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FTC v. Actavis: Has the Dust Really Settled?

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I. INTRODUCTION

Three months now have passed following the Supreme Court's decision in *FTC v. Actavis*, 133 S. Ct. 2223 (2013), which subjects to "rule of reason" antitrust scrutiny certain pharmaceutical patent settlements involving a cash payment by the branded drug company to the generic drug company. With the benefit of time and hindsight we can say two things are certain: First, litigants and courts are struggling to construct a framework to implement the Court's holding. Second, the narrow parameters of *Actavis* invite continued attacks on pharmaceutical patent settlements where value other than cash payments is exchanged.

These two developments create a level of uncertainty that will forestall the objectives of the Hatch-Waxman Act and, derivatively, impact and delay competition in the pharmaceutical industry until resolved.

II. REPRISE OF *ACTAVIS*

Actavis imposed on Hatch-Waxman settlement agreements the "rule of reason" antitrust analysis, with the size of the "reverse payment" playing a featured role in the anticompetitive effects assessment. The Court emphasized:

> [I]t is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps to determine whether the patent litigation is a sham). An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness. The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm. In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.[2]

The issue on which the Court granted certiorari was whether reverse-payment agreements are *per se* lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud or, instead, are presumptively anticompetitive and unlawful. The decision, however, restricts this standard — and, arguably, the application of an antitrust assessment in any sense — to settlements that involve a cash payment from the patentee to the patent challenger.

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[1] Partners in the Litigation/Trial Practice Group of Haynes and Boone, LLP.

[2] 133 S. Ct. at 2236-37 (citations omitted).

III. IMPLEMENTING THE *ACTAVIS* STANDARD

As it is wont to do, the Supreme Court left to the district courts the task of creating a framework for this standard. The Court provisioned two core, but enigmatic, "guidelines" that will likely result in a scatter graph of methodologies in the near- and mid-term:

1. "Guideline" 1: "A reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects." How big is too big? Should it be measured in absolute terms or by the robustness of the justification? With respect to the risk a "large and unjustified" payment "can" bring, how great must that risk be in order to shift the burden to the settling parties to demonstrate the pro-competitive benefits of the settlement? Should it be similar to a non-patent Section 2 claim, which requires proof of actual harm to competition, or does the context of the conduct suggest a more lenient standard, like that in a Clayton Act Section 3 claim?

2. "Guideline" 2: "[A] court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent." Given that the Court expressly rejected the "quick look" standard (which presumes anticompetitive effects) with regard to settlements involving cash payments, the assessment required is a full-blown rule of reason balancing. How might a court conduct that full-blown assessment without considering the validity (or infringement, for that matter) of the underlying patent?

   Further, does "without litigating" relate to whether evidence could be submitted or, instead, how that evidence should be assessed? Is some part of the analysis to be conducted only for purposes of a court (as opposed to a jury) decision, along the lines of a *Markman* hearing? Branded and generic pharmaceutical companies are still likely to want to litigate the issue in any antitrust action as part of their defense to show that the settlement, presumably with an early date for generic entry, is pro-competitive. But this month, in its challenge to a Hatch-Waxman settlement involving the sleep disorder drug Provigil, the FTC moved to preclude at trial any evidence regarding "potential validity, enforceability, or infringement" of the Provigil patent, arguing that under *Actavis* a cash payment that exceeds litigation cost is "unexplained" and "appropriately understood as a payment to delay generic entry" notwithstanding the strength of the patent.

The market-opening objective of Hatch-Waxman likely will be curtailed until courts construct a framework with sufficient flexibility, reliability, and consistent efficacy to allay concerns of parties settling Hatch-Waxman cases.

IV. NEW ATTACKS ON HATCH-WAXMAN SETTLEMENTS

The Chief Justice's dissent suggested (and the majority opinion did not dispute) that *Actavis* only addressed whether cash payments from a patentee to a patent challenger raised antitrust concerns. It did not address whether other forms of consideration flowing from a patent holder to a generic pharmaceutical company as part of a settlement similarly may run afoul of the antitrust laws.

In fact the Court, in an effort to downplay the concern that a rule of reason analysis would lead to the very litigation of validity and/or infringement (but in an antitrust action) that

the settlement sought to avoid, stated that "parties may well find ways to settle patent disputes without the use of reverse payments." The FTC, however, clearly believes that suspicion of these settlements does not dissipate when the consideration exchanged is a value other than a cash payment.

On August 14, 2013, the Commission submitted an amicus brief in *In re Effexor XR Antitrust Litigation* (D.N.J.), in which it argues that a commitment by a branded company not to introduce an "authorized generic" should be treated just like a cash payment under *Actavis*. Although the FTC will likely want to co-opt the concept of using the value conveyed as a surrogate for the burden of proving anticompetitive effects (the brief does not address this detail), the application of that concept in a non-cash context should not be so readily accepted. Non-cash "consideration" proliferates the issues presented by the questions presented above, starting with the valuation of the non-cash consideration, and thereby increases the likelihood of litigation on issues beyond the patent dispute.

V. CONCLUSION

Although the rule of reason standard that *Actavis* imposes does not limit the settling parties' evidentiary presentation on that assessment, it suggests, without meaningful guidance, that a court could assess certain settlements, *e.g.*, those involving a "large and unjustified" cash payment, without deciding every issue relating to the settlement. This approach guarantees a period of uncertainty as settlement challengers test-drive a fleet of novel theories intended to achieve the "quick look" standard that *Actavis* expressly rejected.

Until the dust settles and a framework is implemented, whether *Actavis* will benefit or hinder competition remains to be seen, but what it clearly means is more antitrust litigation. In a report available from its website, the FTC had identified 94 settlements as of 2011 involving first-filing generics that the Commission considered competitively suspect and, since the *Actavis* decision, class actions have surfaced challenging settlements involving Loestrin, Skelaxin, Solodyn, and Niaspan.