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Calif. Cipro Case Puts Pay-For-Delay Deals Under Scrutiny

By **Erin Coe**

Law360, San Diego (February 11, 2015, 1:45 PM ET) -- The California Supreme Court will hear oral arguments next month in a proposed class action brought by purchasers of antibiotic Cipro alleging Bayer Corp. illegally paid several generics makers nearly $400 million to delay market entry, and experts say a ruling that subjects pay-for-delay settlements to a stricter standard of review could reverberate nationwide, deterring drug companies from entering into these pacts.

The state high court plans to hear arguments in the case on March 3, nearly two years after the U.S. Supreme Court ruled in Federal Trade Commission v. Actavis Inc. that patent law didn't shield pay-for-delay settlements from antitrust challenges by the agency and private plaintiffs.

Although Bayer agreed in July 2013 to pay $74 million to exit the current case, the plaintiffs and the generics makers continue to wrangle over whether the Actavis ruling supports reviving the state law antitrust claims under the Cartwright Antitrust Act alleging Bayer illegally paid nearly $400 million to Barr Laboratories Inc., Hoechst Marion Roussel Inc., The Rugby Group Inc. and Watson Pharmaceuticals Inc. to delay market entry.

“A ruling in this case will be one step on the path toward getting some consensus on what Actavis means,” said James Martin, business development head of Dickstein Shapiro LLP's antitrust and financial services practice. “Even if it applies a different rule than other courts, it will give attorneys more information so that they can help counsel branded or generic manufacturers in these types of patent infringement cases.”

The plaintiffs have asked the court to find that pay-for-delay agreements — Hatch-Waxman Act settlements in which branded-drug makers pay generic-drug manufacturers an alleged share of their monopoly profits to delay market entry — should be reviewed under either a “quick look” rule of reason analysis or under a per se test.

A “quick look” or “constrained” rule of reason test requires courts to weigh the pro-competitive benefits of the settlements against any anti-competitive harm they cause. Under a per se test, pay-for-delay settlements would be subject to the strictest view of being automatically illegal.

But the defendants have argued that the U.S. Supreme Court rejected both approaches, instead concluding that because the settlements were neither presumptively lawful nor presumptively unlawful, they must be analyzed using the traditional antitrust rule of reason.

“The reason that plaintiffs and enforcement agencies have pushed for a ‘quick look’ or per se standard is that it would alleviate some of the initial burden on plaintiffs to have to identify and prove traditional market conditions in each instance,” said David Kesselman, a partner at Kesselman Brantly & Stockinger LLP. “A full blown rule of reason requires each side to essentially debate, with the help of their experts, the scope of the market and market power in what ends up being an expensive and difficult undertaking for the plaintiffs or an enforcement agency against some very well-heeled defendants, like the pharmaceutical industry.”

Attorneys are going to be watching this case to see whether the California Supreme Court goes beyond federal law and comes up with more aggressive standards under California antitrust law that pay-for-delay agreements are presumptively illegal or per se illegal, according to Michael Carrier, a professor at Rutgers University School of Law who wrote an amicus brief on behalf of dozens of professors in favor of the plaintiffs.

If the state high court finds a pay-for-delay deal can be reviewed as presumptively illegal, more of these agreements would be at risk of being struck down and plaintiffs would be encouraged to take challenges of these pacts to state courts in California and beyond, he said.

“If the California Supreme Court issues a ruling that significantly favors the plaintiffs, all of a sudden that opens up another front for those wishing to challenge these concerning settlements,” he said. “A reversal [of the lower court’s dismissal of the plaintiffs’ case] could make California a destination for plaintiffs challenging these agreements. In addition, other state and even federal courts could adapt and follow the reasoning from the California Supreme Court's decision.”

A California Supreme Court ruling finding that reverse payment settlements could be reviewed under a “quick look” test could make branded- and generic-drug companies reluctant to enter such deals in California, and because the Golden State is such a huge market, it also could affect U.S. agreements, according to Kesselman.

“If enforcement agencies, the California attorney general and private enforcers could bring cases in situations where a ‘quick look’ rule applied, it would make the pharmaceutical industry more reticent to enter into these agreements unless it could truly justify that a reverse payment wasn’t going to harm competition,” he said.

If the court allows for a stricter standard of review, drug companies would be less inclined to reach pure pay-for-delay agreements, and attorneys would have to help them develop a different kind of deal, according to Martin.

“I think lawyers always figure out clever ways to resolve problems,” he said. “If the court takes the option of reverse payment agreements off the table, it would force lawyers to figure out another way to go forward that doesn’t expose the parties to antitrust liability."

The California attorney general has taken the position in the case that pay-for-delay settlements should be subject to a stricter standard because the Cartwright Antitrust Act is broader in scope than federal antitrust law, and Kesselman said it’s a compelling argument.

“The literature and amount of writing suggest that these reverse payments are anti-competitive and that consumers have to pay significantly more for drugs when these kinds of deals are consummated

because generics are not available in the marketplace," he said.

A ruling that departs from the U.S. Supreme Court standard and is more favorable to plaintiffs would create more uncertainty for companies over what rule applies to reverse payment transactions and breed litigation, according to Stephen Kastenberg, a partner at Ballard Spahr LLP.

"To the extent the California Supreme Court goes off in a different direction, it's going to create confusion over the different standards and that tends to increase litigation," he said. "We could see copycat suits in federal courts seeking to take advantage of a more pro-plaintiff standard."

However, Carrier said a decision for the plaintiffs would likely lead to a marginal increase in pay-for-delay antitrust suits.

"The reason for the increase is that plaintiffs could then seek to file lawsuits in state court, particularly in California," he said. "The reason it would be marginal is that plaintiffs have already increased litigation after the U.S. Supreme Court's Actavis decision."

The plaintiffs are represented by Joseph R. Saveri of Joseph Saveri Law Firm, Eric B. Fastiff, Brendan Glackin, Jordan Elias and Dean M. Harvey of Lieff Cabraser Heimann & Bernstein LLP; Mark Lemley of Durie Tangri LLP; Dan Drachler of Zwerling Schachter & Zwerling LLP; and Ralph B. Kalfayan of Krause Kalfayan Benink & Slavens LLP.

Barr is represented by Jay P. Lefkowitz, Karen N. Walker, Edwin John U and Gregory L. Skidmore of Kirkland & Ellis LLP. The other generics defendants are represented by David E. Everson, Heather S. Woodson and Victoria Smith of Stinson Leonard Street LLP. All of the generics defendants are represented by Joann Rezzo of Edleson & Rezzo and Kathryn E. Karcher of Karcher Harmes LLP.

The case is In re: Cipro Cases I & II, case number S198616, in the California Supreme Court.

--Additional reporting by Melissa Lipman. Editing by Jeremy Barker and Philip Shea.

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