Activating *Actavis*

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1. Introduction

In *Federal Trade Commission v. Actavis, Inc.*, the Supreme Court at last provided fundamental guidance about how courts should handle antitrust challenges to reverse payment patent settlements.[1] The Court came down strongly in favor of an antitrust solution to the problem, concluding that "an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed."[2] At the same time, Justice Breyer's majority opinion acknowledged that the Court did not answer every relevant question. The opinion closed by "leav[ing] to the lower courts the structuring of the present rule-of-reason antitrust litigation."[3]

This article is an effort to help courts and counsel fill in the gaps. We identify and operationalize the essential features of the Court's analysis. We describe the elements of a plaintiff's affirmative case and justifications that may be offered by defendants. For private cases, we outline an appropriate procedure for evaluating damages and suggest specific jury instructions.

2. The Essence of *Actavis*: Inferring Harm to Competition

The Court describes the basic reverse payment situation this way:

> Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a "reverse payment" settlement agreement. And the basic question here is whether such an agreement can sometimes unreasonably diminish competition in violation of the antitrust laws.[4]

As we shall explain, the court answered with a resounding "yes." Reverse payments can violate the antitrust laws and they do so when they are payments to delay competition, or otherwise to limit the risk of competition, payments which we call "payments for delay."

Future cases are likely to involve variations on the basic reverse-payment fact pattern, which has two essential elements: (1) a large payment, in some form, from the patentee to the alleged infringer, and (2) a requirement that the alleged infringer refrain from competing, for some period of time and in some respects, using the patented technology. The Court's formulation is

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[1] 133 S. Ct. 2223 (2013).

[2] *Id.* at 2236.

[3] *Id.* at 2238.

[4] *Id.* at 2227.

not limited to settlements between rival drug makers, and future cases could involve settlements in other industries.

A. The Key Source of Inference: A Large Reverse Payment

The essence of the Court's opinion is that "the size of the reverse payment can provide a workable surrogate for a patent's weakness" and that a large reverse payment creates an inference that the settlement is anticompetitive.[5] The Court considers a settlement anticompetitive if it reduces the extent or likelihood of competition, even by a small amount:

> 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.[6]

Our Appendix presents a simple model showing that sound economics underlie the Court's inference of competitive harm from a large reverse payment.[7] Whenever the reverse payment exceeds the patent holder's prospective litigation costs plus the value to the patent holder of any other goods and services provided by the allegedly infringing firm, the model indicates that the settlement diminishes the expected period of competition and harms consumers. Such settlements are aptly called "payments for delay" and are anticompetitive under the Court's rule of reason.

B. Absolute Patent Weakness is Neither Inferred Nor Needed

A large reverse payment does not necessarily mean the patent is weak in any *absolute* sense. As Chief Justice Roberts' dissent points out, a patent holder might "pay a good deal of money to rid itself of [a] 5% chance of a finding of invalidity."[8] The model in the Appendix provides a rigorous basis for this assertion, by relating the patent holder's payment to an upper bound on patent strength. The upper bound on patent strength consistent with the reverse payment can be quite large.

However, the possibility that the patent has a high chance of being found valid and infringed does not undermine the logic or validity of the Court's approach. The Court is quite explicit on this point, as shown by the quotation above. A settlement can reduce competition even if it eliminates only a "small risk of invalidity" (or, presumably, non-infringement) and thereby eliminates the associated "risk of competition."[9] This happens if the agreed period of competition is smaller than what could be expected from that small probability of the patentee

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[5] *Id.* at 2236–37.

[6] *Id.* at 2236.

[7] The model considers settlements involving a reverse payment and a negotiated entry date after which a duopoly obtains. The patent holder is assumed to be risk neutral. The model compares the period of competition under the settlement with the expected period of competition under litigation of the patent. This model is based on the more general analysis in Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003).

[8] *Actavis*, 133 S. Ct. at 2244 (Roberts, C.J., dissenting).

[9] *Id.* at 2236 (opinion of the Court).

losing the patent litigation. Crucially, this is exactly what one can reasonably infer whenever the net reverse payment exceeds the patentee's avoided litigation expense. More specifically, what can be inferred is not that the patent is weak in any absolute sense, but rather that it is *sufficiently* weak that the settlement reduces competition in expectation, thereby depriving consumers of some of the benefits from competition. For that reason, as the Court emphasized, preventing even a small risk of competition "constitutes the relevant anticompetitive harm."[10]

C. A Consumer Welfare Test

The Court adopts a consumer welfare approach to antitrust, in contrast to a total welfare approach that would also count producer profits. The basic problem arises, in the Court's view, when a firm "maintain[s] and . . . share[s] patent-generated monopoly profits,"[11] because, when that happens, "the consumer loses."[12] That consumer loss is the cognizable harm, the Court makes clear, without inquiry into what part of the loss takes the form of deadweight loss, or instead is transferred to producers as extra profit.

For purchasers of patented drugs, the consumer losses from delayed competitive entry are large. When generic entry occurs, the price drops, often dramatically. To take just one example, a leading cholesterol drug used by millions of Americans dropped from more than $150 for a month's supply to $7, less than a year after entry.[13] An industry-commissioned study estimated savings of $1 trillion from generic competition over the past decade.[14]

The Court appears to be unanimous in adopting the consumer welfare approach. The dissent writes: "The point of antitrust law is to encourage competitive markets to promote consumer welfare."[15] The dissent's core position is that the case should be decided as a matter of patent policy, rather than antitrust law; nowhere does the dissent urge the inclusion of producer profits as an offset to consumer harm.

The use of consumer welfare as the relevant measure is unsurprising. The Supreme Court, and the courts more generally, virtually never approve horizontal arrangements found to create a market-wide output reduction and higher prices simply because they believe that producer surplus is large enough to compensate for any consumer losses. Rather they insist that there be no consumer loss at all.[16]

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[10] *Id.*

[11] *Id.* at 2237; see also *id.* at 2235 ("The payment may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.").

[12] *Id.* at 2235.

[13] *See* C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 952 (2011) (characterizing generic entry as to Zocor).

[14] IMS Health, *An Economic Analysis of Generic Drug Usage in the United States* (IMS Health, Falls Church, VA, ed. 4, 2012).

[15] *Id.* at 2238 (Roberts, C.J., dissenting).

[16] *See* Herbert Hovenkamp, *Implementing Antitrust's Welfare Goals*, 81 FORDHAM L. REV. 2471 (2013).

3. The Plaintiff's Case: Establishing Payment for Delay

Just what must an antitrust plaintiff establish, under the structured and circumscribed rule-of-reason approach called for by the Court?

A. "Rule of Reason" vs. "Quick Look" Approach

The Court rejected the FTC's "quick look" approach under which "reverse payments are presumptively unlawful."[17] However, the Court also made clear that a "long form" rule of reason was not necessary, and that both anticompetitive effect and market power could be inferred from large reverse payments themselves.

The Supreme Court in general and Justice Breyer in particular have never embraced a bipolar "quick look" analysis in which all presumptions favor the plaintiff. Rather they have twice observed that there is a "sliding scale" for appraising reasonableness, in which the nature of the proof varies with the circumstances.[18] The *Actavis* decision is consistent with that approach. In particular, the Court held that "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."[19]

The patentee is willing to pay an amount up to litigation costs to get as much protection from competition as it expects to get from litigation. If the patentee is offered valuable services by the claimed infringer as part of the settlement, it may in addition be willing to pay that amount. Payment beyond this threshold, however, looks suspiciously like payment to avoid more competition than the patent court would shield the patentee from. Therefore, proving such a large payment creates an inference that the settlement is anticompetitive. Unless there is another explanation for the payment, that inference should stand.

Under the Court's focused rule of reason inquiry, no separate showing of market power is necessary. Economically, this is appropriate. Market power is but a proxy to identify when anticompetitive effects are plausible. As the Court points out, market power may likewise be inferred from payment size, and without any need to define a relevant market.[20] A producer in a highly competitive market would not pay anything to keep a rival out because price-cost margins are already low and keeping one firm out would not improve that situation. In contrast, a firm with market power typically will enjoy high margins, and protecting those margins by excluding

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[17] *Actavis*, 133 S. Ct. at 2237. See, paragraph B.1. Reply Brief for Petitioner, FTC v. Actavis, 2013 WL 1099171.

[18] *Id.* at 2237-38, quoting California Dental Ass'n v. F.T.C. 526 U.S. 756, 780 (1999), which was in turn quoting 7 PHILLIP E. AREEDA, ANTITRUST LAW ¶1500 (1986).

[19] The Court delineates the relevant considerations in examining the size of the reverse payment as follows:

> [T]he 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. The existence and degree of any anticompetitive consequence may also vary as among industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases. *Actavis*, 133 S.Ct. at 2237.

[20] *Id.* at 2236 ("[T]he size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power . . . .") (internal quotation omitted).

rivals can be very valuable. Following this logic, a large reverse payment indicates that market power exists, just as it indicates that the settlement is anticompetitive.

B. Plaintiff's Affirmative Case

From the above, we see that the plaintiff's case involves a narrowly focused inquiry. The plaintiff must establish (1) that the claimed infringer has agreed to abstain, in some respect, from competing using the patented technology for a period, and (2) that there was an otherwise unexplained payment from the patent holder to the claimed infringer.

The payment prong involves the following steps: (a) value any consideration flowing from the patentee to the claimed infringer, which may be made over time and may take forms other than cash; (b) deduct from that payment the patent holder's avoided litigation costs; (c) deduct from that payment the value of goods, services, or other consideration, provided by the claimed infringer to the patent holder as part of the same transaction (or linked transactions).[21] The resulting *net* payment is "otherwise unexplained" and, if it is a positive quantity, may be understood to be payment for delaying entry. Where the payment takes a form other than a simple cash transfer from the patentee to the claimed infringer, consideration should be valued from the perspective of the patentee.[22]

Payment from the patent holder to the claimed infringer, step (a) above, can take many forms. Valuing this consideration is sometimes an intricate proposition. For example, the payment could include forgiving a debt owed by the claimed infringer to the patent holder. The debt may take the form of patent infringement damages. The claimed damages could pertain to the product whose infringing entry is at issue (if there has been entry)[23] or another product. The consideration could also take the form of a "sweetheart" deal on goods purchased from the patentee.[24] The payment could also take the form of a patentee agreeing to abstain from vigorous competition once the claimed infringer enters the market, where such abstention lowers the patentee's profits and increases the alleged infringer's profits.[25] For example, in the pharmaceutical context, the patentee may agree not to market its own unbranded generic. Although sometimes intricate, handling this complexity is well within the competence of a district court.

Valuing the consideration flowing from the claimed infringer to the patent holder, step (c) above, also may be intricate. In the particular context of pharmaceuticals, most reverse payment cases arise in the context of payments that are described by defendants as consideration for value furnished by the generic firm. In the *Actavis* case, for example, defendants argue that the

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[21] An agreed entry date prior to patent expiration is not a form of consideration under steps (a) or (c).

[22] This analysis applies in cases in which the source of the benefit to the claimed infringer is something costly to the patentee. We do not address situations, such as the "bottleneck" that arises in some reverse payment cases, in which the benefit to the claimed infringer is achieved at little or no cost to the patentee.

[23] There are no such damages in cases where the settlement precedes entry by the claimed infringer.

[24] For a further analysis of various forms of compensation, see C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 665–66, 682–85 (2009).

[25] Such an arrangement can also be directly analyzed as an illegal non-compete agreement, in which the patentee agrees to pull its competitive punches in exchange for the claimed infringer delaying entry.

payments were in exchange for promotion and backup manufacturing services by the generic drug maker, rather than delay.[26] In other cases, defendants have argued that the alleged infringer provided valuable intellectual property licenses to the patentee.[27]

The *Actavis* Court gives district courts extensive discretion to develop a procedure to collect and appraise this evidence within the rule of reason.[28] In particular, the trial court is free to "create and revise presumptions of varying strengths to arrive at sensible decisions in the face of the many uncertainties of business reality."[29]

Here is how we recommend making appropriate use of that discretion. In its *prima facie* case, the plaintiff must show a restriction on competition by the alleged infringer and a large payment by the patentee. To show a "large" payment, the plaintiff has the burden of establishing steps (a) and (b), including the value of any non-cash consideration provided by the patentee, and that the payment is larger than the patentee's avoided litigation expense. The defendant has the burden of production as to step (c), that the payment was for valuable services, rather than delay.

Such a shift in the burden is a common feature of rule of reason cases, and it is particularly appropriate here.[30] After all, the defendants are in possession of the relevant evidence about their side deals. Moreover, the complexity is the result of the defendants' own actions. The elephant in the room here merits naming. The parties to a payment for delay have ample reason to pack complexities into the deal (such as relatively unimportant services) to conceal its genuine nature. Ordinarily, a genuinely valuable fee-for-service deal could be kept separate from the settlement to avoid antitrust problems. A degree of skepticism is therefore warranted with regard to complex reverse payment settlements where the parties would justify the large payments by subsidiary consideration. Plus, if this skepticism causes future parties to unbundle these settlements into separate deals, we doubt much will be lost to parties who are genuinely not paying for delay. Furthermore, the valuable-services argument is made weaker, at least in the

[26] Second Amended Complaint at 29–32, Federal Trade Commission v. Watson Pharms., Inc., No. 09-955 (N.D. Ga. May 28, 2009).

[27] *See, e.g.*, First Amended Complaint at 15, Federal Trade Commission v. Cephalon, Inc., No. 08-2141 (E.D. Pa. Aug. 11, 2009) (noting a variety of "side-term inducements" including licenses to intellectual property, supply agreements, and co-development deals). For a detailed review of these and other side deals, see Hemphill, *Aggregate Approach*, supra note 24, at 663-65; Kenneth Glazer & Jenée Desmond-Harris, *Reverse Payments: Hard Cases Even Under Good Law*, ANTITRUST, Spring, 2010, at 14.

[28] *See Federal Trade Commission v. Actavis, Inc.*, 133 S. Ct. 2233, 2237–38 ("[T]here is always something of a sliding scale in appraising reasonableness, and as such the quality of proof required should vary with the circumstances."); *id.* at 2238 (exhorting trial courts to "structure" the litigation appropriately).

[29] 7 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶1508c, p. 509 (2d ed. 2010), cited with approval in *Actavis*, 133 S. Ct. at 2238.

[30] The district court has discretion to go further, and assign the burden of persuasion as to step (c) to the defendants. *See* 7 PHILLIP E. AREEDA & HERBERT HOVENKAMP ¶ 1508c, p. 509 (2d ed. 2010), cited with approval in *Actavis*, 133 S. Ct. at 2238 ("We might also transfer the usual burden of persuasion from the plaintiff to the defendant on some or all issues"); *see also* NCAA v. Board of Regents of the University of Oklahoma, 468 U.S. 85, 113 (1984) (assigning to the defendant, under the rule of reason, the "heavy burden of establishing an affirmative defense" of justification).

pharmaceutical context, by the fact that brand-name firms apparently seek out these services from generic firms only in the context of settlement.[31]

In the end, the plaintiff bears the ultimate burden of persuading the fact-finder that the patent holder made some payment for delay. This involves more than just establishing a reverse payment, because reverse payments can be explained as other than payments for delay.

4. Explanations and Justifications

The defendants will presumably attempt to demonstrate that any payment can be explained as payment for services or avoided litigation costs and so is not a payment for delay. If the defendants prevail on this point, the plaintiff's case fails.

The Court leaves the door open to other "justifications" for a reverse payment, but is skeptical, and does not explicitly identify any. Justice Breyer's opinion merely says: "There may be other justifications" besides avoided litigation costs and services provided by the generic.[32] However, this statement clearly seems directed at explaining the reverse payment as something other than payment for delay, not at justifying a payment for delay. The Court later says, "An 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."[33] But notice again that the inquiry is focused on "*explaining* the presence of the challenged term," i.e., the otherwise unexplained payment.

Ultimately, any explanation must go to show that there was no payment for delay. As in *Professional Engineers*,[34] it will not work to defend a payment for reduced competition by arguing that the absence of competition is justified.

A. Patent Strength

Prior to *Actavis*, courts frequently struggled with the question of what role, if any, evidence of patent strength plays in the analysis of an alleged payment for delay. The purpose of such an analysis, as the Supreme Court explained, is "to demonstrate what would have happened to competition in the absence of the settlement."[35] For example, a defendant might present evidence that the patent was valid and infringed. That evidence might take the form of detailed technical evidence showing that the patent was nonobvious, or that the alleged infringer proposed to make a product within the claims of the patent. Or it might take the form of internal analyses by the patentee or infringer expressing a candid view of the strength of the patent.

Such evidence might be thought valuable by providing a baseline for identifying the expected amount of competition absent the settlement, which could then in principle be compared to the terms of the settlement. If the patentee were sufficiently likely to have won the patent case, then (a defendant might argue) a settlement with a particular entry date provides as much competition

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[31] Hemphill, *Aggregate Approach*, *supra* note 24, at 666–68.

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

[33] *Id*.

[34] National Society of Professional Engineers v. United States, 435 U.S. 679, 693–95 (1978).

[35] *Actavis*, 133 S.Ct. at 2234.

as the expected outcome of patent litigation.[36] Call this the patent strength approach, in contrast to the payment approach advanced by the *Actavis* Court.

The Court makes clear that litigating the patent is not necessary for the affirmative case, but can the defendants offer to prove that the patent was very likely valid and infringed as a defense, as the dissent suggests? The Court never flatly states that patent strength has no place in the determination of liability, but we think that is the best reading of the Court's statement that it is "normally not necessary to litigate patent validity,"[37] and other statements to like effect. The dissent states that the majority's claim cannot be so "unless [the Court] means to suggest that the defendant (patent holder) cannot raise his patent as a defense in an antitrust suit."[38] We think the Court must mean exactly that. Otherwise, such a defense would invariably be raised and it would normally be necessary to litigate patent validity and infringement, directly contrary to the Court's repeated assertions. In brief, allowing such a defense would defeat the Court's stated purpose of cutting to the chase in these cases.

The appellate court in *Actavis* refused to litigate patent strength because the conclusions from such a patent mini-trial inside an antitrust case would be unreliable and require "attempt[ing] to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment."[39] The appellate court considered an inquiry into the merits of the patent suit to be a "turducken" approach, comparing it to a dish in which a boneless chicken is stuffed inside a boneless duck, and in turn into a turkey. The *Actavis* Court picked up on this concern about a turducken patent trial within an antitrust trial, as an event that would be "time consuming, complex, and expensive," and likely "not worth the litigation candle."[40]

The entire Supreme Court appears to agree that a patent mini-trial inside an antitrust case is to be avoided.[41] Plus, even if the antitrust court could reliably find that the patent case was strong, this finding would be of limited utility in assessing liability. After all, as Chief Justice Roberts points out and the model in the Appendix confirms, a large payment may be made to eliminate a small probability of losing litigation. Yet that is enough for an antitrust violation, as the Court's opinion makes clear.

We read *Actavis* to disallow patent mini-trials, but even if we are wrong, the Court's opinion certainly disfavors it. At the least, a trial court has ample license to limit evidence on the validity and scope of the patent and to only hear evidence to the extent that it is highly probative in

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[36] A variation on this theme is that a patentee with a strong enough patent should have a special exemption from antitrust, i.e., that there is no need to evaluate the settlement provided that the patent is probably valid and infringed. This approach was squarely rejected by the Court's "risk of competition" approach discussed above.

[37] *Actavis*, 133 S. Ct. at 2236. The qualifier "normally" refers to the unusual case in which an antitrust plaintiff alleges that the patent litigation is a sham, and hence the merits of the patent must be evaluated in detail. *Id.*

[38] *Id.* at 2244 (Roberts, C.J., dissenting).

[39] Federal Trade Commission v. Watson, 677 F.3d 1298, 1315 (11th Cir. 2012), *rev'd on other grounds*, 133 S. Ct. 2223 (2013).

[40] *Actavis*, 133 S. Ct. 2223, 2234 (2013).

[41] *Compare id. with id.* at 2243 (Roberts, C.J., dissenting) (noting bad results if "immediately after settling, the parties would have to litigate the same issue—the question of patent validity—as part of a defense against an antitrust suit").

establishing whether there was payment for delay, not simply to establish that the original patent case was strong.

B. Patent Law and Policy

The Court rejected a set of arguments, offered by the defendants and emphasized by the dissent, that are rooted in the language of the Patent Act and considerations of patent policy. They do not enjoy a second life as purported justifications for payment-for-delay settlements.

Defendants may not offer justifications based on the Patent Act that reject the basic structure of the Court's analysis. They may not assert that the patent confers insulation from antitrust scrutiny by its very existence. Such an approach is question-begging, and the Court rejected it.[42] Comparing the consumer benefits from delayed entry with entry at patent expiration—essentially arguing that the settlement is a blessing, compared to the worst case—is similarly off the table.[43]

As for patent policy, the Court notes at several points that its analysis is an accommodation of antitrust and patent principles.[44] However, these statements do not open the way to creative defenses rooted in patent policy. After all, an important "patent-related policy" is to "eliminat[e] unwarranted patent grants so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification.'"[45] The context in which the Court makes these points is in seeking—and failing to find—any provision in which "'the patent statute specifically gives a right' to restrain competition in the manner challenged."[46]

Defendants may not argue that an otherwise anticompetitive settlement can be justified on the ground that the higher patentee profits are actually beneficial because they incentivize or fund further innovation. Nor may they offer the related defense that delayed entry provides the needed incentive for the patentee to develop an even better product. These kinds of arguments have already been considered, and rejected, en route to developing the Court's particular accommodation between antitrust and patent law. Indeed, this sort of argument was part of the fundamental approach of the dissent, which favored an exception to antitrust law premised on the

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[42] *Id.* at 2230–31 (opinion of the Court) ("[T]o refer, as the Circuit referred, simply to what the holder of a valid patent could do does not by itself answer the antitrust question."); id. at 2231–32 ("Whether a particular restraint lies 'beyond the limits of the patent monopoly' is a *conclusion* that flows from that analysis and not, as THE CHIEF JUSTICE suggests, its starting point.") (emphasis in original).

[43] *See id.* at 2234–35 (noting and explicitly rejecting that approach).

[44] *See id.* at 2231 ("it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well."); *id.* at 2231 (noting with approval that previous cases used "traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents."); *id.* at 2233 ("finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition").

[45] *Id.* at 2233 (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).

[46] *Id.* at 2231 (quoting *U.S. v. Line Material Co*, 333 U.S. 287, 311 (1948)); see also 2233 (criticizing dissent because it did "not identify any patent statute that it understands to grant such a right to a patentee, whether expressly or by fair implication").

presence of a patent, to encourage innovation.[47] The dissent lost on this point. Thus settlements must be evaluated based on the competition lost due to the horizontal restraint, without an offset for allegedly increased innovation due to the settlement.

C. Risk Aversion

Defendants may try to argue that the patentee is highly risk averse and agreed to relatively early entry as a result. A sufficiently risk averse patentee might in principle pay the defendant an amount in excess of avoided litigation costs and also agree to an entry so early that consumers enjoy more competition under the settlement than would be expected from litigation. The patentee would do so to avoid the risk of facing even more competition if the patent litigation went south. Put differently, risk aversion could disturb the inference from the large settlement payment that the settlement entails less competition than litigation, because sufficient risk aversion can justify large payments to avoid small risks.

The Court says that payments to avoid even a small risk of competition are antitrust violations. That is reason enough to deny a risk aversion defense. The Court also points out that, without the reverse payment, the parties might have reached a settlement with an earlier entry date, to compensate the claimed infringer for the lost payment.[48] Compared to this benchmark, the payment for delay harms consumers and hence constitutes an antitrust violation, whether or not the patentee is risk averse.[49] These arguments suggest rejecting the risk aversion argument. If a trial court is nevertheless inclined to consider such an argument, we recommend that any claim of risk aversion be subject to a demanding standard of verifiability akin to what courts require for efficiencies in mergers.

D. Other Defenses

The Court left open the possibility for other defenses that justify the reverse payment. However, the Court expressed some skepticism about what these justifications might be. We cannot predict what other defenses will be offered, but we encourage courts to restrict their attention to arguments that involve showing that the challenged settlement will lead to a longer period of competition, or stronger competition, than would an alternative settlement without the payment.

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[47] *Id.* at 2238 (Robert, C.J., dissenting) ("The point of patent law is to grant limited monopolies as a way of encouraging innovation. Thus, a patent grants the right to exclude others from profiting by the patented invention. In doing so it provides an exception to antitrust law, and the scope of the patent—i.e., the rights conferred by the patent—forms the zone within which the patent holder may operate without facing antitrust liability."). *See also id.* at 2247 (criticizing Court on ground that its ruling "weakens the protections afforded to innovators by patents").

[48] *Id.* at 2237 (opinion of the Court) (the parties "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.").

[49] It is possible, of course, that without a large reverse payment the defendants would have litigated their patent dispute, and with a highly risk averse patentee this litigation conceivably could have made consumers worse off in expectation. We discount this possibility because the overwhelming majority of all patent litigation settles; the main question is on what terms.

5. Private Actions

A. Liability Standard

The *Actavis* case was brought by the Federal Trade Commission under §5 of the FTC Act. However, the FTC often applies Sherman Act standards in such cases, and nothing in the Supreme Court's opinion suggests that the Court was applying a broader liability rule available only to the FTC under §5 of the FTC Act. This was, for all intents and purposes, a Sherman Act case. Thus, the inference and procedure described above is also available to private plaintiffs.

B. Causation and Damages

The difference between private actions and government enforcement actions is that the private plaintiff must show injury, causation, and must quantify any damages. As discussed above, the patent holder's motive for making a payment for delay is to prevent the price erosion that would have resulted from entry. If the plaintiff is a purchaser, then injury and causation requirements will be met by a showing that there was a such a payment for delay, which in fact delayed the price erosion. Individual plaintiffs will then prove damages by showing the time period during which competition was reduced by the settlement, the magnitude of price erosion caused by entry, and the extent of their purchases during the damages period.[50]

Pharmaceuticals are commonly sold through various intermediaries, thus making end users indirect purchasers. These purchasers would ordinarily be denied a damages action under federal law, but often they could obtain damages under a state antitrust indirect purchaser provision. Under federal law, however, even indirect purchasers may obtain an injunction against enforcement of a pay-for-delay agreement found to be anticompetitive.[51]

Like most price-fixing cases, these cases should be readily amenable to class action treatment when the plaintiffs are direct purchasers. The purchasers could be end users, but they could also be distributors, pharmaceutical chains or stores, health plans, government agencies, or any other entity that purchases directly from the pioneer.

One interesting question is whether the settling claimed infringer is equally liable for damages along with the settling patent holder. We see no reason for deviating from the usual rule that all participants in a cartel or market division agreement can be held liable, and also from the ordinary rules of joint and several liability making each accountable separately or together. These are not cases in which the claimed infringer is "coerced" to enter a conspiracy. Rather, the claimed infringer enters the unlawful arrangement in contemplation of a higher payoff.

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[50] In cases where generic entry has actually taken place prior to the antitrust trial, the real-world experience following generic entry is likely highly probative regarding the "but-for" prices and thus regarding damages. The size of the payment may provide helpful information regarding the length of the damages period: dividing the payment by an estimate of the annual difference between the patentee's profits without and with entry provides a lower-bound measure of the expected number of years by which the settlement delayed competition, or would have absent a subsequent antitrust challenge.

[51] See 2A PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶346d (4th ed. 2013).

C. Model Jury Instructions

In private cases, we suggest that the jury be asked whether there is a payment for delay, i.e., a payment not accounted for by avoided litigation costs and other services provided by the claimed infringer to the patent holder. This is the key finding of fact required to determine whether the challenged settlement is anticompetitive. As noted above, the plaintiff bears the burden of persuasion on this issue.

We propose the following jury instructions on the specific issue of whether a patent settlement involves payment for delay.[52]

> A settlement of patent litigation violates §1 of the Sherman Act if it harms competition. Competitive harm may be inferred if one party has agreed in the settlement that for a period of time it will not compete with the patent holder in certain respects (such as using the patented technology) and if that party has received an unreasonably large payment from the patent holder.
>
> In assessing whether this payment is unreasonably large, you may consider whether the payment is no greater than the patent holder's anticipated litigation costs that are avoided through settlement. You may also consider whether the challenged agreement represents no more than reasonable compensation, based on market values, for services that the claimed infringer has agreed to render to the patent holder. You may also consider the defendants' argument that no part of the payment was made to delay competition or to avoid the risk of competition. If you find that the payment is unreasonably large, then you must find that it produces competitive harm.
>
> You may not consider the validity of the patent as a defense. Nor may you consider as a defense that the term of the pay-for-delay agreement fell within the remaining term of the patent -- that is, that the agreement did not last beyond the expiration date of the patent.

If a trial court decides to include a market power instruction, separate from a finding of competitive harm, this instruction should explain that market power can be inferred from a large payment just as competitive harm can be.[53]

6. Conclusion

The Court has provided a well-marked roadmap by which courts can evaluate patent settlements involving reverse payments. The Court's rule-of-reason approach acknowledges that not all reverse payments are anticompetitive: some payments represent avoided litigation expenses; some are fair compensation for valuable services rendered by the alleged infringer; and some may have other legitimate justifications, though the Court wonders skeptically what those might be. With that said, the Court makes clear that payments made to delay competition or to avoid the risk of competition (in the event that the patentee loses the patent litigation) violate the antitrust laws. They do so even if the claimed infringer has only agreed to abstain from competition during a portion of the patent period.

The essence of the Court's opinion is that whenever the reverse payment is otherwise unexplained, a fact-finder can infer that the patentee has paid for delay, and hence that the settlement is anticompetitive. Here, with the assistance of a model of reverse payment

[52] We envision this instruction being used along with a more general set of antitrust jury instructions.

[53] *Actavis*, 133 S. Ct. at 2236, ("At least, 'the size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power' – namely the power to charge prices higher than the competitive level.") (internal citation omitted)

settlements, we clarify what payments are sufficiently large to justify the inference that a settlement is anticompetitive.

In the wake of *Actavis*, the job of a fact-finder is to conduct a focused inquiry to determine whether the reverse payment can be explained by the patent holder's avoided litigation costs and other consideration flowing from the alleged infringer to the patent holder. Importantly, our model justifies what the court clarifies and emphasizes: direct evidence of the strength of the patent at issue is not necessary to make this inference. The focus of the inquiry carries over to possible explanations and justifications. These must show that the challenged settlement leads to earlier or more competition than would a settlement without the reverse payment. Other defenses should be rejected.

Appendix

The Impact of Reverse-Payment Settlements on Competition

The patent holder is Firm A. The potential entrant is Firm B. The remaining patent lifetime is T. For simplicity, assume no time discounting. The patent holder places a probability P on winning the patent litigation, i.e., that the patent will be found valid and infringed. For this base case, the patent holder is assumed to be risk neutral. Significant risk aversion would alter these results.

Monopoly profits for Firm A are M_A. Duopoly profits for Firm A are D_A. Consumer surplus is higher under duopoly, S_D, than under monopoly, S_M. All profits and consumer surplus are per unit time. The two firms can settle or litigate. A settlement involves two parameters: the entry date E for the potential entrant and a reverse payment X from the patent holder to the potential entrant. The patent holder's litigation costs are C_A.

Firm A's payoff from settling on terms $[E,T]$ is $EM_A + (T-E)D_A - X$. Firm A's expected payoff from litigating is $T[PM_A + (1-P)D_A] - C_A$. If we observe a settlement, we may reasonably infer that it was better for Firm A than litigating, so we can infer that $EM_A + (T-E)D_A - X > T[PM_A + (1-P)D_A] - C_A$. Simplifying, this can be written as

$$E > PT + \frac{X - C_A}{M_A - D_A}.$$

Here PT is the expected amount of time when the market will be monopolized by the patent owner if the patent is litigated. In the absence of any reverse payment or litigation costs, $X = C_A = 0$, this inequality becomes $E > PT$.

This inequality allows an assessment of patent strength, although as explained below, no assessment of patent strength is necessary to determine whether consumers are harmed by the settlement. For example, if the settlement allowed the potential entrant to enter after 80 percent of the remaining patent lifetime, we could infer that the patent holder estimated patent strength as no greater than 80 percent. Reverse payments push down the upper bound on patent strength. Note that reverse payments and litigation costs are best measured in proportion to the extra profits that the patent holder stands to gain from keeping out the potential entrant, $M_A - D_A$.

How do consumers fare under the settlement compared with litigation? Under the settlement, consumer surplus is $ES_M + (T-E)S_D$. Under litigation, expected consumer surplus is $T(PS_M + (1-P)S_D)$. Consumers are worse off under the settlement if and only if $T(PS_M + (1-P)S_D) > ES_M + (T-E)S_D$. Simplifying, and using $S_M < S_D$, this can be written as

$$E > PT.$$

We consider the settlement anticompetitive if it leads to more monopoly and less duopoly, thereby harming consumers, compared to litigation. This is the standard used in Shapiro (2003). Under this standard, the settlement is anticompetitive if $E > PT$. This is precisely the inference we can make, using the previous inequality, if (but only if) $X > C_A$, i.e., if (but only if) *the reverse payment exceeds the patent holder's avoided litigation costs*. We do not need to know the absolute level of patent strength to reach this conclusion.

Finally, the model provides insight regarding the extent of competition lost due to the settlement. The expected period of competition lost due to the settlement is equal to the difference between the expected period of competition under patent litigation and the period of competition provided for under the settlement. A lower bound on this quantity is $(X - C_A)/(M_A - D_A)$. This is an important input into the calculation of damages in private cases, because it places a lower bound on the duration of any overcharge.