

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.

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.

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).

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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]
. . . .

(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).

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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 indication⁵) 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 for 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

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.

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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

