

**STATE OF MICHIGAN**  
**COURT OF APPEALS**

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ATTORNEY GENERAL, STATE OF  
MICHIGAN and CARBOLOGY, INC.,

Plaintiffs-Appellees,

v

MERCK SHARP & DOHME CORPORATION  
f/k/a MERCK & CO., INC.,

Defendant-Appellant.

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FOR PUBLICATION  
March 17, 2011  
9:00 a.m.

No. 292003  
Ingham Circuit Court  
LC No. 08-001132-CZ

Before: SAWYER, P.J., and FITZGERALD and SAAD, JJ.

SAAD, J.

Defendant, Merck Sharp & Dohme Corporation (Merck), appeals the trial court's order that denied its motion for summary disposition. For the reasons set forth below, we reverse and remand for further proceedings.

**I. NATURE OF THE CASE**

Michigan's attorney general claims that because Merck misrepresented the safety and efficacy of Vioxx in its marketing and because Michigan reimbursed providers who prescribed or dispensed Vioxx, Michigan would not have incurred such expenses but for Merck's fraudulent activity. The state now claims a right to recover these sums under the Medicaid False Claim Act, but Merck counters that Michigan's Legislature has immunized it from liability in suits that seek to adjudicate a drug's safety when the federal Food and Drug Administration approved the drug. Michigan's attorney general maintains that the statute only exempts drug makers in traditional products liability actions in which an end user of the drug, i.e., a consumer, is injured by the ingestion of the drug. Merck argues that, regardless of the label that the attorney general gives this lawsuit, the claim and ultimate right to recovery center on the safety and efficacy of a drug that the FDA approved and the immunity statute, therefore, bars the claim.

Michigan's immunity statute is the only one of its kind in the United States and the claims made by the parties raise an issue of first impression under Michigan law. We hold that

where, as here, the drug in question was approved by the FDA, the state's suit to recover Medicaid money premised on fraud by the drug company in its representations regarding the safety and efficacy of the drug is barred by MCL 600.2946(5), which exempts drug companies from product liability suits regarding FDA-approved drugs.<sup>1</sup>

## II. FACTS AND PROCEEDINGS

Merck is the manufacturer of the prescription pain reliever Vioxx. In May 1999, the Food and Drug Administration (FDA) approved Vioxx for the treatment of osteoarthritis, the management of acute pain in adults, and the treatment of primary dysmenorrhea. Subsequent clinical trials and independent studies showed an increased risk of heart attack in persons who used Vioxx. In 2004, Merck voluntarily removed Vioxx from the market.<sup>2</sup>

On August 21, 2008, the Michigan attorney general filed this action under the Medicaid False Claim Act (MFCA), MCL 400.601 *et seq.*, and alleged that Merck made false and deceptive statements about the safety and efficacy of Vioxx. Plaintiffs relied on § 607 of the MFCA, which provides, in pertinent part:

(1) A person shall not make or present or cause to be made or presented to an employee or officer of this state a claim under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, upon or against the state, knowing the claim to be false.

(2) A person shall not make or present or cause to be made or presented a claim under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, that he or she knows falsely represents that the goods or services for which the claim is made were medically necessary in accordance with professionally accepted standards. [MCL 400.607(1) and (2).]

Vioxx had been prescribed to Medicaid beneficiaries from 1999 until 2004 when it was taken off the market. Plaintiffs alleged that, as early as 2000, Merck knew that Vioxx was associated with an increased risk of heart attack, and Merck concealed or misrepresented the scientific data from clinical trials that demonstrated this risk. Plaintiffs asserted that if Merck had been truthful about the safety and efficacy of Vioxx, they would not have paid all or part of the cost of Vioxx

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<sup>1</sup> To assert a claim under the Medicaid False Claim Act against a pharmaceutical company that has undertaken the rigorous and requiring process to obtain FDA approval for a prescription drug appears to be an interpretation of the Act not intended by the Legislature, but in light of our ruling that the attorney general's suit is barred by MCL 600.2946(5), we need not address this issue of first impression under Michigan law.

<sup>2</sup> A plethora of lawsuits followed the removal of Vioxx from the market, resulting in billions of dollars in settlements and jury awards under various legal theories.

prescribed to Michigan Medicaid beneficiaries, which cost them more than \$20 million. Plaintiffs also sought recovery under a theory of unjust enrichment.

Merck moved for summary disposition pursuant to MCR 2.116(C)(8) and argued that plaintiffs' claim is a "product liability action" pursuant to MCL 600.2945(h)<sup>3</sup> and is therefore barred by MCL 600.2946(5),<sup>4</sup> which provides that a manufacturer or seller of a drug is not liable in a "product liability action" if the drug was approved for safety and efficacy by the FDA and labeled in compliance with FDA standards. Merck relied on *Duronio v Merck & Co, Inc*, unpublished opinion per curiam of the Court of Appeals, issued June 13, 2006 (Docket No. 267003), in which this Court affirmed a trial court's grant of summary disposition in favor of Merck in a similar case. In *Duronio*, the plaintiff asserted a fraud claim and violation of the Michigan Consumer Protection Act (MCPA), MCL 445.901 *et seq.*, based on allegations that Merck misrepresented or concealed the risks associated with Vioxx.

Here, the trial court denied Merck's motion for summary disposition. The court disagreed in part with the *Duronio* panel's interpretation of the phrase "product liability action." The court ruled that plaintiffs' claims do not constitute a product liability action because, unlike a product liability action, plaintiffs' claims under the MFCA and their theory of unjust enrichment do not require proof of a defective or unsafe product. The court also looked to the legislative intent underlying MCL 600.2946(5), and concluded that the Legislature did not intend to foreclose actions under the MFCA.

### III. ANALYSIS

Merck argues that this is a product liability lawsuit, which is barred under MCL 600.2946(5). Merck maintains that the trial court erred in construing "product liability action" by looking to legislative intent and public policy concerns instead of to the plain language of MCL 600.2945(h) and this Court's interpretation of it in *Duronio*. Merck argues that the statute defines "product liability action" broadly enough to encompass plaintiffs' claims. Merck also

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<sup>3</sup> MCL 600.2945(h) states:

"Product liability action" means an action based on a legal or equitable theory of liability brought for the death of a person or for injury to a person or damage to property caused by or resulting from the production of a product.

<sup>4</sup> MCL 600.2946(5) states in pertinent part:

In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

contends that even if public policy implications are relevant, the trial court erred in its analysis. MCL 600.2946(5) does not bar all claims against pharmaceutical manufacturers in the hypothetical situations posed by the court. Claims involving ineffective drugs, or ineffective performance of drugs, would be permitted as long as the safety of the drugs were not implicated. Merck also argues that allowing plaintiffs' claims to proceed would subvert legislative intent by leaving pharmaceutical manufacturers exposed to high-stakes litigation, while shielding them from smaller claims brought by individuals such as the *Duronio* plaintiff. Merck contends that the trial court improperly focused on the labels of plaintiffs' claims, rather than their substance.

Plaintiffs distinguish their case from a product liability action, which they describe as a specialized branch of tort law involving the sale of defective products to individual consumers or end users. Plaintiffs argue that their case differs because they seek reimbursement for money paid by a third party payor that never bought or used the product. Plaintiffs maintain that the immunity granted by statute does not expand the traditional scope of product liability litigation beyond consumers who sue manufacturers. Plaintiffs also argue that *Duronio* is not controlling and that the Court should focus on the different purposes of the MFCA and the product liability statute.

This Court reviews a trial court's grant of summary disposition de novo. *Maiden v Rozwood*, 461 Mich 109, 118; 597 NW2d 817 (1999). A motion under MCR 2.116(C)(8) tests the legal sufficiency of a claim on the basis of the pleadings alone. *Id.* at 119-120. The motion is properly granted if the claim is so unenforceable as a matter of law that no factual development could possibly justify recovery. *Id.* This Court also reviews the interpretation and application of a statute de novo as a question of law. *Health Care Ass'n Workers Compensation Fund v Director of the Bureau of Worker's Compensation*, 265 Mich App 236, 243; 694 NW2d 761 (2005).

In 1995, the Legislature amended MCL 600.2946 to provide immunity for products liability claims against a manufacturer or seller of a drug that was approved for safety and efficacy by the FDA and labeled in compliance with FDA standards.<sup>5</sup> MCL 600.2946(5); *Taylor v Gate Pharmaceuticals*, 468 Mich 1, 6-7; 658 NW2d 127 (2003). MCL 600.2946(5) states in pertinent part:

In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

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<sup>5</sup> There is no dispute that the FDA approved Vioxx and its labeling before the drugs left Merck's control.

In interpreting this provision, our Supreme Court in *Taylor* stated that “*the Legislature has determined that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie.*” *Taylor*, 468 Mich at 7 (emphasis added).

The central issue is whether plaintiffs’ claim is a “product liability action” within the meaning of MCL 600.2946(5). Plaintiffs assert that it is not, but a court is not bound by a party’s choice of labels. *Johnston v City of Livonia*, 177 Mich App 200, 208; 441 NW2d 41 (1989). Rather, we determine the gravamen of a party’s claim by reviewing the entire claim, and a party cannot avoid dismissal of a cause of action by artful pleading. *Maiden, supra*, 461 Mich at 135. MCL 600.2945 defines “product liability action” and “production” as follows:

(h) “Product liability action” means an action based on a legal or equitable theory of liability brought for the death of a person or for an injury to a person or damage to property caused by or resulting from the production of a product.

(i) “Production” means manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instruction, marketing, selling, advertising, packaging, or labeling. [MCL 600.2945(h) and (i).]

As this Court explained in *McElhaney ex rel McElhaney v Harper-Hutzel Hosp*, 269 Mich App 488, 493; 711 NW2d 795 (2006):

The primary goal of judicial interpretation of statutes is to ascertain and give effect to the intent of the Legislature. The first step is to examine the plain language of the statute itself. The Legislature is presumed to have intended the meaning it plainly expressed. If the statutory language is clear and unambiguous, appellate courts presume that the Legislature intended the meaning plainly expressed, and further judicial construction is not permitted. [Citations omitted.]

Pursuant to the plain language of the statute, the claim asserted by the attorney general is a “product liability action” subject to the immunity provision of MCL 600.2946(5) if (1) the action is based on a legal or equitable theory of liability, (2) the action is brought for the death of a person or for injury to a person or damage to property, and (3) that loss was caused by or resulted from the construction, design, formulation, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling of a product.

Here, it is clear that elements (1) and (3) are met. Plaintiffs’ action is clearly based on a legal or equitable theory of liability. Plaintiffs allege that Merck is liable for violating § 607 of the MFCA and under the equitable principles of unjust enrichment. Further, plaintiffs’ allege that their loss was caused by the marketing and advertising of Vioxx. Plaintiffs claim that Merck made deceptive statements about the *safety and efficacy* of Vioxx, and that they would not have paid all or part of the cost of Vioxx prescribed to Michigan Medicaid beneficiaries had Merck not made the allegedly false and deceptive statements. Moreover, plaintiffs specifically allege that these deceptive statements came in the form of marketing and advertising.

With regard to the second element, the question is whether plaintiffs' claim was brought for the death of a person or for injury to a person or damage to property. Plaintiffs have made no allegation of a death or physical injury to a person, but seek money damages for alleged "Medicaid overpayments wrongfully received by Defendant." There is no published authority interpreting MCL 600.2946(5) in this context. However, generally, "[a] person whose property is diminished by a payment of money wrongfully induced is injured in his property." *Reiter v Sonotone Corp*, 442 US 330, 340; 99 S Ct 2326; 60 L Ed 2d 931 (1979), quoting *Chattanooga Foundry and Pipe Works v Atlanta*, 203 US 390, 396; 27 S Ct 65, 66, 51 L Ed 241 (1906) (where a city was induced to pay more than the value of the item received). We also find persuasive the analysis in the unpublished opinion in *Duronio*.<sup>6</sup> In *Duronio*, the plaintiff sought money damages for the purchase price of Vioxx and costs related to expenses for a medical consultation recommended by the FDA and Merck in connection with Merck's voluntary withdrawal of Vioxx from the market. *Duronio*, slip op pp 1-2. The plaintiff alleged fraud and violation of the Michigan Consumer Protection Act (MCPA), MCL 445.901 *et seq.*, claiming "that Merck disseminated information to the general public that concealed or downplayed potential cardiovascular risks and falsely implied that Vioxx provided superior pain relief to over-the-counter medications, and that Merck's pharmaceutical representatives misled prescribing physicians regarding the safety of Vioxx for their patients." *Id.*

The trial court granted the Merck motion for summary disposition and ruled that, in substance, the plaintiff's claim was a product liability claim, as defined in MCL 600.2945(h), and therefore Merck was immune from suit under MCL 600.2946(5). *Duronio*, slip op p 2. This Court affirmed and agreed that the plaintiff's claim was a product liability action within the meaning and scope of MCL 600.2945(h). The panel specifically ruled that the plaintiff's claim for money damages was based on a theory of liability "for damage to property resulting from the production" of Vioxx:

Because plaintiff did not allege any injury to his person, the trial court could only find a legal or equitable theory falling within the scope of MCL 600.2945(h) if plaintiff's action could be characterized as one for "damage to property" caused by or resulting from the production of Vioxx. . . .

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MCL 600.2945(h) does not use the word "damages," but rather requires an "action based on a legal or equitable theory of liability brought for the death of a person or for injury to a person *or damage to property* caused by or resulting from the production of a product." Examined in context, we reject plaintiff's claim that "damage to property" only encompasses physical damage to property. The phrase is broad enough to include both physical damage to an object and injury or harm

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<sup>6</sup> Unpublished cases are not binding on this Court, MCR 7.215(C)(1), but we may view them as persuasive when there is limited case law on the issue. *Dyball v Lennox*, 260 Mich App 698, 705 n 1; 680 NW2d 522 (2003).

to rights or interests associated with an object, so long as the damage is caused by or results from the production of the product. . . .

The fact that the alleged injury in this case is in the form of monetary loss does not preclude application of MCL 600.2945(h). Money itself is a form of property, *Garr[a]s v Bekiares*, 315 Mich 141, 148-149; 23 NW2d 239 (1946), and a consumer's expenditure of money for overvalued goods can constitute an injury to property. [*Duronio*, slip op pp 4-5 (emphasis in original).]

In addition to holding that the plaintiff's claim for reimbursement was a claim for damage to property, the *Duronio* panel looked beyond the plaintiff's "fraud" label for his claim, and ruled that "the safety and efficacy of Vioxx [was] essential to his monetary loss claim." *Id.*, slip op p 6. Therefore, the plaintiff's claim was barred under MCL 600.2946(5):

. . . [P]laintiff presented a claim as arising from misrepresentations and omissions, and denied that the alleged concealed risks of using Vioxx ever materialized for him, but it is clear that the safety and efficacy of Vioxx is essential to his monetary loss claim.

Because plaintiff brought the claim for damage to property (money) caused by or resulting from the production (marketing, selling, advertising, packaging, or labeling) of Vioxx, plaintiff's pleaded common-law fraud claim for a refund of the cost of purchasing Vioxx is, in substance, a product liability action within the meaning of MCL 600.2945(h). Assuming for purposes of our review that plaintiff's request to have Merck pay for a medical consultation is actionable in tort, plaintiff's alleged loss of a right or interest in money to obtain a medical consultation constitutes damage to property within the meaning of MCL 600.2945(h). Any additional claim for lost income or expenses to obtain the medical consultation is merely a pecuniary loss flowing from that injury. *Citizens for Pretrial Justice v Goldfarb*, 415 Mich 255, 268; 327 NW2d 910 (1982).

The trial court properly determined that plaintiff's common-law fraud claim is, in substance, a product liability action subject to the absolute defense established by MCL 600.2946(5). [*Duronio*, slip op p 6.<sup>7</sup>]

Here, we hold that plaintiffs' allegations fall within the statutory definition of "product liability action," because plaintiffs have asserted legal and equitable theories of liability for damage to property resulting from the production of a product. MCL 600.2945(h). Pursuant to

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<sup>7</sup> The Court in *Duronio* did not decide whether the plaintiff's MCPA claim was also a product liability action and therefore also barred by the immunity provision in MCL 600.2946(5). *Duronio*, slip op at 7. Rather, this Court ruled that the trial court correctly dismissed plaintiff's MCPA claim because an exemption within the MCPA statute applied, MCL 445.904(1)(a). *Id.*

the ordinary meaning of the phrase as examined by this Court in *Duronio*, plaintiffs' claim of monetary loss based on alleged misrepresentations regarding the safety and efficacy of Vioxx constitutes "damage to property."

We agree with Merck that nothing in the statute limits its application to claims brought by consumers and that the statute in no way precludes a claim pursued under the MFCA or described as an action for unjust enrichment. Again, by its own terms, MCL 600.2946(5) applies to actions "based on a legal or equitable theory of liability," which includes the claims at issue here. If the plain language of the statute results in an outcome that the Legislature now deems improper, it is for the Legislature, not this Court, to narrow the application of the statute by amending or redrafting its terms.

Like the plaintiff's allegations in *Duronio*, plaintiffs' claims here are indisputably based on Merck's representations about the safety and efficacy of Vioxx. Although a claim under the MFCA does not require proof of an unsafe product, in this case the safety and efficacy of Vioxx is central to plaintiffs' claim, as plaintiffs' counsel acknowledged at oral argument. Viewing the complaint in its entirety, the substance of plaintiffs' claim concerns the safety and efficacy of Merck's drug, and Merck's representations in that regard. Because the FDA approved the safety and efficacy of Vioxx, plaintiffs' claims are barred by MCL 600.2946(5).

For these reasons, we hold that the trial court erred when it failed to apply the plain language of MCL 600.2945(h) and MCL 600.2946(5). Further, because plaintiffs' lawsuit constitutes a "product liability action" under the controlling statutory language, Merck is not liable under the terms of the statute and the trial court erred by denying Merck's motion for summary disposition.

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

/s/ Henry William Saad  
/s/ David H. Sawyer