RENDERED: FEBRUARY 10, 2012; 10:00 A.M.
TO BE PUBLISHED

Commonwealth of Kentucky

Court of Appeals

NO. 2011-CA-000234-MR

MERCK & COMPANY, INC.,
n/k/a MERCK SHARP & DOHME CORP. APPELLANT

v.

APPEAL FROM PIKE CIRCUIT COURT
HONORABLE STEVEN D. COMBS, JUDGE
ACTION NO. 04-CI-01493

JAMES RATLIFF, ON BEHALF OF HIMSELF
AND ALL OTHERS SIMILARLY SITUATED APPELLEES

OPINION
REVERSING AND REMANDING

** ** ** ** **

BEFORE: ACREE, CLAYTON, AND WINE,[1] JUDGES.

WINE, JUDGE: Merck & Company, Inc., n/k/a Merck Sharp & Dohme Corporation (Merck) appeals from an order of the Pike Circuit Court certifying a class for a class action lawsuit initiated by James Ratliff, on behalf of himself and

[1] Judge Thomas B. Wine authored this opinion prior to his retirement effective January 6, 2012. Release of the opinion was delayed by administrative handling.

others similarly situated.[2] In the underlying lawsuit, Ratliff alleges that Merck concealed the dangerous side effects of the prescription medication, rofecoxib, marketed under the name "Vioxx." Merck argues on appeal that class certification was inappropriate under CR 23 and seeks a reversal of the class-certification order. Upon a thorough review of the record and applicable caselaw, we reverse the order of the Pike Circuit Court.

Facts and Procedural History

On May 21, 1999, the Food and Drug Administration (FDA) approved Vioxx for sale in the United States. Vioxx quickly gained widespread acceptance among physicians treating patients with arthritis and other conditions causing chronic or acute pain. However, Vioxx was withdrawn from the market on September 30, 2004, after a study was released indicating that Vioxx increased the risk of cardiovascular thrombotic events, such as heart attack and stroke. After Vioxx was withdrawn from the market, the FDA issued a public health advisory to all Vioxx users to contact their physician regarding the discontinuation of the drug and alternative therapies. A flurry of lawsuits ensued in both the state and federal courts. *See, e.g., In re Vioxx Products Liability Litigation*, 401 F. Supp. 2d 565, 571 (E.D. La. 2005); *Merck & Co., Inc. v. Garza*, 347 S.W.3d 256, 261 (Tex. 2011); *In re Merck & Co., Inc. Securities, Derivative & ERISA Litigation*, 493 F.3d 393, 398 (3rd Cir. 2007).

[2] Although an appeal from a class certification order was previously considered interlocutory, such appeals are no longer interlocutory due to the enactment of Kentucky Rules of Civil Procedure (CR) 23.06 by the Supreme Court in January of last year. Under the new CR 23.06, parties may appeal directly from a certification order.

Ratliff is a resident of Pike County and a former user of Vioxx. He was diagnosed with chronic osteoarthritis in 1994 at the age of thirty-seven. After experimenting with other drugs, including Daypro and Celebrex, his doctor recommended that he try Vioxx, a new non-steroidal anti-inflammatory drug (NSAID) on the market. Ratliff began using Vioxx in January of 2000, twice per day. Although Ratliff's insurance paid for most of the cost of the drug, which was at the time approximately $66 per month, Ratliff contributed about $5 each month out of pocket.

After experiencing severe chest pains, labored breathing, lethargy, bleeding, and other uncomfortable side effects, Ratliff discontinued using Vioxx in early 2004, mere months before the drug was officially removed from the market. Ratliff thereafter spent money, out of pocket, on a medical consultation to determine whether he sustained any cardiovascular injury from using Vioxx. He did not.

In 2004, Ratliff brought the present action on behalf of himself and all Kentucky residents who have purchased and taken Vioxx and who, upon recommendation of the FDA, have contacted or *will contact* their physician seeking advice regarding their use of Vioxx. Ratliff seeks to represent the class of similarly situated individuals, who used Vioxx but have not been diagnosed with specific cardiovascular injuries therefrom. Thus, most of the members of the class

would have low-dollar-amount damages similar to his, which he approximates at $350.[3]

Ratliff alleged in his complaint that Merck "deceived [him] and the members of the proposed class in violation of the Consumer Protection Act by promoting and/or allowing the sale of Vioxx with the use of unfair, false, misleading or deceptive acts or practices." Ratliff contends that although Merck knew of the potentially harmful side effects of the drug as early as 1999, it "undertook to downplay, conceal, obfuscate and mislead physicians and others, including consumers, as to the harmful side effects of the drug, while vigorously promoting the drug's use." Ratliff further maintains that Merck promoted Vioxx as having a superior safety profile to other NSAID's on the market. Ratliff additionally states that the results of a 1999 study were misrepresented to the medical community. He argues that, despite increasing evidence after the 1999 study that Vioxx caused increased risk of cardiovascular injury, Merck continued to disseminate materials discrediting suggestions that Vioxx posed serious health risks.

As a result of these alleged actions and behaviors, Ratliff claims that he and other Kentucky residents purchased Vioxx when they otherwise would not

[3] The complaint does not seek compensation for personal injuries or medical conditions caused by taking Vioxx. Rather, the damages sought by Ratliff on behalf of the putative class are those incurred by Vioxx users for diagnostic testing and examination to discover if they had an adverse medical condition related to the use of Vioxx. The putative class, then, contains consumers who required diagnostic testing because they took Vioxx, but needed no actual treatment for any adverse side effects after testing.

have, suffered economic loss connected with the purchase of the drug, and have suffered (and will in the future suffer) further economic losses in connection with medical consultations and procedures, including lost income and other expenses.

As grounds for relief, Ratliff pled in the complaint: (1) violations of the Kentucky Consumer Protection Act (the KCPA); (2) fraudulent concealment and/or misrepresentation; (3) negligent and/or grossly negligent misrepresentation; and (4) unjust enrichment. He sought compensatory damages for reimbursement of the cost of the drug, reimbursement for the cost of the medical exam, and lost wages for lost work-time spent receiving the medical exam for himself and members of the putative class, if certified.

On November 29, 2004, Merck filed an answer in state court, removed the action to federal court, and also filed a motion with the Judicial Panel on Multidistrict Litigation to transfer the case to a single court for pretrial management pursuant to 28 United States Code (U.S.C.) §1407. On January 1, 2005, Ratliff filed a motion to remand to state court. The Federal District Court determined that it did not have jurisdiction over the cause of action because Merck failed to show that Ratliff's damages would exceed $75,000. Thus, the case was remanded to state court on March 3, 2005. *Ratliff v. Merck & Co., Inc*., 359 F. Supp. 2d 571 (E.D. Ky. 2005).

Ratliff thereafter moved again to have the action certified as a class action pursuant to CR 23.01 and CR 23.02(c). Merck opposed class certification on the grounds that the plaintiffs' causes of action would require individualized

proof not appropriate for a class action such that common issues would not predominate, that Ratliff was not a typical or adequate class representative, and that the proposed class definition was unworkable as far as ascertaining membership in the class. At the same time, Merck moved for summary judgment. After extensive briefing and oral arguments from both sides, the Pike Circuit Court finally entered an order certifying the class on April 2, 2010. The Pike Circuit Court also entered an order denying Merck's motion for summary judgment on that date. Merck then filed a writ of mandamus with this Court to force the circuit court to vacate the order, or, in the alternative, to enter summary judgment in its favor.

This Court denied the writ and the Supreme Court affirmed on the ground that mandamus review was not appropriate for a certification order and that there existed no extraordinary circumstances warranting review of the circuit court's denial of summary judgment. However, the Supreme Court expressed no opinion concerning the review of an appeal stemming from CR 23.06.

After Rule 23 was amended on January 1, 2011, Ratliff moved the court for an amended certification order. The court entered an amended order on January 27, 2011. Merck then appealed from the amended certification order. That appeal was abated by this Court pending the Supreme Court's above ruling in the writ action. The Supreme Court rendered its opinion in *Merck & Co., Inc. v. Combs*, 2011 WL 1104133 (Ky. 2011)(2010-SC-00059-MR), in March of 2011, denying mandamus review of Merck's writ.

After the Supreme Court's opinion denying mandamus review became final, the Rule 23 appeal before this Court was removed from abeyance. The issue having now been briefed to this Court, it is ripe for review.

Analysis

After a long and circuitous path, we finally reach the merits of Merck's arguments, raised first via writ and now on appeal through CR 23.06—that a class action is inappropriate under the present circumstances and that Ratliff is an inadequate class representative. On appeal, Merck argues that the amended class-certification order fails to address Merck's evidence that Ratliff's claims do not satisfy the predominance, typicality, and superiority requirements for the certification of a class, and that the amended certification order ignores Merck's arguments that Ratliff is not an adequate class representative.

We review a certification order for abuse of discretion. *Sowders v. Atkins*, 646 S.W.2d 344 (Ky. 1983). In doing so, we recognize that the trial court's more intimate knowledge of the facts places it in a more favorable position to judge whether the requirements for class certification have been met. *Id.* at 346. Indeed, the circuit court is given substantial leeway in determining whether to certify a class because "it possesses the inherent power to manage and control its own pending litigation." *Reeb v. Ohio Dept. of Rehabilitation and Correction*, 435 F.3d 639, 643 (6th Cir. 2006). In determining whether the requirements of CR 23 are met, a lower court should generally accept the substantive allegations of the complaint as true. *See, e.g, Reeb v. Ohio Dept. of Rehabilitation and Correction*,

81 Fed.Appx. 550, 555 (6th Cir. 2003)(Court should not inquire into the merits of the representative's underlying claims, but should accept the allegations in the complaint as true). Nonetheless, despite this general rule, we recognize that a rigorous analysis of whether the merits of Rule 23 have been met will often "entail some overlap with the merits of the plaintiff's underlying claim. That cannot be helped." *Wal-Mart Stores, Inc. v. Dukes,* 131 S. Ct. 2541, 2551, 180 L. Ed 2d 374, 79 USLW 4527 (U.S. 2011).

The prerequisites necessary for the certification of an action as a class action are set forth in CR 23.01. Under CR 23.01,

> one or more members of a class may sue or be sued as representative parties on behalf of all only if (a) the class is so numerous that joinder of all members is impracticable, (b) there are questions of law or fact common to the class, (c) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (d) the representative parties will fairly and adequately represent the interests of the class.

If these prerequisites are met, the trial court may certify the action as a class action so long as one of the requirements of CR 23.02(a), (b), or (c) is satisfied. In the present case, the trial court granted certification under CR 23.02(c). Under this subsection, a class action may be maintained if:

> the court finds that the questions of law or fact common to members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy.

CR 23.02(c).

Numerosity and the presence of common questions of law and fact under 23.01(a) and (b) are not disputed. However, Merck argues that common questions of law and fact do not predominate under CR 23.02(c), that class action is not the superior method for adjudication under CR 23.02(c), and that Ratliff is not a typical or adequate representative under CR 23.01(c) and (d).

We first address the argument by Merck regarding predominance under CR 23.02(c). Merk contends that Ratliff's claims for violation of the KCPA, and for fraudulent and negligent misrepresentation, will require individualized proof such that common questions would not predominate. Merck states that individual proof will be necessary to show that Merck made fraudulent or negligent misrepresentations toward each putative class member or his or her physician through the marketing and sale of Vioxx, that the alleged misrepresentations were received by each putative member's physician, that each putative member's physician relied on such representations in his or her decision to prescribe Vioxx over another drug, and the amount of any damages suffered by each putative member. Thus, Merck argues that common questions do not predominate but, instead, individualized questions predominate.

The trial court found that common questions of law and fact did predominate, stating as follows in its amended certification order:

> [T]here is a common nucleus of facts from which the potential plaintiffs' claims arise. All of the potential plaintiffs were prescribed Vioxx by doctors who relied on Merck's assertions that it was safe and effective . . . . All of the potential plaintiffs spent money to purchase

> Vioxx, and when it was removed from the market all were directed by Merck and the FDA to seek medical consultations . . . . All of the potential plaintiffs were victims of Merck's [alleged] ***fraud upon the market*** . . . . In such circumstances, where the plaintiffs are similarly situated, and seek recovery under identical theories of law and based on the identical conduct of the defendant, common questions of law and fact predominate, making certification . . . appropriate[.] [Emphasis added].

After careful consideration, we must disagree with the trial court. Nonetheless, it should first be acknowledged that we agree with the trial court on several initial points. Indeed, we agree that Ratliff's and the putative class members' claims hinge upon whether Merck knowingly or negligently distributed false or misleading information while Vioxx was on the market. This common question threads through each potential class member's claims. We further acknowledge that predominance does not require that each and every possible issue be common to all class members, but only that common issues *substantially predominate* over those issues which are individual in nature. *Wiley v. Adkins*, 48 S.W.3d 20, 23 (Ky. 2001).

The court's order certifies claims made under the KCPA and claims made for fraudulent misrepresentation, negligent misrepresentation, and unjust enrichment. While there are fewer obstacles to a class claim proceeding under the KCPA, the claims of fraudulent misrepresentation and negligent misrepresentation require more individualized proof and, thus, pose particular problems for class certification.

Under the KCPA,

> [a]ny person who purchases or leases goods or services primarily for personal, family or household purposes and thereby suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of a method, act or practice declared unlawful [under the Act], may bring [a civil action] in the Circuit Court[.]

Kentucky Revised Statutes (KRS) 367.220(1). Taking the allegations in the complaint as true for the purposes of review, it is clear that Merck's actions would be unlawful under the Act. A Missouri court, analyzing a consumer protection statute nearly identical to our own[4] in a case involving Vioxx, found that the statute required that the plaintiff's economic *loss* resulted from Merck's unlawful practices, but did not require that the plaintiff's *purchase* of Vioxx be caused by the unlawful practice. *Plubell v. Merck & Co., Inc*., 289 S.W.3d 707, 714 (Mo. App. 2009). Under this interpretation, causation need not be shown with respect to each individual class member's decision to purchase Vioxx, but merely that a loss resulted from the practice. Further, the Missouri court found that the loss may be shown through a "benefit-of-the-bargain" theory that the product or service received (Vioxx) was not worth what the consumer paid for it. *Id*. at 715 (Holding that damages are not measured under the Act by the purchase price of the product in question, but by the difference in value between the product "as represented" and the "actual value" of the product received). A New Jersey court utilized

[4] The Missouri statute contains the following language: "Any person who purchases or leases merchandise primarily for personal, family or household purposes and thereby suffers an ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of a method, act or practice declared unlawful . . . may bring a private civil action." V.A.M.S. 407.025(1). The Kentucky statute, KRS 367.220, contains nearly identical language.

similar arguments regarding the certification of a claim under the state's consumer protection act regarding Vioxx. *Kleinman v. Merck & Co., Inc*., 8 A.3d 851 (N.J. 2009)(Also applying a "benefit-of-the-bargain" theory of value/loss). Interestingly, despite agreeing on the former, each court came to a different conclusion regarding the certification of a class for consumer protection violations brought by purchasers of Vioxx. *Id.; Plubell,* 289 S.W.3d 707.

However, the case we are presented with is not so simple as the cases presented to the courts in *Kleinman* and *Plubell*. Rather, this case involves not only claims under the KCPA (and for unjust enrichment), it also involves state law claims of fraud and misrepresentation. Fraudulent concealment/misrepresentation and negligent misrepresentation pose additional problems because they each contain the element of reliance. *See, e.g. United Parcel Service Co. v. Rickert*, 996 S.W.2d 464, 468 (Ky. 1999); *Ann Taylor, Inc. v. Heritage Ins. Services, Inc*., 259 S.W.3d 494 (Ky. App. 2008). In the present case, each of the putative class members would have to show that his or her respective physicians individually relied upon the false or misleading information disseminated by Merck when prescribing Vioxx to them.[5] It is exactly this type of individualized proof which generally makes class litigation inappropriate in fraud and misrepresentation cases. *See, e.g., In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 133-4 (Cal. App. 2nd Dist. 2009)(Holding that the decision to prescribe Vioxx is an individual decision made by a physician based on various factors, and that such individual issues prevailed

[5] It is of note that Ratliff's own physician testified he might still prescribe Vioxx, if it was still on the market, in limited cases where the benefits to the patient would outweigh the risks.

over common issues); *In re St. Jude Medical, Inc*, 522 F.3d 836, 838 (8th Cir. 2008)(Fraud cases are generally not certifiable because of individualized questions of reliance); *Sandwich Chef of Texas, Inc. v. Reliance Nat. Indem. Ins. Co*., 319 F.3d 205, 219 (5th Cir. 2003)(Questions of individual reliance typically preclude class certification).[6]

Nonetheless, we recognize that in some cases involving fraud and/or misrepresentation, class action may still be appropriate where common issues predominate over individualized questions and arise from a single fraudulent scheme or conspiracy or from identical representations. *See, e.g, Klay v. Humana, Inc.,* 382 F.3d 1241, 1257 (11th Cir. 2004); *Wiley*, 48 S.W.3d at 23. Indeed, fraud and misrepresentation claims only tend to be uniformly denied for class certification where there is a "material variation in the representations made [to the putative class members] or in the degrees of reliance thereupon." *Simon v. Merrill Lynch, Pierce*, *Fenner & Smith, Inc.,* 482 F.2d 880, 882 (5th Cir. 1973).

Ratliff alleges a consistent pattern of deception lasting essentially the entire time that Vioxx was on the market, and thus argues that generalized proof may be used to show the elements of fraud and misrepresentation in this case. He argues that any individualized proof necessary would be minimal. This theory concerning generalized proof regarding Merck's conduct is similar to the rebuttable presumption of reliance and causation known in securities litigation as

[6] Further, class certification is typically not granted in prescription drug cases because of the individualized inquiries such litigation typically involves. *See, e.g., In re Baycol Products Litigation*, 218 F.R.D. 197, 204 (D. Minn. 2003)

the "fraud-on-the-market" theory. Indeed, the trial court's order, as drafted and proposed by Ratliff, describes Merck's behavior as "fraud upon the market." Ratliff avers that "[a]ll of the potential plaintiffs were prescribed Vioxx by doctors who relied on Merck's assertions that it was safe and effective to treat their individual ailments." Ratliff further alleges that because every patient in the class must have had a prescription for Vioxx, every patient in the class would have necessarily received a service from his or her physician that was based upon incomplete or inaccurate information. Based upon this theory, Ratliff avers that individualized evidence concerning Merck's representations will not be necessary. Further, he states that any individual questions would be few, and would not overwhelm the common questions of law and fact.

Typically, individual reliance must be shown in fraud and misrepresentation cases. *United Parcel Service Co. v. Rickett, supra; Ann Taylor, Inc. v. Heritage Ins. Services, Inc., supra*. However, as stated, in some fraud actions in securities litigation, elements such as reliance, ascertainable loss and causal nexus, may be presumed under the fraud-on-the-market theory. Under the fraud-on-the-market theory, the United States Supreme Court has adopted a presumption of reliance in the securities fraud context where it is found that a corporate defendant disseminates information or materials into the marketplace that are fraudulent or misrepresentative. *Basic Inc. v. Levinson*, 485 U.S. 224, 108 S. Ct. 978, 99 L. Ed. 2d 194 (1988).

In the present case, we have a corporate defendant that has allegedly disseminated false, fraudulent, or misrepresentative information into the marketplace. However, while we have sympathy for the users of Vioxx whose physicians may have relied upon such false or incomplete information, the "fraud-on-the-market" approach has never been recognized in this jurisdiction for a fraud or misrepresentation case. Further, every other jurisdiction we found which has been confronted with the theory has rejected it outside of the securities litigation context. *See, e.g., Kaufman v. i-Stat Corp*, 754 A.2d 1188, 1191 (N.J. 2000); *International Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co., Inc*, 929 A.2d 1076, 1088 (N.J. 2007); *Mirkin v. Wasserman*, 858 P.2d 568, 584-95 (CA. 1993); *Southeast Laborers Health and Welfare Fund v. Bayer Corp*., 2011 WL 5061645 (11th Cir. 2011)(10-13196); *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001)(Rejecting somewhat similar "fraud on the FDA" theory).

For this reason, we decline to recognize a similar theory here. Causation, reliance, and damages are required to be shown on an individual basis. Thus, if the action were tried as a class, after the common questions of Merck's representations in its marketing campaign were decided, the case would essentially fragment into a series of amalgamated "mini-trials" on each of these individualized questions. *Kleinman,* 8 A.3d at 859 ("[T]he benefit of a class action must outweigh the problems of an unmanageable amount of mini-trials that may result after a uniform determination of common questions . . . ."). Further, we find that a

claim of unjust enrichment, which necessitates that a party has conferred a benefit on another for value, requires that the retention of the benefit be inequitable. *See, e.g., Guarantee Elec. Co. v. Big Rivers Elec. Corp*., 669 F. Supp. 1371, 1380 (W.D. Ky. 1987). Here, since each plaintiff may have had different medical conditions and circumstances at the time they were prescribed the drug, and because each may have experienced different effects from the drug as compared to its risks, a separate risk/benefit analysis would effectively have to be undertaken for each putative class member.

Thus, we find that common questions do not predominate. Further, because these individualized questions would substantially overtake the litigation, and would override any common questions of law or fact concerning Merck's conduct, we find that a class action is not the superior mechanism by which to try these cases. *See, e.g., Zinser v. Accufix Research Institute, Inc*., 253 F.3d 1180, 1192 (9th Cir. 2001)("[W]hen the complexities of class action treatment outweigh the benefits of considering common issues in one trial, class action treatment is not the 'superior' method of adjudication"). Therefore, class certification is inappropriate under CR 23.02(c) and the trial court abused its discretion by entering a certification order.

Because we find that the class cannot be certified, we do not need to address whether Ratliff is an adequate or typical representative for the class. We reverse and remand to the Pike Circuit Court with instructions for the court to vacate its prior order.

ALL CONCUR.

BRIEFS FOR APPELLANT:

Susan J. Pope
Lexington, Kentucky

PRO HAC VICE FOR APPELLANT:

John H. Beisner
Washington, DC

BRIEF FOR APPELLEES:

Richard A. Getty
Jessica K. Case
Lexington, Kentucky