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FTC v. Cephalon, The Fray Begins

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Last year in a landmark decision, the Supreme Court ruled that pharmaceutical "reverse payment" settlements in Hatch-Waxman Act "Paragraph 4" patent litigation are subject to challenge, departing from the rule that most Circuits had adopted. *FTC v. Actavis*, 133 S.Ct. 2223 (2013). In these cases, patent owners are compelled to bring patent infringement actions against generic drug makers who file a notice with the FDA indicating their view that any existing patents protecting the branded drug are invalid. Branded and generic litigants sometimes resolve these cases through a settlement that involves a "reverse payment" from the branded company patent holder to the generic manufacturer, together with timed negotiated entry, allowing the generic drug maker to begin selling the generic product before the patent expires. In some cases the reverse payment settlement can also include an acknowledgement that the patent is valid and performance of marketing or distribution services by the generic drug maker. Much has been written about all this. Cases have been decided for years about all this. And yet, it feels the story is only now beginning.

Specifically, in *Actavis*, five Supreme Court justices subjugated patent law to the antitrust laws, following years of vigorous attempts by the Federal Trade Commission to create a Circuit split in rulings on reverse payments. Most Circuit Courts held that reverse payment settlements within the scope and realm of the patent are lawful. One did not, and the Supreme Court changed the landscape, holding that reverse payment settlements are not immune from antitrust scrutiny and must be analyzed under an antitrust rule of reason. In theme, acknowledging some contrary economic literature, the Supreme Court questioned the motivation behind these payments and alluded to the strong potential for anticompetitive effects.

Notably three Justices disagreed with the five-person majority in a dissent the Chief Justice authored. That dissent admonished that "[t]he majority's rule will discourage settlement of patent litigation. Simply put, there would be no incentive to settle if, immediately after settling, the parties would have to litigate the same issue—the question of the patent validity—as part of a defense against an antitrust suit." *Id*. At 2243. Chief Justice Roberts, for the dissent, also wished "[g]ood luck to the district courts that must, when faced with a patent settlement, weigh the likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances." *Id*. at 2245.

Among the first to try their luck was the Eastern District of Pennsylvania, an important district in the mix given the number of pharmaceutical cases that circle through its dockets. The case, *FTC v. Cephalon, Inc.*, E.D. Pa. (July 29, 2014), may be as important for its ancillary holdings as its ultimate holding—that a firm which has engaged in fraud on the patent office cannot stand on its patent to defend reverse payment antitrust claims. That proposition, in line with the *Actavis* Dissent's reasoning, is not necessarily remarkable in that it fits a long line of cases holding that patents procured by fraud are no defense to antitrust misconduct.

To get there, however, the district court rejected FTC arguments that themselves show the agency's vigor to push the boundaries of *Actavis*. The FTC argued "that a patent's strength or weakness is irrelevant to antitrust analysis of a reverse payment settlement." *Id*. That argument appears inconsistent with the *Actavis* opinion where the Court held that the litigants could proffer procompetitive justifications for the settlement. The strength or weakness of the patent would appear to play a compelling role in that story. The Eastern District of Pennsylvania went out of its way to "doubt" the FTC's position. The FTC's argument itself, however, can be expected to resurface, as the agency has demonstrated a strong (and ultimately successful) propensity to repeat its positions in reverse payment cases in the face of adverse court rulings.

Also important, the district court accepted Cephalon's argument that the reasonableness of the settlement should be determined at the time it was made, not after a subsequent finding of invalidity. More specifically, Cephalon argued that litigation uncertainty is relevant to the antitrust analysis of a reverse payment, and that reasonableness under the antitrust laws should be assessed at the time of the agreement. The district court agreed that Cephalon's argument had merit. But in the case at hand, the court held that Cephalon had committed fraud to procure the patent, superseding any ability to proffer a procompetitive justification based on litigation risk regarding a patent it knew was invalid. Put in terms consistent with the simple approach of the *Actavis* dissent and the long line of prior cases outlined, actions to enforce or reach restrictive settlements regarding a patent procured by fraud are beyond the scope of the patent.

In sum, the *Cephalon* decision feels more a fit with the *Actavis* dissent than the majority opinion. The district court's decision can be viewed in line with the dissent's simple test articulated in prior case law as easily as any new antitrust rule of reason approach. Also as the dissent presaged, the antitrust questions regarding the reverse payment settlement followed an adjudication that the patent had been procured by fraud, indicating for future cases the likelihood that defending the antitrust implications of a reverse payment settlement could require the very adjudication of the patent the parties attempted to settle, discouraging settlements. The initial tally just might be Supreme Court dissent 1, majority 0, for those counting.

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