STATE OF MICHIGAN

COURT OF APPEALS

WILLIAM JACKSON,

Plaintiff-Appellant,

v

PERRY DRUG STORES, INC.,

Defendant-Appellee.

UNPUBLISHED
December 9, 1997

No. 195680
Wayne Circuit Court
LC No. 95-507986-NP

WILLIAM JACKSON,

Plaintiff-Appellant,

v

PERRIGO COMPANY,

Defendant-Appellee.

No. 195681
Wayne Circuit Court
LC No. 96-610567-NP

Before: Bandstra, P.J., and Cavanagh and Markman, JJ.

PER CURIAM.

Plaintiff, William Jackson, appeals as of right orders granting summary disposition pursuant to MCR 2.116(C)(8) to each defendant in these consolidated actions. We reverse and remand.

Plaintiff filed separate actions against each defendant, alleging that he suffered renal failure as a result of his ingestion of non-prescription Perry brand ibuprofen sold by Perry Drug Stores, and manufactured by Perrigo. Plaintiff alleged several grounds of negligence, including failure to properly test and inspect the drug, providing misleading labeling, failure to adequately warn, and negligently placing an unsafe drug on the market. The trial court granted summary disposition to the defendant in both cases, and consolidated the two cases.

Plaintiff argues that the trial court erred when it granted summary disposition to defendants on the basis that plaintiff's tort claims were preempted by federal law. We agree. This Court reviews a grant of summary disposition de novo. A motion under MCR 2.116(C)(8) relies on the pleadings alone, and this Court accepts as true all well-pled allegations in the complaint, as well as any reasonable inferences or conclusions that can be drawn from those allegations. *Peters v Dep't of Corrections*, 215 Mich App 485, 486; 546 NW2d 668 (1996). Such a motion should be granted "only when the claim is so clearly unenforceable as a matter of law that no factual development could possibly justify a right of recovery." *Harrison v Dep't of Corrections*, 194 Mich App 446, 450; 487 NW2d 799 (1992).

Under the Supremacy Clause, US Const, art VI, cl 2, federal law supersedes state law and may preempt it in several different ways. *Hillsborough County v Automated Med Labs*, 471 US 707, 712-713; 105 S Ct 2371; 85 L Ed 2d 714 (1985). First, Congress may expressly preempt state law by indicating its intent to do so. *Id*. Second, in the absence of express preemption, Congressional intent to preempt will be inferred where a scheme of federal regulation is so comprehensive or pervasive as to leave no room for state action in the field. *Id*. Third, state law is preempted when it directly conflicts with federal law, either because it is physically impossible to comply with both federal and state law or because the state law frustrates the purpose and objective of the federal law. *Id*.

In the case at bar, defendant concedes that Congress has not expressly preempted state tort actions. Defendant contends, however, that preemption is implied because the Federal Food Drug and Cosmetic Act, 21 USC 355 *et seq*. ("FDCA") occupies the entire field of drug labeling regulation given the pervasiveness of the FDA's regulation of drug labeling. We disagree. In addressing a similar argument in *Hillsborough County, supra*, at 719, the United States Supreme Court noted that "the regulation of health and safety matters is primarily, and historically, a matter of local concern." Where the field is one traditionally occupied by the states, the Court assumes "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." *Id*. at 715 [quoting *Rice v Santa Fe Elevator Corp*, 331 US 218 at 230; 67 S Ct 1146; 91 L Ed 1447 (1947)]. The Court concluded that it would "seldom" infer an intent to preempt in a field related to health and safety merely because federal regulations were comprehensive. *Id*. at 718. The presumption against preemption in the areas of health and safety has been recognized by this Court. *Walker v Johnson & Johnson*, 217 Mich App 705, 711; 552 NW2d 679 (1996). In addition, the presumption "is even stronger against preemption of state remedies, like tort recoveries, when no federal remedy exists." *Abbot by Abbot v American Cyanamid Co*, 844 F2d 1108, 1112-1113 (CA 4, 1988).

Defendants in the instant case have offered no basis for overcoming the strong presumption that plaintiff's state tort remedy should not be preempted merely because of the comprehensiveness of the FDA's regulations. Plaintiff would have no counterpart remedy under federal law if his state tort claim were preempted. Since defendants have not distinguished their implied preemption argument from the unsuccessful arguments made in *Hillsborough County, supra*, we hold that the FDCA and regulations pursuant thereto do not impliedly preempt plaintiff's state tort claim against defendants. While we are not oblivious to the potential burdens placed upon a business when it is subject to the legal authority of

both the federal and state governments, recourse for this must be addressed to the political processes operating upon such governments rather than to a redefinition of the legitimate authority of the states within our constitutional structure.

Defendants further contend that plaintiff's claim should be preempted because a direct conflict exists between a state jury finding that defendants are liable for failure to adequately warn and 21 USC 355(j)(2)(A)(v), which requires that defendants provide labeling which is the "same as" the approved labeling for the listed drug to which defendants compared ibuprofen when filing an abbreviated application for approval of the drug. If a jury were to hold defendants liable for using the very labeling required by federal law, defendants argue, then it would be physically impossible to comply with both federal and state law. We disagree. Defendants' argument only addresses plaintiff's failure to adequately warn claims, and provides no reason why the remaining claims, including failure to properly test and inspect the drug and negligently placing the drug on the market, would directly conflict with federal law. Further, even plaintiff's failure to warn claim does not directly conflict with federal law. In *In re Tetracycline Cases*, 747 F Supp 543, 545 (W D Mo., 1989), as here, the defendant drug manufacturer argued that it could not be required by a state jury to provide warnings different from or broader than those required by the FDA to be used without change. The Court held against preemption, and noted that

> a jury could find defendants might have taken other actions supplementing and complementing the FDA warning requirements, and such actions need not be inconsistent or conflicting with the federal requirements. For example, writing additional letters to doctors, distributing brochures to consumers, and posting notices at . . . clinics all perhaps could have been done without violating FDA requirements or frustrating FDA's policy and purpose. Such conditions lack the sort of direct conflict . . . needed to find implied preemption. [*Id*. at 549-550.]

Similarly, in the case at bar, defendants could have complemented or supplemented the FDA warnings without changing the labeling approved by the FDA. Since it would not have been impossible for defendants to comply both with federal law and with their state tort duty to provide adequate warnings, no direct conflict has been established to justify preemption. Again, while we are not unsympathetic to defendants' dilemma, it is not an irresoluble one and it is a dilemma whose impact must be ameliorated by the representative branches of government not by this Court. The extent to which defendants complied with federal law, as well as the extent to which compliance with both federal and state law might be difficult or burdensome, are factors that may be considered only in the context of plaintiff's various claims of negligence.

Finally, defendants' reliance on MCL 600.2946; MSA 27A.2946, which provides in part that a drug is not defective if approved by the FDA, is misplaced. Plaintiff's complaint was filed before March 28, 1996, the effective date of the act. The statute is therefore not relevant to the issue of whether federal law preempts plaintiff's state tort claim that was filed before the statute went into effect.[1]

Reversed and remanded for further proceedings consistent with this opinion. We do not retain jurisdiction.

/s/ Richard A. Bandstra
/s/ Mark J. Cavanagh
/s/ Stephen J. Markman

[1] With respect to plaintiff's other argument on appeal-- that the trial court erred in commenting upon the fact that plaintiff took ibuprofen for over two years despite a label which stated that it should not be taken for more than ten days-- we see nothing in these comments that were unwarranted on the basis of the record or that would otherwise require reversal. We not do address here any potential bases for summary disposition apart from that grounded in federal preemption.