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Antitrust Alert

District Court Precludes Defense Based on Strength of Patent in *FTC v. Cephalon* "Reverse Payment" Litigation

In the first decision since *FTC v. Actavis* to address whether parties to a "reverse payment" antitrust case may litigate the strength of the patent at issue in the challenged settlement, the federal court in Philadelphia precluded a defendant from relying on the "strength of its patent, or litigation uncertainty and business risk" to defend its settlements against claims that they were unlawful "pay for delay" deals. The court relied heavily on the fact that it had previously found that the defendant had procured the patent by fraud on the patent office and rejected the FTC's argument that *Actavis* precluded such defenses in all cases, signaling that there is likely a role for such defenses in appropriate circumstances.

On July 29, 2014, the Eastern District of Pennsylvania held in Federal Trade Commission v. Cephalon, Inc., Civil Action No. 2:08-cv-2141, that collateral estoppel barred a branded pharmaceutical company from presenting evidence related to the potential validity, enforceability or infringement of its patent as a defense to antitrust claims based on its "reverse payment" settlements with generic challengers. The court had previously held the patent invalid and unenforceable, the latter based on a finding that Cephalon had engaged in inequitable conduct in obtaining it.

Last June, in *Federal Trade Commission v. Actavis*, 133 S. Ct. 2223 (2013), the Supreme Court held that the lawfulness of a "reverse payment" settlement—that is, a settlement of patent litigation pursuant to which the plaintiff branded pharmaceutical company makes a payment to the generic firm seeking approval to market a competing drug—must be judged under the traditional rule of reason. The Court gave little guidance as to how the analysis should be conducted, opting instead to leave "to the lower courts the structuring of the present rule-of-reason antitrust litigation." Trial courts have just begun to grapple with some of the many questions *Actavis* leaves unanswered, the most prominent of which is the threshold question of what sort of consideration constitutes a payment triggering antitrust scrutiny.

The *Cephalon* decision touches on another issue left open by *Actavis*: the extent to which the merits of the underlying patent case can be considered in evaluating the legality of the settlement. Specifically, the decision addressed whether a firm whose patent has been found unenforceable on inequitable conduct grounds can nevertheless defend its settlement by relying on the "strength of its patent, or litigation uncertainty and business risk." The court answered that question in the negative, granting the FTC's motion to preclude Cephalon from presenting evidence on those issues under the doctrine of collateral estoppel.

The effect of the decision, however, should be limited to cases involving similar circumstances. In the underlying patent case—which was before the same judge—Cephalon was found to have procured the patent by intentionally misleading the PTO. The court reasoned that Cephalon, knowing that its patent was unenforceable, "should not be allowed to justify a reverse payment on the grounds that it resolved 'uncertainty and risk' that existed because of its own affirmative misconduct."

The court was careful to distinguish between cases like this one, where a patent was deemed unenforceable on inequitable conduct grounds, from those in which a patent was later held invalid: "[I]f the question before me is whether a later determination of invalidity by itself forecloses proof of litigation uncertainty, the answer is conceivably no." The court accordingly rejected the FTC's argument that the strength of the patent is always irrelevant when evaluating a reverse payment settlement. The court pointed out that the *Actavis* Court itself said only that it "is normally not necessary to litigate patent validity to answer the antitrust question," not that it never is: "[T]he use of the word 'normally' reflects the Court's expression that under certain discrete circumstances there could be situations where the validity of the patent should be litigated within a reverse payment antitrust trial." Indeed, the opinion acknowledges that "[p]rior to verdict, the parties are likely to disagree in good faith about the merits of the claim," and suggested that a subsequent finding of invalidity would not necessarily foreclose an argument that the settlement was a good faith resolution of the dispute.

Although this United States District Court decision will not be binding on courts struggling with similar issues in the wake of *Actavis*, it is a reminder to parties settling patent litigation that prior rulings adverse to the patent holder are likely to be asserted against them in a subsequent antitrust case, until such time as there is a sufficient body of post-*Actavis* law to define the boundaries of the rule-of-reason analysis required by that decision.

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