Cite as 2009 Ark. 547

SUPREME COURT OF ARKANSAS

No. 08-1257

LOUISE DePRIEST, IVA DUNCAN, GLADYS EATON, CAROLYN KNIGHT, GERALDINE HARRIS, BERNICE MILAM, WANDA HAMILTON, EDDIE LOU SANDERS, and LISA SANDERS,

APPELLANTS,

VS.

ASTRAZENECA PHARMACEUTICALS, L.P.; ASTRAZENECA, PLC; ZENECA, INC.; and ASTRAZENECA U.S.,

APPELLEES,

Opinion Delivered November 5, 2009

AN APPEAL FROM THE CIRCUIT COURT OF SEARCY COUNTY, ARKANSAS, NO. CV-04-77, HONORABLE MICHAEL A. MAGGIO, CIRCUIT JUDGE

AFFIRMED.

ELANA CUNNINGHAM WILLS, Associate Justice

This appeal arises from a lawsuit filed by nine named plaintiffs (hereinafter "Appellants") against drug manufacturer AstraZeneca Pharmaceuticals, Inc., alleging that AstraZeneca fraudulently marketed its drug Nexium. The Searcy County Circuit Court granted AstraZeneca's motion to dismiss the Appellants' complaint on August 7, 2008. We find no error and affirm.

AstraZeneca's drug Nexium (esomeprazole) and its predecessor medication, Prilosec (omeprazole), are both so-called proton pump inhibitors (PPIs) that are used in the treatment of gastro-esophageal reflux disease (GERD), or heartburn. Prilosec, which had been long

advertised as "the Purple Pill," was AstraZeneca's most profitable drug by the time its patent expired in 2001.[1] Facing the expiration of that patent, AstraZeneca sought approval from the Food and Drug Administration (FDA) for a new PPI drug, Nexium. In 2001, the FDA approved AstraZeneca's request to market Nexium for three GERD-related conditions: the healing of erosive esophagitis ("EE," or damage to the lining of the esophagus), maintenance of healing esophagitis, and the treatment of symptomatic GERD.

The original plaintiffs—Wanda Hamilton, Eddie Lou Sanders, and Lisa Sanders—filed their initial complaint against AstraZeneca in Searcy County Circuit Court on November 30, 2004, alleging that AstraZeneca's actions in marketing Nexium as a superior product to Prilosec were fraudulent and violated the Arkansas Deceptive Trade Practices Act, Arkansas Code Annotated section 4-88-107 (Repl. 2001). In addition, Appellants raised claims for common law fraud, breach of contract, promissory estoppel, unjust enrichment, and violations of the Arkansas Unfair Practices Act and Arkansas Medicaid Fraud False Claims Act.

In essence, Appellants alleged that AstraZeneca had falsely marketed Nexium as "new" and "better" than Prilosec, when the two drugs were, in fact, very similar and had similar therapeutic results. Moreover, Appellants contended that AstraZeneca had positioned Nexium as a "new" drug in order to cause purchasers to pay a higher price for it than they had been paying for Prilosec.

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[1] Prilosec is now sold in both an over-the-counter (OTC) formulation and in its generic form, omeprazole.

Appellants filed first, second, and third amended complaints on December 2, 2004, January 14, 2005, and January 20, 2005, adding and dropping various named plaintiffs and including additional allegations. AstraZeneca removed the action to federal district court on January 21, 2005, but Appellants moved to remand the action, and the federal district court granted that motion on September 21, 2005. On October 11, 2005, AstraZeneca then filed a motion to dismiss the third amended and substituted complaint pursuant to Ark. R. Civ. P. 12(b)(6), contending that Appellants had failed to state a cause of action. The circuit court held a hearing on AstraZeneca's motion to dismiss Appellants' third amended complaint on May 15, 2006. Before the court could render a ruling, however, Appellants filed their fourth amended complaint on May 15, 2006. This complaint added five new plaintiffs.

In a letter opinion dated May 24, 2006, and filed on May 31, 2006, the circuit court granted AstraZeneca's motion to dismiss the third amended complaint. The court noted that:

> The crux of the plaintiffs' complaint is not that this new Nexium product is harmful, ineffective, or of poor quality, but rather that it is inappropriately marketed as "new," when in fact there is nothing new chemically about it and when it was not actually superior to the previous AZ product.
>
> While the plaintiffs' entire complaint appears to be well researched, it is convincing only to the point that a giant corporation has flexible power to control and enhance its own profits. It offers little or no proof that the defendants committed an actionable tort against the plaintiffs in Searcy County, Arkansas, or anywhere. The complaint would perhaps make an excellent article in a scientific magazine, but it fails as a legal pleading.

Accordingly, citing Ark. R. Civ. P. 12(b)(6), the court found that the complaint "should be dismissed for failure to meet the prima facie elements of any of the causes of action stated in the pleadings and for failure to state any claim for relief that could be granted."

Appellants filed a motion for reconsideration on May 31, 2006, contending that the circuit court had not yet considered their fourth amended complaint. In addition, Appellants filed a motion asking the trial judge to recuse on June 6, 2006, suggesting that the court's language in the letter opinion "reflect[ed] the appearance of having a mind-set that cannot be reconciled with the proposition that the trial judge is committed to hear and decide all issues that are relevant, weighing the issues, and arriving at a judicious result." Appellants would also file a second motion to recuse on June 16, 2006, which the court also denied.

On June 7, 2006, Appellants filed their 290-page fifth amended complaint. AstraZeneca again moved to dismiss the complaint pursuant to Ark. R. Civ. P. 12(b)(6). In addition, AstraZeneca argued that Appellants' claims were preempted by federal law. After an October 31, 2006 hearing on the motion to dismiss, the circuit court issued a letter opinion stating that it would grant AstraZeneca's motion to dismiss.

The court's letter opinion was formalized in an order entered on August 7, 2008. The court found that Appellants' claim for violation of the Arkansas Deceptive Trade Practices Act was barred by that statute's "safe harbor" provision, Ark. Code Ann. § 4-88-101 (Repl. 2001). The court further found that Appellants' price-fixing claims and claims under the Arkansas Unfair Practices Act and the Arkansas Medicare Fraud False Claims Act failed

because those statutes do not afford a private right of action. In addition, the court rejected Appellants' claims for common law fraud, breach of contract, promissory estoppel, and unjust enrichment. Finally, the court found, as independent grounds for dismissal, that all of Appellants' claims were preempted by federal law and that Appellants had failed to plead the required elements of their claims, "including that AstraZeneca's alleged misconduct caused them to purchase Nexium and that they were injured as a result."[2] Appellants filed a timely notice of appeal on August 26, 2008.

We review a trial court's decision on a Rule 12(b)(6) motion to dismiss by treating the facts alleged in the complaint as true and by viewing them in the light most favorable to the plaintiff. *Sluder v. Steak & Ale of Little Rock, Inc.*, 361 Ark. 267, 206 S.W.3d 213 (2005); *Branscumb v. Freeman*, 360 Ark. 171, 187 S.W.3d 846 (2004).[3] In viewing the facts in the light most favorable to the plaintiff, the facts should be liberally construed in plaintiff's favor.

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[2] The court's ruling also disposed of all other outstanding motions, granting AstraZeneca's motion to strike Appellants' fourth amended complaint, denying as moot AstraZeneca's motion to strike the fifth amended complaint, denying as moot Appellants' motion to proceed as a class action, and denying Appellants' motions for the court to recuse.

[3] We note that AstraZeneca attached a copy of the Nexium labeling as an exhibit to its motion to dismiss. Ordinarily, this would have converted this 12(b)(6) motion into a motion for summary judgment. *See, e.g.*, *Nielsen v. Berger-Nielsen*, 347 Ark. 996, 69 S.W.3d 414 (2002) (a motion to dismiss is converted to a motion for summary judgment when matters outside of the pleadings are presented to and not excluded by the court). The original complaint, however, incorporated essentially the same information and language as was found on the label in AstraZeneca's exhibit. Therefore, we conclude that this appeal is properly treated as an appeal from an order of dismissal under Rule 12(b)(6).

Sluder, *supra*. Our rules require fact pleading, however, and a complaint must state facts, not mere conclusions, in order to entitle the pleader to relief. Ark. R. Civ. P. 8(a)(1); *Faulkner v. Ark. Children's Hosp.*, 347 Ark. 941, 69 S.W.3d 393 (2002).

Because our standard of review requires us to examine the facts that were alleged in the complaint, we set out the pertinent allegations here. At the heart of Appellants' complaint was their contention that AstraZeneca, when faced with the patent expiration on their "blockbuster" drug Prilosec, set out to replace Prilosec with Nexium. Appellants alleged that AstraZeneca's strategy was to aggressively market Nexium as a new and improved medication for heartburn that was more effective than Prilosec, despite studies and medical reviews that showed the two drugs offered similar benefits. Advertising associated with the launch of Nexium touted the new drug as "more powerful" than Prilosec and declared that it was "clinically proven to heal more reflux esophagitis patients in a shorter period of time compared to [Prilosec]."

AstraZeneca initially offered Nexium at a lower price than Prilosec and offered large quantities of free samples to physicians. In addition, as part of the marketing campaign, AstraZeneca conducted direct-to-consumer advertising that offered a seven-day free trial of Nexium with a prescription from a physician. Sales of Nexium quickly eclipsed sales of Prilosec, and AstraZeneca raised the prices of Nexium. By the time Appellants filed their complaint, one Nexium pill cost an average of $4.46, while the over-the-counter version of Prilosec sold for $0.59 per pill.

According to the complaint, the success of Nexium was due to AstraZeneca's allegedly "false and misleading" advertising campaign that, as noted above, promoted Nexium as superior to Prilosec. Appellants contended, however, that clinical trials of Nexium showed that it was not significantly better than Prilosec. They pointed to statements from an FDA medical review of Nexium that concluded that there was "no scientific basis for [AstraZeneca's] statement that, compared to [Prilosec], [Nexium] offers a faster and improved resolution of heartburn symptoms and higher rates of healing in the treatment of erosive esophagitis."

Appellants alleged that they had been harmed by AstraZeneca's conduct in various ways. For example, plaintiff Geraldine Harris alleged that, after seeing advertisements for Nexium on television, she asked her doctor for a prescription for her heartburn. Harris filled the prescription, making her insurance company's co-payment, but it eventually became too expensive for her to continue to purchase Nexium. Therefore, she switched to Prilosec OTC and was satisfied with the results of that medication.

Plaintiff Louise DePriest alleged that her doctor suggested that she try Nexium and told her that it was the best thing available. Based on her doctor's representations, DePriest never tried Prilosec OTC. Plaintiff Iva Duncan took Nexium after asking for a prescription from her doctors based on information she saw in Nexium's advertising. Plaintiff Gladys Eaton received two prescriptions for Nexium from her doctors and tried the drug, but found that it did not do her much good. Therefore, she started buying Prilosec OTC and discovered

that it worked better than Nexium. Eaton compared the package inserts for Nexium and Prilosec and determined that there were essentially the same thing, and because Prilosec worked better for her, she continued to use it instead of Nexium.

Plaintiff Bernice Milam asked her doctor for a prescription for Nexium after seeing the drug's advertisements. She used Nexium until it became too expensive, and then her doctor switched her to Prilosec OTC, with which she got better results than she did with Nexium. Plaintiff Carolyn Knight saw Nexium's advertising and asked her physician for a prescription. Her doctor gave her samples of Nexium, telling her that an AstraZeneca sales representative had told him that Nexium was superior to Prilosec. After getting a prescription for Nexium, however, Knight discovered that she could not afford it, so she began taking two Prilosec OTC pills each day instead of one Nexium.

Plaintiffs Wanda Hamilton, Eddie Lou Sanders, and Lisa Sanders alleged that they suffered from heartburn and had been prescribed Prilosec. They contended that AstraZeneca both limited quantities of Prilosec after introducing Nexium and delayed the introduction of the generic version of Prilosec, and so they were unable to purchase Prilosec to treat their heartburn. They claimed that they believed Nexium's advertising that it was superior to all other PPI drugs, so they refrained from purchasing any other drugs to treat their heartburn.

On the basis of the foregoing, Appellants claimed that they had been damaged, both monetarily and physically, by AstraZeneca's alleged false and misleading advertising. As noted above, the circuit court dismissed all of their claims. On appeal, Appellants do not challenge

the court's dismissal of their claims for breach of contract, price fixing, and violations of the Arkansas Unfair Practices Act and the Arkansas Medicaid Fraud False Claims Act. These issues, therefore, are considered abandoned on appeal. *See, e.g.*, *Wagner v. Gen. Motors Corp.*, 370 Ark. 268, 258 S.W.3d 749 (2007).

In their first point on appeal, Appellants argue their cause of action for violations of the Arkansas Deceptive Trade Practices Act (ADTPA) was not barred by the statutory "safe harbor" found in that Act. The ADTPA, Arkansas Code Annotated sections 4-88-101—502 (Repl. 2001), prohibits deceptive and unconscionable trade practices, which include, among other things, "[k]nowingly making a false representation as to the characteristics, ingredients, uses, benefits, alterations, source, sponsorship, approval, or certification of goods or services, or as to whether goods are original or new, or of a particular standard, quality, grade, style, or model[.]" Ark. Code Ann. § 4-88-107(a)(1) (Repl. 2001).[4] The Act does not apply, however, to

> (1) Advertising or practices which are subject to and which comply with any rule, order, or statute administered by the Federal Trade Commission; [or]
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> . . . .
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> (3) Actions or transactions permitted under laws administered by . . . [a] regulatory body or officer acting under statutory authority of this state or the United States.

[4] The ADTPA provides a private cause of action to "[a]ny person who suffers actual damage or injury as a result of an offense of violation as defined in this chapter." Ark. Code Ann. § 4-88-113(f) (Repl. 2001).

Ark. Code Ann. § 4-88-101(1) & (3) (Repl. 2001). This is the so-called "safe harbor" provision of the ADTPA.

The trial court noted that federal law specifically permits drug manufacturers to promote their drugs to consumers and physicians in a manner that is consistent with and supported by the labeling approved by the Food and Drug Administration. The court thus found that all of the promotional and advertising activity that the appellants challenged was supported by Nexium's FDA-approved labeling and therefore fell with the ADTPA's safe harbor.

The FDA is vested with the authority to approve labeling for any new drug. *See* 21 U.S.C. § 355(d). As part of the application process for new-drug approval, the applicant must submit such things as full reports of investigations showing whether the drug is safe and effective; a statement of the composition of the drug; and a description of the methods used in the manufacture, processing, and packaging of the drug. *See* 21 U.S.C. § 355(b)(1). In addition, the FDA regulates prescription-drug advertising. *See* 21 U.S.C. § 352(n). Any advertisement for a prescription drug must "present a true statement of information in brief summary relating to side effects, contraindications, . . and effectiveness." 21 C.F.R. § 202.1(e)(1). In a notice from the FDA regarding a public meeting on professional product labeling, the FDA noted the following:

> The major purpose of prescription drug product labeling is to help ensure that prescribing health care professionals have the information necessary to prescribe products in a safe and effective manner. When the agency determines that a sponsor has provided the requisite scientific data to allow

> marketing of a product in the United States, the approved labeling communicates the conclusions of FDA review of the data in the product's new drug application (NDA). Because the NDA review process provides access to the raw data from clinical trials, the product labeling may provide the only comprehensive, independently reviewed source of medical/scientific information about newly approved products and new indications for older products.
>
> The approved labeling also serves as the basis for product promotion. FDA regulations specify that all advertising claims made about a product be consistent with its approved labeling (21 CFR 202.1(e)(4)). The approved labeling serves as the basis for fulfilling the requirement of the Federal Food, Drug, and Cosmetic Act (the act) that prescription drug advertising include information in brief summary relating to side effects, contraindications, and effectiveness." (section 502(n) of the act (21 U.S.C. 352(n)).

Professional Product Labeling; Public Meeting, 60 Fed. Reg. 52196 (Oct. 5, 1995).

In this case, the FDA-approved labeling for Nexium, a copy of which was incorporated into the complaint, presents the analysis of clinical studies conducted to determine the efficacy of the drug in healing erosive esophagitis. Those clinical studies evaluated the healing rates of Nexium 40mg, Nexium 20mg, and Prilosec 20mg (which was the approved dose of omeprazole for that indication[5]) in patients with endoscopically diagnosed erosive esophagitis in four multicenter, double-blind, randomized studies. The healing rates of Nexium 40mg, as compared to Prilosec 20mg, showed that, for one group of patients at week four of the study, 75.9% of the Nexium 40mg patients experienced

[5] The FDA had previously found that omeprazole 40mg was not superior to the 20mg dose for healing erosive esophagitis, and therefore the higher dosage was not approved for that indication.

healing of their symptoms, while 64.7% of the Prilosec 20mg patients experienced healing.[6] At week eight, the percentages of patients in that particular group with healing were 94.1% for Nexium 40mg and 86.9% for Prilosec 20mg.

The same studies of patients with erosive esophagitis examined the percent of patients who experienced sustained heartburn resolution and the time it took for them to obtain sustained heartburn resolution. Those studies showed that Nexium 40mg provided statistically significant increases in patients with sustained resolution of their heartburn symptoms (64.8% for Nexium 40mg compared to 56.5% for Prilosec 20mg at day fourteen of the study, and 74.2% for Nexium 40mg compared to 66.6% for Prilosec 20mg at day twenty-eight). In addition, the studies also demonstrated that patients taking Nexium 40mg experienced faster symptom resolution; the "range of median days to the start of sustained resolution (defined as 7 consecutive days with no heartburn) was 5 days for Nexium 40mg, 7-8 days for Nexium 20mg, and 7-9 days form omeprazole 20mg." On the basis of these studies, the FDA approved Nexium at both 20mg and 40mg doses for the healing of erosive esophagitis.[7]

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[6] Appellants complain that some of the studies included in the labeling showed there to be no statistical significance between the healing rates of Nexium and Prilosec. However, the FDA approval process declares that the Secretary may determine, "based on relevant science, that data from *one* adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness." 21 U.S.C. § 355(d) (emphasis added).

[7] As noted above, Prilosec 20mg—but not Prilosec 40mg—had been approved for healing erosive esophagitis.

After obtaining approval of its label for Nexium, AstraZeneca introduced an advertising campaign that included phrases such as "the proof is in the healing rates," called Nexium "the powerful new PPI," and invited patients to "Relieve the Heartburn. Heal the damage. It's possible with Nexium." These are among the assertions that Appellants claim constitute "false" and "misleading" advertising.

As noted above, the circuit court found that Appellants' ADTPA cause of action was barred by the Act's "safe harbor" provision, Ark. Code Ann. § 4-88-101(1) & (3). That subsection provides that the ADTPA does not apply to advertising that is subject to and complies with any rule, order, or statute administered by the Federal Trade Commission, nor does it apply to actions permitted under laws administered by a regulatory body acting under the statutory authority of the United States. The court found that "federal law specifically permits [drug] manufacturers to promote their drugs to consumers and physicians and to do so in a manner supported by the 'labeling' approved by the [FDA]." Here, the circuit court determined that the activity fell within the safe harbor provision of the ADTPA because the challenged promotional and advertising activity was supported by Nexium's FDA-approved labeling.

On appeal, Appellants rely heavily on an unpublished district court case from California's Los Angeles County Superior Court, *Ledwick v. AstraZeneca Pharm. LP*, Case No. BC 324 518. In that case, the plaintiffs alleged that AstraZeneca deceptively marketed Nexium in violation of California's Business & Professions Code sections 17200, that state's

Unfair Competition Law. The California trial court denied AstraZeneca's motion for demurrer on the basis of preemption, concluding as follows:

> Assuming drug labeling or the FDA's authority to prescribe it qualify as federal law for purposes of preemption analysis, defendants [AstraZeneca] do not explain, and the court cannot fathom, how Nexium's labeling affirmatively supports defendants' claim that Nexium is superior to Prilosec. The court is unaware of any allegation that Nexium's labeling even mentions Prilosec, much less demonstrates Nexium's superiority to it. Additionally, the court is unaware of any allegation that the promotional statements at issue were derived by defendants from Nexium labeling. Rather, it appears the challenged statements arose after Nexium was approved and do little, if anything, to reference the labeling. Even if the advertising were somehow derived from the labeling it would be nonsensical to hold all advertising valid or immunized simply because it does not "conflict" with the labeling. If all advertising were permissible simply because it does not conflict with the label, a manufacturer could say virtually anything, so long as he avoid the label's limited purlieu. (A claim that snake oil cures dandruff does not conflict with the label identifying the oil as coming from a snake.)

Ledwick, Case No. BC 324 518, at *10. The *Ledwick* court also rejected AstraZeneca's "safe harbor" argument for the same reason. *Id.* at *12-13. Appellants ask this court to adopt the reasoning of the California court and conclude that their ADTPA action was not barred by the Act's safe harbor provision.

We decline to do so. This unpublished trial court order is of absolutely no precedential value for this court. In addition, as AstraZeneca points out, California's Unfair Competition Law does not itself contain a statutory safe harbor provision. *See*, *e.g.*, *Yabsley v. Cingular Wireless, LLC.*, 176 Cal. App. 4th 1156, 98 Cal. Rptr. 3d 657 (2009) ("Although section 17200 broadly prescribes 'any unlawful, unfair or fraudulent business act or practice,' it does not apply when *specific legislation* provides a 'safe harbor' for the conduct at issue") (emphasis

added) (citing *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal.4th 163, 83 Cal. Rptr. 2d 548, 973 P.2d 527 (1999)).[8] Arkansas's ADTPA, by contrast, contains a safe harbor provision that specifically exempts conduct that is permitted under laws administered by a federal agency. *See* Ark. Code Ann. § 4-88-101(3).

Appellants next contend that AstraZeneca claimed, through direct-to-consumer marketing, that Nexium is superior to Prilosec, even though "there is no proof that Nexium is more effective or superior than Prilosec or other PPIs at equivalent standard doses." However, the FDA-approved labeling did, in fact, indicate that the approved dose of Nexium was superior to the approved dose of Prilosec at healing erosive esophagitis. Therefore, because the advertising complied with the product's labeling and "present[ed] a true statement of information in brief summary relating to . . . effectiveness," 21 C.F.R. § 202.1(e)(1), the challenged conduct is advertising that is "permitted under laws administered by . . . [a]

[8] The statutory "safe harbor" in *Yabsley* was found in a portion of the California Code of Regulations pertaining to the collection of gross receipts taxes, not in the California Unfair Competition Law under which the plaintiff filed his suit.

regulatory body . . . of . . . the United States"—in this case, the FDA.[9] Ark. Code Ann. § 4-88-101(3).

The information included in the labeling of a new drug reflects a determination by the FDA that the information is not "false or misleading." *See* 21 C.F.R. § 314.125(b)(6) (stating the FDA must deny a new drug application if it determines that "[t]he proposed labeling is false or misleading in any particular."). By approving information to be included in the drug labeling, the FDA has determined that the information complies with its rules and regulations. Therefore, if the FDA labeling supports the statements made in advertising for an FDA-approved drug, the statements are not actionable under the ADTPA.

Here, as discussed above, the advertising for Nexium is supported by the FDA-approved labeling. For example, one advertisement declared, "Relieve the heartburn. Heal the damage." As discussed above, Nexium was demonstrated to have greater healing rates

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[9] The Federal Trade Commission and the FDA originally shared jurisdiction over regulation of drug marketing. *See* Pub. L. No. 87-781 (1962). Congress gave the agencies concurrent jurisdiction with respect to regulating prescription drug advertising until the FDA promoted regulations on the subject, and in 1971, the agencies agreed that the FDA had "primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising." 36 Fed. Reg. 18,539 (Sept. 16, 1971). That statement did not preclude FTC regulation of prescription drug advertising, but instead acknowledged that the FDA would take the lead in regulating such activities. The FDA subsequently promulgated its own regulations for prescription drug advertising. *See* 21 U.S.C. 352; 21 C.F.R. 202.1. FDA's promulgation of these regulations effectively eliminated the FTC's authority in this area. *See Penn. Employees Benefit Trust Fund v. Zeneca, Inc.*, 499 F.3d 239 (3rd Cir. 2007) (vacated by *Penn. Employees Benefit Trust Fund v. Zeneca, Inc.*, ___ U.S. ___, 129 S. Ct. 1578 (2009), cert. granted, judgment vacated, and remanded to Third Circuit "for reconsideration in light of *Wyeth v. Levine*, 555 U.S. ___, 129 S. Ct. 1187 (2009).").

than Prilosec in patients with erosive esophagitis. Another print advertisement stated that Nexium was "clinically proven to heal more reflux esophagitis patients in a shorter period of time compared to omeprazole." Again, the drug's labeling indicated that this claim was true and thus permitted AstraZeneca to make this statement.[10] Therefore, the circuit court correctly concluded that the challenged conduct fell within the ADTPA's statutory safe harbor. *See*, *e.g.*, *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 941 (7th Cir. 2001) (where statements concerning Zantac 75 and Zantac 150 did not falsely claim that one could not be substituted for another and comported with the FDA-approved label, the Illinois Consumer Fraud Act would not impose higher disclosure requirements than those that are sufficient to satisfy federal regulations; therefore, if drug manufacturer was doing something *specifically authorized* by federal law, safe harbor provision of Illinois CFA would protect it from liability, and plaintiffs failed to state a cause of action (emphasis in original)); *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228 (S.D. Fla. 2007) (where FDA-approved label for Lipitor supported the claim that the drug reduced the risk of heart attacks in some patients, advertisements making that claim fell within the safe harbor provisions of both Florida and Massachusetts consumer

[10] When pressed at oral argument to list other specific examples of allegedly false or misleading claims, Appellants' counsel was only able to cite "numerous advertisements that [were] referenced in the complaint." Counsel did point to an alleged "switch letter" sent out by Wal-Mart's pharmacy that encouraged pharmacy patients to switch to Nexium; however, the complaint did not allege that any of the named plaintiffs had ever seen a copy of this letter. Therefore, this letter could not have constituted a false or misleading statement made to the plaintiffs and thus does not state facts sufficient to support Appellants cause of action.

fraud acts, and plaintiffs' complaint was therefore dismissed); *Cytyc Corp. v. Neuromedical Systems, Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) (where defendant's statements concerning "ThinPrep" cervical cell screening system that plaintiff claimed were false were actually consistent with the substantive claims approved by the FDA on ThinPrep's label, such statements failed to state a claim under New York's General Business Law §§ 349–350); *Prohias v. AstraZeneca Pharm., LP.*, 958 So.2d 1054, 1056 (Fl. Dist. Ct. App. 2007) (allegedly false advertising of Nexium by AstraZeneca "falls within the safe harbor of the Florida Deceptive and Unfair Trade Practices Act . . . because the promotional and advertising activity attacked in the complaint is supported by the FDA-approved labeling for Nexium and thus is 'specifically permitted' by federal law"; therefore, the plaintiffs' complaint failed to plead a valid claim under the Florida DUTPA).[11]

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[11] Appellants raise one final argument in which they claim that AstraZeneca's actions were fraudulent because it was aware of an FDA medical review that indicated that Nexium was not superior to Prilosec for treating heartburn. However, as AstraZeneca points out, the statements in a medical review do not reflect the conclusions of the FDA:

> A statement or advice given by an FDA employee orally, or given in writing but not under this section of § 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

21 C.F.R. § 10.85(k).

Accordingly, we conclude that AstraZeneca's advertisements constituted actions permitted under laws administered by the FDA, and therefore, the ADTPA, by its own terms, does not apply to the challenged conduct. *See* § 4-88-101(a)(3). Because we conclude that the advertisements fall within the ADTPA's safe harbor provision, we decline to address Appellants' claim that the trial court erred in concluding that they failed to plead the required elements of their ADTPA claim.

We next turn to Appellants' claims of common-law fraud, promissory estoppel, and unjust enrichment. The circuit court found that Appellants' common-law fraud claim failed because "[a]dvertising statements supported by the FDA-approved labeling cannot be deemed false or misleading as a matter of law, and Plaintiffs have failed to identify any actionable promotion. Plaintiffs have also failed to plead sufficiently the required elements of reliance, causation, and injury." On appeal, Appellants dispute this conclusion, contending that their complaint stated a cause of action for common law fraud against AstraZeneca for its practices in the prices and mass marketing of Nexium.

Our rules of civil procedure require that claims of fraud be pled with specificity. Rule 9(b) provides that "[i]n all averments of fraud, . . . the circumstances constituting fraud . . . shall be stated with particularity." Ark. R. Civ. P. 9(b). In addition, to state a claim for fraud, a plaintiff must plead the existence of five elements: (1) a false representation of material fact; (2) knowledge that the representation is false or that there is insufficient evidence upon which to make the representation; (3) intent to induce action or inaction in

reliance upon the representation; (4) justifiable reliance upon the representation; and (5) damage suffered as a result of the reliance. *McAdams v. Ellington*, 333 Ark. 362, 970 S.W.2d 203 (1998); *Scollard v. Scollard*, 329 Ark. 83, 947 S.W.2d 345 (1997).

As discussed above, the circuit court correctly found that AstraZeneca's claims regarding Nexium were supported by the FDA-approved labeling. Stated another way, we agree that, because AstraZeneca's advertisements were in accordance with that labeling, they were thus not false or misleading as a matter of law. In the absence of the pleading of a false representation of a material fact, Appellants' fraud claim fails to state a cause of action.

Similarly, Appellants' unjust enrichment claim was premised on the notion that AstraZeneca was unjustly enriched at Appellants' expense when it received money from customers who purchased Nexium based on advertisements that contained "misrepresentations" about the efficacy of Nexium. The circuit court found that the complaint failed to state a claim "for the same reasons underlying dismissal of the ADTPA and fraud claims. There cannot be any 'unjust' enrichment where AstraZeneca's alleged conduct falls within what is permitted by federal law and Nexium's labeling." We agree.

To find unjust enrichment, a party must have received something of value, to which he or she is not entitled and which he or she must restore. *See El Paso Prod. Co. v. Blanchard*, 371 Ark. 634, 269 S.W.3d 362 (2007). One who is free from fault cannot be held to be unjustly enriched merely because he or she has chosen to exercise a legal or contractual right. *Id*. In short, an action based on unjust enrichment is maintainable where a person has received

money or its equivalent under such circumstances that, in equity and good conscience, he or she ought not to retain. *Id.* (citing *Merch. & Planters Bank & Trust Co. v. Massey*, 302 Ark. 421, 790 S.W.2d 889 (1990)).

As discussed above, AstraZeneca's advertisements that were pled in the complaint were not misleading and did not contain misrepresentations; the advertisements complied with federal labeling regulations. Because AstraZeneca's advertisements were not misleading, and the company was entitled to set the price for Nexium,[12] Appellants have failed to state facts to allege a cause of action for unjust enrichment, and we affirm the circuit court's granting of AstraZeneca's motion to dismiss on this issue.

Next, The trial court found that Appellants' claims of promissory estoppel failed because they did not allege the existence of an enforceable promise or reliance. Appellants argue on appeal that AstraZeneca "reasonably expected that the promise in their advertisements that Nexium was 'more powerful,' 'more effective,' and offered 'significant improvements over Prilosec' would induce reliance and cause patients to request Nexium from their physicians for heartburn, resulting in a financial detriment to the patient when the patient purchased the higher priced Nexium and discovered it offered no significant improvement over Prilosec for the treatment of heartburn."

[12] The original claim that AstraZeneca engaged in price fixing was rejected by the trial court and is not pursued on appeal.

The black-letter law on promissory estoppel is found in the Restatement (Second) of Contracts:

> A promise which the promisor should reasonably expect to induce action or forbearance on the part of the promisee or a third person and which does induce such action or forbearance is binding if injustice can be avoided only by enforcement of the promise. The remedy granted for breach may be limited as justice requires.

See K.C. Props. v. Lowell, 373 Ark. 14, 280 S.W.3d 1 (2008); *Rigsby v. Rigsby*, 356 Ark. 311, 149 S.W.3d 318 (2004).

Appellants' complaint alleged that AstraZeneca "promised" that Nexium was more powerful and more effective, that AstraZeneca intended to induce Appellants and their physicians to rely on those "promises," and that Appellants relied on that promise to their financial detriment because Nexium was priced higher than other heartburn treatments. However, Appellants cite no authority that a product advertisement constitutes a quasi-contractual "promise." Therefore, we affirm the circuit court on this issue as well.[13]

Finally, Appellants contend that the circuit court should have granted their motions to recuse. The first of the two motions alleged that the court's letter opinion of May 24, 2006, gave the "appearance of having a mind-set that cannot be reconciled with the proposition that the trial judge is committed to hear and decide all issues that are relevant,

[13] The circuit court's order found, as an independent basis to grant dismissal of the complaint, that Appellants' causes of action were preempted by federal law. Because we affirm the lower court's dismissal of the case on the grounds discussed above, it is unnecessary for us to reach the preemption issue.

weighing the issues, and arriving at a judicious result." The motion pointed to language in the letter opinion that Appellants apparently found objectionable, such as the court's comments that the complaint, while

> well researched, . . . is convincing only to the point that a giant corporation has flexible power to control and enhance its own profits. It offers little or no proof that the defendants committed an actionable tort . . . . The complaint would perhaps make an excellent article in a scientific magazine but it fails as a legal pleading."

Appellants urged that the court should only have considered whether or not to grant AstraZeneca's motion to dismiss, and this kind of language, they contended, gave the appearance that the court was "not being fair and unbiased."

A judge has a duty to hear a case unless there is a valid reason to disqualify. *Porter v. Ark. Dept. of Health*, 374 Ark. 177, 286 S.W.3d 686 (2008). Moreover, a judge is presumed to be impartial, and the party seeking recusal must demonstrate bias. *Id.*; *Nash v. Hendricks*, 369 Ark. 60, 250 S.W.3d 541 (2007). A judge must refrain from hearing a case in which he or she might be interested and must avoid all appearances of bias. *Dolphin v. Wilson*, 328 Ark. 1, 942 S.W.2d 815 (1997); see also Ark. Code of Judicial Conduct Canon 3B(5).[14] This court, however, will not reverse a judgment on the basis of a trial judge's decision not to disqualify unless the judge has abused his or her discretion. *Porter*, *supra*. In determining whether there was an abuse of discretion, this court reviews the record to determine if any prejudice or bias

[14] As of July 1, 2009, this Canon is now embodied in Canon 2, Rule 2.3(A) of the Arkansas Code of Judicial Conduct.

was exhibited. *Id*. The question of bias is generally confined to the conscience of the judge. *Id*.

In *Porter*, *supra*, this court found no abuse of discretion in the trial court's denial of a motion to recuse where the court, at a hearing on a family-in-need-of-services petition, advised a witness that he had given a "bad answer" when asked why he let his fifteen-year-old daughter marry a thirty-four year old man. This court noted the trial judge's comment to the parties that her statement "in no way addressed the merits" and that "the fact that [the] court felt that [Porter] made a bad choice is not an indication of the court's future rulings." *Porter*, 374 Ark. at 191, 286 S.W.3d at 697. Thus, we concluded there was no abuse of discretion in declining to recuse.

Here, although Appellants complain that the court seemed to be "prejudging" the case, the letter opinion was, in fact, an order granting AstraZeneca's motion to dismiss the third amended complaint. It was not "prejudging," but rather was rendering the judgment. This court has noted that, unless there is an objective showing of bias, there must be a communication of bias in order to require recusal for implied bias, and the mere fact that a judge has ruled against a party is not sufficient to demonstrate bias. *See Searcy v. Davenport*, 352 Ark. 307, 100 S.W.3d 711 (2003). Here, the court's comments do not objectively reflect bias; they objectively reflect the court's belief that Appellants' complaint failed to state a cause of action. Therefore, the trial court did not abuse its discretion in declining to recuse on this issue.

Appellants' second motion to recuse stemmed from an alleged ex parte communication between the court and AstraZeneca's counsel. In this motion, Appellants complained that counsel for AstraZeneca had faxed a letter to the trial court, and the court had faxed a letter back. Thus, Appellants alleged that the court had communicated with the attorneys for AstraZeneca but did not also communicate with Appellants' counsel.

The letter faxed from AstraZeneca's counsel to the court was a note enclosing a copy of AstraZeneca's "motion to strike Appellants' fourth substituted and amended complaint and response in opposition to Appellants' motion for reconsideration, amended objection to entry of final order and request for findings of fact and conclusions of law and a brief in support." The letter also asked the court to set a hearing on the motion to strike. The fax sent from the court to AstraZeneca's counsel was a copy of AstraZeneca's cover page sent with the above letter with a handwritten note that said, "need order to strike 4th amend. complaint." In addition, AstraZeneca filed a notice of communication with court, notifying Appellants of the written communication from the court to AstraZeneca's counsel.

Appellants' second motion to recuse alleged that the court's communication with AstraZeneca's counsel "without simultaneously communicating, in whatever form the court took in that communication, with the attorneys for Appellants, . . . thereby creates the appearance of impropriety under the circumstances." They further allege on appeal that the communications gave the appearance that the judge was not impartial and had prejudged the Fifth Amended Complaint before he read it.

The fax from the court asking for an order to strike the fourth amended complaint does not demonstrate that the court had already prejudged the fifth amended complaint. There is no showing of actual bias, as the court received and considered the fifth amended complaint and (much later) addressed the merits of it. Appellants' argument on appeal merely concludes that the court's statement evidences bias; however, we conclude that the communication was merely the court's ministerial request for a precedent from opposing counsel. *See Searcy v. Davenport*, *supra* (the mere fact that a judge has ruled against a party is not sufficient to demonstrate bias). The circuit court did not abuse its discretion in declining to recuse.

Affirmed.