FTC v. Actavis and the Future of Reverse Payment Cases

Remarks of Joshua D. Wright *
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Good evening. Thank you for the kind introduction and warm welcome. I am delighted to be here today. I would like to thank Concurrences Journal, and especially Nicolas Charbit, for the generous invitation to share my views, and Frederic Jenny and Ilene Gotts for organizing this terrific dinner. Thank you also to Eric Stock for agreeing to share with me the welcome burden of addressing you this evening. Not only does it mean that I can speak for half as long, but more importantly, it allows me to return for the first course twice as fast. I very much look forward to Eric's thoughtful remarks.

* The views stated here are my own and do not necessarily reflect the views of the Commission or other Commissioners. I am grateful to my attorney advisor, Jan Rybnicek, for his invaluable assistance in preparing this speech.

I should confess at the outset that Eric and I have conspired in preparing our remarks this evening. Together we have settled upon a topic we believe provides fodder for fruitful and hopefully entertaining discussion from both the federal and state perspectives: the Supreme Court's recent "reverse payment" decision in FTC v. Actavis.[1] My remarks will highlight some of the most interesting aspects of the Court's decision, and also will make some general observations about what the decision might mean for the Commission's reverse payment enforcement agenda going forward.

Before I begin, however, I want to emphasize that my remarks represent my own views and not those of the Commission or any other Commissioners. With that out of the way, let me set the stage by summarizing some of the decision's key points

it brings these agreements firmly within the scope of the antitrust laws and rejects the so-called "scope of the patent" test. The victory follows upon nearly a decade of research and reporting by the Commission, and numerous amicus filings and lawsuits urging the federal courts to stop such deals when anticompetitive. [3]

Central to the Supreme Court's decision in Actavis was the recognition that "there is reason for concern that [reverse payment] settlements . . . tend to have

agreement does not exceed the scope of the patent.[6]

The Court, however, did not deliver a complete victory to the Commission. It also explicitly rejected the Commission's argument that these arrangements should receive "quick look" treatment.[7]

payment "will at least sometimes prove unjustified ."[10] The Court observed that "[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement."[11]

Third, the Court recognized that a brand-name drug manufacturer that makes a reverse payment likely has the power to bring about anticompetitive harm .[12] As the Court explained, "a firm without that power" is unlikely "to pay 'large sums' to induce 'others to stay out of its market.'"[13]

Fourth, the Court found

Finally, the Court recognized that parties in the pharmaceutical industry can and do settle patent litigation without reverse payments, specifically rejecting the defendants' argument that such payments are necessary for settlement.[16]

Significantly, although the Supreme Court explicitly endorsed the rule-of-reason framework, it left considerable room for lower courts to structure the contours of that analysis. Further, although the Court identified a number of potentially relevant factors for determining whether a reverse payment is likely to result in anticompetitive effects—in particular, payment size—the Court did not purport to offer an exhaustive list of such factors and courts appear to be free to weigh other considerations within the traditional antitrust rule-of-reason framework.[17]

For its part, the dissent argued that the majority had applied a novel approach whereby courts are supposed to "ignore the patent, and simply conduct an antitrust analysis of the settlement without regard to the validity of the patent."[18] The dissent framed the relevant debate largely in terms of the battle between patent law and antitrust rather than choosing to attempt to incorporate patent-related concerns into the relevant antitrust inquiry. Chief Justice Roberts argued the "correct approach should . . . be to ask whether the settlement gives [the brand-name manufacturer] monopoly power beyond what the patent already gave it," and to reject antitrust claims where the

[16] Id. at 2237.
[17] Id.
[18] Id. at 2240.

power granted is within the exclusionary rights afforded by a patent adjudicated as valid.[19]

With that overview as a guide, let me move next to briefly discussing some immediate-term consequences for the Commission that stem from the Supreme Court's decision in Actavis. The Commission will continue to protect consumers from anticompetitive drug settlements that result in higher drug costs. The Commission will proceed with its litigation against Actavis, the maker of the drug AndroGel, and two generic drug manufacturers, charging that the companies agreed that the generic manufacturers would abandon their patent challenges relating to AndroGel and delay for nine years the marketing of a generic formulation of the testosterone replacement drug in return for certain "exclusion payments."

The Commission also will continue its challenge in federal court to a pay-for-delay agreement by Cephalon with four generic rivals for its branded drug Provigil, a treatment for sleep apnea, narcolepsy, and shift-work sleep disorder. The case had been on hold in federal district court pending the Supreme Court's decision in Actavis. Finally, the Commission will continue pending investigations into pay-for-delay agreements between branded and generic drug manufacturers, examine new

Modernization Act of 2003 and investigate those that raise anticompetitive concerns, and consider and analyze potential procompetitive efficiencies for these settlements.

A critical next step for these challenges and later challenges by the Commission, states, and private plaintiffs, is to begin to answer the important questions left open by Actavis. For example, it remains an open issue how the rule-of-reason will be applied in reverse payment cases, when and to what extent the validity of the patent will need to be tested as part of the rule-of-reason analysis, what types of direct economic evidence lower courts might consider when assessing the competitive effects of the reverse payment, what indirect evidence will serve as the most useful evidence of anticompetitive effects, whether market definition will play a meaningful role in the analysis, and how courts will analyze potential efficiencies that the Court acknowledged can arise from such agreements.

I will turn next to some of these open questions and what they may mean for future reverse payment cases. But first, let me foreshadow one theme in my remarks that will please the economists in the crowd: in my view, although it is difficult to predict precisely how lower courts will respond to the decision,

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size to demonstrate likelihood of harm sufficient to satisfy their prima facie burden. Perhaps the strongest evidence that the mere showing of a large reverse payment will not be sufficient to satisfy the plaintiff's prima facie burden, without more, is the Court's clear rejection of a general presumption that reverse payments are unlawful.[22] Indeed, the Court explicitly stated that reverse payment agreements—many involving sizeable payments—are not of the type that "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question have an anticompetitive effect on customers and market" and thus do not qualify for quick-look treatment.[23]

To be clear, I do not dispute the more general proposition that Actavis appears to direct lower courts to apply the rule-of-reason with a relatively light touch in the reverse payment context. Nor do I dispute the proposition that the Court clearly endorsed size of payment as a "strong indicator" of anticompetitive effects.[24] In the Court's own words, "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."[25] The

[22] FTC v. Actavis, 133 S. Ct. 2223, 2237-38 (2013).
[23] Id. at 2237 (quoting Cal. Dental Ass'n v. FTC, 526 U.S. 756, 770 (1999)).
[24] Id. at 2236.
[25] Id. at 2237.

Court also observes that the risk of anticompetitive effects is especially significant where the reverse payment is "large and unjustified." [26]

The central question for lower courts in light of Actavis thus becomes what constitutes a "large and unjustified" payment?

Holding aside procompetitive justifications for reverse payments for the moment, the question of how lower courts will assess the relevance of payment size, and what that approach means for the parties' relative evidentiary burdens, is particularly interesting in light of the Court's observation that "it is normally not necessary to litigate patent validity to answer the antitrust question." [27] To repeat the question many economists surely mouthed to themselves while reading the Court's opinion: "large and unjustified compared to what?"

One can imagine several possible benchmarks for comparison. The Court suggests at least one relevant inquiry is the size of the payment relative to the sum of expected litigation costs and the value of any services provided by the generic. These are measurable benchmarks; though measurement of the latter may well be especially complicated in post-Actavis settlements, which will undoubtedly become more complex. Did I mention I expect Actavis will be a boon for economic litigation consulting firms?

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A second possibility is to compare the size of the payment to a theoretical competitive benchmark. Professor Hovenkamp raises this possibility in a recent article in which he contends that "in a competitive market the value of keeping a competitor out is close to zero, but becomes higher as price-cost margins increase," and thus contends a large payment implies the presence of significant market power and does away with any need for market definition. [28] Perfect competition is not, in my view, a useful benchmark for antitrust analysis generally for all of the standard reasons the view is generally rejected by economists,[29] including that most competitive markets in the modern economy involve brand-name differentiated products with firms facing downward sloping demand curves, charging prices greater than marginal cost, and yet earn(v)-1(e)3(7 0.33 0 e4-7(t)-16 -0 -9(f)99(ys)8(i)t vT5(c)8()7((on)6(te)g(n)6(v)-(s)8(c)8((r)-1(f(n)-

be a burdensome approach by comparison, simply pulling a number out of the air to

"that as economic learning and market experience evolve, so too will the class of restraints subject to summary adjudication." [34]

The Supreme Court's instruction to lower courts to adopt the traditional rule-of-reason framework, which includes the application of case-specific presumptions in an appropriate case, raises the possibility that a particular type of reverse payment agreement could be "convicted in the court of consumer welfare." [35] The "direct evidence" approach to such a presumption is unlikely because, by their very structure and the fact entry has not yet occurred, courts typically will be unable to measure the actual effect of the settlement on prices at trial. But a case-specific presumption could potentially arise from general evidence that a particular type of agreement is always or almost always anticompetitive based upon economic and judicial learning. Although it is clear the Supreme Court does not believe the existing evidence presented to it by the Commission and amici concerning the competitive effects of reverse payment agreements is sufficient to draw such conclusions today, new evidence may permit a

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justifies the size of the payment or the payment is otherwise not competitively suspect in light of the strength of the patent.