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Antitrust

Latest Reverse Payments Ruling Could Be Game Changer

BNA Snapshot

King Drug Co. of Florence, Inc. v. Cephalon, Inc., E.D. Pa., No. 2:06-cv-01797-MSG, 11/5/15

Key Development: Court allows drugmakers to use testimony at trial about the strength of the underlying patent in reverse payment cases.

Broad Implications: By injecting additional uncertainty into how district courts should interpret the U.S. Supreme Court's 2013 decision in *FTC v. Actavis*, the ruling could ultimately lead to the high court hearing yet another reverse payments case.



By Dana A. Elfin

Nov. 10 — In an opinion that could very well be a game-changer for drug companies involved in antitrust cases challenging the legality of patent litigation settlements, a federal judge Nov. 5 ruled that a 2013 U.S. Supreme Court holding doesn't bar the door to testimony about the strength of the patent underlying a challenged settlement (*King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, E.D. Pa., No. 2:06-cv-01797-MSG, 11/5/15).

Judge Mitchell Goldberg of the U.S. District Court for the Eastern District of Pennsylvania said that the U.S. Supreme Court's ruling in *FTC v. Actavis* didn't preclude consideration of the strength or weakness of patents underlying the challenged settlement.

The district court's Nov. 5 ruling on what expert testimony will be allowed came in the *King Drug* case, which is scheduled to go to trial in early 2016. The case involves an antitrust challenge to patent settlements with reverse payments between drugmaker Cephalon Inc. and four generic drug companies over Cephalon's flagship drug, the narcolepsy treatment Provigil (modafinil) (see related item).

Reverse payments generally involve payments from branded drug companies to generic drug companies in exchange for the generic staying off the market. Underlying the challenged settlements in this case was Cephalon's U.S. Patent No. RE 37,516.

"I find that *Actavis* does not preclude consideration of the strength or weakness of the RE '516 patent," Goldberg said in the opinion.

"The ruling is an important decision that levels the playing field for drugmakers."

—Eric Grannon, White & Case LLP

'Big Win' for Defense Bar

Goldberg's ruling is a big win for the defense bar, James M. Burns, an antitrust attorney in the Washington office of Baker, Donelson, Bearman, Caldwell & Berkowitz, PC, told Bloomberg BNA Nov. 10.

Eric Grannon, an antitrust attorney in the Washington office of White & Case, agreed, telling Bloomberg BNA Nov. 9 that the ruling "is an important decision that levels the playing field for drugmakers."

The decision, he said, buttresses drugmakers' arguments that they should be allowed to present evidence that counters plaintiffs' claims that the patent underlying the settlement was weak and that the generic challengers would have prevailed in the patent litigation if the case had gone to trial.

Plaintiffs' Lawyer Calls Ruling 'Unremarkable.'

But Joseph R. Saveri, founder of the Joseph Saveri Law Firm in San Francisco, who represents plaintiffs in antitrust cases, disagreed with the notion that the ruling is a game changer.

In a Nov. 10 e-mail to Bloomberg BNA, Saveri said that the ruling needs to be read in context.

Plaintiffs in the case had moved for a blanket ruling that any evidence offered to establish the strength of the defendants' patent position in the Hatch-Waxman paragraph IV litigation should be excluded, Saveri said, and the judge said "no" to the blanket challenge.

The judge, Saveri said, indicated in the ruling that evidence regarding the weakness of the patent will be admissible under the rule-of-reason analysis as evidence that the payments were made to keep the generic defendants off of the market. The judge then ruled that the defendants would have an opportunity to rebut that evidence, he said.

"To me, that is an unremarkable ruling," Saveri told Bloomberg BNA.

Supreme Court's 2013 Ruling

In *FTC v. Actavis*, the Supreme Court held that large and unjustified payments made by the brand-name drug patent holder to the alleged generic patent infringer to settle litigation will subject the settlement to antitrust scrutiny under the rule of reason (137 S. Ct. 1172, 6/21/13).

But the *Actavis* opinion left open the question of whether the strength of the underlying patent is relevant to the antitrust analysis in reverse payments cases. Goldberg's ruling says that the underlying patent is indeed relevant.

"Plaintiffs in reverse payment cases invariably argue that the relevant patent was weak and the generic company was sure to prevail in the patent litigation but for the settlement," Grannon said.

And he said, "This decision logically explains why defendants must be able to introduce evidence, including expert testimony, to counter such allegations. That reasoning should be persuasive to the numerous district judges who will face that issue going forward and could lead some plaintiffs to abandon 'weak patent' arguments."

Burns said that Goldberg's ruling allowing expert testimony about a drugmaker's "reasonable belief" about the validity of the patent takes some of the focus off the size of the payment as a surrogate for assessing patent validity. This, he said, allows a drug firm to explain the rationale for its reverse payment in greater context.

But Saveri said it's likely that little of that evidence will be admissible, and the court deferred that ruling until trial.

Saveri added it's significant that the court excluded the opinions of the experts offered by the defendants to testify on patent validity. In addition, the court also largely excluded the opinions on infringement and other matters, he said.

But Saveri said, "I think the court is plainly wrong that the benefits of settlement can be taken into account under a rule of reason analysis. It seems inconsistent with *Actavis*, and appropriately should be excluded."

"I also don't see why this is the proper subject of expert testimony," he said. "The words and deeds of the defendants' executives are the evidence the jury should consider."

Lower Courts Struggle With Actavis

The ruling on expert testimony in *King Drug* underscores the difficulty facing the lower courts in trying to implement the holding in *Actavis*, which left open the issue of whether the strength of the underlying patent is relevant to the antitrust analysis.

"The decision opens the door to further confusion regarding how *Actavis* should be implemented by the lower courts," Burns told Bloomberg BNA. Lower courts are already split on the issue of whether reverse payment settlements need to include cash payments to subject the settlement to antitrust scrutiny under *Actavis*, he said. Goldberg's ruling now brings into play the additional issue of the extent to which the lower courts will permit an inquiry into patent strength, he said.

"It will be very interesting to see how this evidence is presented and how the jury is instructed on these points," Saveri said. "I think this is part of the process of the court sorting through what *Actavis* means and how to apply that in the trial context."

“The tension is that the rule of reason announced in Actavis is structured to a significant degree,” he said, and “not all evidence is admissible under this standard.”

“It is becoming increasingly likely that the Supreme Court will ultimately need to revisit Actavis.”

—James M. Burns, Baker Donelson

“Courts that ignore the structure and broadly admit evidence under the rule of reason are incorrect,” he added.

Burns predicted that these issues could very well end up back at the high court again.

“As these issues continue to multiply, it is becoming increasingly likely that the Supreme Court will ultimately need to revisit Actavis,” he said, either through the King Drug case or one of the other reverse payment cases in

which the lower courts have struggled to implement Actavis.

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For More Information

The district court opinion is at <http://src.bna.com/OP>.