

Why A "Large and Unjustified" Payment Threshold is Not Consistent with Actavis

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Citation to Publisher Carrier, Michael A. (2016). Why A "Large and Unjustified" Payment Threshold is Not Consistent with Actavis. *Washington Law Review* 91(1), 109-118. <https://www.law.uw.edu/wlr/print-edition/print-edition/vol-91/1/why-a-large-and-unjustified-payment-threshold-is-not-consistent-with-actavis/>.

Citation to this Version: Carrier, Michael A. (2016). Why A "Large and Unjustified" Payment Threshold is Not Consistent with Actavis. *Washington Law Review* 91(1), 109-118. Retrieved from [doi:10.7282/T3B27ZDH](https://doi.org/10.7282/T3B27ZDH).

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WHY A “LARGE AND UNJUSTIFIED” PAYMENT THRESHOLD IS NOT CONSISTENT WITH *ACTAVIS*

Michael A. Carrier*

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INTRODUCTION

*FTC v. Actavis, Inc.*¹ was a landmark antitrust decision. The Supreme Court held that a brand-name drug company’s payment to a generic firm to delay entering the market could have “significant adverse effects on competition” and violate the antitrust laws.² The Court explained that exclusion-payment³ settlements should be analyzed under not only patent law but also antitrust law.⁴ And it rejected a patent-focused test applied by lower courts that tended to immunize settlements.⁵

There are many ways to undercut *Actavis*. One is to limit the ruling to cash payments. Another is to allow the settling parties, whenever they wish, to introduce evidence relating to the patent merits. A third, the focus of this Article, is to create new thresholds and frameworks not articulated or envisioned by the Court.

In particular, some lower courts and defendants have sowed ambiguity in the post-*Actavis* case law by latching onto the discussion in

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1. ___ U.S. ___, 133 S. Ct. 2223 (2013).

2. *Id.* at 2231.

3. The phrase “exclusion payment” captures the exclusion that brands obtain by paying generics to delay entry. The *Actavis* Court referred to such consideration as “reverse payments” because the payment flows from the patentee to the alleged infringer (unlike typical settlements in which alleged infringers pay patentees). *See id.* at 2233.

4. *Id.* at 2231.

5. *Id.* at 2231–32.

Actavis of a “large and unjustified” payment.⁶ For example, the district court in *In re Loestrin 24 FE Antitrust Litigation*⁷ imposed a framework that required analysis of (1) whether “there [is] a reverse payment” and (2) whether “that reverse payment [is] large and unjustified,” before (3) addressing the rule of reason.⁸ The *Loestrin* court borrowed this framework from the district court in *In re Lamictal Direct Purchaser Antitrust Litigation*.⁹ And defendants have contended, for example, that “*Actavis* requires a plaintiff challenging a reverse-payment settlement . . . to prove, as a threshold matter, that the . . . payment was both large and unjustified”¹⁰ and that “under *Actavis*, [plaintiffs] . . . have to prove that [a] . . . payment was ‘large’ (as well as unexplained).”¹¹

This Article offers three reasons why a requirement that a plaintiff demonstrate a large and unjustified payment before reaching the rule of reason is not consistent with *Actavis*. First, nearly all of the Court’s discussion of large and unjustified payments occurred in contexts unrelated to the antitrust analysis that future courts were to apply. Second, the Court instructed lower courts to apply the rule of reason, not a new framework with a threshold it never mentioned. And third, such a threshold is inconsistent with the Court’s (1) allowance of shortcuts for plaintiffs to show anticompetitive effects and market power and (2) imposition of the burden on defendants to show justifications for a payment.

I. THE *ACTAVIS* COURT’S DISCUSSION OF LARGE AND UNJUSTIFIED PAYMENTS

The first reason “large and unjustified” payments do not present a threshold can be traced to the use of the phrase in the *Actavis* decision

6. *Id.* at 2237.

7. 45 F. Supp. 3d 180 (D.R.I. 2014), *vacated*, Nos. 14–2071, 15–1250, 2016 WL 698077 (1st Cir. Feb. 22, 2016).

8. *Id.* at 189.

9. 18 F. Supp. 3d 560, 564–66 (D.N.J. 2014), *rev’d sub nom.* *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015); *see King Drug Co.*, 791 F.3d at 411 (“[T]he District Court [in *Lamictal*] mistook the ‘five sets of considerations’ that persuaded the *Actavis* Court ‘to conclude that the FTC should have been given the opportunity to prove its antitrust claim’ under the rule of reason as a redefinition of the ‘rule of reason’ itself,” despite the fact that “the general contours of the rule of reason are well-mapped.” (citation omitted)).

10. *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 405 (E.D. Pa. 2015).

11. Teva’s Memorandum in Support of Directed Verdict Motion on Threshold Issue of a Large and Unexplained Payment at 12–13, *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231 (D. Mass. 2014) (No. 1:12-md-02409-WGY), ECF No. 1187.

itself. The Court referred to such payments four times: twice with the formulation “large and unjustified” and twice using language about “unexplained large . . . payment[s].”¹² Three of the four uses had nothing to do with the antitrust analysis to be applied by future courts, and the fourth only potentially intimated a role for the concept.

Each of the four uses occurred in the section of the opinion in which the Court explained why the “general legal policy favoring the settlement of disputes” did not displace ordinary antitrust analysis.¹³ For a decade before the *Actavis* decision, most appellate courts that had considered exclusion-payment agreements had immunized them largely based on the policy in favor of settlements, which conserve resources and provide certainty. For example, the Eleventh Circuit in *Schering-Plough Corp. v. FTC*¹⁴ stated that “[t]he general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.”¹⁵ Similarly, the Federal Circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*¹⁶ highlighted the “long-standing policy in the law in favor of settlements, . . . [which] extends to patent infringement litigation.”¹⁷

In the first use of the phrase, the *Actavis* Court stated that “[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival.”¹⁸ These doubts help show that “it is normally not necessary to litigate patent validity to answer the antitrust question.”¹⁹ The reason is that “the payment’s objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market.”²⁰ In other words, the Court referred to an unexplained large payment to explain why courts did not need to litigate patent validity. It did not use such a phrase to provide a template for antitrust analysis.

12. *FTC v. Actavis, Inc.*, ___ U.S. ___, 133 S. Ct. 2223, 2236–37 (2013).

13. *Id.* at 2234.

14. 402 F.3d 1056 (11th Cir. 2005).

15. *Id.* at 1072.

16. 544 F.3d 1323 (Fed. Cir. 2008).

17. *Id.* at 1333; see also Michael A. Carrier, *How Not to Apply Actavis*, 109 NW. U. L. REV. ONLINE 113, 116 (2014) (citing decisions in *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 203 (2d Cir. 2006); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003); and *Schering-Plough*, 402 F.3d at 1075, in which courts deferred to settlements so as not to harm incentives for innovation).

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

19. *Id.*

20. *Id.*

Second, the Court continued this discussion by asserting that “[t]he owner of a particularly valuable patent might contend . . . that even a small risk of invalidity justifies a large payment,” but “the payment (if otherwise unexplained) likely seeks to prevent the risk of competition,” which “constitutes the relevant anticompetitive harm.”²¹ The Court thus concluded that “the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”²² Mirroring the first instance, the use of a “large” payment that is “unexplained” prevents the risk of competition and displaces the need to litigate the patent merits. The Court’s discussion does not offer guidance on the specific antitrust analysis to be applied.

In the third use, the Court asserted that “the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit.”²³ The Court discussed other types of settlements available to the parties, such as those without a brand payment to a generic.²⁴ The existence of settlement options that do not include large, unjustified payments signals the propriety of antitrust enforcement and lack of immunity bestowed by the pro-settlement policy. But the parties’ ability to settle without payment does not provide guidance on the antitrust framework that courts should apply.

Fourth, the Court provided its only indication that a large and unjustified payment could conceivably play a role in the antitrust analysis:

In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; 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 parties may well find ways to settle patent disputes without the use of reverse payments.²⁵

The Court concluded that “these considerations, taken together, outweigh the single strong consideration—the desirability of

21. *Id.*

22. *Id.* at 2236–37.

23. *Id.* at 2237.

24. *Id.*

25. *Id.*

settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.”²⁶

This fourth use of the phrase is susceptible to two potential interpretations. The first implies that the concept is a necessary element of the plaintiff’s case. In other words, the statement that “a . . . payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects” means that payments that are not large and unjustified cannot bring about those risks.

The second interpretation implies only an illustrative role for the phrase. The Court could have used the phrase “large and unjustified” to show the type of payment that was most likely (though not necessary) to result in significant anticompetitive effects. Support for this interpretation can be found in the Court’s assertions in subsequent clauses that (a) “one who makes such a payment may be unable to explain and to justify it” (which refers to all—not just unjustified—payments), and (b) a court can assess likely anticompetitive effects and justifications “by examining the size of the payment” (which refers to all—not just large—payments).²⁷ Finally, this second interpretation gains support from the Court’s discussion elsewhere in the opinion of anticompetitive effects, which is typically not accompanied by references to large and unjustified payments. In fact, of the thirteen times the Court refers to anticompetitive effects (not including the fourth use of the phrase just discussed), only one addresses significant unjustified anticompetitive consequences,²⁸ with one other mentioning only “high” payment,²⁹ three others referencing only unjustified payments,³⁰ and the other eight not referring to either large or unjustified payments.³¹

26. *Id.*

27. *Id.*

28. *See id.* at 2238 (explaining that district courts can structure antitrust litigation to focus on “the basic question” of “significant unjustified anticompetitive consequences”).

29. *See id.* at 2235 (asking whether parties would enter into anticompetitive agreements and mentioning “high” payment that could provoke additional challenges).

30. *See id.* at 2235–36 (noting that anticompetitive consequences could be unjustified); *id.* at 2236 (finding that justified payments could lack anticompetitive effects); *id.* (linking unjustified payment with anticompetitive harm and market power).

31. *See id.* at 2230 (rejecting scope-of-patent test); *id.* at 2231 (not measuring anticompetitive effects solely against patent law); *id.* (considering traditional factors in antitrust analysis); *id.* at 2236 (noting anticompetitive consequence of maintaining high prices); *id.* (explaining that preventing the risk of competition constitutes the anticompetitive harm); *id.* at 2237 (noting that courts could assess anticompetitive effects and justifications without litigating the patent merits); *id.* (remarking that the likelihood of anticompetitive effects depends on various factors); *id.* (explaining that anticompetitive effects could vary by industry). Two other mentions of anticompetitive effects

In short, only one of the Court's four uses of the phrase "large and unjustified" payment could possibly be interpreted as providing guidance (though not in the form of a threshold) on the type of antitrust analysis for future courts to apply. Even that single phrase is ambiguous, with evidence indicating that the formulation was not intended to offer an applicable antitrust framework. And again, each of the uses appears, not in the section of the opinion in which the Court offers guidance to lower courts about the antitrust analysis to be applied, but in the section in which it explains why a pro-settlement policy does not immunize settlements.

Taking a conservative approach, the remainder of this Article assumes that the Court implied, through one dependent clause, to inculcate a role in future antitrust analysis for a large and unjustified payment. But such a role is far from a foregone conclusion.³²

II. RULE-OF-REASON FRAMEWORK

The second reason large and unjustified payments do not present a threshold plaintiffs must satisfy before reaching the full antitrust analysis is located in *Actavis*'s emphasis on the rule of reason. The Court "[left] to the lower courts the structuring of the present rule-of-reason antitrust litigation."³³ Such a framework "consider[s] traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations."³⁴ And the Court instructed trial courts to

structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences.³⁵

In short, it had in mind a rule-of-reason analysis, albeit one structured to avoid detailed, exhaustive analysis that is unnecessary when

occur in the setting of the lower courts' applications of the scope-of-the-patent test, *see id.* at 2227, 2230, and one occurs in the excerpting of language from *California Dental Ass'n v. FTC*, 526 U.S. 756 (1999), *id.* at 2237.

32. *Cf. In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 241–42 (D. Conn. 2015) (noting that *Actavis* "did not discuss in any detail whether or why the reverse payment alleged in that case was 'large' or 'unjustified'").

33. *Actavis*, 133 S. Ct. at 2238.

34. *Id.* at 2231.

35. *Id.* at 2238.

agreements are clearly anticompetitive.³⁶

The Court did not mention or envision a threshold plaintiffs needed to clear before reaching the rule of reason. As the court in *King Drug Co. of Florence v. Cephalon, Inc.*³⁷ correctly observed: “nowhere in the *Actavis* opinion does the Supreme Court state that plaintiffs bear a ‘threshold burden’ of demonstrating that the reverse payment was large and unjustified.”³⁸ Rather, as the *Cephalon* court synthesized: “[w]hile the terms ‘large’ and ‘unjustified’ are used several times in the opinion, and certainly appear to be important, perhaps the clearest guidance given to trial courts is that antitrust cases involving reverse-payment settlements must be analyzed under the rule of reason.”³⁹

If “large and unjustified” is to be part of an antitrust analysis, it would best be considered in the setting of the rule of reason itself. For example, the plaintiff could, as part of its initial burden of persuasion under the rule of reason, show a large payment. The defendant could then attempt to justify the payment, with the plaintiff having the ultimate burden of showing that the payment is unjustified. Such a framework is consistent with the structure articulated by the courts in *Cephalon*⁴⁰ and *In re Nexium (Esomeprazole) Antitrust Litigation*.⁴¹ And it is consistent with the *Actavis* Court’s emphasis on an antitrust analysis based on the rule of reason.

Incorporating concepts based on large and unjustified payments into the rule of reason also would be preferable to the duplicative analysis that would result from imposing a separate threshold requirement. Such an inefficient framework would require courts to analyze factors relating to the size of, and justifications for, the payment as part of the threshold analysis and then again as part of the rule of reason. In addition, as discussed more fully in the next Part, a threshold requirement would not allow parties to present, and courts to consider, evidence at the stage of the analysis that aligns most directly with the shifting burdens of production that characterize the rule of reason.⁴²

36. See *infra* Part III.

37. 88 F. Supp. 3d 402 (E.D. Pa. 2015).

38. *Id.* at 414; see also *id.* at 413 (“The phrase ‘threshold burden’ does not appear anywhere in *Actavis*.”).

39. *Id.* at 414–15.

40. *Id.* at 414 (adopting approach by which plaintiffs establish large payment, defendants justify payment, and plaintiffs rebut justification).

41. 42 F. Supp. 3d 231, 262–63 (D. Mass. 2014) (offering framework in which plaintiffs bear initial burden of proof, burden shifts to defendants to show justification, and burden returns to plaintiffs to show, on balance, anticompetitive settlement).

42. See Michael A. Carrier, *The Real Rule of Reason: Bridging the Disconnect*, 1999 BYU L.

III. SHORTCUTS AND DEFENDANT BURDENS

The third reason why large and unjustified payments do not present a threshold is because of the inconsistency between such a concept and two glosses the *Actavis* Court put on the rule of reason.

First, the Court anticipated shortcuts that plaintiffs could use in satisfying their burdens under the rule of reason. It explained that exclusion payments have the “potential for genuine adverse effects on competition.”⁴³ And it made clear that the “size of the payment” can serve as “a strong indicator of [market] power.”⁴⁴ In making these assumptions, the Court offered elements of an approach similar to presumptive illegality.⁴⁵ Erecting a threshold that requires plaintiffs to show unjustified payments as part of their initial case will typically block them from court and is not consistent with a streamlined rule of reason that offers plaintiffs shortcuts in proving anticompetitive effects and market power.

Second, the Court anticipated that defendants would bear the burden of demonstrating a payment’s justifications. It explained that “[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.”⁴⁶ The Court also noted that “one who makes such a payment may be unable to explain and to justify it.”⁴⁷

Such a burden makes sense given the defendants’ likely possession of

REV. 1265, 1268–69 (surveying rule-of-reason cases in modern era and concluding that (1) “[i]n the initial stage, the plaintiff must show a significant anticompetitive effect resulting from the restraint”; (2) the burden then “shifts to the defendant to demonstrate a legitimate procompetitive justification”; (3) “the burden then returns to the plaintiff to show either that the restraint is not reasonably necessary to achieve the objectives of the restraint or that the objectives could be achieved by alternatives ‘less restrictive’ of competition”; after which (4) the court balances anticompetitive and procompetitive effects).

43. *FTC v. Actavis, Inc.*, ___ U.S. ___, 133 S. Ct. 2223, 2234 (2013).

44. *Id.* at 2236; *see also id.* at 2237–38 (explaining that plaintiffs need not “present every possible supporting fact or refute every possible pro-defense theory”).

45. *See* Thomas F. Cotter, *FTC v. Actavis, Inc.: When Is the Rule of Reason Not the Rule of Reason?*, 15 MINN. J.L. SCI. & TECH. 41, 42–43 (2014) (“In reality, the Court appears to have all but in name adopted the presumptive illegality approach it purported to reject.”); Christopher Sagers, *Just What on Earth Did Actavis Really Say? And Does It Mean Something for Section 1 More Broadly?*, ANTITRUSTCONNECT BLOG (July 1, 2013), <http://antitrustconnect.com/2013/07/01/just-what-on-earth-did-actavis-really-say-and-does-it-mean-something-for-section-1-more-broadly/> [<https://perma.cc/KJM8-5U43>] (noting that the Court “lay[s] out the elements of what looks like a special § 1 cause of action, which doesn’t look at all like a full rule of reason inquiry”).

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

47. *Id.* at 2237.

evidence relating to the justifications for the payment. As the California Supreme Court recognized in *In re Cipro Cases I & II*,⁴⁸ “a settling party’s own litigation costs and the existence and value of any collateral products or services provided as part of a patent settlement” are “matters about which the settling parties will necessarily have superior knowledge.”⁴⁹ Similarly, the court in *In re Aggrenox Antitrust Litigation*⁵⁰ explained that “very precise and particularized estimates of fair value and anticipated litigation costs may require evidence in the exclusive possession of the defendants,” and that “these issues are sufficiently factual to require discovery.”⁵¹ Requiring plaintiffs to prove, as part of their prima facie case, that a payment is unjustified does not make sense. How, at the motion-to-dismiss stage, could a plaintiff obtain access to information relating to a brand’s payment for generic services to know whether such a payment is justified?

In short, a threshold based on a large and unjustified payment is inconsistent with the Court’s (1) allowance of shortcuts for plaintiffs to show anticompetitive effects and market power and (2) imposition of the burden on defendants to show justifications for the payment.

CONCLUSION

Requiring plaintiffs to demonstrate a large and unjustified payment before reaching the rule of reason is not consistent with *Actavis*. It distorts the Court’s discussion of large and unjustified payments, ignores the Court’s instruction to apply the rule of reason, and is inconsistent with the Court’s shortcuts for plaintiffs and burdens for defendants. In short, a threshold based on a large and unjustified payment cannot be

48. 348 P.3d 845 (Cal. 2015).

49. *Id.* at 867; *see also id.* (noting that “defendants have the burden of coming forward with evidence of litigation costs and the value of collateral products and services”); *cf. In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 264 (D. Mass. 2014) (reasoning that *Actavis* does not “place the initial burden on the Plaintiffs to prove, in their prima facie case, that a transaction was for something other than fair market value”).

50. 94 F. Supp. 3d 224 (D. Conn. 2015).

51. *Id.* at 244; *see also* Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7, 24 (2014) (“Given the complexity of these arrangements and their greater access to the information, the defendants should have the burden of showing that the payment is justified.”); Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1730 (2003) (explaining, in the context of determining patent infringement, that “the burdens of production and proof properly rest with the antitrust defendants (or proponents of the settlement) because they typically control the information upon which resolution of the infringement issue will be made”); *cf.* Aaron Edlin et al., *Activating Actavis*, 28 ANTITRUST 16, 18 (2013) (“The parties to a payment for delay have ample reason to pack complexities into the deal (such as relatively unimportant services) to conceal its genuine nature.”).

reconciled with—and significantly threatens the viability of—*Actavis*.