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Commonwealth Court Ruling Let's Case Go to Discovery Stage

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Discovery may proceed in the state's lawsuit against 13 pharmaceutical companies that allegedly engaged in a price-inflation scheme now that the Commonwealth Court has rejected most of the defendants' preliminary objections.

The decision last week is a victory for the Pennsylvania Attorney General's Office and the Philadelphia firm of Kline & Specter, which is prosecuting the case with the state's lawyers.

Both were dealt a setback in February when the court dismissed the attorney general's action on preliminary objections for a lack of "specificity" as required by the Rules of Civil Procedure.

But with its 44-page opinion in Commonwealth v. TAP Pharmaceutical Products Inc., the unanimous seven-judge panel has found the state's amended complaint adequate, rejecting most of the preliminary objections raised by the defendant companies.

The court did sustain preliminary objections to the state's parens patriae claims against Bayer AG and subsidiary Bayer Corp. on Medicaid reimbursements involving certain drugs subject to a 2001 settlement agreement Bayer signed with the state.

The court also deferred ruling on the personal jurisdiction objections of three companies - Bayer AG, AstraZeneca PLC and AstraZeneca Holdings.

Shanin Specter, a Kline & Specter partner and lead attorney for the state, said the most significant aspect of the ruling is the court's finding that the attorney general has standing to pursue parens patriae claims for alleged unfair trade practices committed by the defendants.

The court found that such a claim may be brought by the state to protect "the economic well-being of the commonwealth and its citizens."

The state's action stems from allegations that the pharmaceutical companies manipulated a pricing standard known as the average wholesale price to increase profit margin by generating more money from product sales and increasing market shares.

Specifically, the state alleged that the manipulated AWP increased revenues for doctors and pharmacy benefit managers who buy pharmaceutical products in bulk to resell to patients and consumers, and then obtain reimbursements from state medical funding programs. By inflating the AWP, the state claimed, these companies created an incentive for the physician and pharmacy manager middlemen to buy their products.

"Because the reimbursement rate is based on the inflated AWP, the middleman receives a windfall of sorts, and the greater the windfall, the more likely the middleman is to choose such drugs," Commonwealth Court President Judge James Gardner Colins explained.

The Attorney General's Office brought its action in March 2004, naming as defendants AstraZeneca PLC, Bayer AG, GlaxoSmithKline PLC, Pfizer Inc., Amgen Inc., Schering-Plough Corp., Bristol-Myers Squibb Co., Johnson & Johnson, Baxter International Inc., Aventis Pharmaceuticals Inc., Boehringer Ingelheim Corp., Dey Inc. and Takeda Chemical Industries Ltd. - as well as subsidiaries of those companies. (Takeda was dismissed from the case in the February ruling, although a subsidiary of the company, TAP Pharmaceutical Products Inc., is still a defendant.)

According to the court's opinion, the state is asserting four causes of action: unjust enrichment, unfair trade practices, fraud and civil conspiracy.

Got Standing?

In addition to challenging the state's parens patriae standing on the unfair trade practices count, the defendants also contested the state's authority to bring a private action altogether under the Unfair Trade Practices and Consumer Protection Law.

The defense argued that under Section 9.2 of the statute, only individuals may sue for damages arising from the purchase or lease of "goods and services primarily for personal, family or household purposes[.]" The state is not a person, the defendants said.

The court, however, found persuasive reasoning in a 1990 Superior Court decision that said the state's "representative capacity renders it a person under Section 9.2."

In Valley Forge Towers South Condominium v. Ron-Ike Foam Insulators Inc., the Superior Court described a "person" eligible to bring an unfair trade practices claim under Section 9.2 as "natural persons, corporations, trusts, partnerships, incorporated and unincorporated associations, and any other legal entities." Colins found this definition broad enough to encompass the state as a "person" under the law.

Colins also noted Valley Forge Towers' emphasis that lawsuit restrictions under the UTPCPL are based not on the type of product, but rather the purpose of the purchase.

"Here, as in that case, the drugs are ultimately used for a personal, family or household purposes," Colins wrote.

Next, the defendants challenged the state's parens patriae standing to recover damages on behalf of individual Pennsylvania consumers.

Colins said the question boils down to whether the state is acting out of a "quasi-sovereign interest" in bringing such a claim, or whether it is simply representing the interests of individuals who could sue on their own behalf.

Considering case law, Colins found that "a state's interest in the economic well-being of its people" may be considered a "quasi-sovereign interest." In this case, he said, the state's complaint adequately pleads this interest by arguing "that the use of AWPs has affected the economic health and well-being of its citizens by requiring those purchasers and reimbursers of the defendants' drugs to pay inflated amounts for the defendants' drugs."

The defendants also invoked the filed rate doctrine to challenge the state's claims involving the state PACE program and Medicaid Part B.

The filed rate doctrine, used to set rates for public utilities, holds that "courts have less competence to address certain rate-making issues and should not undermine the rate-making process by interfering with administrative determinations," Colins explained.

The defendants urged the court to apply the doctrine to the administrative scheme used to set the AWP.

Colins said unlike proceedings in the public utility sector - in which formulas are crafted "to balance the needs of end users against the manufacturers' right to a fair rate of return" - the formulas used to calculate the AWP are designed to set reimbursement rates for medical providers. There also is no case law supporting the application of the filed rate doctrine to the reimbursement formulas at issue in this case, he said.

The defendants also objected to the lawsuit under the state action and the federal preemption doctrines.

On the state action doctrine, Colins said the question of whether the state's action is the direct cause of the alleged harm is factual and cannot be decided in preliminary objections.

On the federal preemption doctrine, he noted that the case was already removed to federal court but remanded to state court after a U.S. district court judge found that the federal courts lacked jurisdiction.

The defendants jointly and individually raised several other objections to the amended complaint, many arguing that it still lacked the adequate specificity under court rules - all of which were rejected by the court.

Among the individual claims raised were Bayer and Bayer AG's objection to the parens patriae count involving Medicaid reimbursement. These reimbursements were for the drugs Koatec,

Kogenate, Konyne-80, Gamimune N 5 Percent,Gamimune N 10 Percent and Thrombate III, which were subject to a 2001 AWP settlement agreement between Bayer and the state.

According to Colins, the agreement required Bayer to provide average sales prices to the state, which, Bayer asserted, vitiates any of the state's claim regarding the pricing of those drugs subject to the agreement.

Colins agreed and sustained that part of Bayer's objections pertaining to the named drugs.

Colins was joined on the en banc panel by Judges Bernard L. McGinley, Doris A. Smith-Ribner, Rochelle S. Friedman, Bonnie Brigance Leadbetter, Renee Cohn Jubelirer and Mary Hannah Leavitt.

Barbara Petito, deputy press secretary in the Attorney General's Office, said that the state is pleased with the court's decision.

"We're moving forward with the case to prove that the commonwealth and consumers have overpaid for prescription drugs, and our goal is to seek a return of overcharges," she said.

Specter said now that the preliminary objections have been overruled, the state will proceed immediately with discovery on the liability issues.

Specter noted that some relevant discovery has already been conducted in multidistrict litigation currently under way in Boston that also involves some of the pharmaceutical companies in this case. Specter also said his firm was recently asked to serve as additional co-lead counsel in that litigation, which, he said, "will be helpful to both cases by streamlining discovery."

In addition to Specter, James A. Donahue and Alexis R. Barbieri of the Attorney General's Office have also been active in the state's case. Donald E. Haviland Jr. of Kline & Specter argued the matter.

John C. Dodds of Morgan Lewis & Bockius in Philadelphia, counsel for Pharmacia Corp., a subsidiary of Pfizer, argued the preliminary objections on behalf of the defendants. He could not be reached for comment yesterday.

(Copies of the 44-page opinion in Commonwealth v. TAP Pharmaceutical Products Inc., PICS No. 05-1789, are available from The Legal Intelligencer. Please call the Pennsylvania Instant Case Service at 800-276-PICS to order or for information. Some cases are not available until 1 p.m.)