Federal Trade Commission

Antitrust Analysis of Reverse Payment Settlements After **Actavis***:*
Three Questions and Proposed Answers

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Good evening. I am thrilled to have the opportunity to speak with you tonight at the Antitrust Masters Course. I want to thank the ABA Section of Antitrust Law, and in particular, Howard Feller, Ted Voorhees, and Rebecca Valentine, for the invitation. Before proceeding further, let me begin by emphasizing that the views I express this

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[♠] The views stated here are my own and do not necessarily reflect the views of the Commission or any of its other Commissioners. I am grateful to my attorney advisors, Derek Moore and Jan Rybnicek, and to my economic advisor, Joanna Tsai, for many valuable discussions on these topics and for their invaluable assistance in preparing these remarks.

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With that disclaimer out of the way, my remarks will focus upon the antitrust analysis of reverse payment settlements after *Actavis*. Sixteen months after the Supreme Court's decision, the post-*Actavis* landscape remains unsettled with respect to a number of critical questions concerning how lower courts will and should evaluate reverse payment settlements. I will focus upon three of these questions and provide my views on the correct answers.

The first question has been heavily contested in the lower courts as of late: does *Actavis* apply to non-cash payments?

The second is whether reverse payments larger than avoided litigation costs are "large and unjustified" within the Court's framework, and thus likely to reduce consumer welfare.

The third is whether courts and agencies should, in the context of evaluating non-cash reverse payment settlements, balance against any competitive harms associated with delayed generic entry of a particular drug any consumer welfare benefits to consumers of *other* drugs that would not occur but for the settlement.

Because this is the Antitrust Masters Course, I will presume some passing familiarity with the Supreme Court's decision in *Actavis*. Nonetheless, for those of you unfamiliar, I will quickly cover the highlights. In June of 2013, 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 rule-of-reason.[1] 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.

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."[2] 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.[3] 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 FTC'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

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[1] FTC v. Actavis, 133 S. Ct. 2223 (2013).
[2] *Actavis*, 133 S. Ct. at 2231.
[3] *Id.* at 2236.

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 agreement does not delay entry beyond the scope of the patent.[4]

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.[5] Instead, the Court held that 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."[6]

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

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[4] *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).
[5] 133 S. Ct. at 2237-38.
[6] *Id.*

list of such factors and courts appear to be free to weigh other considerations within the traditional antitrust rule-of-reason framework.[7]

With that primer as background, let us turn to our three questions and proposed answers.

I. Does *Actavis* Apply to Non-Cash Reverse Payments?

One question that has arisen in the aftermath of *Actavis* is whether a reverse payment must take the form of cash to be subject to the antitrust laws, or whether non-cash forms of consideration also are subject to antitrust scrutiny. There are many hard questions about how the rule-of-reason analysis should be structured to evaluate reverse payment settlements after *Actavis*. In my view, this is not one of them. Indeed, the question is not even a close one: *Actavis* clearly applies to reverse payment settlements involving non-cash compensation.

Those who contend that *Actavis* is limited to cash considerations appear to rely primarily upon the fact that *Actavis* itself involved only a monetary payment. They argue the Court's reasoning was confined only to the harms that might arise when a branded firm and generic firm exchange money to delay the generic's entry into the market, and contend that nothing in *Actavis* expressly provides that a settlement conferring a benefit other than money can constitute a payment.

[7] *Id*. at 2237.

As you can imagine, whether *Actavis* applies to non-cash consideration is an issue of significant and growing importance for reverse payment litigation. Even before *Actavis*, branded and generic pharmaceutical manufacturers had begun entering into increasingly complex and creative settlement agreements that frequently included non-cash consideration. Indeed, today settlement agreements between branded and generic firms include any number of non-monetary elements, including so called "no-AG" agreements under which a branded firm agrees not to introduce an authorized generic that might compete with the generic firm's product, complex supply agreements, and marketing and other advertising arrangements.

The question of whether *Actavis* applies only to payments of cash has been considered by at least seven district courts. Two district courts have interpreted *Actavis* as requiring cash payments,[8] and five district courts have interpreted *Actavis* as applying to non-cash reverse payments.[9] In reaching the conclusion that *Actavis* only applies to cash payments, one court observed that "[b]oth the majority and the dissenting opinions reek with discussion of payment of money" and placed great weight on the fact that Justice Breyer's introductory hypothetical outlining the basic

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[8] *In re* Lamictal Direct Purchaser Antitrust Litig., No. 12-cv-0995, 2014 WL 282755 (D.N.J. Jan. 24, 2014); *In re* Loestrin 24 Fe Antitrust Litig., MDL No. 13-2472-S-PAS (D.R.I. Sept. 4, 2014).

[9] *In re* Effexor XR Antitrust Litig., No. 11-5479, 2014 WL 4988410 (D.N.J. Oct. 6, 2014); Time Insurance Co. v. Astrazeneca, No. 14-cv-4149, 2014 WL 4933025 (E.D. Pa. Oct. 1, 2014); *In re* Lipitor Antitrust Litig., MDL No. 2332, 2013 WL 4780496 (D.N.J. Sept. 12, 2014); *In re* Niaspan Antitrust Litig., MDL No. 2460, 2014 WL 4403848 (E.D. Pa. Sept. 5, 2014); *In re* Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367 (D. Mass. 2013).

factual foundations of a reverse payment case specifically involved an exchange of cash.[10] Of course, the widespread discussion of money should not be surprising— after all, *Actavis* did involve a cash payment. In my view it is odd to end the analysis there rather than trying to understand the concerns at the core of pay-for-delay litigation. Now, to its credit, the court did go on to examine Black's Law Dictionary 's definition of "payment," which appears to convincingly provide that a payment is "the performance of an obligation by the delivery of money *or some other valuable thing* accepted in partial or full obligation."[11] Despite this, the court surprisingly concluded that "support for this broadened reading of 'payment'" in *Actavis* "is thin," and that "there are only a few scattered indications that the Supreme Court intended its holding to apply to non-monetary payments."[12] I do not find this to be a compelling argument or an accurate reading of *Actavis*, and despite the significant attention the issue has received, once again, I do not view the question of whether *Actavis* applies to non-cash payments to be a particularly close one for a number of reasons.

Nothing in *Actavis* suggests that the Supreme Court intended to limit its ruling to payments in cash. Indeed, to conclude otherwise would create artificial limitations that simply do not make economic sense and would impose a rule that elevates form over substance. Put simply, the anticompetitive concern identified in *Actavis* is that a

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[10] *In re* Lamictal Direct Purchaser Antitrust Litig., 12 WL 282755, at * 7.
[11] *Id.*
[12] *Id.*

branded firm might use a reverse payment to induce a potential generic competitor to agree to enter the relevant market later than it otherwise would based upon traditional and legitimate settlement considerations.[13] As an economic matter, there is simply no reason to believe that such an inducement cannot occur when the consideration offered by the branded firm is something of substantial value other than cash.

The distinction between cash and non-cash payments has raised at least one interesting question in the post-*Actavis* litigation related to the difficulties of valuation of non-cash compensation. At least one district court has, after holding that *Actavis* applies to non-cash payments, dismissed a complaint because it could not survive *Twombly*'s plausibility standard without a reliable estimate of the value of the non-cash payments.[14] The district court determined that without a "reliable foundation" from which to infer that a non-cash payment is "large and unjustified," plaintiff's complaint was vulnerable to a motion to dismiss. I will turn to discussing the appropriate benchmark against which to measure the value of any non-cash payments later. Lower courts' trepidation about their ability to accurately value non-cash payments also

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[13] *See Actavis*, 133 S.Ct at 2234-36.

[14] *In re* Effexor XR Antitrust Litigation, No. 11-5479, 2014 WL 4988410, at *20 (D.N.J. Oct. 6, 2014) ("*Twombly* and *Iqbal* establish a flexible pleading benchmark, and in a case where a non-monetary payment is alleged in an antitrust suit, the pleading must demonstrate the reliable foundation showing a reliable cash value of the non-monetary payment through the use of more facts upon which Plaintiff depends.") *See also* In re Lipitor Antitrust Litig., 2014 WL 4543502 (D.N.J Sept 12, 2014) (dismissing plaintiff's claims for failure to reliably estimate the value of the non-monetary compensation).

suggests that the Commission and private plaintiffs will need to be particularly careful to provide reliable economic evidence of the magnitude of non-cash consideration.

II. Are Reverse Payments Greater Than Avoided Litigation Costs "Large and Unjustified?"

In *Actavis*, the Supreme Court emphasized the potential analytical link between reverse payment size, patent strength, and anticompetitive effects. The Supreme Court observed that, "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects" and that "a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects…"[15] This led many, myself included, to contemplate the economic conditions under which inferences about competitive harm can reliably be drawn from a large payment and how exactly one interested in enforcing the antitrust laws or counseling clients would proceed to identify such payments.

The answer, as it turns out, is not so obvious. Since *Actavis*, some of the brightest economic and legal minds in antitrust have attempted to operationalize the Court's analysis and provide an economic basis to identify the large, unjustified, and likely anticompetitive payments it contemplated. However, the answer is not at all clear, and the debate is still hot and ongoing.

[15] *Actavis*, 133 S.Ct. at 2237.

The first group of top-notch economists and lawyers attempting to tackle this issue includes Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, and Carl Shapiro, who published jointly an article, entitled "Activating *Actavis*," just a few months after the *Actavis* decision.[16] Their collective insight is that if the payment size is positive after deducting the patent holder's avoided litigation costs and the value of any goods, services, or other consideration provided by the claimed infringer to the patentee, the remaining payment likely reflects a relatively weak patent and "may be understood to be payment for delaying entry." The Edlin, Hemphill, Hovenkamp, and Shapiro analysis favors what might be described as the "avoided litigation cost" benchmark for evaluating reverse payment size.

Since then, another impressive group of scholars have also analyzed this issue and questioned the litigation cost benchmark. In their paper, "Activating Actavis: A More Complete Story," economists Barry Harris, Kevin Murphy, Robert Willig, and Matthew Wright countered that the avoided litigation cost benchmark "fails to account for a variety of issues… including factors that indicate that reverse payments can result in settlements beneficial to consumers, with entry by the generic occurring earlier than would have been expected in the absence of the settlement."[17] This quartet of economists focuses upon incorporating factors such as risk aversion and differing

[16] Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, & Carl Shapiro, *Activating Actavis*, 28 ANTITRUST 16 (2013).

[17] Barry C. Harris, Kevin M. Murphy, Robert D. Willig, & Matthew B. Wright, *Activating Actavis: A More Complete Story*, 28 ANTITRUST 83 (2014).

beliefs of the settling parties as to the likelihood of success in litigation to argue that the avoided cost of litigation benchmark may deter some consumer welfare-enhancing settlements.

One common thread between these two economic analyses of reverse payment settlements is that entry into this market apparently requires four co-authors. The more important commonality among these and other recent economic analyses of reverse payment settlements is that they are based upon a monopoly-to-duopoly model that assumes a single generic entrant. Specifically, these economic analyses model the Brand's decision to litigate or settle based upon the assumption that if the Brand loses litigation to a generic entrant it will subsequently share duopoly profits with a single generic entrant. The avoided litigation benchmark is based upon the result from these monopoly-to-duopoly models that settlements must reduce consumer welfare if the size of the reverse payment exceeds the patentee's litigation costs.[18]

Does the avoided litigation cost benchmark provide a sound basis for identifying anticompetitive reverse payment settlements? I do not think so for reasons I will

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[18] Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003); Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, & Carl Shapiro, *Activating Actavis*, 28 ANTITRUST 16 (2013), *Actavis and Error Costs*, _ ANTITRUST SOURCE _ (2014); Murat Mungan, *Reverse Payments, Perverse Incentives,* 27 HARV. J. L. & TECH. 1 (2013); Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 TEX. L. REV. 283 (2012). But *see* Barry C. Harris, Kevin M. Murphy, Robert D. Willig, & Matthew B. Wright, *Activating Actavis: A More Complete Story*, 28 ANTITRUST 83 (2014) (using monopoly-duopoly model, but criticizing antitrust limits on reverse settlements); Mark R. Patterson, *Leveraging Information about Patents: Settlements, Portfolios and Holdups*, 50 HOUS. L. REV. 483 (2012) (analyzing the informational effect of patent challenges and estoppel rules).

discuss shortly. Indeed, taking the cue from earlier entrants into the field, I have joined a quartet of co-authors addressing the issue. In a recent working paper I co-authored with my former colleague at George Mason, Bruce Kobayashi, Judge Douglas Ginsburg, and my economic advisor, Joanna Tsai, we find that in fact, litigation costs are an inappropriate benchmark for evaluating reverse payments under the rule of reason.[19] The issue we highlight is that the simple monopoly-to-duopoly model providing the analytical basis for the litigation cost benchmark is incomplete and ignores critical institutional details.

The simplifying assumption is easy to understand. The monopoly-to-duopoly models effectively assume that the marketing exclusivity period lasts precisely until the expiration of the patent. Under this assumption, there is a single ANDA generic entrant prior to the expiration of the patent and the first ANDA entrant that invalidates the brand patent obtains duopoly profits until the patent expires. However, in reality, entry by multiple firms can follow the invalidation of a patent.[20] Instead of obtaining duopoly profits for the duration of the life of the patent, as is assumed in the simple monopoly-to-duopoly model, the generic entrant that successfully challenges the validity of the brand's patent obtains duopoly profits only for a period limited to a 180-

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[19] Bruce H. Kobayashi, Joshua D. Wright, Douglas H. Ginsburg, & Joanna Tsai, *Activating Actavis: Taking the Story Beyond the Temporary Duopoly, available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2508094.

[20] Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents?* 98 AM. ECON. REV. 1347 (2008) (examining the effect of multiple entrants on the incentive to litigate patents generally).

day period of exclusivity. After this period, both the brand with the invalidated patent and the generic entrant that successfully invalidated the patent in litigation obtain only the lower profits associated with free entry. This limitation is jointly imposed by the Hatch-Waxman Act and by the doctrine of collateral estoppel under *Blonder-Tongue v. University of Illinois Foundation*,[21] which prevents the patentee with an invalidated patent from relitigating the validity of the patent against subsequent generic entrants.

Accounting for this critical institutional detail in a more generalized monopoly-to-duopoly model alters significantly the economic analysis of reverse payment settlements and, in turn, results in important and different implications for patent settlements, welfare, and application of the rule of reason after *Actavis*. This more realistic model implies the payoff for the generic entrant who files the first Paragraph IV ANDA and invalidates the patent is considerably smaller than the litigation payoffs assumed in the monopoly-to-duopoly model. This reduced payoff decreases the entrant's litigation threat point. At the same time, litigating a patent under a rule of defensive non-party, non-mutual collateral estoppel imposes greater losses upon the patentee than in the case where there is a single entrant. This, in turn, increases the litigation threat point facing the patentee. The result is a significantly broader settlement range than under the simple monopoly-to-duopoly model that yields robust

[21] Blonder-Tongue v. Univ. of Ill. Found., 402 U.S. 313 (1971).

and legitimate incentives for the brand and generic entrant to settle the case. In short, taking into account the institutional reality that a successful patent challenge results in free entry rather than duopoly implies consumer welfare-increasing settlements can occur with very large payments, including payments several times greater than avoided litigation costs.

This broad settlement range renders attempts to regulate the size of patent settlements, or infer anticompetitive effects based upon payment size, ineffective. A litigation cost benchmark does not reliably identify anticompetitive settlements and generates considerable risk of chilling consumer welfare-increasing settlements. Incorporating multiple serial entrants also decouples the litigation-adjusted expected value of the patent and the consumer welfare standard and, most importantly, weakens the relationship between patent strength and the size of the settlement which has motivated numerous calls to deem presumptively unlawful all payments greater than anticipated litigation costs.

The antitrust policy question for the lower courts going forward is how to fashion a relatively accurate and administrable procedure under the rule of reason that minimizes the sum of error costs and direct costs.[22] As lower courts continue to

[22] *See* Joshua D. Wright, *FTC v. Actavis and the Future of Reverse Payment Cases*, Remarks at the Concurrences Journal Annual Dinner (Sept. 26, 2013), http://www.ftc.gov/sites/default/files/documents/public_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis.pdf.

struggle with how to identify reverse payment settlements that likely reduce consumer welfare, it is important to accurately identify the relationship between payment size and harm before concluding payment size is indeed a "workable surrogate for a patent's weakness," as the Court suggested it may be. Our analysis suggests lower courts should be reluctant to rely upon a truncated litigation cost benchmark substitute for a more full-blown rule of reason inquiry.

III. Should the Rule of Reason Require Courts to Balance All of the Harms and Benefits of Non-Cash Reverse Payment Settlements?

Given that the distinction between a cash payment for delayed generic entry and a non-cash payment for delayed generic entry makes no economic sense and ought to have no legal significance, and, assuming we can identify a large payment, the next relevant task is to figure out how to analyze large non-cash payments under the rule of reason. As discussed, many lower courts have already suggested some discomfort with this task and the challenge of evaluating the competitive consequences of non-cash reverse payments is likely to arise frequently and in many forms. The task also raises some important and interesting antitrust questions. For example, what if the "payment" from the brand manufacturer to the generic manufacturer actually creates cognizable consumer benefits? Should courts balance those benefits against the costs to consumers caused by delayed generic entry?

The most common form of non-cash payment from a brand manufacturer to a generic manufacturer to delay entry comes in the form of a No-AG agreement – that is,

a commitment by the brand manufacturer not to exercise its right to compete with the generic manufacturer with an authorized generic version of the branded drug. In a hypothetical world but-for a pay-for-delay agreement, once the generic enters the market to compete with the brand, the brand would introduce its own authorized generic version of the drug, making three drugs—one brand and two generics—available for consumers. In the typical No-AG pay-for-delay arrangement, the generic manufacturer is being compensated for agreeing to delay entry by the brand manufacturer's own commitment to delay entry with its authorized generic, in effect allowing the generic manufacturer to keep *generic* prices higher than they would be otherwise. The consumer welfare impact of such an arrangement is simple to analyze because the No-AG commitment offers no consumer benefits.

But what if the settling parties structured their arrangement in a different way? As the FTC has recognized, pharmaceutical companies are settling their patent disputes in ever-more complex fashion, often attempting to disguise the reverse payment.[23] Given that some district court decisions have pointed, mistakenly in my view, to the complexity of valuing the non-cash components of the reverse payment as a reason to dismiss antitrust claims under *Actavis*, clever parties have an even stronger incentive to make their non-cash reverse payments as complicated as possible.

[23] *See* Fed. Trade Comm'n Brief as *Amicus Curiae*, *In re* Effexor XR Antitrust Litig., No. 3:11-cv-05479 (D. N.J. Aug. 14, 2013) ("[A]fter the FTC began challenging cash-only reverse-payment agreements, pharmaceutical companies turned to other payment arrangements . . . designed to evade antitrust scrutiny.").

Let's say, for example, that the brand manufacturer holds patents over two drugs, Drug 1 and Drug 2, that the generic manufacturer has received FDA approval for both drugs, but that the generic has certified under Paragraph IV of Hatch-Waxman for Drug 1 but not Drug 2. What if, in settling the brand's patent infringement suit against the generic over Drug 1, the brand "pays" the generic for delay in the market for Drug 1 by allowing the generic early entry in the market for Drug 2. Such an arrangement would undeniably create *some* consumer benefits: the terms of the agreement allow for generic entry in the market for Drug 2 earlier than would have occurred in the but-for world. The question then becomes: how should antitrust law treat these benefits?

One position is that Section 1 of the Sherman Act requires an antitrust analysis that incorporates these benefits and balances them against any competitive harms: *Actavis* says that reverse payment settlement agreements are governed by the rule of reason, the rule of reason requires an analysis of all costs and benefits associated with the challenged conduct, and this scenario is no different from the ordinary scenario where challenged conduct has both costs and benefits.[24] Another position might be to say that any consumer benefits that occur in the market for Drug 2 should not count under the law because the markets for Drug 1 and Drug 2 are different, or are not

[24] *See* Bd. of Trade of Chi. v. United States, 246 U.S. 231, 238 (1919) ("[T]he court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts.").

sufficiently related, to render the consumer benefits from increased competition over Drug 2 cognizable under Section 1. I think the law, sound economics, and common sense require us to balance.

The *Actavis* decision itself provides only limited guidance. The Court recognizes that a reverse payment "may 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 that item" and that "[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason."[25] The Court's opinion therefore generally supports the proposition that a defendant may point to benefits associated with the settlement agreement and that these benefits are relevant to an analysis under the rule of reason. But it does not speak directly to the question of whether the type of cross-market balancing I have hypothesized is required or even appropriate.

An analogy can be drawn to the treatment of out-of-market efficiencies in the agencies' approach to merger review. The Guidelines state explicitly that the agencies myopically focus upon "each relevant market and normally will challenge the merger if

[25] *Actavis*, 133 S. Ct. at 2236.

it is likely to be anticompetitive in any relevant market."[26] The Guidelines do state, however that in some cases, the Agencies might credit efficiencies outside the relevant market if the out-of-market efficiencies are "inextricably linked" to the relevant market in which harm is alleged to occur.[27] I have said before that this approach is misguided in that it can allow the agencies to challenge a merger that helps consumers more that it harms them, and that the agencies should not be in the business of challenging such mergers.[28]

Notwithstanding the fact that the approach taken in the Merger Guidelines does not govern—nor should it—the legal analysis of restraints of trade challenged under Section 1 of the Sherman Act, I think the efficiencies in the market for Drug 2 are indeed inextricably linked to the harms in the market for Drug 1, and would be counted under the approach taken in the Guidelines. Some might argue the linkage depends upon whether there is any economic connection between the markets for the two drugs. I don't think that matters to my hypothetical. In my view, the two markets in my hypothetical are necessarily "inextricably linked." This is because a necessary condition for a reverse payment settlement to violate the antitrust laws is that there be a *payment* from the brand manufacturer to the generic manufacturer. The theory of harm—brand

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[26] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES 30 n.14 (2010), *available at* http://www.justice.gov/atr/public/guidelines/hmg-2010.html.
[27] *Id.*
[28] Jan M. Rybnicek & Joshua D. Wright, *Outside In or Inside Out?: Counting Merger Efficiencies Inside and Out of the Relevant Market*, *in* 2 WILLIAM E. KOVACIC: AN ANTITRUST TRIBUTE- LIBER AMICORUM 443 (2014), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2411270.

pays generic for delaying entry in the market for Drug 1 by allowing the generic to accelerate entry in the market for Drug 2—itself supplies the economic linkage between the two markets.

One can imagine other hypothetical scenarios by which one conspirator induces a co-conspirator to restrain trade in one market by compensating the conspirator through some mechanism, say a license to valuable IP, that yields consumer benefits in a different market. Whether we ought to count the benefits that accrue in the second market would depend, of course, upon the facts of the particular case at issue, including the theory of liability. But what makes the pay-for-delay example special is that the underlying antitrust offense requires some sort of payment from the brand manufacturer to the generic. By alleging that this payment has taken the form of early entry in the market for a different prescription drug, the antitrust plaintiff is in effect admitting that the "out-of-market" efficiencies are inextricably linked to the alleged anticompetitive effects. This is because without a "payment"—early entry in the market for Drug 2 in my hypothetical—there can be no actionable pay-for-delay agreement.

One might argue that that the benefits in the market for Drug 2 are not linked to the harms in Drug 1 because the parties could have structured their pay-for-delay arrangement in a way that did not involve the market for Drug 2 at all, *e.g.*, a cash payment or a No-AG agreement in the market for Drug 1. This argument is misguided for a number of reasons. A common refrain from would-be antitrust plaintiffs is that

would-be defendants could have structured their arrangement in a different way. The usual theme of this argument is that a court should condemn particular conduct because the defendant could have achieved the same consumer benefits without imposing as many costs on consumers, *i.e.*, the defendant could have used "less restrictive means." Notwithstanding that the analysis of whether there are less restrictive means available to the defendant is a component of the balancing of pro- and anticompetitive effects under the rule of reason,[29] the argument that we shouldn't count the benefits in the market for Drug 2 is different in a material way. Instead of arguing that conduct should be condemned because its benefits could have been achieved in a different and less-harmful way, the argument here is that we should not count the beneficial effects of certain conduct because the defendant could have produced the same consumer harm *without also* creating consumer benefits. This sounds a lot more like a "less beneficial means" analysis than a "less restrictive means" analysis. It is akin to arguing that we should ignore any consumer benefits that accrue from a monopolist's loyalty discount program because we know the monopolist could have excluded its competitor from the market by burning down the competitor's factory instead. This does not sound like good analysis to me, and I know of no antitrust case that would support this approach.

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[29] *See* XI PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 1913 (3d ed. 2011).

Furthermore, plaintiffs—including agencies—should not fear having to satisfy the burden of showing that the harm in the market for Drug 1 outweighs the benefits in the market for Drug 2. Indeed, it is likely to be an easy burden for a plaintiff to clear. The defendant, of course, would bear the burden of establishing the benefits in the market for Drug 2. Moreover, it is highly unlikely that we would see a pay-for-delay arrangement like this occur in the real world if the harm in the market for Drug 1 did not outweigh the benefits in the market for Drug 2. This is because a brand monopolist in the markets for both Drug 1 and Drug 2 would not exchange accelerated entry in the market for Drug 2 for delayed entry in the market for Drug 1 unless the benefits *to the monopolist* of delay in the market for Drug 1 outweigh *the monopolist's* foregone profits in the market for Drug 2. Because the monopolist earns enough profit from delayed entry in the market for Drug 1 to outweigh the cost of allowing accelerated entry in the market for Drug 2, it is highly likely that the cost *to consumers* of delayed entry in the market for Drug 1 outweighs the benefit *to consumers* of accelerated entry in the market for Drug 2. There may be some cases with unusual facts that make these propositions untrue, but my intuition is that most arrangements structured this way that are *bona fide* pay-for-delay arrangements will result in net consumer harm.

Whether or not that intuition is ultimately correct, or correct in particular cases, the fundamental point is that the rule of reason under Section 1 of the Sherman Act contemplates a full accounting of the competitive costs and benefits to consumers from

the allegedly unlawful conduct. Further, an approach that rejects balancing of otherwise cognizable benefits would be antithetical to the shift in antitrust law over the last four decades from a formalistic approach to an effects-based regime powered by economic analysis and following the lodestar supplied by the consumer welfare standard.

IV. Conclusion

Each of these three questions, and others not addressed here, remain open and heavily contested in the literature among economists and lawyers as well as in the courts. For its part, the Commission has played a tremendously positive role in influencing courts and developing the law in this area based upon careful legal thinking and economic research. I have no doubt it will persist in its attempts to educate courts on the easy questions, and will deploy with full force its talented lawyers and economists to grapple with and answer the tougher questions as it sets it priorities for reverse payment enforcement in the post-*Actavis* landscape.

Thank you for your time.