RENDERED: OCTOBER 12, 2012; 10:00 A.M.
TO BE PUBLISHED

Commonwealth of Kentucky

Court of Appeals

NO. 2010-CA-000626-MR

SANDOZ INC. APPELLANT

APPEAL FROM FRANKLIN CIRCUIT COURT
v. HONORABLE ROGER L. CRITTENDEN, JUDGE
ACTION NO. 04-CI-01487

COMMONWEALTH OF KENTUCKY
ex rel. JACK CONWAY, ATTORNEY
GENERAL APPELLEES

AND NO. 2011-CA-000225-MR

ASTRAZENECA, LP AND
ASTRAZENECA PHARMACEUTICALS, LP. APPELLANTS

APPEAL FROM FRANKLIN CIRCUIT COURT
v. HONORABLE ROGER L. CRITTENDEN, JUDGE
ACTION NO. 04-CI-01487

COMMONWEALTH OF KENTUCKY
ex rel. JACK CONWAY, ATTORNEY
GENERAL APPELLEES

OPINION
REVERSING AND REMANDING

** ** ** ** **

BEFORE: COMBS AND MOORE, JUDGES; LAMBERT,[1] SENIOR JUDGE.

LAMBERT, SENIOR JUDGE: Sandoz, Inc., AstraZeneca Pharmaceuticals, LP, and AstraZeneca LP appeal in this consolidated appeal from judgments of the Franklin Circuit Court upon adverse jury verdicts. Following a jury trial, Sandoz was found liable to the Commonwealth under the Kentucky Medicaid Fraud Statute, KRS 205.8463(4), the Kentucky False Advertising Statute, KRS 517.030, and the Kentucky Consumer Protection Act, KRS 367.170, for misrepresenting the "average wholesale prices" of its prescription drugs. In a separate trial, AstraZeneca was found liable to the Commonwealth under the Kentucky Medicaid Fraud Statute and the Kentucky Consumer Protection Act for misrepresenting the "average wholesale prices" of its prescription drugs. After a thorough consideration of the record and the issues at law, we reverse the judgments of the Franklin Circuit Court.

History

[1] Senior Judge Joseph E. Lambert sitting as Special Judge by assignment of the Chief Justice pursuant to Section 110(5)(b) of the Kentucky Constitution and Kentucky Revised Statutes (KRS) 21.580.

These consolidated actions involve the submission of "average wholesale prices" for prescription drugs to industry publications, upon which the Commonwealth based reimbursement formulas for the State's Medicaid program. The Commonwealth, through its Attorney General, filed suit against numerous pharmaceutical companies, including the present actions against Sandoz and AstraZeneca, alleging that the drug companies engaged in false or inflated reporting of average wholesale prices, causing the State to pay inflated prices to pharmacies for those companies' pharmaceuticals.

Medicaid is a voluntary state program designed to provide prescription drug coverage and medical care to persons whose income and resources are insufficient to meet the costs of such care. 42 United States Code (U.S.C.) § 1396, *et. seq*. Under federal law, states can opt into the program so long as they comply with the applicable laws. 42 U.S.C. § 1396(a); *Atkins v. Rivera*, 477 U.S. 154, 156, 106 S.Ct. 2456, 2458, 91 L.Ed.2d 131 (1986). The federal government, in turn, shoulders most of the cost burden by paying approximately 70% of the state's costs.

At the federal level, the Medicaid program is administered by the Center for Medicare and Medicaid Services. All states are required by law to submit their Medicaid plans for approval by the federal government through the Center for Medicare and Medicaid Services. As part of its plan, each state must submit reimbursement formula showing how the state intends to reimburse pharmacies for prescriptions filled by Medicaid users.

During the time period relevant herein, each state had its own formula for determining Medicaid prescription reimbursements to pharmacies. At the same time, federal law also placed spending limits on prescription drugs and each state formula had to comply with the federal Medicaid spending limits. These limits were based upon the "estimated acquisition cost" and "reasonable dispensing fee" for each drug. For some drugs, ceilings or "federal upper limits" were set by the federal Center for Medicare and Medicaid Services. States' aggregate reimbursement to pharmacies could not exceed the federal upper limits set for the drugs upon which such a limit was imposed. 42 C.F.R. § 447.331(a) (later renumbered as § 447.512). Any drugs without a federal upper limit were required to have an aggregate reimbursement that did not exceed the lower of: (1) the sum of the estimated acquisition cost and dispensing fees on all prescriptions, or (2) the sum of the providers' "usual and customary charges to the general public." *Id.* at (b)(2). Each state had its own formula for how to arrive at estimated acquisition cost.

The Commonwealth's formula for "estimated acquisition cost" involved the insertion of an "average wholesale price" into an equation. Where this equation yielded a number higher than the federal upper limit, the Commonwealth paid at the federal limit, but when the number was lower than federal limits, the Commonwealth paid at the lower rate yielded by its formula. The Commonwealth, like many states at that time, relied upon published price data for its "average wholesale prices." The Commonwealth purchased this data from a

price publisher, First DataBank. The industry averages available through price publishers like First DataBank were called AWPs (short, for "average wholesale prices"). Although the Commonwealth used AWP in its formula, the federal government had advised the States decades ago that state reimbursement formulas should take into consideration the fact that AWPs are far higher than actual transaction prices.[2] Since that time, the Commonwealth had tacitly acknowledged this fact by "discounting" from the AWPs supplied by price publishers and reimbursing pharmacies at less than AWP.

In 2004, following changes in federal regulations related to Medicaid, and following the lead of several other states, the Commonwealth filed suit against over forty drug manufacturers for reporting false and inflated AWPs to price publishers.[3] The Commonwealth filed suit against Sandoz and AstraZeneca at this same time, alleging that the companies provided false AWPs to FirstDataBank and alleging violation of the Kentucky Medicaid Fraud Statute, the Kentucky Consumer Protection Act, and the False Advertising Statute. Because AWP was the only variable in the state's reimbursement equation, it alleged that inflated AWPs meant inflated reimbursements. Damages were alleged in the form of millions of dollars in overpayments.

[2] In 1984, the Commonwealth received a report from the Office of the Inspector General that AWP represented a list price that did not reflect discounts, and that pharmacies purchased drugs at prices significantly discounted from AWP.

[3] The term "average wholesale price" was phased out of the Medicare reimbursement scheme by the 2003 Act, which stipulated that reimbursements for drugs furnished on or after January 1, 2005, would be based on either a competitive acquisition program or an average sales price, a term defined to include all discounts and rebates. *See* 42 U.S.C. §§ 1395u(o), 1395w-3, 1395w-3a, 1395w-3b (2006). The damages period in the present case runs from 1999 to 2005.

At the conclusion of a jury trial in the underlying case of *Commonwealth v. Sandoz*, a Franklin County jury found Sandoz liable under all three theories, and returned a verdict awarding the Commonwealth $16 million in compensatory damages. Likewise, in the underlying case of *AstraZeneca v. Commonwealth*, another Franklin County jury found AstraZeneca liable under two of the theories, the Kentucky Medicaid Fraud Statute and the Kentucky Consumer Protection Act, and awarded the Commonwealth $14.7 million in compensatory damages, $100 in punitive damages, and additional civil penalties under the Kentucky Consumer Protection Act. Both defendants moved for judgments notwithstanding the verdict (JNOVs) or a new trial, each of which was denied by the trial court. Sandoz and AstraZeneca now appeal from their respective adverse judgments, which appeals have been consolidated for the purposes of review.

Further facts will be developed as necessary.

Analysis

On appeal, Sandoz argues: (1) that the verdict was not supported by sufficient evidence, (2) that the Commonwealth failed to prove causation, (3) that the claims were barred by the separation of powers doctrine and the political question doctrine, (4) that the trial court's award of penalties under the Kentucky Consumer Protection Act should be vacated, and (5) that individual errors by the trial court necessitate a new trial. Similarly, AstraZeneca argues: (1) that its AWPs were not actionable and caused no harm to the Commonwealth, (2) that the Commonwealth's Kentucky Consumer Protection Act and Kentucky Medicaid

Fraud Statute claims must fail as a matter of law, (3) that the Commonwealth's claims violate the Kentucky Constitution and are preempted by federal law, and (4) that a new trial is warranted because the jury instructions failed to instruct on the Commonwealth's knowledge.

Because we are reversing the Franklin Circuit Court, we will not address each issue individually, but address only the grounds for reversal.

Upon a thorough review of the record, we find that JNOVs should have been granted in favor of both Sandoz and AstraZeneca because the Commonwealth failed to establish causation of damages. More specifically, since the Commonwealth was aware for decades that the AWPs were inflated, it could not have relied upon them as accurate figures, and thus, no damages resulted.

The Appellants maintain that the trial court erred in failing to grant their motions for a JNOV because the jury's finding of liability was not supported by sufficient evidence. When reviewing a trial court's denial of a motion for a JNOV, we view the evidence in a light most favorable to the prevailing party, drawing every fair and reasonable inference in its favor. *Radioshack Corp. v. ComSmart, Inc*., 222 S.W.3d 256, 261 (Ky. App. 2007). The question on review of a denied motion for JNOV or a new trial, is whether there was "a complete absence of proof on a material issue." *Id.* quoting *Taylor v. Kennedy*, 700 S.W.2d 415, 416 (Ky. App. 1985). *See also Bierman v. Klapheke*, 967 S.W.2d 16, 18 (Ky. 1998). On appellate review, we will not reverse a jury's verdict unless the result reached

by the jury was "clearly unreasonable." *Commonwealth v. Benham*, 816 S.W.2d 186, 187 (Ky. 1991).

To recover damages, the Commonwealth had to prove that Sandoz and AstraZeneca's conduct was "a substantial factor" in causing it to over-reimburse. *Hargis v. Baize*, 168 S.W.3d 36, 46 (Ky. 2005). Restated, the Commonwealth had to show that it would have paid less if Sandoz and AstraZeneca's AWPs had not been false, fraudulent, misleading, or unfair. Sandoz and AstraZeneca have argued that the Commonwealth failed to show this. We agree.

The result reached by the jury was clearly unreasonable. Indeed, there was a complete absence of proof on the issue of causation of damages. The crux of the Commonwealth's failure to prove causation stems from the Commonwealth's knowledge that AWPs were inflated and that AWPs did not represent actual prices. Because the Commonwealth was aware AWPs were inflated prices, and was further aware of the degree of inflation, it could not show that the Appellants' conduct was "a substantial factor" in causing it to over-reimburse pharmacies.

We recognize, however, that there was ample evidence from which the jury could have properly determined that Sandoz did, in fact, submit AWPs in a false, misleading, or deceptive manner. The jury heard evidence that when Sandoz launched a new drug on the market, it set its initial AWP about 10% lower than the AWP for the equivalent "brand" drug, or, if other generics were on the market, equivalent to such generics. Thereafter, Sandoz's expert said they "just [didn't]

bother to change it." Competition for new generics for a particular drug would then increase the "spread" between Sandoz's AWP, which did not change, and the falling actual prices of the drugs. Thus, there was an ever-increasing spread between the actual wholesale prices and the AWP, thus creating greater profits for pharmacies. The record shows that Sandoz and AstraZeneca had a vested interest in keeping the spread large in order to keep pharmacies happy and buying their generics.

However, none of this information was unknown to the Commonwealth and that is the real crux of this case. The protection of spread through inflated AWPs was endemic in the system, and states across the nation were aware that pharmaceutical companies were reporting bloated AWPs. Further, the Commonwealth itself commissioned a private study of AWP and discovered that AWP was significantly inflated; that Kentucky pharmacies were making a substantial profit off the Medicaid program, and that Medicaid reimbursements could be cut significantly and pharmacists would still make a profit. Despite this information, the Commonwealth chose not to implement the suggested reimbursement reductions. It is of particular note that the Commonwealth even took affirmative action on occasion to protect spreads due to fear that pharmacies would stop filling prescriptions for Kentucky Medicaid users if the profit margin was not high enough.[4] Clearly, the Commonwealth was aware that AWPs were not

[4] The predecessor of the Center for Medicare and Medicaid Services, the Health Care Financing Administration (HCFA), even ordered the Commonwealth in 1985 to stop using undiscounted AWP in its formulas. The HCFA suggested adopting a non-AWP formula that would produce a price at around 13.9% below AWP, and "more realistically reflect actual cost." In response, the

the actual prices paid for generic drugs. In light of this fact, it is wholly untenable for the Commonwealth to now claim millions of dollars in compensatory damages for harm caused by the false or fraudulent reporting of AWPs to price publishers.

Because the Commonwealth was fully aware of the practices in the industry with respect to AWP, there can be no causation of damages. Frankly, it is appalling that the Commonwealth had actual knowledge of this "shell game" method of pricing employed by the drug companies, the wholesalers, and the pharmacists. However, even more appalling is the fact that, in spite of that knowledge, it acquiesced, billed accordingly, and now seeks reimbursement by way of compensatory and punitive damages.

The Commonwealth was entirely complicit in this system of pricing. Apart from the fact that JNOVs should have been granted in favor of Sandoz and AstraZeneca, basic equitable principles also prohibit the Commonwealth from recovering. In situations such as the present one, where a party's actions are *in pari delicto* with the tortfeasor, recovery is barred by the principles of equity. *York v. Petzl America, Inc*., 353 S.W.3d 349, 353 n. 4 (Ky. App. 2010); quoting *Forbes v. City of Ashland*, 55 S.W.2d 917, 919-920 (Ky. 1932)("The *'in pari delicto'* doctrine is generally stated as 'when both parties are guilty, the court will leave them where it finds them.'"); *Eline Realty Co. v. Foeman*, 252 S.W.2d 15, 19 (Ky.

Commonwealth reduced its reimbursement, but only to AWP minus 5%. Between 1998 and 2003, the Commonwealth commissioned detailed reports by a private company that indicated AWP ranged from 32% to 85%, depending on the year and category of drug. Yet, the Commonwealth continued to reimburse pharmacies at a level that provided a substantial profit. A 1999 report indicated that access and political considerations played into the Commonwealth's reimbursement rate analysis.

1952)("Equity will not relieve one party against another where both are in pari delicto.") Here, the Commonwealth's actions were *in pari delicto* with the drug companies and other players in the Medicaid reimbursement scheme –a scheme in which the Commonwealth systematically participated by submitting those same figures to the federal government as true and accurate.

Conclusion

In light of the foregoing, we reverse the judgments as unsupported by the evidence and remand to the Franklin Circuit Court with directions to enter judgment for the Appellants.

ALL CONCUR.

BRIEFS FOR APPELLANT SANDOZ INC.:

William E. Johnson
Frankfort, Kentucky

David V. Kramer
Crestview Hills, Kentucky

Vicent R. FitzPatrick, Jr.
Joseph Angland
Heather K. McDevitt
Michael J. Gallagher
New York, New York

ORAL ARGUMENT FOR APPELLANT SANDOZ INC.:

Joseph Angland
New York, New York

BRIEFS FOR APPELANTS ASTRAZENECA LP AND ASTRAZENECA PHARMACEUTICALS LP:

Margaret E. Keane
Holland N. McTyeire V
Louisville, Kentucky

Joel M. Cohen
New York, New York

Gerson A. Zweifach
John E. Schmidtlein
Mark E. Haddad
Paul J. Zidlicky
Washington, DC

BRIEFS FOR APPELLEE:

Jack Conway
Attorney General of Kentucky

C. David Johnstone
LeeAnne Applegate
Office of Attorney General
Frankfort, Kentucky

George F. Galland, Jr.
Robert S. Libman
Chicago, Illinois

ORAL ARGUMENT FOR APPELLEE:

George F. Galland, Jr.
Chicago, Illinois

ORAL ARGUMENT FOR
APPELANTS ASTRAZENECA LP
AND ASTRAZENECA
PHARMACEUTICALS LP:

Mark E. Haddad
Washington, DC