Understanding *Actavis*: How Courts Misinterpret *FTC v. Actavis, Inc.*, and How to Get It Right

Bryan Gant*

ABSTRACT

In FTC v. Actavis, Inc., the Supreme Court held that a large, unexplained "reverse payment" from an infringer to a patentee in connection with a patent settlement could sometimes raise antitrust concerns, but that "traditional" settlement forms would not. Lower courts have since struggled to apply this standard, at times expressing open frustration with what they perceive as Actavis's lack of guidance. Actavis seems inscrutable, however, only when courts fail to faithfully apply the framework the Court adopted.

To understand Actavis, a court must first understand the inference on which it relied. Because Actavis addressed patent settlements entered prior to any determination of the patent's validity, the Court sought to use the patentee's willingness to make a large, unexplained payment as a basis from which to infer possible patent weakness and thus the potential for anticompetitive effect. This inference provides the framework by which to apply Actavis, as to support such an inference a reverse payment must be: (1) a sacrifice by the patentee—rather than the normal, mutually-beneficial integrative bargaining so critical to the resolution of complex disputes; (2) large enough in the context of the settlement to suggest patent weakness; and (3) "unusual" rather than "traditional" under the considerations explained in Actavis.

* Bryan Gant is a partner in the Global Competition Group of White & Case, LLP and represents defendants in ongoing cases involving *Actavis*. The views expressed herein are his own, and do not necessarily reflect the views of White & Case or its clients. He would like to thank Ross Elfand, Kristen O'Shaughnessy, Kevin Adam, Dan Grossbaum, Eugene Hutchinson, Naari Ha, and Helen J. Gant for their comments and suggestions.

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I. Introduction

There have now been several articles seeking to "activate" the Supreme Court's decision in *FTC v. Actavis, Inc.*,[1] but before activating *Actavis* courts must first understand it.[2] Though it sits at the intersection of patent, antitrust, and dispute resolution principles, *Actavis* is not as inscrutable as some have suggested[3]—and can be

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

2. Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, & Carl Shapiro, *Activating* Actavis, 28 Antitrust 16 (Fall 2013); Sumanth Addanki & Henry N. Butler, *Activating* Actavis*: Economic Issues in Applying the Rule of Reason to Reverse Payment Settlements*, 15 Minn. J.L. Sci. & Tech. 77 (Winter 2014); Barry C. Harris, Kevin M. Murphy, Robert D. Willig, & Matthew B. Wright, *Activating* Actavis*: A More Complete Story*, 28 Antitrust 83 (Spring 2014).

3. *See, e.g.*, *In re* Loestrin Antitrust Litig. ("Loestrin"), 45 F. Supp. 3d 180, 195 (D.R.I. 2014) *rev'd* 814 F.3d 538 (1st Cir. 2016) (Justice Roberts "sardonically wished

applied as the Court intended by simply understanding the decision's basic framework.

Actavis addressed so-called "reverse payment" patent settlements, in which a patentee makes a payment to a patent challenger and in return the challenger allegedly agrees not to introduce a competing or "generic"[4] form of the patented product for a period of time.[5] The Supreme Court suspected that a patentee would not make a "large," "unexplained" payment to settle a patent case unless it viewed its patent as sufficiently weak to merit such a sacrifice and expected to recoup its sacrifice through delay in the entry of its generic rivals. Thus, the Court held that the fact of such a payment could suggest that further antitrust scrutiny could sometimes be appropriate.[6]

The Supreme Court's approach therefore provides courts with a three-part framework for applying *Actavis* at the pleading stage:

Does the complaint plausibly allege that the patentee made an initial sacrifice in entering the agreement? *Actavis* would infer potential harm to competition from the patentee's willingness to take a loss in the first instance, which it might expect to "recoup" by delaying the onset of generic competition.[7] Therefore, to state a claim under *Actavis*, a complaint must first plausibly allege such a sacrifice.[8] Importantly, a patentee sacrifice cannot be inferred

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'[g]ood luck to the district courts'" tasked with applying the majority's decision) (quoting *Actavis*, 133 S. Ct. at 2245 (Roberts, J., dissenting)); *In re* Lipitor Antitrust Litig. ("Lipitor"), 46 F. Supp. 3d 523, 542 (D.N.J. 2014); *In re* Aggrenox Antitrust Litig. ("Aggrenox"), 94 F. Supp. 3d 224, 242 (D. Conn. 2015); Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's* Actavis *Decision*, 15 MINN. J.L. SCI. & TECH. 3, 3–4 (2014).

4. The Court suspected that most *Actavis* cases would arise out of pharmaceutical patent litigation, and thus we will use the terms "brand" and "generic" throughout to refer to patentees and patent challengers, respectively. *See Actavis*, 133 S. Ct. at 2227. *But see* Order at 12, United Tactical Sys., LLC v. Real Action Paintball, Inc., 14-cv-04050-MEJ (N.D. Cal. Feb. 10, 2016), ECF 211 (refusing to dismiss *Actavis* claim in irritant projectiles market unrelated to pharmaceuticals).

5. *See Actavis*, 133 S. Ct. at 2227. Such a payment is "reverse" because it flows from the patentee to the would-be infringer rather than vice versa. *Id*.

6. *See infra* Part II (explaining the *Actavis* inference and framework). While courts can draw certain inferences from a properly defined, large, unexplained reverse payment, such inferences cannot substitute for evidence that the patent was actually invalid and thus that the settlement rather than the patent caused any harm to competition. *See infra* Part I(B). The *Actavis* inference is therefore properly drawn only at the pleading stage.

7. *See Actavis*, 133 S. Ct. at 2230.

8. *See infra* Part III.

from allegations of a generic *benefit*, as mutually-beneficial integrative bargaining[9] often creates value for *both* sides, and thus that one side benefited does not suggest that the other side sacrificed.[10] Rather, only where the patentee is plausibly alleged to have been "out-of-pocket" in some way is there a potential reverse payment settlement.[11]

Courts must therefore reject other standards, under which an agreement could be condemned without a patentee sacrifice if it (1) provided the generic with value (the "any value" test),[12] (2) failed to recreate a hypothetical agreement that parties in the settling parties' position would have been expected to enter outside of litigation (the "outside litigation" test),[13] (3) offered one or more of the parties more advantageous terms for a product or service than would have been available on the open market (the "market value" test),[14] or (4) benefited both parties but benefited one more highly than the other (the "equal value" test).[15]

Does the complaint plausibly allege a sacrifice that is large enough to provide meaningful information about the patent's strength or weakness? Because Actavis depends on inferring potential patent weakness based on the patentee's willingness to make a large, unexplained sacrifice, any alleged payment can be suspect only if the sacrifice is large enough in context to provide meaningful information regarding the patent's potential weakness.[16] By definition, such a payment must at absolute minimum exceed what the patentee would have paid or lost by continuing to litigate—as otherwise the patentee has made no "sacrifice" by choosing to settle.

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9. Integrative bargaining integrates parties' interests to reach a mutually-beneficial solution. "Distributive" bargaining, by contrast, seeks to distribute a fixed "pie." *See* MICHAEL WATKINS & SUSAN ROSEGRANT, BREAKTHROUGH INTERNATIONAL NEGOTIATION: HOW GREAT NEGOTIATORS TRANSFORMED THE WORLD'S TOUGHEST POST-COLD WAR CONFLICTS 29–31 (2001); G. RICHARD SHELL, BARGAINING FOR ADVANTAGE: NEGOTIATION STRATEGIES FOR REASONABLE PEOPLE 11–12 (2d ed. 2006).

10. *See infra* Part III(A)(2); *see also* Part III(A)(3) (focus on patentee sacrifice also promotes judicial efficiency). This requirement is only half of the equation—if the generic does *not* receive value from an agreement, then the arrangement cannot be categorized as a suspect reverse payment, as a "payment" requires a sacrifice by the patentee for the generic's *benefit*. *See infra* Part III(A)(5). Moreover, the requirement of a patentee sacrifice is present regardless of the size of the generic's alleged benefit. *See infra* Part III(A)(4).

11. *See infra* Part III(B).

12. *See infra* Part III(C)(1).

13. *See infra* Part III(C)(2).

14. *See infra* Part III(C)(3).

15. *See infra* Part III(C)(4).

16. *See infra* Part IV(A).

In determining if a sacrifice exceeds such saved litigation costs, courts should look not only to direct costs (e.g., attorney fees), but also "indirect" costs, such as waste caused by the litigation process, that can be avoided through choosing to settle.[17]

Is the agreement plausibly alleged to take a form that Actavis viewed as suspicious, or is it instead traditional? *Actavis* also recognized that many traditional forms of settlement could incorrectly be characterized as involving "reverse payments"—but would not support an inference of potential patent weakness or anticompetitive effect. The Court offered at least five bases for determining when an "unusual" agreement can be appropriately subject to antitrust scrutiny, and four examples of agreements that are instead "traditional" under this rubric. An agreement may be unusual if it (1) has the potential to harm competition and (2) lacks any immediate justification for such harm; (3) suggests that the patentee has sufficient market power to recoup its sacrifice and thus benefit from the harm to competition; (4) suggests that the patentee perceives its patent as potentially weak and paid to avoid the risk of invalidation; and (5) can be distinguished from traditional settlements, such that courts would not be forced to condemn all settlements to antitrust scrutiny.[18] Examples of agreements that do not fit this rubric and that are therefore "traditional" include, but are not limited to, those that (1) offer the patentee "fair value;"[19] (2) "pay" the generic only through the opportunity to enter the market and thus compete;[20] (3) involve only forms of agreement authorized by the Patent Act;[21] or (4) represent a compromise of offsetting claims, such as in a compromise on damages entered as part of a patent settlement.[22]

By following this framework, courts can understand *Actavis* and apply it as the Supreme Court intended.

17. *See infra* Part IV(B).
18. *See infra* Part V.
19. *See infra* Part V; *Actavis*, 133 S. Ct. at 2236.
20. *See infra* Part V; *Actavis*, 133 S. Ct. at 2234.
21. *See infra* Part V; *Actavis*, 133 S. Ct. at 2231, 2234.
22. *See infra* Part V; *Actavis*, 133 S. Ct. at 2233.

II. The Supreme Court's Decision in *FTC v. Actavis* Relies on an Inference that Defines the Reach of Antitrust Scrutiny for Patent Settlements

Actavis addressed the following situation, which it believed would arise primarily in the context of pharmaceutical patent settlements[23]:

> 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.[24]

Because such settlements are often entered before a final decision on the patent merits, their competitive impact can be unclear. On one hand, if the patent would have been held valid and infringed then any restraint on competition results from the patent itself and cannot constitute an antitrust claim—indeed if a settlement allows a generic to enter before expiration of a valid patent, such a settlement may be substantially *procompetitive*.[25] On the other hand, if the patent would have been held invalid or not infringed then paying the

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23. *Actavis* assumed reverse payments would arise largely or exclusively in patent litigation based on the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch–Waxman Act"), which seeks to encourage brand name pharmaceutical innovation and eventual generic competition by (a) restoring the brand name pharmaceutical manufacturer's patent term (a portion of which might otherwise be lost to the FDA approval process) and (b) offering generic pharmaceutical manufacturers a streamlined means by which to challenge pharmaceutical patents and obtain FDA approval. *See Actavis*, 133 S. Ct. at 2227–29 (explaining operation of Hatch-Waxman Act).

24. *Id.* at 2227.

25. In several cases settlements with patent challengers have been followed by subsequent patentee victories against other challengers with respect to the same patent. *See, e.g.*, Pozen, Inc. v. Par Pharm., 696 F.3d 1151 (Fed. Cir. 2012) (upholding patents against challenge by three generic manufacturers after patentee settled with fourth); *In re* Ciprofloxacin Hydrochloride Antitrust Litig. ("Ciprofloxacin"), 544 F.3d 1323 (Fed. Cir. 2008) (one generic settled and obtained early entry; four others unsuccessfully litigated); *In re* Tamoxifen Citrate Antitrust Litig,, 466 F.3d 187 (2d Cir. 2006) *abrogated by Actavis*, 133 S. Ct. 2223 (one generic settled and entered nine years prior to patent expiration; three others litigated and lost). For example, in one case, regulators prevented an early entry settlement for a patent that was ultimately upheld—thus costing consumers $2.6 billion in otherwise-available savings that would have resulted. *See* Sanofi-Synthelabo v. Apotex Inc., 492 F. Supp. 2d 353

generic to drop its patent challenge may "sometimes" (but by no means always) raise competitive concerns.[26] However, it is often not possible to determine whether the patent involved in a settlement would have been held valid had the litigation continued, and thus it is often not possible to determine whether a reverse payment settlement furthers or instead harms competition in any given case.[27]

A. Actavis *Relies on an Inference of Perceived Potential Patent Weakness and Potential Anticompetitive Effect*

Before *Actavis*, courts and the FTC had thus taken two approaches to the "basic question" addressed in *Actavis*. Several circuit courts applied the "scope of the patent" test, under which a settlement containing a reverse payment was lawful as long as any restraint did not extend beyond the terms of the still-valid patent.[28] By contrast, the FTC[29] and one circuit court[30] adopted a "quick look" rule under which any agreement providing value to the generic was assumed to be anticompetitive.

Actavis accepted neither approach.[31] Instead, the Court held that the patentee's willingness to make a large, unexplained reverse payment could *sometimes* serve as a "workable surrogate" for the patentee's view of the strength of its patent—what other authors have called the "*Actavis* inference"[32]—and thus provide a basis on which to

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(S.D.N.Y. 2007), *aff'd* 550 F.3d 1075 (Fed. Cir. 2008); *see also* Sanofi-Synthelabo v. Apotex Inc., 488 F. Supp. 2d 317, 323–24 (S.D.N.Y. 2006); Sanofi-Aventis v. Apotex Inc., 659 F.3d 1171, 1175–76 (Fed. Cir. 2011); Corey Davis et al., *FTC Call for Settlement Ban Is . . . Full of Sound and Fury, Signifying Nothing* 7 (Jan. 14, 2010) (calculating loss to consumers).

26. *See Actavis*, 133 S. Ct. at 2235–36.

27. Courts tasked with evaluating the competitive impact of such settlements thus described it as a "turducken" task—a patent case inside an antitrust case, with settlement concerns thrown in for good measure. *See, e.g.*, FTC v. Watson Pharm., Inc., 677 F. 3d 1298, 1315 (11th Cir. 2012), *rev'd sub nom* FTC v. Actavis, Inc. 133 S. Ct. 2223 (2013).

28. *See, e.g.*, *Watson Pharm*., 677 F. 3d at 1315; *see also Tamoxifen*, 466 F.3d 187 (applying "scope of the patent" test); *Ciprofloxacin*, 544 F.3d 1323; Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294 (11th Cir. 2003). Such an agreement could thus be anticompetitive only if the restraint exceeded the scope of the restraint imposed by the patent itself.

29. *See* Brief for Petitioner at 46, F.T.C. v. Actavis, Inc., 133 S. Ct. 2223 (2013), (No. 12-416), 2013 WL 267027.

30. *In re* K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012).

31. In setting out this framework we seek to describe rather than approve of *Actavis*. Whether *Actavis* was rightly decided or should be revisited by the Supreme Court is a question beyond this Article's scope.

32. *See* Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, Carl Shapiro, *The* Actavis *Inference*, 67 RUTGERS L. REV. 585 (2015).

infer the *possibility* that the patent was weaker than the agreed-upon generic entry date would suggest.[33] In other words, the Court held that a court could infer, based on the existence of a large, unexplained reverse payment, that absent such a payment the patentee would have expected generic entry to occur earlier than the entry date the parties agreed to in their settlement—and thus that the agreement "delayed" competition by some amount of time.[34]

Of course, this is only a rough inference appropriate to the pleading stage as the patentee's actual views on patent strength may bear little relation to what its alleged sacrifice might suggest, and those views may further bear little relation to the actual strength of the patent.[35] However, with this surrogate a court could "sometimes"[36] infer that the risk-adjusted entry date the patentee would have expected from litigation might have been earlier than the agreed-upon entry date.[37]

B. *The Court's Approach to Patent Weakness Includes Four Crucial Limitations*

In adopting this "surrogate" approach, the Supreme Court did not throw the procompetitive baby out with the antitrust bathwater by subjecting *all* patent settlements to antitrust scrutiny, or even all patent settlements involving the exchange of "value" as the FTC's proposed "quick look" approach had advocated. Instead, the Court described four limitations to its ruling, each of which flows from the above inferences.

Requires a patentee sacrifice. As discussed in Part III, *Actavis*'s inferences can only be applied where the patentee can plausibly be alleged to have made an initial *sacrifice*—as a mutually-beneficial agreement that initially *benefits* the patentee offers no basis to infer patent weakness or competitive harm, and on the contrary is likely procompetitive. The Court thus held that where "a reverse

33. *See Actavis*, 133 S. Ct. at 2236 ("In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness"); *infra* Part III (explaining why it is the patentee's expectations that matter under *Actavis*). However, the Supreme Court did not rule out the possibility that courts may need to consider the patent merits in order to determine whether there is anticompetitive harm. *See infra* Part II(B).

34. *See Actavis*, 133 S. Ct. at 2236; Transcript of Oral Argument at 20, *F.T.C. v. Actavis,* 133 S. Ct. 2223 (2013) (No. 12-416) (Malcolm L. Stewart, Deputy Solicitor General) ("the natural effect of [a reverse payment] is not to facilitate . . . a picking of a point between the dates that the parties would otherwise insist on.").

35. *See id.* at 2237.

36. *See id.* at 2227.

37. *See id.* at 2236.

payment reflects traditional settlement considerations, such as . . . fair value for services, there is not the same concern that a patentee is using its monopoly profits[38] to avoid the risk of patent invalidation."[39]

The sacrifice must be large. As discussed in Part IV, *Actavis*'s inferences depend on deriving meaningful information about patent strength or weakness from the existence of a large, unexplained payment—but such information is available only if the payment is large relative to the value of the overall patent and in the context of the overall settlement. This is because, as the Court noted, "the likelihood of a reverse payment bringing about anticompetitive effects depends upon," *inter alia*, "its size [*and*] its scale in relation to the payor's anticipated future litigation costs."[40]

The agreement form must be unusual, not traditional. As discussed in Part V, *Actavis* cannot be applied to "traditional" forms of settlement "quite different" from a reverse payment, as these fail to permit the inference of patent weakness on which *Actavis* depends.[41] The Court explained what makes a settlement *unusual*:

> [A] reverse payment, where large and unjustified, [(1)] can bring with it the risk of significant anticompetitive effects; [(2)] one who makes such a payment may be unable to explain and to justify it; [(3)] such a firm or individual may well possess market power derived from the patent; [(4)] 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; and [(5)] parties may well find ways to settle patent disputes without the use of reverse payments.[42]

The Court further offered at least four examples of traditional agreements that would not raise the same antitrust concerns: (1) fair value agreements that offer the patentee "fair value for services,"[43] (2) early entry agreements that provide the generic with nothing more than opportunity to enter the market and compete,[44] (3) agreements

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38. Although the Supreme Court spoke in terms of monopoly profits, its inference also makes clear that the mere fact of a patent does not suggest a monopoly. *See also, e.g.*, Ill. Tool Works Inc. v. Indep. Ink, 547 U.S. 28, 31, 45–46 (2006).

39. *Actavis*, 133 S. Ct. at 2236.

40. *Id*. at 2237.

41. *See infra* Part V(A).

42. *Actavis*, 133 S. Ct. at 2237.

43. *Id.* at 2236.

44. *Id.* at 2234.

that derive their "payment" only from a license or other conduct authorized by the Patent Act,[45] and (4) agreements that represent merely a compromise of damages or other offsetting claims.[46]

The inference of patent weakness and anticompetitive effect is only an inference, not a conclusion. Finally, though beyond the scope of this article, the inference of potential patent weakness is a rough and preliminary one, and thus (a) only appropriate at the pleading stage, and (b) only a rebuttable presumption of potential antitrust harm—even where there is a large, unexplained reverse payment, it will only "sometimes" raise antitrust concerns.[47] For example, because the *Actavis* test relies not on patent invalidity but rather only the *perceived risk* of invalidity, even a large, unexplained reverse payment would not have harmed competition if the patent can be shown to ultimately be valid and infringed.[48] In such a case, it is the patent—not the agreement—that foreclosed competition. Moreover, even if there had been a real risk of invalidation, a payment cannot be used to truly quantify that risk, because a risk-averse patentee may make a large payment even where there is little risk of invalidation—and thus the existence of a large, unexplained payment is useful only for determining whether further antitrust scrutiny is appropriate, not for determining the existence or extent of alleged harm.[49] And in some cases the patent may have been upheld in subsequent litigation, or even may have been upheld later in the same litigation—and in such a case there can be no inference that it was the *settlement*, rather than the fully valid and upheld patent, that was the cause of any alleged delay in generic entry. *Actavis*'s inference of possible anticompetitive effect is therefore only the beginning of the analysis, not the end, and a plaintiff in such a case

45. *Id.* at 2231, 2234.

46. *Id.* at 2233.

47. *See id.* at 2227; *id*. at 2235–36.

48. Some have argued that *Actavis* should be read to treat the patentee's perceptions of patent weakness as definitive, including establishing that the patent was only as valid as the patentee perceived it to be when accounting for risk. *See, e.g.*, Edlin, *Activating* Actavis, *supra* note 2, at 19. Though beyond the scope of this Article, *Actavis* should not be read to create such a result, particularly *sub silentio*. Indeed, if the Court had intended to reach such a result, it would be difficult to understand its rejection of the quick look standard. *See Actavis*, 133 S. Ct. at 2237. However, *Actavis* provides only an inference useful as a starting point in the analysis—not an ultimate conclusion on patent validity—and this inference should not be treated as conclusive.

49. *Actavis*, 133 S. Ct. at 2236.

must prove its claim under the rule of reason as it would in any other case.[50]

III. *Actavis*'s Approach Depends on a Patentee Sacrifice, and a Fair Value Settlement Lacks Such a Sacrifice

Actavis first depends on a plausibly-alleged patentee sacrifice from which the court can infer that the patentee viewed its patent as potentially weak. Importantly, this sacrifice cannot be inferred from a *generic benefit*, as some courts mistakenly have held—as "win-win" agreements are common, and will not support the inference of patent weakness in *Actavis*.

To understand the importance of this distinction between patentee sacrifice and generic benefit, we begin with a hypothetical. To settle a patent case regarding a $10 billion per year product, a brand manufacturer patentee ("Brand") agrees to provide the generic challenger ("Generic") with 1 billion units of raw material at $0.50 per unit, the manufacture of which will cost Brand $0.45 per unit (compared to $0.55 for any other producer), and the market price of which would otherwise be $0.60 per unit. Generic receives a price discount of $0.10 versus the market price ($0.50 instead of $0.60 per unit)—and therefore saves $100 million. Brand does not, however, *sacrifice* $100 million, because if Brand charged market price Generic would prefer to purchase the raw material from another supplier rather than enrich its competitor. The agreement therefore creates $150 million in value for the parties: $50 million in otherwise-unavailable profits for Brand, and $100 million in savings for Generic. As a result, Generic becomes more willing to reach agreement on an entry date—and Brand likewise may well be more flexible regarding the entry date it will allow—thus bridging the difference between the parties' perceptions of the strength of their respective positions.

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50. *Id*. at 2237. The roughness of this inference could help explain what some have called the "circular" nature of *Actavis*. *See* Joshua B. Fischman, *The Circular Logic of Actavis*, 66 Am. U. L. Rev. 91 (2016) (arguing that *Actavis*'s use of settlement terms to predict the likely strength or weakness of a patent requires treating predictions about litigation as effectively determinative of litigation merits, an approach generally not followed in other areas of law). *Actavis* does not hold that the existence of even a large, unexplained reverse payment is *determinative* of patent weakness or anticompetitive effect. *See id.* at 117 (rejecting as unworkable an approach to patent litigation that depends on "probabilistic" patent validity). Rather, *Actavis* holds only that where there is a payment fitting the Court's criteria of "large" and "unexplained," there may sometimes be reason to consider the settlement in more depth—and thus *Actavis* applies only an inference, not a determination. *See id.* at 123 (recognizing that *Actavis* can be read to use reverse payment settlements only for their "epistemic value for determining the strength of the patent").

Is such a mutually-beneficial agreement suspect under *Actavis*? Some courts would appear to say yes, on the short-sighted theory that Generic receives $600 million of raw material (1 billion units with a market value of $0.60 per unit) and thus has been "paid" $600 million.[51] But this is surely error. Brand did not "pay" Generic $600 million—*Generic* paid *Brand* $500 million for raw material that cost Brand $450 million, thus earning Brand a $50 million profit. Nor, as demonstrated below, has Generic been "paid" $100 million merely because it saved $100 million compared to the market price.[52] Finally, such a result is at odds with *Actavis* for the reasons discussed in Part III(C)(3), *infra*—as *Actavis* spoke of "fair value" agreements, not "market value" agreements. Even if a traditional supply agreement of this type should ever be treated as a suspect reverse payment (and as demonstrated in Part V(A) below it should not), this hypothetical lacks the patentee sacrifice "surrogate" from which *Actavis* would infer potential patent weakness, and thus the potential for anticompetitive effect.

We explain below why this is so. In subpart A, we explain why *Actavis* depends on a plausible allegation that the patentee initially has sacrificed something of value from its perspective, why a generic benefit will not suffice as a substitute for this sacrifice, and why mutually-beneficial agreements are not suspect even if the value they create is substantial. In subpart B we explain why courts must draw this distinction at the pleading stage to avoid deterring procompetitive settlements. Finally, in subpart C we explain why other approaches would contradict *Actavis* and therefore must be rejected.

A. *Payments Must Be Viewed from the Patentee's Perspective by Looking for a Patentee Sacrifice*

As noted in Part II above, *Actavis*'s inference of potential anticompetitive effect depends on the presence of an initial large, unexplained sacrifice by the patentee, from which one might then infer potential patent weakness and potential generic delay.[53] We now (1) demonstrate that *Actavis* relied on the presence of a patentee sacrifice, not primarily on a generic benefit, in analyzing reverse payments, (2) explain why approaching *Actavis* from the perspective of the patentee protects traditional "integrative" or "win-win" bargaining essential to the resolution of complex disputes, (3) explain why

51. *See, e.g.*, *In re* Niaspan Antitrust Litig. ("Niaspan"), 42 F. Supp. 3d 735, 750 (E.D. Pa. 2014).

52. *See infra* Part III(C)(3).

53. *See Actavis*, 133 S. Ct. at 2236–37.

this approach promotes judicial efficiency by first looking to whether a patentee made a sacrifice rather than asking whether the generic received too much or too little value, (4) explain why a mutual benefit can never be the basis for a claim regardless of its size, and, finally, (5) discuss the additional requirement, inherent in the concept of a payment, that the generic benefit from the patentee's sacrifice.

1. Actavis *Focused on a Patentee Sacrifice, Not (Just) a Generic Benefit*

The need for a reverse payment to include a patentee sacrifice is apparent from *Actavis* itself, but also confirmed by courts and commentators that have addressed the issue.[54] As a starting point, the Court held that the patent in *Actavis*, "if valid and infringed, might have permitted it to charge drug prices sufficient to *recoup* the reverse settlement payments it agreed to make to its potential competitors."[55] It goes without saying that to "recoup," a party must first take a *loss*—a party cannot recoup its own gain.[56] And the term "payment" itself similarly implies a sacrifice by the payor—as "paying" someone usually requires taking money (or the like) from one's own pocket and giving it to another. Similarly, *Actavis* notes that a reverse payment "amounts to a purchase by the patentee of the exclusive right to sell its product"[57]—the "purchase" of a right implies a sacrifice of something of value in exchange for that right. Finally, the Court repeatedly noted that its concern was the "sharing" of monopoly profits by the patentee to the generic—an act that would require the patentee to give up something of value to accomplish.[58] *Actavis*

54. *See, e.g.*, King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp. ("Lamictal"), 791 F.3d 388, 405 (2015), *cert. denied*, No. 15-1055, 2016 U.S. LEXIS 6717 (Nov. 7, 2016) (asking whether "the source of the benefit to the claimed infringer is something costly to the patentee"); Edlin, *Activating* Actavis, *supra* note 2, at 18 ("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."); Edlin, *The* Actavis *Inference*, *supra* note 32, at 594 ("for non-cash reverse payments, the courts should seek to measure the dollar value sacrificed by the patent holder as a result of the agreement it reached with the alleged infringer"); Rahul Guha & Eric Grannon, *Profitability as Safe Harbour Against Pay-for Delay Claims*, Global Competition Review (Jan. 5, 2015) ("The antitrust laws are not designed to punish firms for taking a less profitable approach, as opposed to another profitable approach.").

55. *Actavis*, 133 S. Ct. at 2230 (emphasis added).

56. *See, e.g.*, *Recoupment*, BLACK'S LAW DICTIONARY (7th ed. 1999) ("The recovery or regaining of something.").

57. *Actavis*, 133 S. Ct. at 2234.

58. *Id*. at 2235 (competitive concerns arise when brand "share[s] . . . its monopoly profits" with the generic); *id.* at 2237 ("shar[ing] patent-generated monopoly profits").

thus consistently spoke in terms that involve a sacrifice of value by the patentee.

This focus on the patentee's sacrifice in the language of *Actavis* is further confirmed by the fact that *Actavis*'s fundamental inference of patent weakness depends on such a sacrifice—the only basis for inferring patent weakness in *Actavis* is the conclusion that a patentee would not make such a sacrifice unless it perceived some such risk of patent weakness.[59] By contrast, a patentee would accept a *benefit* regardless of the merits of its patent, simply because it is better to receive a benefit than not to receive a benefit, and thus no inference of patent weakness can be drawn based on a patentee's willingness to do so.

Similarly, the Court said that a large, unexplained payment by the patentee might suggest that the patentee held market power, as the Court suspected that a patentee would not sacrifice value unless it had the market power to recoup its sacrifice—but here again the Court's inference necessarily depends on the existence of a sacrifice by the patentee, as no market power could be inferred from a patentee's willingness to break even or receive a benefit.[60]

Finally, the Court noted that a payment smaller than saved litigation costs could not be anticompetitive, regardless of the benefit it might provide the generic, presumably because the *patentee* was simply paying its opponent what it would otherwise pay its lawyers and thus making no sacrifice.[61] Much of *Actavis* thus depends on a patentee sacrifice—not (just) a generic benefit.

2. *The Supreme Court's Focus on a Patentee Sacrifice Preserves Integrative Bargaining*

This distinction between a patentee sacrifice and a generic benefit is crucial, as any other rule would outlaw traditional integrative "win-win" bargaining and the procompetitive outcomes such bargaining permits. Courts that rely on a generic benefit to show potential harm to competition therefore fail not only to follow *Actavis*, but also

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59. *See id.* at 2236 ("An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival.").

60. *Id.* ("Neither is a firm without [market] power likely to pay 'large sums'").

61. *See id*. Some commentators nonetheless have argued that even a payment smaller than saved litigation costs should be suspect because such a payment could impact the generic's willingness to settle. Edlin, *The* Actavis *Inference*, *supra* note 32, at 620. But where a patentee has paid its opponent what it would otherwise have paid its lawyers, it cannot have made a sacrifice and thus has not "paid" the generic.

to respect traditional forms of settlement long favored by scholars and courts.[62]

In integrative bargaining—examples of which include techniques such as "expanding the pie" or "problem solving"—parties who would otherwise be at an impasse seek to work together outside of the dispute, creating sufficient value to bring each side to the middle. In their landmark negotiation treatise Getting to Yes, Roger Fisher & William Ury give the example of two children arguing over an orange, unable to reach resolution because neither realizes that one only wants the fruit and will throw away the peel while the other wants only the peel for baking and will throw away the fruit.[63] The children could mutually benefit by dividing the orange according to their interests—the whole peel for one, the whole fruit for the other.[64] Integrative bargaining looks for such opportunities to integrate interests, create value, and achieve settlement—and is thus the "textbook" way to reach agreement in complex disputes.[65] Such techniques can include expanding the pie to create value, or can—as in Fisher & Ury's example—involve problem solving to realize otherwise-unrealized value. These techniques are traditional, commonplace, and heavily favored by negotiation experts, scholars, and courts.

Nonetheless, some assume that *Actavis* requires the parties to avoid such mutually-beneficial solutions precisely because they are

62. *See, e.g.*, *In re* Nexium (Esomeprazole) Antitrust Litig. ("Nexium"), 42 F. Supp. 3d 231, 263–64 (D. Mass. 2014) (generic benefit sufficient because "[n]owhere in *Actavis* does the Supreme Court suggest that fair value is a silver bullet against antitrust scrutiny."); King Drug Co. of Florence v. Cephalon, Inc. ("Cephalon"), 88 F. Supp. 3d 402, 419 (E.D. Pa. 2015) (fair value cannot avoid antitrust liability); *In re* Opana ER Antitrust Litig., 2016 WL 521005, at *716 (N.D. Ill. Feb. 10, 2016) (mere *possibility* that generic benefited sufficient to state reverse payment claim); *Aggrenox*, 94 F. Supp. 3d at 242; United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc. ("Lidoderm"), 74 F. Supp. 3d 1052, 1071 (N.D. Cal. 2014); *Niaspan*, 42 F. Supp. 3d at 750.

63. ROGER FISHER, WILLIAM URY, & BRUCE PATTON, GETTING TO YES 58–59 (Penguin Books, 3d Ed. 2011).

64. *Id*.

65. A large, unexplained reverse payment could in some cases be described as a form of integrative bargaining, in that it might sometimes "create" value from delay in generic entry. However, in permitting antitrust scrutiny of this *one form* of integrative bargaining the Court did not subject *all forms* of integrative bargaining to antitrust review.

mutually-beneficial, creating value for both the patentee *and* the generic, and to instead adopt a "fixed pie" distributive approach to settlement.[66] This assumption of a fixed pie assumes a single "right answer" that the parties are expected to discover through distributive bargaining.[67] The assumption thus relies on the belief not only that a patent has a single objective probabilistic value, for example that it is 50% likely to be upheld and thus effectively 50% valid, but also that the parties are able to discern and agree on this probabilistic value.

Such easy compromises are frequently not available, however.[68] Instead, parties often have differing views regarding likely litigation outcomes, based on, *inter alia*, (a) different views regarding the patent merits, (b) different philosophies on patent law generally, (c) different levels and types of risk to each party, (d) different risk tolerances, and (e) information asymmetries.[69] These views tend to lead parties to systematically overstate their positions, such that one experienced negotiator noted that if each side was asked its likelihood of success in litigation, the sum of the two sides' expected litigation outcomes would often exceed 150 percent.[70]

There is thus no "right" answer in patent litigation, much less one the parties can always reach through distributive bargaining.[71]

66. *See* WATKINS & ROSEGRANT, *supra* note 9, at 29–31 ("Sometimes there's a fixed pie to be divided among the parties: anything one side gains the other loses. A situation of this kind is a *distributive negotiation*.").

67. *See, e.g.*, Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should be Per Se Illegal*, 41 RUTGERS L.J. 255, 261 (2009) (arguing that a ban on reverse payments would force parties into a distributive bargaining model).

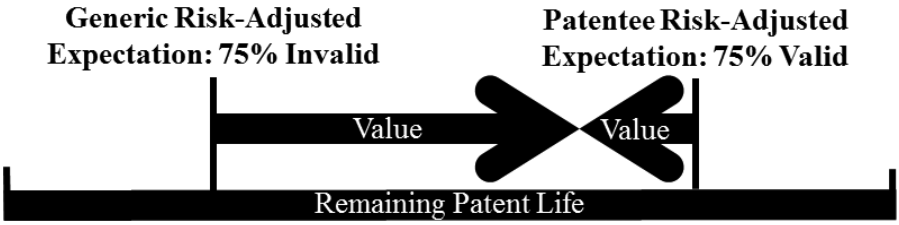
68. *See, e.g.*, Time Ins. Co. v. AstraZeneca AB, 52 F. Supp. 3d 705, 712 (E.D. Pa. 2014); FISHER & URY, *supra* note 63, at 155–56; Dale Eilerman, *Agree to Disagree—The Use of Compromise in Conflict Management*, (Oct. 2006), Mediate.com.

69. *See* DWIGHT GOLANN, MEDIATING LEGAL DISPUTES 217 (Little, Brown and Co., 1996) ("[T]hat disputants talk about principles and face the same alternative [litigation] does not mean that they reach agreement easily. In practice, disagreements over how a case will be decided on the merits are a major cause of bargaining impasses."); HARRIS, *supra* note 2, at 84.

70. GOLANN, *supra* note 69, at 243.

71. *See, e.g.*, PAUL J. ZWIER & THOMAS F. GUERNSEY, ADVANCED NEGOTIATION AND MEDIATION THEORY AND PRACTICE 7 (NITA 2005); FISHER & URY, *supra* note 63, at 3. In some cases, of course, the parties *are* able to reach agreement because their positions sufficiently overlap to allow settlement on a distributive basis—or they are able to agree on a royalty that will allow the bridging of small differences. That settlement

The recognized solution to this problem is therefore to create value by finding ways for the parties to work together,[72] and then to use that value to bridge the gaps between the parties' respective risk-adjusted positions.[73]



Such bargaining allows agreement by making settlement preferable to litigation, without forcing the parties to abandon deeply-held positions regarding the underlying dispute.[74]

Moreover, compromises based on such integrative bargaining will tend to be procompetitive. In our hypothetical above, for example, the parties create $150 million in cost savings and otherwise-unrealized profits—and the cost savings for Generic may allow it to offer its product at a lower price than it could if forced to buy raw

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is sometimes possible on this basis, however, should not be confused with its being *always* possible. Moreover, even where settlement eventually becomes possible, foreclosing settlement possibilities will tend to extend litigation, as the parties can bridge gaps only after developments in the case make clear how the court is likely to rule. *Actavis* should not be read to promote a rule requiring such inefficiencies.

72. *See* SHELL, *supra* note 9, at 12 (integrative, "cooperative," or "problem-solving" bargaining the "ideal" way to reach agreement in complex situations).

73. *See* Duffy Tool & Stamping, L.L.C. v. NLRB, 233 F.3d 995, 998 (7th Cir. 2000) (Posner, J.) ("A negotiation is more likely to be successful when there are several issues to be resolved . . . rather than just one, because it is easier in the former case to strike a deal that will make both parties feel they are getting more from peace than from war."); *In re* Cipro Cases I & II, 348 P.3d 845, 868 (Cal. 2015) ("Parties can still use financial considerations to bridge small gaps arising from differing subjective perceptions of their probabilities of success in litigation."); WATKINS & ROSEGRANT, *supra* note 9, at 29–31; GOLANN, *supra* note 69, at 243; FISHER & URY, *supra* note 63, at 58 (urging negotiators to "Invent Options for Mutual Gain"); WILLIAM URY, GETTING PAST NO 118 (Bantam, 1991); Alex J. Hurder, *The Lawyer's Dilemma: To Be or Not to Be a Problem-Solving Negotiator*, 14 CLINICAL L. REV. 253, 266 (2007).

74. Hurder, *supra* note 73, at 255 ("Negotiation theory assumes that the possibility of creating value greater than the sum of the parts is the motivation for the parties to negotiate an agreement."); URY, *supra* note 73, at 160 (goal "*not to win over them, but to win them over*"); Eilerman, *supra* note 68 ("Compromise is more successful when the parties have a range of tangible outcomes that are open for consideration such that the final decision is one that remains 'within the box' for both parties.").

material from less-efficient producers.[75] Similarly, a co-development agreement between settling parties may create a valuable new product that substantially benefits consumers.[76] Integrative bargaining therefore will tend to be frequently procompetitive.

Such traditional win-win compromises would be threatened, if not curtailed entirely, by the application of the antitrust rule of reason (with its extremely expensive litigation process[77]). Such antitrust scrutiny cannot be justified as avoiding delay in generic entry. On the contrary, under *Actavis* an initial benefit for the patentee (rather than an initial sacrifice) should if anything be inferred to have encouraged *earlier* entry than the patentee's risk-adjusted litigation expectation.[78] In the same way that a court could infer from the existence of a patentee sacrifice that it might have received a later entry date, a court could infer from a patentee *benefit* that it might have been willing to allow an earlier entry date in exchange for receiving the benefit of the settlement. Such an agreement should thus, under *Actavis*'s reasoning, be viewed as likely procompetitive, and certainly not as suspect.[79] Mutually-beneficial integrative bargaining therefore would seem to be encouraged—and certainly cannot be condemned—under *Actavis*.

3. *Focusing on the Patentee Sacrifice Promotes Judicial Efficiency*

The final reason for focusing on the patentee's sacrifice is that the alternative would be unworkable. Courts that instead focus on the generic's benefit cannot use *Actavis*'s inference of patent weakness to guide their analysis, because the generic's receipt of a benefit tells us nothing about the strength or weakness of the patent—a generic generally would accept such a benefit even if it viewed the patent as incredibly strong. Instead, courts adopting this standard would be tasked with comparing the benefit the generic received against a hypothetical ideally-competitive alternative agreement—

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75. *See, e.g.*, Paladin Assocs. v. Mont. Power Co., 328 F.3d 1145, 1157 (9th Cir. 2003) (more efficient systems procompetitive); Seagood Trading Corp. v. Jerrico, Inc., 924 F.2d 1555, 1570 (11th Cir. 1991) (economies of scale procompetitive).

76. *See, e.g.*, United States v. Brown Univ., 5 F.3d 658, 674–75 (3d Cir. 1993) ("Enhancement of consumer choice is a traditional objective of the antitrust laws and has been acknowledged as a procompetitive benefit.").

77. Kimble v. Marvel Entm't, LLC, 135 S. Ct. 2401, 2411 (2015) (rule of reason inquiry "produces notoriously high litigation costs and unpredictable results").

78. *See supra* Part III(A).

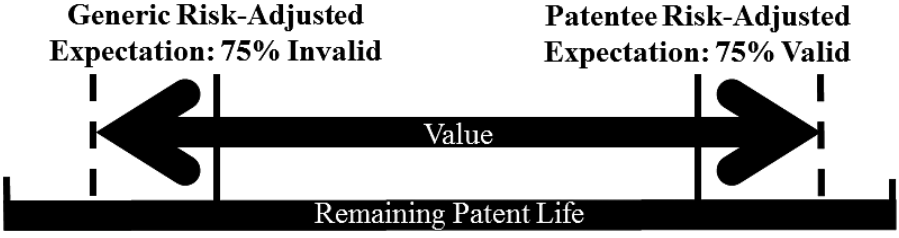
79. *See id.*

determining what the generic "should" have received in a competitively "perfect" settlement, and asking whether the settlement achieved that "right" answer.[80]

No wonder that courts taking this approach view *Actavis* as inscrutable, as a court focusing on the generic's benefit will find little or nothing in *Actavis* to help them determine the potential competitive impact of an agreement. Such a rule thus would leave courts forced either to construct their own framework for assessing such benefits, or to accept the idea that all settlements involving the exchange of value—including all integrative bargaining—should be subject to full-blown antitrust litigation.[81]

4. *Even a Substantial Mutual Benefit Cannot Create Antitrust Concerns under* Actavis

As shown above, mutually-beneficial agreements that merely bridge gaps between the parties' positions thus must be distinguished from the large, unexplained reverse payments in *Actavis*. In some cases, however, the parties may do more than merely bridge a gap—they may create such substantial value that they no longer have a gap to bridge, but rather multiple points of overlap.[82]



Settlement in such a case should be achievable, as each party now prefers settlement to litigation—and the parties have a range of possible settlement outcomes from which to choose.[83] However, it might be argued that such an agreement, if sufficiently valuable, could result in generic entry later than the patentee's risk-adjusted

80. *See infra* Part III(C)(3) (explaining the difficulties of such an inquiry).

81. *See infra* Part III(C)(1).

82. Harris, *supra* note 2, at 87 ("[A]s the payment grows the Generic's reservation entry date eventually reaches, and then surpasses, [Brand's] reservation entry date.").

83. JOHN BURWELL GARVEY & CHARLES B. CRAVER, SKILLS AND VALUES: ALTERNATIVE DISPUTE RESOLUTION: NEGOTIATION, MEDIATION, COLLABORATIVE LAW AND ARBITRATION 35 (2013) (When overlap exists, the "participants should be able to achieve accords.").

litigation expectation, and thus that it should be suspect under *Actavis*. This view is incorrect for three reasons.

First, as noted, *Actavis* depends on an inference of delayed generic entry based on the patentee's sacrifice.[84] Where, as here, there is no such sacrifice, there is likewise no basis for such an inference—and thus courts would be left to subject *all* mutually-beneficial agreements to antitrust litigation just in case a full examination of the patent merits (as would be required without *Actavis*'s inferences) might show that the agreement was anticompetitive.[85] *Actavis* does not permit or require such inquiries.

Second, similar to the *Trinko* Court's refusal to condemn conduct merely because some other conduct might have been more procompetitive, arms-length settlements should not be condemned because there might have been an alternative approach that would further enhance competition.[86]

Finally, as shown above, *Actavis* does not require a patentee to forego a profitable side agreement purely so that it can prevent the generic from profiting, any more than each child in Fisher & Ury's example must throw away half the orange to prevent the other child from benefiting.[87] *Actavis* is not intended to avoid the creation of value, but rather only the creation of value *from delay in generic entry*. Where the parties mutually benefit, there is no basis to infer such delay.

5. *Both a Patentee Sacrifice and Generic Benefit Must Plausibly Be Alleged*

As shown above, courts must focus primarily on whether the patentee sacrificed by entering an agreement. One caveat is appropriate, however. There may be cases in which the patentee makes a sacrifice, but the generic receives no benefit—a "lose-lose" agreement that makes both parties worse off, and which could not therefore be treated as a suspect reverse payment any more than a "win-win" fair

84. *See supra* Part II(B).

85. *See supra* Part III(A)(3).

86. *See, e.g.*, Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 415–16 (2004).

87. *See supra* Part III(A)(2); *see also* Kent Bernard, *Hatch-Waxman Patent Case Settlements—The Supreme Court Churns the Swamp*, 15 MINN. J. L. SCI. & TECH. 123, 132 (2014) ("[A] payment that can be fully explained as compensating the generic for real services (say, distributing product) almost has to be legal. The alternative would be to hold that once patent litigation is filed, the two parties cannot do ordinary business together, which would be ludicrous.").

value agreement could be. To avoid condemning "lose-lose" agreements, plaintiffs must allege *both* a patentee sacrifice *and* generic benefit, as without both elements there can be no "payment."[88] However, because "win-win" agreements may be more common than "lose-lose" agreements, courts should first ask whether there is a patentee sacrifice—and if not, there is no basis for antitrust scrutiny.

B. *Courts Must Consider the Distinction between Payments and Compromises at the Outset to Avoid Deterring Procompetitive Settlements*

As described above, traditional "win-win" fair value agreements involving an initial benefit to the generic and the patentee will tend to be procompetitive. Courts must therefore be careful to avoid reading *Actavis* in such a way as to chill the very competition the Court meant to encourage—as settling parties will not enter even a procompetitive settlement if doing so predictably will result in antitrust litigation. To avoid deterring such settlements, courts must require plausible allegations that the agreement at issue in any given case contains a patentee sacrifice, not merely fair value for both sides. Where no such allegations are present, reverse payment settlement claims should be dismissed at the outset.

1. Actavis *Recognized the Importance of Settlement*

Actavis reiterated the longstanding principle that courts should defer to out-of-court settlements whenever possible.[89] Settlement avoids unnecessary litigation, thereby saving substantial costs for litigants and often creating value for consumers.[90] It likewise creates substantial societal benefits by easing the burdens on courts and taxpayers.[91] It permits procompetitive patent challenges that might otherwise be avoided if there were no way to subsequently exit the

88. *See, e.g.*, *Lamictal*, 791 F.3d at 388 (requiring plausible allegation of generic benefit in addition to patentee sacrifice).

89. *See Actavis*, 133 S. Ct. at 2230 (acknowledging "public policy favoring settlement of disputes"); *id.* at 2234 ("We recognize the value of settlements . . . ."); Wygant v. Jackson Bd. of Educ., 476 U.S. 267, 305 (1986) ("general policy in favor of settlements").

90. *See, e.g.*, Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FL. L. REV. 747, 748–49 (2002) ("[S]ettlement agreements are voluntary, pareto-optimal, and presumptively efficient arrangements that public policy typically encourages.").

91. *See id.* at 756 ("For every incremental dollar spent in litigation by the litigants, additional costs are often incurred by the judicial system as well.").

litigation without driving it to the bitter end or facing antitrust litigation as a result of settling.[92] And it prevents harm to competition that might result from the process of litigation itself—such as through disclosure of confidential information to competitors in discovery.[93] The "desirability of settlements" thus remains a "strong consideration" after *Actavis*.[94] Reasonably so; though we do not yet know what impact *Actavis* will have on the ability of patentees to settle, studies focusing on patent disputes pre-*Actavis* have shown that most patent cases, by far, were resolved by settlement.[95]

Courts applying *Actavis* must therefore focus on patent settlements that present legitimate antitrust risks, and not expose to litigation (much less liability) those that benefit competition. Although, as Professor Hovenkamp has said, "[s]aying that a practice is subject to the antitrust laws . . . is not to conclude that it violates them,"[96] as

92. *See, e.g.*, *Actavis*, 133 S. Ct. at 2247 (Roberts, J., dissenting) ("Taking the prospect of settlements off the table—or limiting settlements to an earlier entry date for the generic, which may still be many years in the future—puts a damper on the generic's expected value going into litigation, and decreases its incentive to sue in the first place."); *Niaspan*, 42 F. Supp. 3d at 741 (same); *Loestrin*, 45 F. Supp. 3d at 183–85; *see also* Bret Dickey & Jonathan Orszag, *The Benefits of Patent Settlements: New Survey Evidence on Factors Affecting Generic Drug Investment*, GENERIC PHARMACEUTICAL ASSOCIATION (July 23, 2003), at 6–7, http://www.gphaonline.org/media/cms/Dickey_Orszag_Benefits_of_Patent_ Settlements_2012-07-21_FINAL.pdf; *cf.* FTC v. AbbVie Inc., 107 F. Supp. 3d 428, 435 (E.D. Pa. 2015) (*Actavis* does not force "an otherwise blameless patent challenger to litigate to the death").

93. *See* Crane, *Exit Payments*, *supra* note 90, at 757–59 (extending litigation "may impose a variety of 'social costs'" including "enable[ing] either the alleged infringer or the patentee to freeride on its competitor's trade secrets" and "caus[ing] competitor firms to lose confidence in the confidentiality of their internal processes").

94. *Actavis*, 133 S. Ct. at 2237; *see also In re* Effexor XR Antitrust Litig. ("Effexor"), 2014 WL 4988410, at *18 (D.N.J. Oct. 6, 2014) ("[T]he Supreme Court was cognizant of the value of settlements and the strong interest in settling complex and expensive patent infringement litigations"); *AbbVie*, 107 F. Supp. 3d at 435 ("undue scrutiny of settlements between Paragraph IV litigants can endanger the amicable resolution of disputes.").

95. *See* Megan M. La Belle, *Against Settlement of (Some) Patent Cases*, 67 VAND. L. REV. 375, 377 (2014) (finding that roughly two-thirds of patent cases are settled at the district court level, and that others are settled on appeal); Bernard, *supra* note 87 at 124 ("Some ninety-five percent of all patent cases are resolved by settlement before a court judgment. . . . Only someone who has either never litigated, or never worried about a litigation budget, would suggest a 'no settlements' rule.").

96. Herbert Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76 OHIO ST. L.J. 467, 516 (2015).

Justice Roberts noted, "there would be no incentive to settle if, immediately after settling, the parties would have to litigate the same issue."[97] And because such a result prevents procompetitive arrangements, the harm to competition that results from such judicial errors is likely to be substantial.[98]

2. Actavis *Thus Requires Plausible Allegations of a Large, Unexplained Reverse Payment, Particularly Where the Alleged Payment Is Not in the Form of Money*

To protect such settlements, determining whether a given agreement involves a patentee sacrifice is a necessary threshold inquiry in any case under *Actavis*—as without a patentee sacrifice, there is no "surrogate" from which to infer the possibility of anticompetitive harm.[99] However, this threshold inquiry takes on a layer of complexity when the alleged payment is not in the form of money.[100] As discussed below, many non-monetary forms of settlement are not appropriate for *Actavis* scrutiny in the first place as they are "traditional" rather than "unusual" settlement forms.[101] But even where such scrutiny could be appropriate, a court must require plausible allegations that the settlement contains a sacrifice, and not permit claims to proceed based merely on the possibility that a settlement *might*, if exposed to years of antitrust litigation, prove suspect.

For example, in our hypothetical above, Brand supplies Generic with 1 billion units of raw material for $0.50 per unit, receiving a *forward* payment of $500 million. Assuming that this type of traditional supply agreement can be suspect under *Actavis* in the first place—and as discussed below, it should not be—is the settlement

97. *See Actavis*, 133 S. Ct. 2243 (Roberts, C.J., dissenting); *see also Kimble*, 135 S. Ct. at 2411 ("whatever its merits may be for deciding antitrust claims, [rule of reason's] 'elaborate inquiry' produces notoriously high litigation costs and unpredictable results").

98. *See* Frank H. Easterbrook, *On Identifying Exclusionary Conduct*, 61 NOTRE DAME L. REV. 972, 977 (1986) ("[F]alse positives are much more harmful than false negatives. Market processes undercut monopolies wrongfully permitted, but no similar processes undercut judicial decisions that wrongly condemn efficient conduct."); Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co., 549 U.S. 312, 320 (2007) ("costs of erroneous findings of predatory-pricing liability were quite high" and could "chill the very conduct the antitrust laws are designed to protect"); Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 226 (1993) (same).

99. *Actavis*, 133 S. Ct. at 2236–37.

100. Edlin, *The* Actavis *Inference*, *supra* note 32, at 599 ("If the noncash payment consists of products or services, then the associated cost to the branded firm (including the opportunity cost) must be alleged and eventually proven.").

101. *See infra* Part V.

described here plausibly alleged to be a suspect reverse payment? Without a plausible allegation that the brand provided the raw material significantly below cost, the answer must be "no," as this agreement lacks the patentee sacrifice on which *Actavis* depends. Dismissal would therefore be appropriate.

3. *Courts Reaching Contrary Results Tend to Err in One of Four Ways*

Courts reaching a contrary result have made four types of errors:

First, some courts have allowed antitrust litigation to proceed based on nothing more than the allegation that the generic received value—often without even asking whether the patentee *sacrificed* value.[102] But as discussed above, courts must require plausible allegations of a patentee sacrifice.[103] Nor can such a sacrifice be *inferred* from the presence of a generic benefit—while a generic benefits from a win-win compromise, the patentee does so as well. Courts thus cannot assume that a generic "win" is accompanied by a "loss" by the patentee. Indeed, such an assumption would defy common sense—if every agreement that is profitable for party A were therefore a loss to party B, agreements would never be entered.

Second, even focusing on the patentee's perspective, some courts refuse to dismiss in light of the Court's refusal to dismiss under very different circumstances in *Actavis*.[104] But *Actavis* did not adopt a blanket rule under which a plaintiff need only suggest the *possibility* that an agreement was unprofitable to the patentee. Rather, *Actavis* held only that a *plausibly alleged* patentee sacrifice could satisfy the relevant pleading standards. That a patentee sacrifice was perhaps deemed to have been plausibly alleged in *Actavis* thus does not mean that such a sacrifice is plausibly alleged in every case.[105]

Third, some courts misread a passage of *Actavis* to suggest that defendants always have the burden to prove that there is *not* a reverse payment—without the plaintiffs first being required to plausibly plead that there *is* such a payment. *Actavis* made clear that a settlement agreement would not violate the antitrust laws if it represented "fair value for services," but noted that this possibility did not in that case justify dismissal of the complaint because the existence of such "justifications" would need to be shown by the defendant

102. *See infra* note 135 (describing such cases).
103. *See supra* Part III(A).
104. *Actavis*, 133 S. Ct. at 2236.
105. *See, e.g.*, Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) ("The plausibility standard . . . asks for more than a sheer possibility.").

rather than assumed on a motion to dismiss.[106] Some courts have used this language to hold that it is the burden of the defendants to prove that a reverse payment does not exist—that the patentee did not make a sacrifice.[107] For example, under this standard a plaintiff in our hypothetical would need only claim that Brand paid Generic $600 million—and leave it to Brand and Generic to show that a supply agreement with *Generic* paying *Brand* $500 million for product costing Brand $450 million is not a sacrifice by Brand. This is error.

Before a defendant can be required to disprove the claim of a reverse payment, a complaint must first plausibly allege that there *is* such a payment—that the terms of the agreement involve a sacrifice by Brand.[108] True, if such plausible allegations are put forth, the "possibility" that the agreement in fact "reflect[ed] traditional settlement considerations, such as avoided litigation costs or fair value for services"[109] will not be sufficient to avoid antitrust scrutiny. But when there is no plausible allegation of a large, unexplained reverse payment, there is no viable antitrust claim.[110] Indeed, any other approach would not merely reinstate the "quick look" test the Supreme Court rejected in *Actavis*, it would replace it with an *even quicker* look test under which the reverse payment itself is assumed.[111] *Actavis* intended no such result.

Finally, plaintiffs sometimes complain that they may know only that there was a side agreement associated with a settlement (or even just that a settlement was entered), and assert that they wish to bring a claim to *find out* if it involved a suspect payment. Some courts have permitted such claims to proceed, sometimes on the theory that

106. *Id*. at 2236.

107. *See, e.g.*, *Nexium*, 42 F. Supp. 3d at 263–64 (treating the fair value of the settlement agreement solely as a defense).

108. *See Actavis*, 133 S. Ct. at 2236 (where there is no lack of fair value, "there is not the same concern" under *Actavis*). *See also, e.g.*, United States v. Arnold, Schwinn & Co., 388 U.S. 365, 375 (1967) (plaintiff must initially show that "the effect upon competition in the marketplace is substantially adverse"), *overruled on other grounds by* Cont'l T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 58–59 (1977); Clorox Co. v. Sterling Winthrop, 117 F.3d 50, 59–60 (2d Cir. 1997) (requiring initial showing of harm to competition); U.S. Healthcare v. Healthsource, Inc., 986 F.2d 589, 596–97 (1st Cir. 1993) (same).

109. *See Actavis*, 133 S. Ct. at 2236.

110. *See id*.

111. *Id*. at 2237. Under the quick look test, the anticompetitiveness of conduct is assumed and the defendants are then tasked with proving that sufficient procompetitive benefits exist to outweigh that assumed anticompetitiveness. But even under the quick look test, a plaintiff must first show that the conduct *occurred*. Here, a patentee sacrifice would simply be assumed to exist, unless shown not to exist. *Actavis* intended nothing of the sort.

the facts are primarily in the defendants' possession.[112] This approach flies in the face not only of *Actavis* but also of *Twombly*.[113] The *Twombly* rule requiring a *plausible* basis for antitrust claims may reduce to some extent the effectiveness of private antitrust enforcement in cases where the facts are primarily in the possession of a defendant, as the plaintiff may not have the facts available to construct a plausibly-pleaded complaint in some cases. But this concern is hardly limited to *Actavis* cases—and if anything is a greater concern in traditional price-fixing conspiracy cases such as *Twombly* itself, as price-fixing agreements are typically conducted in secret rather than announced in the open like a patent settlement. However, this does not suggest that courts should overrule *Twombly* by permitting antitrust claims *without* a plausible basis—particularly where, as here, allowing such fishing expeditions will deter procompetitive conduct, and where the Medicare Modernization Act of 2003 permits the FTC broad access to patent settlements and the right to enforce the antitrust laws.[114] Courts thus should not read *Actavis* as amending *Twombly*'s plausibility standard.

Courts must therefore require a plausible allegation of a suspect patentee sacrifice, and thus distinguish such agreements from procompetitive, mutually-beneficial agreements the Court did not seek to discourage.[115] However, even where such a claim is plausibly pleaded, this does not mean that it has been proven. That a large, unexplained reverse payment can in some cases be suspect is only the first step in the analysis—suspicion is not liability, and even if the agreement is sufficiently suspect to subject it to the deterrent effects of antitrust litigation, courts must then weigh the agreement under the rule of reason as *Actavis* demands.[116]

C. *Other Approaches Misunderstand* Actavis

As illustrated above, the standard for a reverse payment under *Actavis* is a sacrifice by the patentee for the benefit of the generic.

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112. *See, e.g.*, *In re* Cipro Cases I & II, 348 P.3d at 866–67.

113. Bell Atl. Corp. v. Twombly. 550 U.S. 544 (2007).

114. Medicare Modernization Act of 2003. Pub. L. No. 108-173 § 1112, 117 Stat. 2066, 2461–62 (2003).

115. Plausible allegations of a suspect patentee sacrifice do not necessarily require a showing of "precise figures and calculations at the pleading stage." *See Loestrin*, 814 F.3d at 552. However, a plausible claim under *Actavis* does require meeting the *Twombly* standard of plausibility—which cannot be met by mere conclusions and blanket allegations.

116. *See Actavis*, 133 S. Ct. at 2237.

Courts therefore must avoid other approaches that would not follow the *Actavis* framework. We illustrate four such errors below.

1. *The "Any Value" Test*

The focus on the patentee's sacrifice in *Actavis* represents the Supreme Court's rejection of the "any value" standard, under which, as one court put it, it would be unlawful for the generic to receive "anything of value . . . that can induce [the generic] to 'give up the patent fight.'"[117] Courts that adopt such a standard therefore do so in error for at least three reasons.

First, and most crucially, the "any value" standard requires ignoring *Actavis*'s focus on the patentee as described above. The Supreme Court could have adopted an "any value" approach had it been so inclined, but it chose instead to adopt the approach seen in *Actavis*—which focused instead primarily on the patentee's sacrifice, not the generic's receipt of a benefit.

Second, the "any value" standard would treat all integrative bargaining as reason for a full-blown antitrust case, and treat the very fact that the patent litigants settled (i.e., "g[a]ve up the patent fight") as evidence of anticompetitiveness.[118] This would do substantial damage to the settlement process. For example, in our hypothetical above Brand agrees to a mutually-beneficial arrangement that tends to allow earlier entry. However, under the "any value" test this procompetitive settlement would be condemned to full-blown antitrust litigation, and thus effectively deterred, solely because *both* sides initially benefited, and this benefit convinced the parties to settle. *Actavis* did not accept such a result.[119]

Third, because the "any value" rule would forbid the generic from receiving any benefit that might convince it to compromise away from its litigation position, the rule would force patent litigants to either engage in distributive bargaining—if they happen to agree on the patent merits—or to bridge gaps through a peculiar agreement in which the patentee completely surrenders with respect to the entry date, and the generic compensates the patentee for losing a substantial portion of its patent rights[120]:

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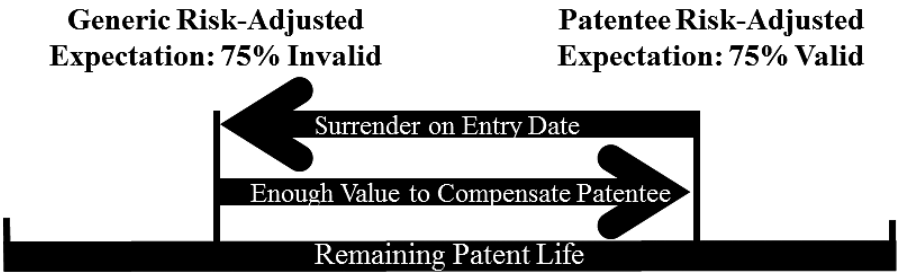
117. *Niaspan*, 42 F. Supp. 3d at 751 (quoting *Actavis*, 133 S. Ct. at 2235–36).

118. *See Actavis*, 133 S. Ct. at 2236; Bernard, *supra* note 87, at 132 (2014) (rejecting view that requires "no value" agreements).

119. *See Actavis*, 133 S. Ct. at 2230 (noting continued value of settlement).

120. *See, e.g.*, Kenneth Glazer & Jenee Desmond-Harris, *Reverse Payments: Hard Cases Under Even Good Law*, ANTITRUST 14, 19–20 (Spring 2010) (arguing for "any value" rule under which only surrender by patentee avoids scrutiny).



Such an agreement, in which the generic pays to move the patentee to its position, is hard to imagine in practice.[121] It is rare that the patentee is willing to completely surrender,[122] and even if it were, such capitulation may not be achievable as virtually nothing a generic challenger could pay could reasonably compensate the patentee for losing its patent rights.[123]

2. *The "Outside Litigation" Test*

Nor should courts limit patent settlements to only those agreements the parties would have entered "outside of litigation"—a rule

121. Nonetheless, some authors prescribe royalties as the sole way that parties should be permitted to bridge gaps between their litigation expectations. *See, e.g.*, Cristofer Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements: Payments by the Patent Holder Should be Per Se Illegal*, 21 RESEARCH IN LAW AND ECONOMICS 475 (Elsevier 2004) (arguing that unless patentee very confident in its patent litigation position, royalties should always permit settlement). But it is unlikely in many cases that any royalty rate would be high enough to compensate for patentee surrender, and harder still to imagine the generic agreeing to pay such rates. *See* Crane, *Exit Payments*, *supra* note 90, at 767 ("even the discounted royalty payment may not provide a sufficient incentive for the alleged infringer to forgo its right to insist that its present use - without any associated royalty cost - is non-infringing"); Addanki & Butler, *supra* note 2, at 82–83 (even if parties recognize "right answer" that patent case 50% likely to succeed, unlikely to reach agreement at 50% patent life); Harris, *supra* note 2, at 87 (in some cases "[n]o settlement is possible without payment by the Brand to the Generic").

122. *See, e.g.*, Bernard, *supra* note 87, at 131 ("[A]*ny* settlement agreement involves some sort of consideration to the defendant—whether in the form of foregone damages, express monetary payment, or other benefit. Settlement, after all, is a compromise—not total surrender.").

123. In the Hatch-Waxman context, such agreements would be even more difficult in light of differences in how the patentee and generic value time-on-the-market. *See* Kevin D. McDonald, *Because I Said So: On the Competitive Rationale of* FTC v. Actavis, 28 ANTITRUST 36, 37 (Fall 2013) (explaining the difficulty of settlement in Hatch-Waxman litigation) (citing Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 408 (2003)).

that seeks to constrain integrative bargaining to the point of strangling it.[124] For example, in our hypothetical above Brand would not ordinarily offer its competitor a $0.10 discount, and Generic would not ordinarily provide its competitor even a $0.05 profit. But settlement is different, because the benefits of peace outweigh the reluctance to deal with litigation adversaries.[125] Perhaps it is true, as some authors note with suspicion, that some types of agreements reached by patent litigants *inside* litigation are not also routinely reached between the same parties *outside* litigation.[126] But, then, neither are settlements.

When parties must bridge gaps between their litigation positions to reach agreement, the integrative bargaining model of negotiation suggests that they should find a way to reach outside their dispute to create value.[127] Such efforts often involve entering agreements that a party might not have entered in the ordinary course of business, but that nonetheless create substantial value and thus allow the parties to bridge gaps between their litigation positions. The ability to find such inventive ways to create value and reach settlement is what makes integrative bargaining procompetitive, not reason to deter it.[128] *Actavis* therefore correctly declined to adopt the "outside litigation" test.

3. *The "Market Value" Test*

Some authors have similarly argued that a patent settlement must proceed on the same terms the parties might have agreed to in

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124. *See, e.g.*, Edlin, *Activating* Actavis, *supra* note 2, at 18 (demanding such a rule); C. Scott Hemphill, *An Aggregate Approach to Antitrust*, 109 COLUM. L. REV. 629, 633 (2009) (same).

125. Michael Moffitt, *Three Things to Be Against ("Settlement" Not Included)*, 78 FORDHAM L. REV. 1203, 1207 (2009) ("The prospect of litigation shapes settlement behaviors and settlement outcomes.").

126. *See, e.g.*, *Hemphill*, *supra* note 124, at 633.

127. *See* Carrie Menkel-Meadow, *Toward Another View of Legal Negotiation: The Structure of Problem Solving*, 31 UCLA L. REV. 754, 771–72 (1984); Bernard, *supra* note 87, at 130 ("[W]hen we evaluate a settlement involving services or products provided by the alleged infringer, the question cannot rationally be whether the parties would have done the deal absent the litigation. Such a test would eviscerate the Court's opinion as to legitimacy of fair value deals.").

128. *See, e.g.*, FISHER & URY, *supra* note 63, at 60–62; Zwier & Guernsey, *supra* note 71, at 6 ("The power of creative problem-solving is particularly evident in situations where adversarial negotiation might lead to deadlock.").

an arms-length transaction in the market—and that a court can decide what those "market value" terms would or should have been.[129] For example, in our hypothetical, Brand provides raw material to Generic at a price below the market rate, resulting in a profit for both sides. Under the "market value" test, this agreement would be condemned to antitrust litigation, however, because Brand theoretically could have charged a higher, market price—though of course Generic would then have bought from someone else. However, when the patentee is made richer (or at least no poorer) by an agreement, the possibility that it might have earned even greater profits through an alternative "market value" agreement cannot transform the patentee's profit into a suspect reverse payment sacrifice.[130] This is so not only because mutually-profitable agreements are often procompetitive, as discussed above,[131] but also for at least five additional reasons.

First, as noted, the Supreme Court held that "fair value" settlements were permissible—it never spoke in terms of "market value" or any similar terms.[132] Courts therefore must not adopt an approach based on requiring the parties to reach "market value."

Second, as with the "outside litigation" test, the "market value" test misunderstands integrative bargaining—which seeks to create value to bridge gaps and facilitate settlement by reaching outside the parties' dispute, not (as these tests assume) to recreate a hypothetical agreement that could or would have been entered outside litigation.[133]

Third, under the "market value" approach courts would be tasked with deciding whether a patentee has made the *best* choice out of all available business options—including deciding which options were realistic and which fit the company's overall business strategies. Such a rule would be unadministrable. For example, in complex business deals, the package of goods or services is often unique and

129. *See* Edlin, *The* Actavis *Inference*, *supra* note 32, at 594 (arguing that settling parties are obligated to obtain the same value from side deals that they would receive by entering into "arms-length, stand-alone" transactions).

130. *See, e.g.*, *AbbVie*, 107 F. Supp. 3d at 436 ("The FTC would have the court allow Count II to go forward simply because the FTC believes Abbott signed a bad deal for itself and a good deal for Teva. What the FTC does not seem to recognize is that the benefit flowing to Teva is also a benefit flowing to consumers who will now be able to purchase the generic form of TriCor at a reduced price."). *But see Nexium*, 42 F. Supp. 3d at 263–64 (concluding that side agreements were not fair value if "highly lucrative" for the generic).

131. *See supra* Part III(A)(2).

132. *See Actavis*, 133 S. Ct. at 2237.

133. *See supra* Part III(C)(2).

difficult to value—often by design, as settling parties' differing valuations facilitate settlement.[134] And even if a comparable package can be found, many a businessperson has taken the second-lowest bid because it offered a better product, has given a good customer a discount, has foregone a deal because it conflicted with overall strategy, etc.[135] A court seeking to determine whether a decision was "market value" must therefore substitute its business—not legal—judgment, and decide which profitable transaction a company *should* have preferred. *Actavis* does not put courts in such an awkward position.[136] Instead, the Court asks only that a settlement be for fair value.[137]

Fourth, as others have pointed out, a rule that condemns profitable agreements because there was a theoretical alternative would conflict with *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*,[138] which held that it was not an antitrust violation to charge an above-cost price simply because an even more profitable (i.e., higher) price would have encouraged greater competition.[139]

Finally, a rule *requiring* that agreements entered in connection with settlement represent "market value" would simultaneously *prevent* market rate agreements.[140] No party would settle for what it

134. *See, e.g.*, GARVEY & CRAVER, *supra* note 83, at 35–36 (noting that "[t]oo many bargainers make the mistake of assuming that the parties have a fixed amount of goods to be divided—i.e., identical value systems and analogous utility functions that generate zero-sum transactions," but that in fact "parties value the various items quite differently," allowing them to "look for exchanges that can simultaneously benefit both sides" by "expand[ing] the overall pie"); FISHER & URY, *supra* note 63, at 75; URY, *supra* note 73, at 118 ("The most common way to expand the pie is to make a low-cost, high benefit trade. Identify items you could give the other side that are of high benefit to them but low cost to you.").

135. *See* Utd. Artists Theatre Co. v. Walton, 315 F.3d 217, 231 (3d Cir. 2003) ("The art of governing [a company] (it is emphatically not a science) is replete with judgment calls and 'bet the company' decisions that in retrospect may seem visionary or deranged, depending on the outcome."). Moreover, business is rarely "zero sum"—a profit on one deal rarely means sacrificing a greater profit elsewhere, as the market value test assumes.

136. *See, e.g.*, United States v. Topco Assocs., 405 U.S. 596, 609 (1972) ("[C]ourts are of limited utility in examining difficult economic problems.").

137. *Actavis*, 133 S. Ct. at 2237. *See also* Gregory J. Werden (Senior Economic Counsel for the DOJ's Antitrust Division), *The "No Economic Sense" Test for Exclusionary Conduct*, 31 J. CORP. L. 293, 304 (Winter 2006) ("Many business decisions ultimately prove unprofitable because of misfortune or ineptitude, and the antitrust laws do not add insult to injury by deeming as exclusionary all unprofitable conduct.").

138. 509 U.S. 209, 226 (1993).

139. Guha & Grannon, *supra* note 54.

140. *See supra* Part III(A)(2) (requiring parties to reach agreement in the shadow of the rule of reason will tend to prevent agreement); Fischman, *supra* note 50, at 131 (noting the feedback loop between *Actavis* and settling litigants).

views as market value if that business judgment would then be subject to second-guessing in antitrust litigation—with plaintiffs seeking to argue that some other arrangement would have been better or closer to "market." A market value test is therefore a test barring market value settlements—a rule *Actavis* never contemplates.

4. *The "Equal Value" Test*

For many of the same reasons, fair value does not mean "equal value." In our hypothetical, both Brand and Generic benefit—Brand through a $50 million profit, Generic through $100 million in savings. Nothing in *Actavis* requires parties to reject such positive outcomes merely to deny their opponents their own positive outcomes.[141] However, when starting from the incorrect premise that there is a "right answer" to patent litigation, there can be a temptation to try to decide who "won" the settlement—and if the generic "won" to then treat that as a "reverse payment."[142] Such a rule would create metaphysical questions about what constitutes a "good" or "equal" deal, and who "wins" when both sides do.

Actavis does not ask courts to deal in such questions.[143] On the contrary, *Actavis* blesses even "unequal" results, for example recognizing that a patentee may choose to pay litigation costs to the generic rather than pay those same costs to its lawyers[144] even though such an outcome is more advantageous for the generic than the patentee.[145] The "equal value" test therefore must also be rejected, and

141. *See supra* Part III(A)(2) (*Actavis* does not require settling parties to throw away half the "orange" by preventing mutually-beneficial agreements).

142. *See supra* Part III(A)(2) (explaining why distributive model of settlement is frequently not available in patent litigation).

143. *See, e.g.*, Fed. Trade Comm'n v. AbbVie Inc., et al., 107 F. Supp. 3d 428, 436 (E.D. Pa. May 6, 2015) (refusing to permit antitrust case to proceed when based on questions about whether the agreement was a "good deal" for generic or "bad deal" for the brand); Mathewson Corp. v. Allied Marine Indus., Inc., 827 F.2d 850, 857 (1st Cir. 1987) ("It ill behooves a court, in the ordinary case, to inquire into the reasons underlying an arm's-length settlement or to attempt to calibrate peculiarly private scales in order to determine who may have gotten the better of the bargain. In a very real sense, all of the parties—and the court, as an institution—win when litigation is settled amicably short of trial.").

144. *See supra* Part III(A)(1).

145. Though *Actavis* did not address the situation in which the patentee pays the generic's sunk litigation costs instead of (or in addition to) the patentee's saved litigation costs, such a payment would be too small to suggest patent weakness for the same reasons discussed generally below. *See infra* Part IV(A) (noting that the size of the payment must be sufficient to provide meaningful information regarding the patent's strength or weakness).

courts must instead look for the plausible allegation of a patentee sacrifice on which *Actavis* relies.

IV. Payments Must Be Large Enough to Provide Meaningful Information Regarding Patent Weakness

Even if a payment is a sacrifice by the patentee, this alone cannot make it suspect under *Actavis*. As discussed in Part II above, *Actavis* relies on a large, unexplained reverse payment as a "surrogate" for patent weakness. Thus a "large" payment necessarily must be sufficiently sizable as to provide meaningful information regarding the patent's merits.[146] To determine whether a sacrifice is large enough to provide such information, *Actavis* looks to the payment's "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."[147] In doing so, the court should not limit the definition of avoided litigation costs to only fees paid to lawyers or experts, but rather should also consider the indirect costs of continuing to litigate a large patent matter.[148] If a payment is insufficient to provide meaningful information regarding the strength or weakness of the patent under this standard, *Actavis* scrutiny should not apply.

A. *The Size of Any Alleged Payment Must Provide Meaningful Information Regarding the Patent Merits*

In our hypothetical, Brand "paid" Generic by selling it 1 billion units of raw material at $0.50 per unit to settle litigation regarding a $10 billion per year product. But now assume that to show a profit sacrifice by Brand, the plaintiff alleges that *other* companies claim that their costs are $0.55 per unit, so that if the same were true for Brand, it would sacrifice $50 million by selling 1 billion units at $0.05 below cost per unit. Assuming that such an allegation is sufficient to state a claim as to *Brand's* costs of making the product (and we do not think that it should be[149]), is such a $50 million payment large enough to provide meaningful information regarding the patent's

146. *See Actavis*, 133 S. Ct. at 2236–37.

147. *Id*. at 2237.

148. *See infra* Part IV(B).

149. By allowing such an allegation, courts would condemn agreements that take advantage of market efficiencies—such as the ability to manufacture a product more cheaply than rivals. For example, here every other company on the market may well require $0.55 per unit to make this raw material, but Brand and Generic can benefit from an agreement precisely because Brand is more efficient and thus can manufacture the material for $0.45 per unit. Courts should be reluctant to condemn such

strength or weakness? In the context of such a valuable patent, it seems unlikely. Even a $50 million payment in this example represents 0.5%—half of one percent—of the *annual* value of the patent. Surely a generic would not accept a fraction of 1% of the annual value of the patent in exchange for meaningful delay—0.5% of a year is less than two days.[150] To hold that such a payment is large therefore would reflect "false precision"—the mistaken belief that immeasurable concepts can be reduced to precise figures, and meaningful inferences can be then drawn from the perceived (but false) precision of those figures.[151]

For example, in *In re Solodyn (Minocycline Hydrochloride) Antitrust Litigation*,[152] a payment above litigation costs was equal to just 4% of one year of the patentee's revenues from the patented product.[153] Yet *Solodyn* allowed the claim to proceed, concluding that the payment was larger than the patentee's saved litigation costs, and holding that any payment greater than saved litigation costs must be large by definition.[154] If this approach were applied to our hypothetical, it is likely—though not certain[155]—that $50 million would exceed saved litigation costs and thus be considered large.[156] But in an agreement for a $10 billion per year product, a $50 million payment cannot meaningfully suggest patent weakness. Instead, the more reasonable inferences include that someone has the math or facts wrong

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agreements as unprofitable simply because they might be unprofitable for a less-efficient manufacturer, and should instead insist on some basis for believing that *Brand's* costs are likewise $0.55 per unit.

150. Forty-three hours and 48 minutes, to be precise.

151. That courts should be careful to avoid the error of false precision is not to suggest that courts should not assess the alleged payment at the pleading stage—it is impossible to know whether an alleged payment is "large" without understanding, at least roughly, just how big it might be. *See Lipitor*, 46 F. Supp. 3d at 545–46.

152. 2015 WL 5458570 (D. Mass. Sept. 16, 2015).

153. *Id*. at *9. The opinion says that the amount was "0.04%" of annual revenues, but this is likely a typo. The alleged payment above litigation costs was $8 million—to be 0.04% of annual revenues, Solodyn revenue would have to be approximately $20 billion, but is in fact closer to $200 million. *See Solodyn Sales Data*, Drugs.com (last visited Nov. 10, 2016), http://www.drugs.com/stats/solodyn. The court thus appears to have meant that the payment was 4% of annual sales—0.04, not 0.04%.

154. *Solodyn*, 2015 WL 5458570, at *9; *compare Cephalon* 88 F. Supp. 3d at 417 (payment large if greater than saved litigation costs *and* large enough to induce generics to abandon patent claim).

155. *See infra* Part IV(B) (explaining that saved litigation costs may include more than the bare costs of paying counsel, and should instead include all other costs associated with the litigation process such as the cost of uncertainty).

156. *See Actavis*, 133 S. Ct. at 2243–44 (Roberts, J., dissenting) (estimating litigation costs at approximately $10 million).

(the plaintiff, or even Brand[157]), that market expectations were too uncertain to be reduced to precise figures, that costs of litigation (hard and soft) were greater than $50 million,[158] that Brand had imperfect information, that the plaintiff's market assumptions are otherwise somehow incorrect, or even just that the amount was too small to matter in the overall scope of the settlement. *Actavis* would not subject patent settlements to antitrust litigation under such circumstances.

Looking to whether the payment exceeds saved litigation costs, as some courts would, therefore makes sense only in conjunction with other standards that consider the overall value of the patent and that seek to measure whether the suspect payment is large in relation to that value—the first dollar above saved litigation costs cannot constitute a "large" payment.[159] Rather, saved litigation costs function as a safe harbor,[160] in that any payment less than saved litigation costs cannot be an antitrust concern because any such payment by definition contains no patentee sacrifice.[161] When there is a sacrifice greater than saved litigation costs, courts must ask if that payment provides meaningful information about the patent—and only when the payment provides such information is it large under *Actavis*, and thus potentially subject to antitrust scrutiny.

B. *Courts Should Consider Not Only Direct but Also Indirect Costs of Litigation*

Courts considering whether a payment is large within the meaning of *Actavis* should consider both direct and indirect costs of litigation. In his dissent, Justice Roberts noted that patent infringement litigation could cost as much as $10 million per suit, but even this estimate appears to include only "hard" litigation costs—the amounts paid to lawyers, expert witnesses, and others involved in the litigation process.[162] However, there are also indirect "soft" costs from the

157. For example, Brand may believe that its costs will be $0.45, when its actual costs will be $0.51. Managing a business is art, not science. *See supra* note 135; *Utd. Artists*, 315 F.3d at 231.

158. *See infra* Part IV(B).

159. *See, e.g.*, *Cephalon*, 88 F. Supp. 3d at 416–17 ("[A] reverse payment is sufficiently large if it exceeds saved litigation costs *and* a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim.") (emphasis added).

160. *See Aggrenox*, 94 F. Supp. 3d at 243.

161. *See supra* Part III(A).

162. *See Actavis*, 133 S. Ct. at 2243–44 (Roberts, J., dissenting) (citing Herman, Note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the*

process of litigation, such as the inability to plan operations, distraction of key employees, and harm to relationships.[163]

Nothing in *Actavis* suggests that paying to avoid these soft litigation costs is in any way inappropriate—and on the contrary, *Actavis*'s rationale for excluding litigation costs would appear to apply equally to the soft costs that flow from the litigation process. As noted, *Actavis*'s approach relies on inferring patent weakness from the patentee's willingness to make a large, unexplained sacrifice.[164] A payment equal to the amount the patentee would have expended or lost to waste by continuing to litigate cannot support such an inference of patent weakness, because it is no sacrifice by the patentee.[165] This rationale applies with equal force to the waste and inefficiency that can be created by the litigation process as it does to the direct costs of paying lawyers—and thus indirect costs are properly included in the definition of litigation costs.[166]

V. Traditional Forms of Patent Settlement Will Not Support Antitrust Scrutiny under *Actavis*'s Approach

As noted, *Actavis*'s "surrogate" approach depends on inferring potential patent weakness and anticompetitive effect from a large, unexplained reverse payment—the sort of payment the Court called "unusual."[167] However, the Court made clear that this inference would not be available when the settlement took a "traditional" form,

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Resolution of Pharmaceutical Patent Litigation, 111 Colum. L. Rev. 1788, 1795, n. 41 (2011)).

163. *See* Daniel A. Crane, Actavis*, the Reverse Payment Fallacy, and the Continuing Need for Regulatory Solutions*, 15 Minn. J.L. Sci. & Tech. 51, 54–55 (Winter 2014) ("Indirect litigation costs often exceed attorney's and expert witness fees. The early elimination of uncertainty around generic entry can allow for better planning by both pioneers and generics, and invention around the patent."); Golann, *supra* note 69, at 239 ("When parties see litigation as cheaper than settlement, it is often because they have not considered the full costs of going to war. As the general counsel of a major utility once commented to a group of litigators, 'you can get into litigation and pillage and burn, but you may destroy a future business relationship.'").

164. *See supra* Part II(A).

165. *Id*.

166. *See, e.g.*, *Mathewson Corp.*, 827 F.2d at 855 (evaluations of settlement value "are the product of intangible criteria which defy quantification."); *id*. (parties settle "to buy peace of mind, avert risk, eschew adverse publicity, put an end to stressful and disruptive litigation, or any or all of the above"); Crane, *Exit Payments*, *supra* note 90, at 771–72 ("[L]itigation expenses, the time value of money, and the distraction of litigation encourage pre-trial settlements.").

167. *See supra* Part II(B); *Actavis*, 133 S. Ct. at 2231.

even if the agreement could otherwise be characterized as a payment.[168] How, though, can courts distinguish between "unusual" settlements that may be subject to antitrust scrutiny and "traditional" ones that should not? Justice Roberts' sardonic "good luck" notwithstanding,[169] *Actavis* does not ask courts to simply figure out on their own when an agreement is unusual and suspect and when it is instead traditional and "quite different" from the payment allegedly at issue in *Actavis*.[170]

A. Actavis *Recognizes that Traditional Forms of Settlement are Quite Different than Unusual Reverse Payments*

Prior to *Actavis*, courts and commentators worried that a rule treating reverse payments as anticompetitive could condemn all compromises involving the exchange of value, on the theory that there is no meaningful difference between agreeing to a fair value side deal or compromise of damages, on the one hand, and paying for delay, on the other. The 2003 district court decision in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* explained this problem:

> [E]ven in the traditional context, implicit consideration flows from the patent holder to the alleged infringer. For instance, suppose a case is ready for trial and the patent holder can prove damages (infringing sales) of $100 million. The parties settle before trial with the alleged infringer paying the patent holder $40 million and agreeing to cease sales of its product. In addition to the $40 million payment to the patent holder, there is an implicit $60 million payment to the alleged infringer to cease its sales. . . . Under plaintiffs' analysis, a settlement such as this, where the patent holder forgoes collecting all damages due, would be a *per se* violation. Such a rule would discourage any rational party from settling a patent case because it would be an invitation to antitrust litigation.[171]

Marc Schildkraut similarly noted, in an article cited by *Actavis*, that "it is likely that consideration is moving from the patent holder to the alleged infringer in most settlements of patent disputes."[172] Though Schildkraut illustrated that such consideration should not be suspect, despite its potential impact on the date of generic entry,[173] he was

168. *Actavis*, 133 S. Ct. at 2233.
169. *See Loestrin*, 45 F. Supp. 3d at 195 (quoting *Actavis*, 133 S. Ct. at 2245).
170. *See Actavis*, 133 S. Ct. at 2233.
171. 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003).
172. 133 S. Ct. at 2233 (citing Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy,* 71 ANTITRUST L.J. 1033, 1046 (2004)).
173. Schildkraut, *supra* note 172, at 1046–47.

concerned that "the logic that would condemn settlements with reverse payments would lead to the condemnation of many or perhaps most patent settlements."[174]

The Supreme Court answered this concern in *Actavis*, offering the same example as the *Cipro* district court but holding that it was possible to distinguish between (a) "traditional" and "commonplace" compromises that provide value to the generic but are lawful, and (b) "unusual" "payments" that may "sometimes" be subject to antitrust scrutiny.[175] As the majority explained the problem:

> Some [references] say that when Company A sues Company B for patent infringement and demands, say, $100 million in damages, it is not uncommon for B (the defendant) to pay A (the plaintiff) some amount less than the full demand as part of the settlement—$40 million, for example. The cited authorities also indicate that if B has a counterclaim for damages against A, the original infringement plaintiff, A might end up paying B to settle B's counterclaim.[176]

The majority held that "[i]nsofar 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," because a true reverse payment is "quite different" from such a "traditional" arrangement:

> [T]he dissent appears also to suggest that reverse payment settlements—*e.g.*, in which A, the plaintiff, pays money to defendant B purely so B will give up the patent fight—should be viewed for antitrust purposes in the same light as these familiar settlement forms. We cannot agree. 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 (something that is usually true of a paragraph IV litigation defendant) walks away with money simply so it will stay away from the patentee's market. That, we think, is something quite different.[177]

However, the difference between a "payment" and a "compromise" could be treated as a narrow one. For example, if the patentee

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174. *Id.* at 1034.

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

176. *Id.*

177. *Id.* (citing Schildkraut, *supra* note 172, at 1046 (suggesting that this hypothetical settlement includes "an implicit net payment" from A to B of $60 million—i.e., the amount of the settlement discount) & Metro–Goldwyn Mayer, Inc. v. 007 Safety Prods., Inc., 183 F.3d 10, 13 (C.A.1 1999) (describing trademark dispute and settlement)) (additional citations omitted).

agrees to forgive damages likely owed by the generic challenger in exchange for the generic's walking away from the patent dispute—a so-called "walk-away" agreement[178]—such a compromise could be characterized as a payment for delay, because the brand is "sacrificing" potential expected damages to avoid the risk of patent invalidation.[179] Nonetheless, *Actavis* held such agreements lawful.[180] Why?

1. *The Five Potential Characteristics of an Unusual Reverse Payment, Not Present in Traditional Agreements*

This question has an oft-overlooked answer. *Actavis* is grounded in five potential characteristics of "unusual" monetary payments which are not present in more traditional forms of settlement, such as a compromise of damages, or in other settlements that are "traditional" and not suspect.[181]

First, the Court noted that unusual monetary payments suggest at least the potential for harm to competition.[182] By contrast, a compromise of damages does not hold the same potential, instead suggesting only that the parties preferred compromise over litigation.[183]

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178. Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698, 700–701 (2004) ("[T]he parties may agree to a 'walk-away' settlement where the defendant discontinues the challenged use and the patentee forgoes its claim for damages. No money exchanges hands, but by forgoing the damages claim the patentee has just as certainly bought out the possibility that it will not prevail at trial as if it paid the defendant in cash.").

179. *See supra* Part III; *see also* Dickey & Orszag, *supra* note 92, at 4 ("[W]here the patent infringer has been on the market for a significant period of time and would owe significant damages if found liable, the parties may agree to a settlement where the infringer pays damages to the patent holder, but those damages are far less than the damages the patent holder is seeking. In this case, the patent holder 'pays' the infringer to settle the suit by accepting lower damages—this payment is just obscured by the fact that on net some compensation flows from the infringer to the patent holder.").

180. *See* Dickey & Orszag, *supra* note 92, at 4.

181. *See Actavis*, 133 S. Ct. at 2234–37; *Effexor*, 2014 WL 4988410, at *19 ("Sometimes there are types of settlements that do not fall within the *Actavis* rationale."); *Loestrin*, 45 F. Supp. 3d at 192 ("These considerations militate in favor of a cautious approach by the district courts, and against a cavalier extension of the *Actavis* holding to virtually any non-cash settlement package that has presumably substantial value.").

182. *Actavis*, 133 S. Ct. at 2234–35 ("*First,* the specific restraint at issue has the 'potential for genuine adverse effects on competition.'") (quoting FTC v. Indiana Federation of Dentists, 476 U.S. 447, 460–61 (1986)) (emphasis in original).

183. *See Actavis*, 133 S. Ct. at 2233 (compromise of damages "quite different" from the "collusion" that characterizes an unusual reverse payment).

And unlike a true reverse payment, which the Court noted was unlikely to arise outside the Hatch-Waxman Act context, a damages compromise can arise in any case involving damages.[184]

Second, the Court noted that a large monetary payment cannot be justified in every case[185]—unlike a compromise of damages, which is easily understood as a compromise between the parties.[186] In determining whether forms of agreement are justifiable, one factor may be whether the Patent Act permits the agreement "expressly or by fair implication."[187]

Third, the Court noted that a large monetary payment may in some cases be "a strong indicator of [market] power,"[188] as "a firm without" the "power to charge prices higher than the competitive level" is not "likely to pay large sums to induce others to stay out of its market."[189] The same is not true of a damages compromise—which requires no market power whatsoever.

Fourth, as discussed above, Actavis depends on the assumption that an "unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival"[190]—again something that would not be true of a damages compromise.[191]

Fifth, the Court believed that the rule it adopted with respect to monetary payments (a) was administrable and (b) would "not prevent litigating parties from settling their lawsuit."[192] By contrast, where antitrust scrutiny would be unadministrable, the "antitrust game"

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184. *See id*. at 2235 (identifying aspects of reverse payments that make them likely to appear only in the context of the Hatch-Waxman Act); *but see* Hovenkamp, *Anticompetitive Patent Settlements*, *supra* note 3, at 17 (concluding that reverse payments were most common in the pharmaceutical industry but could occur in other industries).

185. *Id.* at 2235–36 ("*Second*, these anticompetitive consequences will at least sometimes prove unjustified.") (emphasis in original).

186. *Id.* at 2234.

187. *Id*. at 2233. The Supreme Court did not, however, define what types of agreements would be permitted under the Patent Act "expressly or by fair implication," nor has any court since—leaving open the question of what the Court meant by this language.

188. *Id.* at 2236 ("*Third*, where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice.") (emphasis in original).

189. *Id*. (citations and internal quotation marks omitted).

190. *Id*.

191. *See supra* Part II.

192. *Actavis*, 133 S. Ct. at 2236 ("*Fourth,* an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed. The Circuit's holding does avoid the need to litigate the patent's validity (and also, any question of infringement). But to do so, it throws the baby out with the bath water, and there is

may in many cases simply not be worth the "litigation candle."[193] Treating a compromise of damages as a payment would require re-litigating the patent case to try to determine whether the parties reached the "right" compromise, and thus put in jeopardy a wide range of settlements previously thought unremarkable.[194]

2. *The Four Kinds of Agreements that Are Traditional Rather than Unusual*

These considerations can, as shown below, explain why the Court was unwilling to extend antitrust scrutiny to certain forms of agreement even if they could be classified as involving a sacrifice. The Court offered four such examples, though this list is far from exclusive:

First, a fair value settlement does not raise the same antitrust concerns as a true reverse payment.[195] Although, as noted above, the bare minimum requirement for an agreement to not be "fair value" is that it must involve a patentee sacrifice,[196] under the Court's language it appears possible to have a fair value agreement *even if* the patentee has made an initial sacrifice of some type, so long as the agreement is fair.[197] The Supreme Court defined "fair value" as separate from the question of whether there is a reverse payment—suggesting that an agreement can contain a large, unexplained sacrifice but nonetheless be "fair value."[198]

Second, *Actavis* made clear that where the value provided to the generic flows only from the opportunity to enter the market early and

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no need to take that drastic step. That is because it is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham.") (emphasis in original); *id.* at 2237 ("*Fifth,* the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit.") (emphasis in original); *see also id*. at 2243 (Roberts, J. dissenting) (expressing concern that the majority's approach might create a slippery slope that would apply to all forms of value).

193. *Id.* at 2234; *see also id.* at 2236 (allowing scrutiny of reverse payments in part because doing so can be accomplished without the high cost of re-litigating patents).

194. *See, e.g.*, *Watson Pharm.*, 677 F. 3d at 1315 (explaining "turducken" task of trying patent case within antitrust case).

195. *Actavis*, 133 S. Ct. at 2236.

196. *See supra* Part III(A)(1).

197. *See Actavis*, 133 S. Ct. at 2236.

198. *See id*. ("Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.")

compete, such early entry cannot raise the same concerns as an "unusual" payment because such entry benefits—rather than risks harming—consumers.[199]

Third, where the parties merely exercise rights granted under the Patent Act, this alone cannot be viewed as a "payment."[200] The Court was not explicit about what patent rights it would view as appropriate under this test—but in the next section we will see that exclusive licensing may be an example of a right granted under the Patent Act that, in itself, should not violate the antitrust laws.[201] There may be other examples as well.

Finally, as discussed above, parties remain free to compromise competing claims—such as by compromising a damages claim in connection with a settlement.[202]

Courts therefore must look for the factors that make a payment "unusual," and avoid condemning agreements that instead qualify as "traditional," whether specifically identified in *Actavis* or not.

B. *Applying These Standards to Reverse Payment Allegations*

Actavis thus offers significant guidance to courts seeking to determine whether forms of agreement other than monetary payments should be suspect. We next examine how such guidance should be applied to several types of agreement that some seek to characterize as "reverse payments."

1. *Agreements to Supply Generic*

Above we discussed a hypothetical agreement under which the patentee supplies the generic with raw material in exchange for payment *by the generic*.[203] Such "forward" supply agreements do not fit *Actavis*, as they do not (1) suggest potential harm to competition, or

199. *Id.* at 2234 (settlements "bring about competition, . . . to the consumer's benefit").

200. *Id.* at 2233 (no one has "identif[ied] any patent statute" which, "expressly or by fair implication," granted patentees right to "'simply pa[y] a competitor to respect its patent'"); *id.* at 2231 (to "strike that balance" between patent and antitrust, Court asks "whether 'the patent statute specifically gives a right' to restrain competition in the manner challenged"); Simpson v. Union Oil Co. of Cal., 377 U.S. 13, 24 (1964) (Patent Act in *para materia* with the antitrust laws and "modif[ies] [the antitrust laws] *pro tanto*").

201. *See infra* Part V(B)(2).

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

203. *See, e.g.*, *AbbVie*, 107 F. Supp. 3d 428; *Lidoderm*, 74 F. Supp. 3d 1052.

(2) require justification.[204] Supply agreements are entered into routinely, and by no means only in the Hatch-Waxman context, and typically suggest that one party has material that it is willing to sell to the other party at a price agreed to by the parties.[205] While "something of large value" may pass from the patentee to the generic in a supply agreement, it is "not a reverse payment under *Actavis*."[206] Nor does a supplier's willingness to sell a product suggest (3) market power or (4) patent weakness. Finally, the potential for preventing anticompetitive effects from supply agreements is (5) unlikely to be worth (a) the deterrent effects on routine agreements[207] or (b) the difficulty in distinguishing between profitable and unprofitable supply agreements as would be required.[208] Supply agreements are thus a poor fit for the "unusual" standard in *Actavis*.

2. *Exclusive Licenses*

Exclusive licenses (sometimes pejoratively referred to as "no authorized generic" licenses[209]) are similarly a poor fit for *Actavis* scrutiny. Under such agreements the patentee grants the generic

204. *See In re* Wellbutrin XL Antitrust Litig., 2015 WL 5582289, at *21 (E.D. Pa. Sept. 23, 2015) ("Supply contracts can assure steady supply, limit risk, and allow for long-term planning on the part of the recipient."); *see also AbbVie*, 107 F. Supp. 3d at 436 ("[W]e do not read the Supreme Court to have defined an unwarranted reverse payment so broadly as to include the opportunity afforded [the generic] to buy TriCor in the supply contract before us and then sell it to the public in competition with [the brand].").

205. This holds true even if the patentee allegedly provides the raw material for no cost. *See Lidoderm*, 74 F. Supp. 3d 1052 (alleging such an agreement). *Actavis* held that traditional forms of settlement should not be subject to antitrust scrutiny even if they involve a patentee sacrifice. *See supra* Part V(A). Thus even if the provision of raw material could be characterized as a sacrifice—and it is by no means certain that it could, given that take-or-pay or other contracts may require the patentee to pay for the raw material whether it is used, provided to a generic that is rapidly taking market share, or wasted—the Court has made a policy judgment against subjecting traditional settlements to antitrust scrutiny.

206. *AbbVie*, 107 F. Supp. 3d at 436.

207. Indeed, some plaintiffs have argued that providing raw materials under a supply agreement is procompetitive. *See* La. Wholesale Drug Co. v. Shure LLC (*In re* Adderall XR Antitrust Litig.), 754 F.3d 128, 132–33 (2d Cir. 2014); URL Pharma, Inc. v. Reckitt Benckiser, Inc., 2015 WL 5042911, at *2–3 (E.D. Pa. Aug. 25, 2015).

208. Moreover, one common type of supply agreement has the patentee supply the generic challenger with raw material that may be difficult to source, and without which the generic might not be able to enter the market. A rule that prohibits such agreements is thus also one that may condemn consumers to *no* generic entry.

209. A panel of the Third Circuit in *Lamictal* initially held that such an agreement should not be characterized as an exclusive license, but then withdrew this portion of its opinion. *See Lamictal*, 791 F.3d at 406 n.27. But because the alleged "payment" in connection with such licenses is the exclusivity they grant to licensees, it would seem

challenger a royalty or non-royalty bearing license to enter the market on a given date, and agrees that for a period of time after that entry the generic will not face competition from the patentee's own "authorized generic."[210]

Initially, such exclusive licenses are specifically authorized by the Patent Act,[211] and the value to the generic comes only from the opportunity to enter the market and compete. They thus fall into at least two categories of traditional agreements, and are inappropriate for antitrust scrutiny.

Although the Third Circuit nonetheless found that at least non-royalty bearing exclusive licenses could sometimes be suspect under *Actavis*, in doing so it failed not only to ask whether such agreements were traditional for the reasons described above, but even to ask whether exclusive licenses were unusual under *Actavis*'s five considerations—and in fact they are not.[212] Exclusive licenses are normal, ubiquitous, and authorized by the Patent Act and thus (1) do not suggest anticompetitive harm and (2) require no justification.[213] It can hardly be said that exclusive licenses are limited to the Hatch-Waxman context or that agreeing to grant an exclusive license suggests anticompetitive effect beyond that accepted by Congress under the patent itself. Nor does such licensing (3) tell us anything about the patentee's market power. For example, if a patentee is the smallest

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contradictory to simultaneously claim that the licenses are not at least partially exclusive. Going a step further, Professor Hovenkamp has argued that such agreements should not be treated as licenses at all, given that entry does not occur immediately, but rather as agreements to license in the future. PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2046d6 (Supp. 2016). But agreements to license in the future are commonplace. *See, e.g.*, BRIAN G. BRUNSVOLD, D. PATRICK O'REILLEY AND D. BRIAN KACEDON, DRAFTING PATENT LICENSE AGREEMENTS 154–55 (7th ed. 2012) (providing as example of "Licensed Patents" subject to license agreement all "issued U.S. patents" claiming inventions made within five-year period "beginning with date of execution of [License] Agreement and ending five years after such date); *see also* Imation Corp. v. Koninklijke Philips Elec. N.V., 586 F.3d 980, 986 (Fed. Cir. 2009) (license conveyed a "singular, present grant" of a license to "existing and future patents").

210. *Lamictal*, 791 F.3d at 388.

211. *See, e.g.*, 35 U.S.C. § 261; *Kimble*, 135 S. Ct. at 2406–07 ("While a patent lasts, the patentee possesses exclusive rights to the patented article—rights he may sell *or license* for royalty payments if he so chooses.") (emphasis added); Data Gen. Corp. v. Grumman Sys. Support Corp., 36 F.3d 1147, 1186 (1st Cir. 1994) ("[C]onduct permissible under the patent laws cannot trigger any liability under the antitrust laws." (quoting SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1206 (2d Cir. 1981)), *abrogated on other grounds by* Reed Elsevier, Inc. v. Muchnick, 559 U.S. 154 (2010).

212. *Lamictal*. 791 F.3d at 404–05.

213. *See* 35 U.S.C. § 261 ("The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.").

and least successful player in an 8-product market, it may decide that introducing an authorized generic is not worthwhile and may thus grant an exclusive license instead—if there are now to be 9 players with the newly-introduced generic version of its product, why introduce a 10th? And (4) *Actavis*'s inference that a patent must be weak if the patentee was willing to make a payment does not apply when the "payment" is an exclusive license, as such licenses are granted in countless industries and circumstances, and hardly because the involved patents are weak.[214]

Additionally, (5) treating such licenses as suspect reverse payments is unlikely to be administrable. Unlike a monetary payment, exclusive licenses are quite often profitable for a patentee, even where not royalty-bearing,[215] and determining whether an exclusive license would have been more profitable than the patentee launching its own "authorized generic" product is a question for which courts are not well-suited.[216] Whether to license or produce a product is a question that patentees must answer every day—as the court in *In re Actos End Payor Antitrust Litigation*[217] noted, no "manufacturer is obligated as a matter of law to license an authorized generic,"[218] and under the best of circumstances whether to do so is a sufficiently close call that the FTC conducted a multi-year study to test whether patentees were sacrificing profits *by launching* such products.[219]

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214. *See* Thomas R. Varner, *An Economic Perspective on Patent Licensing Structure and Provisions*, 46 BUS. ECON. 229, 237 (Oct. 2011) (exclusive licenses represent 84 percent of patent licenses in the life sciences sector, 66 percent of patent licenses issued by commercial licensors, and 94 percent of patent licenses issued by universities); *see also* Licensing Executives Society (USA and Canada), Inc., *Global BioPharmaceutical Royalty Rates & Deal Terms Survey*, 7 (Sept. 2010) (82 percent of the licensing deals of surveyed members of the biotech and pharmaceutical industries were exclusive).

215. Because authorized generics "cannibalize" substantial branded product sales, the FTC has found that they are far from universally profitable for brand firms, even discounting royalties. Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (August 2011), http://www.ftc.gov/os/2011/08/2011 genericdrugreport.pdf ("FTC Study") at 73; *id.* at iv (*launching* an authorized generic might involve "sacrifice" of brand revenues)).

216. Crane, *Exit Payments*, *supra* note 90, at 767 ("It is in the interest of the patentee to have its patented product produced and distributed in the most efficient manner possible. Thus, a patentee will typically license another firm to produce or distribute its product if the licensee can perform those tasks more efficiently than the patentee.").

217. 2015 WL 5610752 (S.D.N.Y. Sept. 22, 2015).

218. *Id.* at *18.

219. FTC Study at iii n.7 (noting that this is a significant concern for companies choosing whether to introduce an authorized generic). Introducing an additional low-price, low-margin authorized generic product may in some cases steal such a large volume of sales from the high-price, higher-margin branded product that the patentee

Courts are not well suited to decide which strategy was right for a given product or firm, and should not seek to do so.[220] Exclusive licenses therefore are not "unusual" under *Actavis*, and are not appropriate for antitrust scrutiny under its framework.

3. *Settling Multiple Litigations*

The next "payment" claimed by some plaintiffs (but no government enforcer) involves agreements across multiple outstanding disputes—which we will refer to as "global" settlements (though they need not involve *all* disputes in which the parties are engaged in order to be challenged). Such agreements are in no sense limited to Hatch-Waxman Act litigation or even to the patent settlement context, but rather are ubiquitous.[221] However, some plaintiffs have argued that a settlement with respect to litigation A (as part of a global settlement) could potentially be viewed as a "payment" in respect of litigation B.[222] This is error.

Initially, global settlements are the quintessential example of compromise—in this case a compromise of multiple litigation positions.[223] Though different in detail than a compromise of damages as described in *Actavis*, such agreements raise the same concerns and thus would be considered "traditional" for the same reasons.[224] And if that were not sufficient, because a global settlement typically involves permitting early entry for various products, the purported "payment" to the generic is often nothing more than the opportunity to enter the market and compete—another example of a traditional form of agreement.[225]

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loses rather than makes money. *See id*. at 60 (introducing authorized generic may reduce brand revenues up to 49%). The FTC concluded that the tradeoff of launching an authorized generic could *sometimes* be profitable—but that the average profit of doing so was not "statistically significant." *Id*. at 62, 118. And a patentee may also have many other reasons to prefer an exclusive license over launching its own product, including concerns at points in time that authorized generics might be outlawed or simply internal strategies that focus on the brand firm's specialty: introducing branded products. Indeed, several bills were introduced in the mid-2000s seeking to outlaw authorized generics. *See, e.g.*, H.R. 5993, 109th Cong. (2006); S. 3695, 109th Cong. (2006).

220. *See supra* Parts III(A)(3) & III(C)(3); *see also Linkline*, 555 U.S. at 452.

221. *See, e.g.*, FISHER & URY, *supra* note 63, at 60–61 (increasing topics for negotiation permits parties to solve problems); GARVEY & CRAVER, *supra* note 83, at 36–37 (increasing areas of negotiation can lead to agreement where otherwise impossible).

222. *But see AbbVie*, 107 F. Supp. 3d at 437 (refusing to combine procompetitive agreements to create anticompetitive effect).

223. *See Actavis*, 133 S. Ct. at 2233 (permitting compromises).

224. *See id*.

225. *See id*. at 2234.

Nor is there any basis to instead view them as unusual. When parties settle global disputes, there is (1) no basis to infer that competition will be harmed—as global settlements are normal and ubiquitous.[226] And (2) just as a compromise of damages is *always justifiable*, it takes no imagination to understand why global settlements are popular. The willingness of a patentee to enter a global settlement tells us nothing about (3) its market power or (4) patent weakness—the smallest player, whose resources may otherwise be tied up in litigation, may have the *greatest* interest in global settlements. Finally, (5) a rule subjecting global settlements to antitrust litigation would be unadministrable, as to determine whether a global settlement involved a suspect reverse payment would involve litigating not *one*, but two, three, four, or dozens of cases to determine whether the generic received a "non-fair value" deal in any of them.[227]

Moreover, treating global settlements as potentially-suspect reverse payments would therefore be highly corrosive to the settlement process, as parties would be forced to settle each dispute (or even issue) individually, with substantially greater transaction costs and without normal integrative bargaining—to avoid a claim that an agreement in respect of Product A is somehow a payment in respect of Product B, it would be necessary to space out all settlements to avoid any that could be portrayed as having been close in time and thus "simultaneous."[228] *Actavis* scrutiny is thus inappropriate for such global settlements, which should therefore not be considered suspect.

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226. *Cf. AbbVie*, 107 F. Supp. 3d at 436 ("As the Supreme Court declared . . . , '[t]wo wrong claims do not make one that is right.'") (quoting *Linkline*, 555 U.S. at 457).

227. *See Actavis*, 133 S. Ct. at 2233 (refusing to condemn traditional settlement forms where it would be necessary to undertake a similar inquiry into the merits of a patent).

228. *See supra* Part III(A)(2). This inquiry is unlikely to be simple, as there is virtually no way to tell what would have happened in litigation. *See, e.g.*, Whitmore v. Arkansas, 495 U.S. 149, 159–160 (1990) ("[I]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case."); *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 200 (E.D.N.Y. 2003) ("a legal theory dependent on predicting the outcome of a specific lawsuit is unduly speculative"); *Mathewson Corp.*, 827 F.2d at 857 ("There is, as any courtroom veteran can attest, no broad market by which one can measure precisely the objective value of a lawsuit . . . . Typically, such evaluations are the product of intangible criteria which defy quantification.").

4. *Acceleration Clauses*

So-called "acceleration clauses," the next type of "payment" claimed by some private plaintiffs, are also a poor fit for the *Actavis* rationale. When a settling generic agrees to a fixed entry date sometime in the future, it runs the risk that later generics may obtain an earlier entry date, either by winning their case or through settlement—and may thus eliminate a substantial portion of the value the early-settling generic expected to receive from the settlement. Generics would be hesitant to settle if they risked losing the benefit of their bargain in this way, creating a situation in which each generic challenger would seek to be the *last* to settle. Instead, settling generics typically demand an acceleration clause—a provision in the agreement permitting the generic to enter earlier than the agreed-upon entry date if the patent at issue is later invalidated or if another generic enters. While such provisions *accelerate* competition, antitrust plaintiffs have alleged that they are instead a form of reverse payment because they give a generic challenger the opportunity to compete if other challengers enter earlier, and this opportunity to compete must surely be valuable to the generic.[229] Thus, plaintiffs argue, it must be a "payment."[230]

But the right to compete is quite different than the monetary payments discussed in *Actavis*, as such a "payment" creates value, if at all, only by allowing competition and lower prices.[231] There is thus (1) no basis to infer anticompetitive harm under the *Actavis* rationale, and the competition an acceleration clause creates would (2) ordinarily be justifiable in all cases. Similarly, there is no reason to suspect that a patentee would only grant an acceleration clause if it had (3) market power.[232] And because an acceleration clause is costly to the patentee only if the patent is shown in subsequent litigation to be weaker than it was believed to be at the time of the settlement, by entering such a clause the patentee is betting that its patent will do *at least* as well in subsequent cases—inferring (4) patent weakness from a declaration of patent strength would be incongruous.[233] Finally, (5) a rule transforming acceleration clauses into "payments"

229. *Loestrin*, 45 F. Supp. 3d 180.

230. *Actavis* did not treat the very act of permitting competition as a suspect "payment" by the patentee. *See Actavis*, 133 S. Ct. at 2237.

231. *In re* Actos End Payor Antitrust Litig., 2015 WL 5610752, at *14 (S.D.N.Y. Sept. 22, 2005).

232. *See Actavis*, 133 S. Ct. at 2230.

233. *See id.* at 2236.

would be unadministrable and would have substantial negative effects on settlement.

On the contrary, an acceleration clause is quintessentially nothing more than a guarantee of the chance to enter the market early and compete—something that *Actavis* held would be procompetitive.[234] Such agreements moreover involve nothing more than the exercise of a right granted by the Patent Act—the right to license a licensee to enter the market on appropriate terms at a point in the future.[235] Finally, an acceleration clause surely represents a reasonable compromise between the parties in order to reach agreement, and thus cannot be viewed as a "payment."[236] Acceleration clauses are thus a poor fit for the *Actavis* rationale.

5. *Royalties / Licensing Fees*

It would seem unthinkable that any plaintiff would ever try to take the error of the "any value" approach so far as to claim that royalties themselves could constitute a reverse payment,[237] but at least one plaintiff has alleged exactly that.[238] Perhaps this seemed like the logical next step for the slippery slope that results from misreading *Actavis* to focus on what the generic receives, but this plaintiff was incorrect to claim that it is thus now unlawful to settle except by correctly guessing what some future plaintiff will declare to be the "right" royalty rate.[239]

Even the FTC has noted that royalties are a sign of *earlier* entry, not later entry—and thus low royalties are (1) not suspect and (2) obviously justifiable.[240] Nothing about agreeing to an early entry license with a royalty rate suggests that the parties were seeking to

234. *See id*. at 2234.

235. *See id*.

236. *See id*. at 2233.

237. Some authors have argued that a plaintiff could also allege that royalties are too high. *See* Crane, *Exit Payments*, *supra* note 90, at 766 ("Licensing agreement settlements in which an alleged infringer pays the patentee a royalty to use the patented art clearly give rise to antitrust concerns compared with a baseline of complete competition.").

238. *See* Omnibus Mem. of Law in Support of Plaintiffs' Opp. to Defendants' Mot. *in Limine* at 12, Barba v. Shire US, Inc., 13-cv-21158-Lenard/Goodman (Dec. 10, 2015), ECF 367; Plaintiffs' Response to Shire's Objections to Magistrate Judge Goodman's Report and Recommendations on Plaintiffs' Renewed Motion for Class Certification at 7, Barba v. Shire US, Inc., 13-cv-21158-Lenard/Goodman (Jan. 19, 2016), ECF 390.

239. *See Law Offices of Curtis V. Trinko, LLP*, 540 U.S. at 415–16 (rejecting such arguments).

240. FTC Study at 141 n.4 ("Pursuant to settlement, a generic company may pay a royalty to the brand to gain an earlier entry date than it would get by compromising

delay competition—and indeed negotiation on royalty rates has long been assumed even by plaintiffs to be a permissible way to resolve patent disputes.[241] Indeed, some authors take the position (not accepted by *Actavis*) that royalties should be the *only* way to bridge gaps between parties' positions.[242] Nor could anyone say with a straight face that a patentee would only agree to, for example, a 20% rather than 25% royalty rate if it had (3) market power. And choosing one royalty rate rather than another tells us nothing about (4) patent weakness. Finally (5) a rule requiring that parties choose the "right" royalty percentage would be flatly unadministrable, as even if courts were skilled in setting business terms such as this, there is no "right" such rate to be applied. Such a royalty-based claim is thus absurd under the *Actavis* framework—but illustrative of the danger of treating traditional compromises as a potential reverse payment.

VI. Conclusion

To apply *Actavis* as the Supreme Court intended, courts must look first to whether there is a plausible allegation of patentee sacrifice sufficient to allow the court to make the inferences on which *Actavis* relies. Even where there is a suspect payment, courts must determine whether that payment is large enough to provide meaningful information about patent strength or weakness; if not then antitrust scrutiny is similarly inappropriate. Finally, even if a suspect payment is large under *Actavis*, courts must avoid condemning traditional forms of settlement the Court sought to preserve. By following these principles, courts can not only "activate" *Actavis*, they can understand it and apply it as the Supreme Court intended.

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on the date alone.") (citing Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 14 (2005)).

241. *See* Leffler, *supra* note 121.

242. *See id*. (describing such arguments).