



Federal Trade Commission

FTC v. Actavis and the Future of Reverse Payment Cases

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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.

I. ANTITRUST SCRUTINY FOR REVERSE PAYMENTS: *FTC V. ACTAVIS*

In June of this year, the Supreme Court ruled in *Actavis* that reverse payment settlement agreements between branded and generic pharmaceutical companies are subject to antitrust scrutiny and should be analyzed under the traditional, but not necessarily full-blown, rule-of-reason.² As you no doubt are aware, reverse payment settlement agreements, also called pay-for-delay agreements, involve a brand-name drug manufacturer compensating a potential generic entrant to abandon its patent challenge and agree not to sell its generic drug product for a number of years. The Court's decision in *Actavis* represents a significant victory for the Commission because

¹ 133 S. Ct. 2223 (2013).

² *Id.*

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 significant adverse effects on competition.”⁴ The core concern with these agreements, and what the Court termed “the relevant anticompetitive harm,” is that they may allow the brand to “prevent the risk of competition” by splitting monopoly profits with the prospective entrant.⁵ As a result, these agreements may lead to higher prices for pharmaceuticals by deterring generic entry, and contribute to increased health care costs that consumers, employers, and federal and state governments are struggling to contain.

In reversing the lower court’s dismissal of the Commission’s complaint, and over vigorous dissent from the Chief Justice, joined by Justices Scalia and Thomas, the Court rejected a *per se* rule of legality based upon the “scope of the patent” test. Under the scope of the patent test any agreement to resolve patent infringement is shielded from the antitrust laws, absent fraud in obtaining the patent or sham litigation, so long as the

³ See, e.g., Fed. Trade Comm’n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011), available at <http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf>.

⁴ *Actavis*, 133 S. Ct. at 2231.

⁵ *Id.* at 2236.

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 Instead, the Court held reverse payment settlements should be analyzed under the traditional rule-of-reason framework, and that the plaintiff's prima facie demonstration of a settlement's anticompetitive effects necessarily "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."⁸

The Court outlined five key considerations in justifying its decision to subject reverse payment settlements to antitrust scrutiny that shed some light upon its view of how the rule-of-reason should be applied by lower courts.

First, the Court held that reverse payment settlements have the potential for "genuine adverse effects on competition" as a result of removing the manufacturer most likely to introduce competition.⁹

Second, the Court explained that the anticompetitive harm created by a reverse-

⁶ See *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012) (applying "scope of patent" test); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) (same); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006) (same).

⁷ 133 S. Ct. at 2237-38.

⁸ *Id.*

⁹ *Id.* at 2234-35.

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 that “it is normally not necessary to litigate patent validity” to determine the anticompetitive effects of the settlement, and thus that antitrust claims are feasible to administer.¹⁴ According to the Court, “prevent[ing] the risk of competition” —even where the patentee’s risk of losing the patent suit may be small—is “the relevant anticompetitive harm.”¹⁵ As a result, companies cannot defend their agreements by merely arguing that the brand-name drug company would likely have prevailed had the patent case been fully litigated or that the settlement provided for entry prior to patent expiration.

¹⁰ *Id.* at 2244.

¹¹ *Id.* at 2236.

¹² *Id.*

¹³ *Id.* (citing 7 AREEDA & H. HOVENKAMP, ANTITRUST LAW ¶2046, at 351 (3d ed. 2010)).

¹⁴ *Id.* at 2236.

¹⁵ *Id.*

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 settlements that companies file with the Commission pursuant to the Medicare

¹⁹ *Id.* at 2238.

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, *Actavis's* rule-of-reason framework contemplates and appears to invite significantly greater incorporation of economic analysis into the antitrust analysis of reverse payment settlements—both in understanding their potential anticompetitive consequences and procompetitive justifications.

II. LOCATING ACTAVIS WITHIN SECTION 1 DOCTRINE

Actavis firmly places reverse payment settlement cases within the rule-of-reason framework long established under Section 1 of the Sherman Act. Establishing precisely where within the landscape of Section 1 doctrine these cases are located, and what legal burdens and presumptions should apply to analysis of reverse payment settlements, will be key questions for lower courts to resolve going forward. Some commentators appear to believe that when Justice Breyer's opinion rejected the Commission's invitation to adopt a truncated approach while winking—or perhaps crossing his fingers behind his back—and at a minimum, with an Areeda-like “twinkling of the eye.”²⁰ These commentators argue the Supreme Court *implicitly* endorsed a “quick-look” treatment for such agreements. A typical argument along these lines is that the Court's adoption of the size of the reverse payment as a proxy for market power and anticompetitive effects will for all practical purposes, because size is an excellent predictor of anticompetitive effect, generally result in plaintiffs' successfully shifting the burden to defendants without a detailed showing.²¹

I read the Court's decision differently. I also suspect lower courts will require plaintiffs to make a more rigorous economic showing than simply pointing to payment

²⁰ PHILLIP AREEDA, FED. JUDICIAL CTR., THE “RULE OF REASON” IN ANTITRUST ANALYSIS: GENERAL ISSUES 37-38 (1981), *available at* [http://www.fjc.gov/public/pdf.nsf/lookup/antitrust.pdf/\\$file/antitrust.pdf](http://www.fjc.gov/public/pdf.nsf/lookup/antitrust.pdf/$file/antitrust.pdf).

²¹ *See, e.g.,* Thomas F. Cotter, *FTC v. Actavis: When is the Rule of Reason Not the Rule of Reason?* 15 MINN. J. L. SCI. & TECH. (forthcoming 2013), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2281291.

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?

²⁶ *Id.*

²⁷ *Id.* at 2236.

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 earning only a competitive rate of return. These concerns are obviously applicable to the case of brand-name pharmaceuticals who may earn, in addition to any monopoly rents, rents associated with the return on brand-name investments.³⁰

A third, and even less desirable, possibility is to establish as a benchmark a fixed threshold number determined to be “large.” Although assessing patent validity might

²⁸ Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court’s Actavis Decision*, 15 MINN. J. L., SCI. & TECH. (forthcoming 2013) (manuscript at 15), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2286255.

²⁹ See Benjamin Klein & John Shepard Wiley, Jr., *Competitive Price Discrimination as an Antitrust Justification for Intellectual Property Refusals to Deal*, 70 ANTITRUST L. J. 599 (2003).

³⁰ See generally Benjamin Klein & Keith B. Leffler, *The Role of Market Forces in Assuring Contractual Performance*, 89 J. POL. ECON. 615 (1981). The Supreme Court in *Independent Ink* recognized the economic fallacy inherent in inferring the possession of monopoly power from downward sloping demand and positive margins attributable to patents or other property rights. See Joshua D. Wright, *Missed Opportunities in Independent Ink*, 2005-06 CATO SUP. CT. REV. 333.

be a burdensome approach by comparison, simply pulling a number out of the air to serve as a benchmark may not allow courts to understand the important dynamics at play in a specific case and would fly in the face of antitrust doctrine's increasing preference for economic substance over formal distinctions.

Although, the Court rejected application of a general presumption in favor of plaintiffs, I also find it interesting that the Court did not rule out the possibility of applying case-specific presumptions at a later time. Indeed, the Court acknowledged that "trial courts can structure antitrust litigation," within this framework as they see fit to focus upon the fundamental question of whether the settlement has caused anticompetitive consequences.³¹ How might courts apply a case-specific presumption? Consider the Commission's analysis, later endorsed by the D.C. Circuit, in *Polygram Holdings v. FTC*.³²

There the D.C. Circuit explained that, although practices that are "inherently suspect . . . describe those restraints that judicial experience and economic learning have shown to be likely to harm consumers, the rebuttable presumption of illegality arises not necessarily from anything 'inherent' in a business practice but from the close family resemblance between the suspect practice and another practice that already stands convicted in the court of consumer welfare."³³ Significantly, the court also acknowledge

³¹ *Actavis*, 133 S. Ct. at 2238.

³² 416 F.3d 29 (D.C. Cir. 2005), *aff'g* *Polygram Holding, Inc.*, 2003 WL 21770765 (F.T.C. July 24, 2003).

³³ *Id.* at 36-37.

“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 properly tailored case-specific presumption in the future. For instance, we may be able to deduce that reverse payment settlements for a particular class of drug or with particular contractual features are more likely to be anticompetitive than others. This is an area where I believe the Commission should and will continue to put its institutional advantages in research and reporting to good use.

³⁴ *Id.*

³⁵ *Id.*

III. RULE-OF-REASON ANALYSIS FOR PAY-FOR-DELAY AGREEMENTS

There also remain open questions with respect to the precise contours of the rule-of-reason analysis in reverse payment settlement cases. Indeed, the Supreme Court explicitly left “to the lower courts the structuring of the present rule-of-reason antitrust litigation.”³⁶ I’ve discussed some of those issues with respect to payment size already. One critical question that was hotly debated between the majority and dissent is the role of patent analysis. Whereas the majority believes the question of patent validity need not be litigated in reverse payment antitrust cases, the dissent contemplates a nearly irreconcilable tension between patent and antitrust that leads it to conclude that if the agreement is within the scope, patent law must win.

The Supreme Court rejected the underlying economic logic of the claim that a reverse payment falling within the scope of the patent cannot generate competitive concerns under the Sherman Act. Nonetheless, I suspect that the appeal of that logic is likely to influence lower courts. What role patent validity will play within the rule-of-reason is an open question. *Actavis* rules out the scope of the patent test, and thus the possibility of a safe harbor, but it would be surprising if courts summarily did away with the question of patent validity as part of their analysis altogether. Indeed, one possibility is that after a plaintiff satisfies its prima facie burden by showing a large payment, the defendant will be able to put on evidence that the strength of its patent

³⁶ *Id.* at 2238.

justifies the size of the payment or the payment is otherwise not competitively suspect in light of the strength of the patent.³⁷

Another open question is precisely what efficiencies benefits the lower courts will credit as part of the rule-of-reason analysis. The Supreme Court observed that the “reverse payment . . . may amount to no more than a rough approximation of the litigation expenses saved through settlement” or “reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for the item.”³⁸ This list is not exhaustive and as court experience grows additional justifications may become apparent. Significantly, allowing defendants to show efficiencies is not inconsistent with an approach that permits case-specific presumptions where the conduct, or in this case the agreement, is inherently suspect.

Thank you for your time. I would be happy to answer any questions.

³⁷ For example, Carl Shapiro has argued that, “to compare consumer surplus under a settlement with consumer surplus from ongoing litigation requires an informed judgment as to the strength of the patent at issue.” Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 397 (2003). In more recent work, Shapiro and co-authors argue that *Actavis* “must mean exactly” that defendants may not assert their patent as a defense to the antitrust suit. Aaron Edlin, et al., *Activating Actavis* (Aug. 26, 2013) (unpublished manuscript), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2317241. I do not read the Court’s opinion as requiring lower courts to ignore the validity of the patent altogether.

³⁸ *Actavis*, 133 S Ct. at 2236.