Antitrust

California Ruling in Pay for Delay Case May Create Headaches for Drug Companies

Cipro Decision Hailed As Consumer Victory

Worries for Drug Companies: Attorneys say the ruling may hurt pharmaceutical companies' ability to settle drug patent litigation.

By Dana A. Elfin

May 12 -- The recent California Supreme Court ruling in a pay-for-delay case involving the antibiotic Cipro may hurt the ability of pharmaceutical companies to settle drug patent litigation by limiting available defenses and switching the burden of proof to the defendant, attorneys told Bloomberg BNA.

The *Cipro* decision "stacks the deck heavily in favor of plaintiffs," Richard A. Samp, chief counsel of the Washington Legal Foundation (WLF), told Bloomberg BNA in a May 8 e-mail.

Indeed, Scott L. Nelson, an attorney with the pro-consumer Public Citizen Litigation Group in Washington, told Bloomberg BNA in a May 12 e-mail that the *Cipro* ruling is "a major victory for consumers."

Opinion Issued May 7.

On May 7, the California Supreme Court ruled that a settlement in which Bayer Corp. paid generic drug manufacturers to resolve patent infringement litigation and extend the marketing exclusivity for its ciprofloxacin hydrochloride (Cipro) may violate state antitrust laws (*In re Cipro Cases I & II*,Cal., No. S198616, 5/7/15) (*see related item in this section*).

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Washington Legal Foundation

The court clarified that its opinion on how state courts should assess the legality of reverse payment settlements is consistent with the U.S. Supreme Court's ruling in *FTC v. Actavis, Inc.*, U.S., No. 12-416, (2013) 133 S. Ct. 2223, 2013 BL 158126, and that its new standard merely provided a framework for analyzing the anticompetitive effects of reverse payment patent settlements that was left open by the Actavis ruling.

Per Se Standard Rejected.

At oral argument in the *Cipro* case, the plaintiffs contended that settlement agreements involving reverse payments should be considered per se illegal, and some feared that the California court would wind up adopting that standard .

Although the state court rejected the per se rule for assessing legality of reverse payment settlements under California's Cartwright Act, the differences between the *Cipro* and *Actavis* decisions nonetheless are significant and could create problems for drug companies, Samp said.

New Hurdles for Drug Companies?

Samp said one of the major differences between the decisions is that the *Cipro* decision "creates an easily-met prima facie test, after which the burden of proof switches to the defendant." In contrast, he said, the *Actavis* decision didn't impose any such burden on defendants.

Second, Samp said, the *Cipro* decision significantly limits available defenses. "For example," he said, "the decision seems to say that proof that the challenged patent is both valid and infringed is not a defense, and that the defendants' right to demonstrate that settlement has pro-competitive effects is quite limited."

Third, Samp said the California court also expanded *Actavis* to cover not only cash payments but also payments of anything of value. "The court essentially adopted the position espoused by the U.S. government (but rejected by the Supreme Court) in *Actavis*," he said.

Indeed, Samp said, because of the differences between the two decisions, “there is a strong argument that California antitrust law (as interpreted by*Cipro*) is preempted by federal antitrust law.”

“The Supreme Court has held that although states are permitted to enforce their own antitrust laws, they may do so only if the law is not significantly more restrictive than federal antitrust law,” Samp told Bloomberg BNA. “Because *Cipro* establishes a standard that is significantly more restrictive than the *Actavis* standard, it could very well be overturned (on preemption grounds) should the U.S. Supreme Court ever agree to hear the case.”

WLF, a public interest law firm and policy center, filed a supplemental brief in the *Cipro* case in 2014 urging the California Supreme Court to apply*Actavis*'s “rule of reason” standard to the claims under California antitrust law.

Patent Merits Could Come Into Play.

But Christopher J. Kelly, of Mayer Brown LLP, in Palo Alto, Calif., said that the California court's analysis in the *Cipro* case actually could wind up favoring defendants by bringing into play the merits of the drug patent or patents at issue in the settlement. The *Cipro* court's “riff on what the 'baseline' for the analysis should be--'whether a settlement postpones market entry beyond the average point that would have been expected at the time in the absence of the agreement'--seems almost to beg the parties to bring the patent merits into the discussion,” Kelly said.

And, Kelly said, because the California *Cipro* decision didn't articulate a stricter antitrust standard for Hatch-Waxman settlements than the rule of reason analysis the U.S. Supreme Court adopted in *Actavis*, “we shouldn't be seeing the 'giant sucking sound' ... of Hatch-Waxman antitrust litigation zooming towards California courts.”

“The California court injected a little more structure into the inquiry, assigning burdens of going forward, and describing a prima facie case of anticompetitive effect,” he said, “but it didn't say any more--at least directly--about potential justifications for reverse payment settlements than did the U.S. Supreme Court.”

Ruling Called 'Victory for Consumers.'

Scott L. Nelson, an attorney with Public Citizen Litigation Group in Washington, told Bloomberg BNA the ruling will make it more difficult for drug companies to defend reverse payment patent litigation settlements.

"By allowing suits under state antitrust law (which allows indirect purchasers such as individual consumers to be plaintiffs), the decision will give more bite to antitrust claims against parties to pay-for-delay deals than is available under federal antitrust law alone," Nelson said. "And like the Supreme Court's *Actavis* decision that opened the door to federal antitrust liability for these kinds of anticompetitive arrangements, it should make brand name and generic drug companies much more hesitant to enter into these kinds of deals," he said.

Although Nelson acknowledged that the California court stopped short of declaring pay-for-delay deals per se unlawful, he said, "the factors that the court outlined … seem carefully considered to make truly anticompetitive arrangements very hard to defend."

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"The decision should help promote the benefits of generic competition that the Hatch-Waxman Act was designed to bring about," he said. "It should also contribute to limiting incentives that drug companies have to try to shore up their monopolies with invalid patents that do nothing to promote innovation, but only shield already existing drugs from competition."

Wells Wilkinson, a staff attorney and senior policy analyst at the Community Catalyst, a national nonprofit consumer and community health advocacy organization based in Boston, also hailed the ruling as a consumer victory.

"The decision by California's highest court is a win for consumers, because the court accurately sees any payment in exchange for a delay in generic entry as anticompetitive collusion between drugmakers, allowing discovery of important facts to go forward," Wilkinson told Bloomberg BNA in an e-mail May 13.

"With nearly 200 of these secret deals affecting as many as 160 of the most widely used drug products, according to FTC reports, consumers have likely paid billions more each year than they should have," he said, referring to the Federal Trade Commission.

Background of Cipro Case.

At issue in the case is a $398.1 million payment Bayer Corp. made to generic manufacturers to not enter the market with their generic versions of the blockbuster Cipro.

Bayer no longer is part of the litigation, in which the California Superior Court dismissed, and the California Court of Appeal upheld dismissal of, a state antitrust and unfair competition law challenge against the generic manufacturers.

Litigation, Settlement.

Plaintiffs in suits filed in 2010 challenged Bayer's payment to Barr Laboratories Inc., Hoechst Marion Roussel Inc., Watson Pharmaceuticals Inc. and the Rugby Group Inc. that blocked access to a cheaper generic version of Cipro. A few weeks after the U.S. Supreme Court's decision in *Actavis*, Bayer AG and Bayer Corp. settled for $74 million consumers' claims that the agreement resulted in consumers and third-party payers paying more for the antibiotic, while eight consolidated indirect purchaser suits continued against generic drugmakers that could be liable for treble damages under the Cartwright Act.

The California Superior Court, San Diego, approved the Bayer class settlement in fall 2013.

By Dana A. Elfin

To contact the reporter on this story: Dana A. Elfin in Washington at delfin@bna.com

To contact the editor responsible for this story: Brian Broderick at bbroderick@bna.com