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Because I Said So: On the Competitive Rationale of *FTC v. Actavis*

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THERE HAS BEEN SOME GRUMBLING about the Supreme Court's decision in *FTC v. Actavis*,[1] which held that pharmaceutical patent settlements with "large" payments to a generic challenger are not "immunize[d] . . . from antitrust attack,"[2] even if the settlement does not go beyond the scope of the patent, that is, even if the settlement excludes only products alleged to infringe a presumptively valid patent. Some say that the Court's opinion provides no real answers to explain how "reverse-payment" settlements in Hatch-Waxman drug cases injure competition, and none at all to explain how the rule-of-reason analysis that the lower courts must now apply will actually work. So allow me to perform a public service. I will provide one clear, specific, and rigorously derived answer to a question concerning this case: How do you pronounce "Actavis"?

The question is by no means contrived, because the company changed its name during the course of the Supreme Court litigation. The former name was "Watson," which has been pronounced only one way since Arthur Conan Doyle gave us the gift of Sherlock Holmes. When the case caption changed from *Watson* to *Actavis*, however, there was much discussion and ample confusion.

Some placed the accent on the second syllable and used a long "ā" (Ak-TAVE-iss), so that it rhymed with "Al Davis." Others emphasized the first syllable, using a short "a," yielding "ACT-uh-viss." I decided to resolve the question in the manner my Irish mother used when I brought home a friend with a strange nickname ("We shall call him what his mother calls him."). So I went to the Actavis website to see what the company calls itself. There, a narrated video clip ended (after a dramatic pause) with these words: "We're *Actavis*." The accent was on the first syllable, no long "ā." Think of the word "activist" without the final "t."

I begin this way to make two points. First, this is the last clear answer you will encounter to almost any question arising from this decision. Except for telling us that the FTC won and that the rule of reason must govern, the majority neither addresses the hard questions necessary to its conclusion, nor provides useful guidance going forward.

Second, a thinking mind ordinarily demands a rationale for a particular result. As to some issues, such as pronouncing Actavis, one can accept that there is no rationale—that the emphasis on the first syllable is simply arbitrary. Thus, there is no danger that one will start pronouncing the name Dolores to rhyme with dolorous. As to other issues, however, such as instructing a jury in an antitrust case seeking billions in damages, the demand for a rationale is more acute. If none is apparent, the courts will supply one, and the rationale they choose will have consequences. Which brings us to the problem with *Actavis*.

Rather than supply a rationale for its conclusion, Justice Breyer's opinion simply applies the label "potentially anticompetitive" to an aspect of the settlement that exists in every case: the conveyance of consideration or "value" (what the majority calls "a share of [the patentee's] monopoly profits") in compromise of the risk of losing the litigation ("rather than face what might have been" a loss for the patentee).[3] But what is the rationale by which conveying such consideration and avoiding such risk truly hurts consumers? A rationale grounded in genuine competitive harm requires a demonstration of a "but-for" world in which we can say that *lawful* generic drugs would have entered the market absent the settlement. Only then could consumers turn to lower-priced generic alternatives and avoid paying the patentee's "monopoly" price. But where, as in *Actavis*, the question of patent infringement or validity is concededly disputed in good faith, the conclusion that competition was reduced must account for the possibility that the generic entry posited may have been *unlawful* and thus harmful to consumers. In the words of the FTC's former General Counsel, Willard Tom, "if the settlement prevents *infringing* entry, such prevention in itself is a pro-competitive effect."[4] As we shall see, the *Actavis* majority neither offered, nor discussed, such a rationale.

In making this critique, I acknowledge that some of the questions with which the lower courts must now grapple could not have been addressed in *Actavis* other than in dicta. *Actavis* was a case brought by the government for injunctive relief under Section 5 of the Federal Trade Commission Act, not a private action for damages under Section 4 of the Clayton Act. Section 5 is more broadly worded than the

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Sherman Act, and from the outset of the FTC's investigation of reverse payments some have argued that the FTC could prevail simply by showing a "likelihood of competitive harm" rather than actual harm: "The mere existence of reverse payments may be enough to establish the requisite likelihood, without a further showing that the harm has actually occurred."[5] It is certainly true that private plaintiffs have additional burdens to carry with respect to causation and antitrust injury, not the least of which is showing an *actual* injury to competition from which the plaintiff's injury flows.[6] Does *Actavis* simply mean that reverse payments make anticompetitive effects "likely" and that the rule-of-reason analysis will tell us which likely harms have actually occurred?

There are two problems with this reading, even if one makes the unwarranted assumption that "likely" harm is sufficient under Section 5.[7] First, if reverse payments make competitive harm "likely" for purposes of Section 5, why is the rest of the rule-of-reason analysis necessary? For *Actavis* clearly mandates that *the FTC's* complaint be evaluated under the rule of reason, and that the FTC bears the burden. Why would that be necessary if the FTC had already satisfied Section 5 by showing likely harm? The second problem is that the distinction between likely and actual harm does not cure the underlying failure of *Actavis* to supply a rationale for its result. Given the existence of the patent right and the potential for infringement, it remains unpersuasive to conclude that the settlement is "likely" to be anticompetitive, when it is equally "likely" to be procompetitive—depending on whether the excluded entry was non-infringing (and hence beneficial) or infringing (and hence harmful).

In the end, the distinction between Section 5 and the Sherman Act is yet another question that the lower courts must address without any help from *Actavis*. So the question to be examined here remains: How does an exchange of value to avoid risk actually hurt competition? "Because I said so" is the only answer we have from *Actavis*, and we deserve better.

The Road to *Actavis*

To demonstrate the importance of what the *Actavis* majority did not do in articulating its rationale, it is useful to review some of the central questions raised and resolved by the appellate courts that preceded *Actavis*.

The FTC and private plaintiffs' bar had long argued that Hatch-Waxman patent settlements with payments to the generic challenger were, in essence, market division agreements. The patentee was paying a potential competitor to "delay" its entry. In *Actavis*, the Solicitor General repeatedly argued that a truncated "quick-look" analysis should be applied because the agreement so closely "resembled" a market division agreement that a full rule-of-reason analysis was not necessary.[8] The settlement payments to the generic harmed competition, argued the FTC, because they necessarily resulted in entry dates that were later than if no payment had been made. If payments could not be used, went the argument, the generic would insist on an earlier entry date and the pioneer company would agree.[9]

For more than a decade, these settlements have thus been vilified by the FTC and others as "sweetheart deals" that "pay for delay."[10] Over the same period, however, the circuit courts peeled away the multiple fallacies on which this argument was built.[11]

Patent Agreements and Market Division. First, as the Eleventh Circuit recognized in 2003, the existence of the patent right destroys any analogy to market division: "If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's order. This is not such a case, however, because one of the parties owned a patent."[12] Indeed, if one ignores the patent right, as Professor Phillip Areeda once observed, virtually all patent agreements, whether settlements or licenses, would be per se illegal: "[Patent licensing] agreements would generally be classified as . . . per se unlawful naked horizontal market divisions" in the "absence of a patent."[13]

In antitrust terms, the reason that the patent right is central to the analysis is simple: The antitrust laws do not protect unlawful competition, and the courts have been clear for more than a century that this rule applies to products that infringe a patent. "[T]he public [i]s not entitled to profit by competition among infringers."[14] This is not a principle of patent law that "trumps" antitrust law; it flows from the respect antitrust law pays to the property rights of market actors. As Judge Posner puts it, "We do not want an efficient market in stolen goods."[15]

The Relevance of a "Better Settlement." Nor did the FTC's argument that payments harm competition because they necessarily result in a shorter license (i.e., a later entry date) for the generic fare any better. The argument posited that there is a competitively "ideal" settlement in which the parties agree on only one term, i.e., the generic's entry date. If money to the generic is also included, that entry date must be later than it would be otherwise, because the patentee must be getting something for its money.[16] The shortcomings of this theory were both factual and legal.

On the facts, the argument failed to recognize that, because the generic entrant will charge a lower price than the innovator charges, the parties to these settlements place highly different values on the time period of any license. Thus, there will often be no specific entry date that both can accept.[17] Suppose the parties are only $10 million apart in negotiations. If the generic needs six more months to generate that much extra profit, but those six months will cost the innovator $30 million in profit, no settlement will happen if they are restricted to negotiating only the entry date. In such a case, including a $10 million payment to bridge that gap does not prevent a longer license; it makes the settlement possible.

Limiting the consideration to a split of the patent term may also preclude settlement in the common case where the

parties differ as to their assessment of the patent merits, or one of them is risk-averse. Even Carl Shapiro, an avowed opponent of Hatch-Waxman settlements, admits that payments are not "necessarily anticompetitive" in such cases, concluding that "'reverse cash payments' may be important in more complex settings for successful settlement."[18]

On the law, moreover, the potential existence of a settlement the government deems "more competitive" (i.e., providing for earlier entry) is not legally sufficient to show that the settlement actually reached was unreasonable. By that logic, every two-year non-compete agreement in an employment contract is anticompetitive on the theory that, if two years were not permitted, the parties would still have agreed on one year. The Supreme Court made the point plainly in *Trinko*: "The Sherman Act . . . does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition."[19] Patent litigants, "who wish only to settle the present litigation," are not required "to act as unwilling private attorneys general" for consumers—or at least those consumers that the government seems to prefer.[20]

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The Competitive Relevance of Payments. In light of these principles, the courts noted that it is meaningless to speak of the generic "delaying" its entry or "exiting" the market without knowing whether that entry would have been lawful. All patent litigation seeks to delay or prevent *infringing* entry, and all settlements are "payoffs" to avoid the risk of loss, even if small. "It is uncontested that parties settle cases based on their perceived risk of prevailing in the litigation."[21] What should matter to the antitrust inquiry is the character of the allegedly excluded competition, not the consideration paid or the direction in which it flowed. As the *Valley Drug* court put it, "The failure to produce the competing . . . drug, rather than the payment of money, is the exclusionary effect."[22]

Think of it this way: If we knew with certainty that the generic product did not infringe a valid patent, would we allow *any* settlement that delayed the generic's entry for a period of years? Would the parties say, "Well, sure, the generic has every right to be in the market, and has agreed to refrain, but look—we didn't pay much in consideration"? For the same reason, if we knew with certainty that the generic infringed the patent, there would be no harm to competition from excluding it for the life of the patent, no matter how much was paid. Former Commissioner Thomas Leary, who would go on to author the FTC's *Schering-Plough* decision, made the point with such piercing clarity that no one, as far as I know, has ever tried to refute it:

> In summary, the problem is that the ultimate competitive impact of a pharmaceutical patent settlement is really dependent on the merits of the underlying patent litigation. . . . The "but for" world thus depends on *whether the patent holder had the legal right to exclude the generic altogether, absent any settlement* . . . .[23]

The Origin of the Scope-of-the-Patent Test. All of this is fine, you may say, but we are evaluating a settlement, and we will never know how the patent litigation would have ended. How do we account for the patent merits when we know we don't know? In my view, answering that question led the majority of circuit courts to adopt the so-called scope-of-the-patent test. The test flows from the principles stated above and the traditional placement of the burden of proof in an antitrust case.

To review: Because the antitrust laws do not protect infringing entry, a conclusion of competitive harm depends on whether the entry allegedly excluded by the settlement was lawful. The burden of proving that lawfulness is on the antitrust plaintiff.[24] So, how does one carry that burden? Can we simply retry the patent case during the antitrust case? Every court to consider that question, including the Third Circuit in *K-Dur*,[25] had said no, and for good reason. Where, as in *Actavis*, the underlying patent claim was not alleged to be frivolous ("objectively baseless"), it is true by hypothesis that reasonable minds could differ as to the result. Hence, as the Supreme Court has noted, any conclusion that one side or the other would have won is speculative as a matter of law.[26] The exercise is also pointless. If a claim was admittedly brought with probable cause, we already know that either side could have won. Having an antitrust jury pick a winner on a later date adds nothing to the antitrust analysis. By definition, another jury could reasonably disagree. To raise its proof above the level of speculation, the antitrust plaintiff must therefore show that the generic would have won *every* subsequent trial, because the patent is so weak that every reasonable litigant would consider it "objectively baseless." The tools of antitrust litigation will allow a court to measure with appropriate confidence whether a claim was objectively baseless or not, but not whether—on a question where reasonable minds can differ—one party would have prevailed before a particular jury on a particular day.

K-Dur ***and the Test of Presumptive Illegality.*** In contrast to the courts that adopted the scope-of-the-patent test, the FTC proposed a test of presumptive illegality for any settlement with payments, to be followed by a "quick-look" analysis that switched the burden to the defendant and did not permit consideration of the patent merits.[27] After years of failure, the FTC finally persuaded the Third Circuit to

adopt this standard wholesale, in *K-Dur*.[28] The previous courts recognized that the FTC's test—by excluding the patent merits altogether—would have rendered the patent right a nullity, effectively assuming that the generic would have won the patent suit.[29] As the D.C. Circuit recognized more than 30 years ago, however, applying an antitrust analysis that ignores "the scope of patent protection . . . [has] the effect of applying a per se rule."[30] That is, "once the protection of the patent was removed, the license conditions, like the patent itself, inevitably had the effect of restricting competition."[31]

Still, some argue that the scope-of-the-patent test overcomes this problem by committing the opposite sin—letting the presence of a patent render the settlement per se *legal*.[32] But this complaint sells the scope-of-the-patent test short. Under that test, the plaintiff can prove that the settlement precluded lawful generic entry because it went beyond the scope of the patent—in which case the patent merits are irrelevant. Second, it can prove that the generic would necessarily have prevailed in the patent litigation because the patent claim presented was "objectively baseless." The "objectively baseless" standard is admittedly difficult to meet, but it should be. When the conditions of *Actavis* are met (settlement within the scope and patent claim non-frivolous), we are left with an antitrust claim based on allegedly excluded competition but with no showing that the excluded competition was lawful. When that happens, the party with the burden should lose.

But that did not happen in *Actavis*, even though the Court expressly refused to switch the burden, and expressly rejected any presumption of liability. It is now for the courts that must try these cases to figure out why.

The *Actavis* "Rationale"

In the heart of its opinion, the *Actavis* majority set out five "sets of considerations" that caused it to reverse the Eleventh Circuit. The first—and the one that matters most here—was whether the settlement before it had "the potential for genuine adverse effects on competition."[33] Although the language is loose, this "consideration" resembles the first step in any rule-of-reason analysis, in which the plaintiff must show a genuine adverse effect on competition. Indeed, this was the step that the courts applying the scope-of-the-patent test found the plaintiffs unable to satisfy.[34] But the *Actavis* majority disagreed. The competitive evil lies in the patentee's making a payment that preserved the patentee's "exclusive right" to sell the drug (at least for some period of time), even though that right might have been lost "if the patent . . . were held invalid or not infringed . . . ."[35] This, we are told, means that the patentee is giving the generic "a share of its monopoly profits that would otherwise be lost" if "the patent were held invalid."[36] Such a "payment in return for staying out of the market," we are further told, "simply keeps prices at patentee-set levels . . . . The patentee and the challenger gain; the consumer loses."[37] Thus, we have two aspects that together produce competitive harm: (1) a sharing of "monopoly profit" designed (2) "to prevent the risk of competition."[38] Let's take them in order.

"Monopoly Profits" and Other Evils. Consider first the majority's repeated references to the "sharing" of "monopoly profits." The opinion does not enlighten us as to why such sharing is inherently evil, but simply uses the words as an unexamined epithet. In fact, the attitude of several Justices toward monopoly profits was previewed at the oral argument. There, Justice Breyer used the expression as an apparent synonym for anticompetitive conduct. "[S]ometimes these settlements can be very anticompetitive, dividing monopoly profit."[39] Indeed, four of the five Justices in the majority (save Justice Kennedy) referred to the division or sharing of profits as though it were obviously illegal a total of ten times.[40] In Justice Breyer's view, the easy case for liability is where "they're simply dividing monopoly profit. . . . I can take that in and so can every judge in the country. And what's complicated about that?"[41] Well, not much, if the label becomes a surrogate for analysis.

But, if analysis is permitted, two points come quickly to mind. First, the patentee in this scenario is assumed, for purposes of the motion to dismiss, to be a monopolist. "Monopoly profit" is the only kind of profit this patentee has, and any consideration the patentee is capable of conveying in a settlement must come from it. In other words, all settlement consideration comes from the "monopoly profit" of the patentee, if that is the label one chooses to use. To make the point, let us test Judge Sotomayor's assumption at oral argument that, if the parties merely agree on "an early entry [date] alone . . . there's no sharing of . . . profits."[42] But there is. Suppose the patent has ten years to run, and the pure term-splitting settlement allows the generic to enter after five years. The patentee has obviously "paid" the generic by conveying to it the present value of the profits the generic will receive in the five years of early entry.[43] In exchange, the generic has agreed to "delay" its entry for five years, during which time the patentee will earn "the full patent-related … monopoly return."[44] Under such an agreement, then, the parties are clearly sharing the patentee's "monopoly profits" in the same sense that *Actavis* uses the term, and in a settlement that the opinion blesses as a procompetitive safe harbor.[45]

Second, had the Justices thought harder, they might also have seen that the sharing of monopoly profits *simpliciter* is neither anticompetitive nor suspect. Indeed, as far as the majority knows, the patentee in this scenario (with the merits unresolved) is fully entitled to its monopoly profit. Again, the point was made indelibly by former FTC Commissioner Leary:

> To complicate matters further, *the sharing of monopoly profits* will be harmful to consumers in some situations and benign, or even helpful, in others. If the patent is valid, *the pioneer manufacturer is entitled to its monopoly profit*, and a settlement that merely transfers a portion of that profit to a potential generic manufacturer *causes no harm*.[46]

It is thus telling, though unsurprising, that the majority failed

to cite a single case or other authority for its reflexive condemnation of sharing monopoly profits.[47] Had they gone in search of such authority, they would have found passages like this one from the 2004 decision in *Trinko*:

> The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system. The opportunity to charge monopoly prices . . . induces risk taking that produces innovation and economic growth.[48]

Indeed, the suggestion that a settlement may harm competition because it "keeps prices at patentee-set levels" is directly contrary to the Court's own statement about the settlement agreements it found lawful in *Bement v. National Harrow Co.*: "[T]hat the conditions in the contracts keep up the monopoly . . . does not render them illegal."[49]

The majority appears to have ignored *Bement* for the same reason that it made no attempt to support its disdain for a patentee's profits. A lawful monopolist may divide its profits as it sees fit; only when that division wrongfully maintains the monopoly is antitrust law offended. Thus, a "sharing" of profits that prevents the entry of a *lawful* competitor may cause competitive harm; a sharing of profits that prevents the entry of an *unlawful* competitor does not. In sum, "pay" that does not cause delay is meaningless, and using sneer words like "monopoly profits" does not promote rigor.

But, thinking rigorously or not, the Court has spoken. Although the majority did not deny that all settlements convey "value" to the generic challenger, they have decreed that some forms of value shall be given different antitrust treatment than others. Some forms of consideration to the generic will bear the epithet "a share of the monopoly profits," while others will not. We know, because the majority says so, that the value conveyed in a pure term-splitting settlement does not meet the definition—but we do not know what the definition is. We will consider below the potential consequences for the courts that must live with the rule of *Actavis*. But first let us examine the second aspect of the competitive harm the Court has discovered.

Avoiding the "Risk" of Failure. The anticompetitive evil identified in *Actavis* results not simply because the monopoly profits are divided, but because they are "to be shared . . . *rather than face* what might have been a competitive market."[50] Because this risk that the patentee might lose the case goes unfaced, the majority concludes that "[t]he patentee and the challenger gain; the consumer loses."[51]

Yet, the majority never suggests that the "risk" that the patent may fail is more than that: a risk. The majority chides the patentee for not facing "what *might* have been" a loss of its exclusive right,[52] "if . . . the patent were held invalid."[53] The subjunctive mood concedes that there "might [not] have been a loss" as well. This is why Judge Posner noted in 2003 that "the theory [that reverse payments harm competition] may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent."[54] So the question raised by Commissioner Leary and so many others remains: By what mechanism does the failure to "face" the risk result in actual consumer harm when we do not know whether the patentee had the right "to exclude the generic altogether, absent the settlement"[55]?

This is the critical missing piece of the Court's competitive rationale. The opinion asserts that the failure to face this risk, which is obviously present in every settlement, *might* cause consumer harm, and then stops. That missing piece is what the lower courts must now supply—apparently as part of the now shapeless rule-of-reason analysis the majority opinion envisions.

In supplying that rationale, the courts will be informed by the rationales that the *Actavis* majority did not adopt. One deserves mention, given the majority's fixation on risk, but can be disposed of quickly: the general idea that patent challenges are good things, and that the settlement reduces competition by preventing resolution of the patent challenge. But that is true of every settlement, with or without payments, and whether the patent is strong or weak. Moreover, no one has yet suggested how the testing of any patent in litigation by itself lowers prices or expands output. Even under the FTC's view, the consumer benefit in testing patents depends on the outcome of the litigation, not the process. *K-Dur* was the only court to rely on this policy, even as a background factor.[56] *Actavis* ignored it.

Of greater note is the Court's failure to adopt or otherwise credit the Solicitor General's specific reliance on the "better settlement" theory—the argument that the presence of payments necessarily prevents a settlement with an earlier generic entry date. That was the theory the FTC first set out in its own *Schering-Plough* decision in 2003:

> We cannot assume that [one party or the other would have won the patent case.] In fact, we make neither assumption but rather focus on the effect that Schering's payment to Upsher was likely to have on the generic entry date which the parties would otherwise have agreed to in a settlement.[57]

We have seen above that that conclusion is flawed both factually (the parties value time differently) and legally (an agreement is not illegal because a "more competitive" one can be imagined). Still, it was essential to the government's theory of consumer harm in *Actavis*. The FTC argued that a legal rule restricting the parties to negotiating an entry date alone "has the practical effect of aligning [the generic's] interests in paragraph IV litigation with that of consumers, who benefit from the lower prices that generic competition provides."[58]

But this rationale—this "alignment" of consumer and generic interest—is also fallacious, because it assumes the answer to the very question being litigated and settled. It assumes that the generic product was non-infringing, and early entry is thus beneficial. But it is equally true that, if we knew the generic product was infringing, consumers would *suffer* by early generic entry, as their competitive interest in innovation would be diminished. As Willard Tom and Kent Bernard have pointed out, such a one-sided view of con-

sumer interest will not do: "It is inappropriate to use an analytical model in which the benefits of price competition on one side of the equation are taken into account, but the benefits of innovation on the other side of the equation are not."[59]

The majority's failure even to mention, much less embrace, this central premise of the government's position may be a useful clue to those courts striving to make sense of *Actavis*. The better-settlement theory was the apparent product of the FTC's felt necessity to find a source of consumer harm that did not simply ignore the patent. If the patentee would have provided a longer license *voluntarily*, the patent right does not enter the analysis. The argument's flaws doomed it everywhere but in the Third Circuit, and *Actavis* has now expressly rejected the presumption of illegality that the theory was designed to support. But, if imagining what the FTC called a "differently crafted" settlement will not provide the rationale for consumer harm, what is left?

Shaping the Rule of Reason: The Role of the Patent Right

A court preparing to instruct a jury in a case alleging that a Hatch-Waxman settlement containing reverse payments violates the antitrust laws will find little guidance from *Actavis*. The majority has told us that some, but not all, reverse payments have the "potential" for anticompetitive effects, and that those that do "will *at least sometimes* prove unjustified" by procompetitive effects.[60] Those procompetitive effects are not described with any particularity, but they include an unspecified set of "traditional settlement considerations," which may be augmented by "redeeming virtues" (always preferred to unredeeming virtues).[61] To hammer home the breadth of the inquiry, the paragraph setting forth the rule-of-reason description also contains this sentence: "There may be other justifications."[62] Still, it is for the district courts to discover what they might be.

It is my thesis here that the courts striving to give shape to this inquiry must necessarily supply the rationale for consumer harm that is missing from *Actavis*. That, in turn, will supply the principles that tell the fact-finder what evidence matters and why. For all the reasons stated above, a conclusion of ultimate consumer harm cannot avoid the question of infringement—that is, whether the excluded entry was lawful competition that the antitrust laws protect. As a practical matter, these disputes will be resolved not in FTC proceedings, but in private patent cases where essential elements like antitrust injury, causation, and damages will raise the issue repeatedly. The court must at some point decide whether it can actually award damages to a plaintiff claiming overcharges because it was unable to buy a potentially *unlawful* product. That is the point at which cloudy assertions of avoided "risk" will be seen to fall short of describing the actual injury alleged: the inability to buy a non-infringing generic alternative. That is the point at which the court will find itself unable to avoid the issue that Justice Scalia at oral argument called "the elephant in the room"—the strength of the patent.[63]

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So, what does the opinion in *Actavis* tell us about the relevance of the patent merits to the rule-of-reason analysis? As one might expect, the signals are vague and potentially conflicting. The patent right is featured in the majority's initial description of the scope of any rule-of-reason inquiry, which "consider[s] 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*."[64] Subsequently, however, in a paragraph addressing whether the antitrust case will prove "feasible administratively," the opinion states that "it is normally not necessary to litigate patent validity to answer the antitrust question."[65] The same paragraph, however, ends by saying that, in those cases, courts should not be "force[d] . . . to conduct a *detailed* exploration of the validity of the patent,"[66] leaving us to wonder what sort of non-detailed exploration should take place in those cases where some examination of the patent merits is necessary or acceptable. All of this falls well short of implying that the patent merits are irrelevant to the otherwise boundless rule-of-reason inquiry that includes "redeeming virtues"[67] and any other "legitimate justifications."[68] On the contrary, the majority strains to argue that the patent inquiry can be curtailed where "the size of the unexplained reverse payment can provide a workable surrogate for a patent's *weakness*."[69] Thus, despite its best efforts elsewhere, the majority cannot even stop itself from focusing on Justice Scalia's elephant.

Notwithstanding this language, the FTC has already filed one motion for partial summary judgment, asking the court in its *Provigil* case to ban all evidence of the patent merits, even if introduced by the settling parties.[70] Though it relies on *Actavis*, the Commission's motion conveniently omits the Court's express reference to "off-setting legal considerations, such as "*those related to patents*," as well as the reference to patent "weakness."[71] This is simply an attempt to read *Actavis* as adopting the rationale of the FTC that the Court did not adopt, and to regain the presumption of illegality that the Court expressly eschewed. In my view, the better-reasoned decisions will recognize that the rule-of-reason inquiry—to move beyond potential to actual competitive harm—must include the patentee's right to exclude and the generic's potential infringement. And there is nothing in *Actavis* that says it cannot.

The* Actavis *Legacy: Antitrust Patent Trials. While I believe it unlikely that a court would allow an ultimate finding of antitrust liability without considering the scope-of-the-patent right, I do not suggest that the court will relish doing so. An antitrust trial is long and complex enough without adding the crushing burden of a patent trial within it, raising issues of chemistry and patent law so inscrutable that we have created a specialized court of appeals to consider them. As if the Hatch-Waxman Act had not done enough for patent litigators (by allowing patent trials before any market entry actually occurs), those litigators will now serve as well-compensated expert witnesses in antitrust cases. (I can testify from experience that this is already happening.) The court anticipating this trial may also be struck by the irony of it. The parties settled their patent case precisely to avoid having to resolve the patent claim. Now, under the rule of *Actavis*, the same issue will now be tried in an antitrust case, in which it is claimed that both parties have victimized consumers. The incentive to settle a patent case thus plummets.

Perhaps the only good news for these courts is that the *Actavis* "analysis" by its terms applies only to Hatch-Waxman patent cases. The Court's most important sentence came while addressing the dissent's complaint that other patent settlements just as clearly "pay" the alleged infringer to delay entry or leave the market it has already entered by compromising on the alleged damages due to infringement. The majority tried to distinguish this example:

> In the traditional examples cited above, a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim. In reverse payment settlements, in contrast, a party with no claim for damages . . . walks away with money simply so it will stay away from the patentee's market. That, we think, is something quite different.[72]

The pronouncement that these settlements are "quite different" is the end of the majority's analysis, when it should be the beginning. The majority does not explain why this difference is meaningful, nor can it. In both cases, it is the party with "no claim" (the alleged infringer) who receives the value in question, and in the "traditional" settlement, the generic is allowed to keep a share of the patentee's "monopoly profits" it has allegedly taken improperly. Once again, this distinction makes a difference only because the majority says so.

But, notwithstanding the majority's unpersuasiveness on this point, the critical sentence in this passage is this one: "Insofar as the dissent urges that settlements taking these commonplace forms have not been thought for that reason alone subject to antitrust liability, we agree, and *do not intend to alter that understanding*."[73] This sentence, along with the discussion of other aspects of the Hatch-Waxman Act said to make reverse payments more likely in this context,[74] will ensure that no court need apply *Actavis* to any settlement, license, or other patent agreement that does not arise from Hatch-Waxman litigation. For that, we can all be grateful.

In the Hatch-Waxman cases that do arise, however, the courts may find ways to avoid the unwieldy rule-of-reason trial that *Actavis* portends. The principal means may be putting teeth into the requirement that there be an "unexplained large reverse payment"[75] before a settlement within the scope of a patent becomes suspect. The majority made no effort to define the term "large"—indeed, it did not even define the term "payment." Among the settlements the FTC is now attacking are those in which the patentee agrees to make the settlement license wholly exclusive, by agreeing to license no other "authorized generic," on the ground that such a promise is a "reverse payment."[76] Why? Because the exclusivity has "value." A full discussion of this issue is beyond the scope of this article, and the courts already seem to be divided.[77] But one of the few clear things in *Actavis* is that some forms of the value conveyed to the generic in every settlement come from "monopoly profits" and some do not. Thus, leaving to one side whether it should ever be necessary to defend a patentee's historically unlimited right to award an exclusive license, one finds no support in *Actavis* for the conclusion that such a license is a "reverse payment" as the majority used the term.

Conclusion

The opinion in *Actavis*, as predicted by those who heard the oral argument, raises vastly more questions than it answers. Justice Breyer and his colleagues have chosen a path—an unfettered rule-of-reason inquiry even when the settlement is within the scope of the patent and the patent claim was fairly disputed—that no other court in 14 years (on either side of the issue) has considered feasible. The majority discussed neither the reasons those courts gave for the rule they adopted, nor any other aspect of the circuit court decisions, leaving us to wonder what the purpose was of all those years during which this issue supposedly "percolated" in the lower courts. *Actavis* never suggests that antitrust law protects infringing competition, or that competition is injured by an agreement simply because one can imagine a "better" one, but also never deals with the implications of those principles. As for guidance going forward, the majority has bequeathed a dizzying array of undefined terms, beginning with "payment," and including "large," "otherwise unexplained," "traditional settlement considerations," "redeeming virtues," and "a workable surrogate for weakness."[78]

As a result, for the courts who must apply *Actavis*, there is much work to do, and I suspect it will take a long time—perhaps another decade or more—to do it. But that may give us all time to catch up on some things. I, for one, would like to reread a few of the classics by my favorite authors, like William Faulkner. Some of his titles used three-syllable words that were easy to pronounce, so I may start with *Absalom, Absalom*. I'll have to work my way up to *Sartoris*. ■

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1 FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

2 *Id.* at 2230.

3 *Id.* at 2235–36.

4 Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical*

Patent Settlements: The Need for Context and Fidelity to First Principles, 15 FED. CIR. B.J. 617, 622 (2006).

[5] Thomas B. Leary, Comm'r, Fed. Trade Comm'n, Antitrust Issues in the Settlement of Pharmaceuticals Patent Disputes, Part II at n.27, Address Before the American Bar Association Healthcare Program (May 17, 2001), *available at* http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.shtm.

[6] *E.g.*, George Haug Co. v. Rolls Royce Motor Cars, Inc., 148 F.3d 136, 139 (2d Cir. 1998) (antitrust injury in a private antitrust suit requires "an *actual* adverse effect on competition as a whole in the relevant market.").

[7] The scope of the FTC's authority under Section 5 is subject to much debate. See Intel Corp., Analysis of Proposed Consent Order to Aid Public Comment, FTC Docket No. 9341, 75 Fed. Reg. 48,338 (Aug. 10, 2010) ("[T]he legal standards applicable to some of these practices remain unsettled by the Supreme Court and the federal courts of appeal."); E.I. du Pont de Nemours & Co. v. FTC, 729 F.2d 128, 137 (2d Cir. 1984) (rejecting FTC's attempt to sanction conduct under Section 5 because it was "'analogous' to an antitrust violation").

[8] Brief for Petitioner at 15, 19–20, 34–35, *Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416) [hereinafter *Actavis* SG Brief] (Brief filed by the Solicitor General on behalf of the FTC).

[9] *Id.* at 27–28.

[10] *See, e.g.*, C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1570 (2006) ("Pay-for-delay agreements in the pharmaceutical industry have been an important focus of FTC enforcement efforts and private litigation.").

[11] *See* FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1313 (11th Cir. 2012), *rev'd sub nom.* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 604 F.3d 98 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1606 (2011); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 557 U.S. 920 (2009); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213 (2d Cir. 2006); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005); Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294 (11th Cir. 2003).

[12] *Valley Drug Co.*, 344 F.3d at 1304.

[13] 12 PHILLIP AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2040b (4th ed. 2013).

[14] Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co., 154 F. 358, 364 (7th Cir. 1907). *See also In re* Canadian Import Antitrust Litig., 470 F.3d 785, 790–92 (8th Cir. 2006) (no antitrust liability for precluding illegal importation of drugs); *see also* RSA Media, Inc. v. AK Media Group, Inc., 260 F.3d 10, 15 (1st Cir. 2001) (because RSA was legally ineligible to compete, "[a]ny injury suffered by RSA is therefore unrelated to AK's allegedly exclusionary conduct . . . ."); Access Telecom, Inc. v. MCI Telecomms. Corp., 197 F.3d 694, 712–13 (5th Cir. 1999) ("If there is no legal U.S. export market . . . then there is no antitrust injury."); Hynix Semiconductor Inc. v. Rambus Inc., 527 F. Supp. 2d 1084, 1096 (N.D. Cal. 2007) ("[A]n infringer" has "no legal right to be competing in the product market."); Monarch Marking Sys., Inc. v. Duncan Parking Meter Maint. Co., No. 82 C 2599, 1988 WL 5038, at *5 (N.D. Ill. Jan. 19, 1988) ("Neither [plaintiff] nor consumers have a right to the sale of labels which infringe Monarch's patents."), *partially vacated on other grounds*, 1988 WL 23830 (N.D. Ill. Mar. 8, 1988).

[15] RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 91 (5th ed. 1998).

[16] *Actavis* SG Brief, *supra* note 8, at 28–29.

[17] *See* Mark G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1066 (2004).

[18] Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 408 (2003). *See id.* at 397 ("I treat patent strength as a parameter outside the scope of my economic analysis . . . by treating patent strength as exogenous I cannot address various tricky and deep issues . . . that arise when the two parties differ in their assessments of patent strength.").

[19] Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 415–16 (2004). *See* Am. Motor Inns, Inc. v. Holiday Inns, Inc., 521 F.2d 1230, 1248 (3d Cir. 1975); *see also* Buffalo Broad. Co. v. ASCAP, 744 F.2d 917, 933 (2d Cir. 1984).

[20] Nestle Co. v. Chester's Market, Inc., 756 F.2d 280, 284 (2d Cir. 1985).

[21] *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003).

[22] *Valley Drug Co.*, 344 F.3d at 1309.

[23] Leary, *supra* note 5, at n.5.

[24] *E.g.*, Meijer, Inc. v. Biovail Corp., 533 F.3d 857, 862 (D.C. Cir. 2008) (noting in a Hatch-Waxman antitrust case that "a would-be purchaser suing an incumbent monopolist for excluding a potential competitor from which it might have bought a product at a lower price must prove the excluded firm was willing and able to supply it but for the incumbent firm's exclusionary conduct"). *See generally* Gross v. FBL Fin. Servs., Inc., 557 U.S. 167, 177 (2009) ("Absent some reason to believe that Congress intended otherwise . . . we will conclude that the burden of persuasion lies where it usually falls, upon the party seeking relief.").

[25] *In re* K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012), *vacated and remanded for consideration in light of FTC v. Actavis Inc. by* Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013).

[26] Whitmore v. Arkansas, 495 U.S. 149, 159–60 (1990) ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case."). *See, e.g.*, Joblove v. Barr Labs., Inc. (*In re Tamoxifen Citrate Antitrust Litig.*), 466 F.3d 187, 203 (2d Cir. 2006) ("We cannot guess with any degree of assurance what the [patent court] would have done . . . .").

[27] *Actavis* SG Brief, *supra* note 7, at 15, 19–20, 34–35, 37–39.

[28] *K-Dur*, 686 F.3d at 218 (3d Cir. 2012) ("[W]e will direct the District Court to apply a quick look rule of reason analysis based on the economic realities of the reverse payment settlement rather than the labels applied by the settling parties").

[29] *In re* Tamoxifen Citrate Antitrust Litig., 429 F.3d 370, 390 (2d Cir. 2005) (Reverse payments "are just as consistent with a high probability of validity and infringement as they are with a low probability.").

[30] United States v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1128 (D.C. Cir. 1981).

[31] *Id.*

[32] *E.g.*, *K-Dur*, 686 F.3d at 214.

[33] FTC v. Actavis, Inc., 133 S. Ct. 2223, 2226 (2013) (citation omitted).

[34] *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1332 (Fed. Cir. 2008) (The plaintiffs "had failed to demonstrate . . . an anti-competitive effect on the market for ciprofloxacin beyond that permitted by the patent. Because . . . plaintiffs failed to meet their burden under the first step of the rule of reason analysis, it [was not] necessary to consider the second or third steps of the analysis.") (citations omitted).

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

[36] *Id.*

[37] *Id.* at 2234–35.

[38] *Id.* at 2236.

[39] Tr. of Oral Arg. at 37:3–4, *Actavis*, 133 S. Ct. 2223 (No. 12-416) [hereinafter *Actavis* Tr.].

[40] *Actavis* Tr. 27:8–9; 27:17–19; 34:8–14; 39:1–9 (Sotomayor, four times); *Actavis* Tr. 16:7; 23:5; 37:3–4 (Breyer, three times); *Actavis* Tr. 32:6–10; 33:3–4 (Kagan, twice); *Actavis* Tr. 43:18–22 (Ginsburg, once).

[41] *Actavis* Tr. 16:6–10.

[42] *Id.* 39:7–9.

[43] "[*A*]*ny* settlement agreement can be characterized as involving 'compensation' to the [generic] defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., by designation).

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

[45] *Id.* at 2237.

[46] Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent*

Disputes, 14 ABA ANTITRUST HEALTHCARE CHRON., no. 4, Winter 2000/2001 at 1, 6 (emphasis added).

47 In the entire section devoted to identifying the competitive harm (the first of its "five sets of considerations"), the opinion cites only *Indiana Federation of Dentists*, from which it quoted the words "genuine adverse effects on competition," and three commentators for other propositions. *Actavis*, 133 S. Ct. at 2234–35.

48 Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, 540 U.S. 398, 407 (2004). Three of the Justices in the *Actavis* majority (Kennedy, Ginsburg, and Breyer) joined the opinion in *Trinko*; the other two (Sotomayor and Kagan) were not yet on the Court. There was no dissent in *Trinko*.

49 Bement v. National Harrow Co., 186 U.S. 70, 91 (1902).

50 *Actavis*, 133 S. Ct. at 2236 (emphasis added).

51 *Id.* at 2235.

52 *Id.* at 2236 (emphasis added).

53 *Id.* at 2234.

54 Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 994 (ND Ill. 2003).

55 Leary, *supra* note 5.

56 *In re* K-Dur Antitrust Litig., 686 F.3d 197, 215–16 (3d Cir. 2012), *vacated and remanded for consideration in light of FTC v. Actavis Inc. by* Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013).

57 Schering-Plough Corp., 136 F.T.C. 956, 993 (2003).

58 *Actavis* SG Brief, *supra* note 8, at 54.

59 Bernard & Tom, *supra* note 4, at 621. Professor Bernard and Mr. Tom are surely correct that the FTC's assertion that patent litigation benefits consumers (i.e., increases competition) only when the generic wins is indefensibly one-sided. In my view, however, the flaw in the FTC's reasoning runs even deeper. That is because the antitrust laws are, and of right ought to be, indifferent to the outcome of private civil litigation. A full explanation of that principle is beyond the scope of this article.

60 *Actavis*, 133 S. Ct. at 2234, 2235–36 (emphasis added).

61 *Id.* at 2236.

62 *Id.*

63 *Actavis* Tr. 38:14–17.

64 *Actavis*, 133 S. Ct. at 2231 (emphasis added).

65 *Id.* at 2236.

66 *Id.* at 2237.

67 *Id.* at 2236.

68 *Id.*

69 *Id.* at 2236–37 (emphasis added).

70 Plaintiff's Motion for Preclusion of Patent Issues or, in the Alternative, Partial Summary Judgment, FTC v. Cephalon, No. 2:08-cv-2141 (E.D. Pa. Sept. 20, 2013).

71 *Id.*

72 *Actavis*, 133 S. Ct. at 2233.

73 *Id.* (emphasis added).

74 *Id.* at 2235.

75 *Id.* at 2236.

76 *See* Kevin D. McDonald & Mark R. Lentz, *FTC and Patent Settlements: Agency's Antitrust Crusade Expands Unsuccessfully*, WASHINGTON LEGAL FOUND. LEGAL BACKGROUNDER, Feb. 22, 2013, at 1, 3.

77 *Compare In re* Lamictal Direct Purchaser Antitrust Litig., Civ. No. 12-995 (WHW), 2012 WL 6725580, at *6 (D.N.J. Dec. 6, 2012) ("The Court finds that the term 'reverse payment' is not sufficiently broad to encompass any benefit . . . to [the generic] in a negotiated settlement.") *with In re* Nexium (Esomeprazole) Antitrust Litig., No. 12-md-02409-WGY, 2013 WL 4832176 (D. Mass. Sept. 11, 2013) (exclusive license may be a reverse payment under *Actavis*).

78 *Actavis*, 133 S. Ct. at 2234–37.