally approved drug Reglan. Generic drugs obtain FDA approval under a process known as an abbreviated new drug application (“ANDA”). (See *Colacicco v. Apotex, Inc.* (2008) 521 F.3d 253, 260.) The FDA has stated that “an ANDA must have labeling that is the same as the reference listed drug” (57 Fed. Reg. 17950, 17961.) The FDA also, however, must approve the labeling of the original or “reference” drug. (*Colacicco*

v. Apotex, Inc., supra, 521 F.3d at pp. 257-260.) The FDA has stated that its mechanism for compelling labeling revisions “applies to both ANDA and NDA drug products” and that “[a]fter approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.” (57 Fed. Reg. 17950, 17961.) We therefore see no reason to distinguish between original or “listed” drugs and their generic equivalents for federal preemption purposes. Nor do we see any indication that the FDA itself has ever taken the position that its labeling requirements for generics would invoke federal preemption principles so as to exempt manufacturers of generic drugs from tort liability.

The *Carlin* Case

In *Brown v. Superior Court* (1988) 44 Cal.3d 1049, the California Supreme Court held that a drug manufacturer could not be held strictly liable for failing to warn of risks inherent in a drug even though the manufacturer neither knew, nor could have known by the application of scientific knowledge available at the time of distribution, that the drug could produce the undesirable side effects suffered by the plaintiff. (*Id.* at p. 1065.) In *Anderson v. Owens-Corning Fiberglass Corp.* (1991) 53 Cal.3d 987, the court held that “knowledge or knowability is a component of strict liability for failure to warn” (*id.* at p. 1000), and that evidence of the “state of the art may be relevant to the question of knowability and, for that reason, should be admissible in that context.” (*Id.* at p. 991.) In *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, the court reaffirmed *Brown* and rejected a drug manufacturer’s argument that drug manufacturers should not be held strictly liable for failure to warn of known or reasonably scientifically knowable risks from prescription drugs and should instead be held liable only for simple negligence. (*Id.* at p. 1109.) “In this case we address the question whether a plaintiff alleging injury from ingesting a prescription drug can state a claim against the manufacturer for strict liability and

breach of warranty for failure to warn about the known or reasonably scientifically knowable dangerous propensities of its product. We conclude that she can.” (*Id.* at p. 1108.) The *Carlin* court rejected an argument that this strict liability standard would be inconsistent with federal regulatory policy and expressly noted that “Congress evinced no intention of preempting state tort liability for injuries from prescription drugs.” (*Id.* at p. 1113.)

“We are unpersuaded by Upjohn’s argument that a strict liability standard for failure to warn about known or reasonably scientifically knowable risks from prescription drugs is inconsistent with federal regulatory policy. Upjohn concedes that FDA regulations do not expressly preempt common law tort remedies for failure to warn or occupy the entire field of regulation. As numerous courts have concluded, Congress evinced no intention of preempting state tort liability for injuries from prescription drugs. (See, e.g., *Feldman v. Lederle Laboratories* (1991) 125 N.J. 117, 147 [.]” “[W]e find nothing in the federal scheme to support the assertion that manufacturers of prescription drugs and antibiotics who literally comply with [FDA regulations] must be immune from state tort liability for injuries caused by their products.’]; *Abbot by Abbot v. American Cyanamid Co.* (4th Cir. 1988) 844 F.2d 1108, 1112 [] [federal law does not preempt imposition of state common law liability for failure to warn, despite the fact that labeling, ‘once approved, cannot be changed without FDA approval.’]; *Mazur v. Merck & Co., Inc.* (E.D.Pa. 1990) 742 F.Supp. 239, 247 [‘[M]ere compliance with an FDA suggestion, or for that matter, regulation or order, does not mean that state tort law becomes irrelevant.... [¶] ... State tort law is intended to supplement federal regulation’]; cf. *Medtronic, Inc. v. Lohr* (1996) 518 U.S. __, __ [135 L.Ed.2d 700, 725-726, 116 S.Ct. 2240] [plur. opn. of Stevens, J.) [negligence and strict liability claims for failure to warn about risks of a medical device were not preempted by federal regulations].)” (*Carlin v. Superior Court, supra*, 13 Cal.4th at pp. 1113-1114.)

Application of The Law to Appellant’s Allegations

What has changed since *Carlin* that might cause us to conclude that federal preemption principles would exempt a generic manufacturer of prescription drugs from strict products liability simply because the generic manufacturer must obtain approval from the FDA before issuing any metoclopramide label which deviates from the labeling

previously approved by the FDA? In short, nothing we can see. Purepac points out that the FDA itself has in recent years issued statements pertaining to preemption. “FDA believes that at least the following claims would be preempted by its regulation of prescription drug labeling: ... claims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn (unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning before plaintiff claims the sponsor had the obligation to warn)” (71 Fed. Reg. 3922.) The FDA has also said, however, “FDA recognizes that FDA’s regulation of drug labeling will not preempt all State law actions.” (71 Fed. Reg. 3922.)¹ Furthermore, the FDA’s observation that a manufacturer cannot be held liable in tort for failing to give a warning which the FDA had already determined to be inappropriate mirrors the *Carlin* court’s same statement on that same topic.

“[I]n the case of an alleged ‘known’ risk, if state-of-the-art scientific data concerning the alleged risk was fully disclosed to the FDA and it determined, after review, that the pharmaceutical manufacturer was *not permitted to warn* – e.g., because the data was inconclusive or the risk was too speculative to justify a warning – the manufacturer could present such evidence to show that strict liability cannot apply; the FDA’s conclusion that there was, in effect, no ‘known risk’ is controlling. (See *Feldman v. Lederle Laboratories, supra*, 125 N.J. at p. 135 [] [‘conflict preemption’ occurs when compliance with both federal and state requirements is impossible].)” (*Carlin v. Superior Court, supra*, 13 Cal.4th at p. 1115.)

¹ Appellant has filed a motion asking us to take judicial notice of amicus briefs filed by the FDA in two other cases heard in the United States District Court for the Eastern District of Pennsylvania. The motion is unopposed, and we grant the motion. We note, however, that our decision would be the same even without judicial notice of these two amicus briefs. As our opinion points out, the FDA has published its views on preemption in the Federal Register. The two amicus briefs repeat those same views.

The existence of a conflict preemption defense in the above-described circumstance was made even clearer by the *Carlin* court in its footnote 4, where the court stated: “[T]he FDA’s approval of a particular warning is not determinative of liability. Nor have our courts adopted the approach of the narrow line of cases ... which would insulate manufacturers for failure to warn if they merely gave FDA-approved warnings. It is a very different thing, however, to hold, as we do here, that a pharmaceutical manufacturer may not be held liable for failing to give a warning it has been *expressly precluded* by the FDA from giving.” (*Carlin v. Superior Court, supra*, 13 Cal.4th at p. 1115, fn. 4.)

In the case presently before us, Purepac has not called our attention to anything in the allegations of McKenney’s fourth amended complaint that would demonstrate the necessary applicability of a preemption defense to those allegations. To state this a bit differently, nothing in the McKenney’s fourth amended complaint alleges that Purepac should have given warnings about the use of metoclopramide that the FDA expressly precluded Purepac from giving. The superior court therefore erred in sustaining the demurrer.

Nor has Purepac cited to us any appellate court decision holding that a generic manufacturer of a prescription drug can never be held strictly liable in tort for failure to warn when the generic manufacturer utilizes FDA-approved labeling. In *Colacicco v. Apotex, Inc., supra*, 521 F.3d 253 the court did find federal preemption, but expressly stated that “[o]ur holding is limited to circumstances in which the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires.” (*Id.* at pp. 271-272.) In that case the FDA submitted an amicus brief, and even the FDA itself did not take the position that federal preemption always insulates a generic manufacturer utilizing FDA-approved labeling from tort liability for failure to warn. “The FDA explains in the amicus brief that ‘the basis for federal preemption is not the [labeling] guidelines themselves ..., but rather FDA’s repeated determinations prior to October

2003 that there was insufficient scientific evidence of an association between adult use of SSRI and suicide or suicidality to permit a warning on the labeling for those drugs” (*Colacicco, supra*, 521 F.3d at p. 274.) The proper application of federal preemption principles to failure-to-warn claims is presently before the U.S. Supreme Court in *Levine v. Wyeth* (2006) ___ Vt. ___, 944 A.2d 179, 2006 WL 3041078, cert. granted Jan. 18, 2008 at *Wyeth v. Levine* (2008) 128 S.Ct. 1118 (No. 06-1249). In *Levine v. Wyeth, supra*, the Supreme Court of Vermont noted the “general rule that FDA approval of a drug’s label does not preempt state failure-to-warn claims” (944 A.2d at p. 186) and followed that general rule. A dissenting opinion argued that on the facts of that particular case the plaintiff’s claim was preempted. “It is inaccurate ... to characterize the requirements imposed by the jury verdict in this case as merely requiring a ‘stronger warning.’ Rather, what plaintiff sought was an elimination of a use of Phenergan that had been approved by the FDA.” (944 A.2d at p. 198, dis. opn. of Reiber, C.J.) Nothing in even the dissenting opinion, however, suggests or supports the expansive reach of federal preemption advocated here by Purepac.

DISPOSITION

The judgment is reversed. Costs on appeal are awarded to appellant McKenney.

Ardaiz, P.J.

WE CONCUR:

Levy, J.

Dawson, J.