

After Actavis: Seven Ways Forward

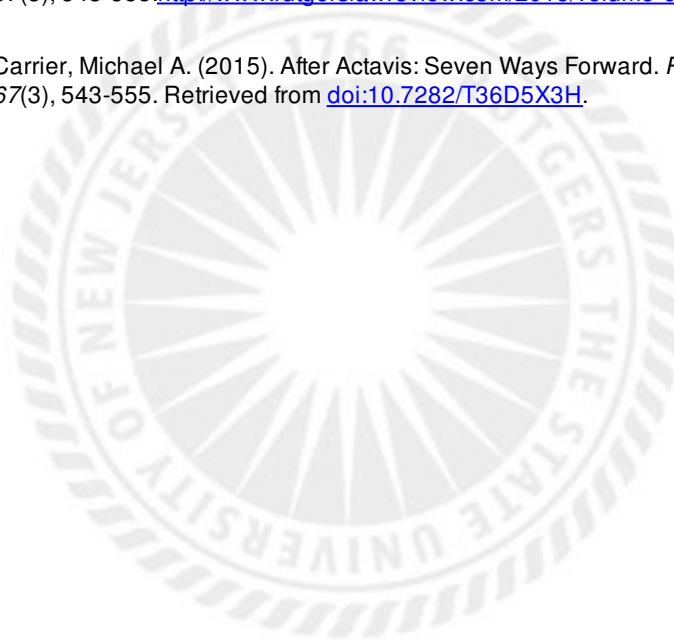
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Citation to Publisher Carrier, Michael A. (2015). After Actavis: Seven Ways Forward. *Rutgers University Law Review*
Version: 67(3), 543-555. <http://www.rutgerslawreview.com/2015/volume-67-spring-2015-issue-3/>.

Citation to *this* Version: Carrier, Michael A. (2015). After Actavis: Seven Ways Forward. *Rutgers University Law Review*
67(3), 543-555. Retrieved from [doi:10.7282/T36D5X3H](https://doi.org/10.7282/T36D5X3H).



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FOREWORD

AFTER *ACTAVIS*: SEVEN WAYS FORWARD

*Michael A. Carrier**

The Supreme Court's decision in *FTC v. Actavis* is one of the most important antitrust decisions in the modern era. In one fell swoop, the Court eliminated the immunity that most lower courts had applied to "reverse payment"¹ settlements (by which a brand-name drug company pays a generic firm to delay entering the market) and made clear that such agreements could violate the antitrust laws.

Despite its significance, the *Actavis* ruling was not the clearest decision ever. The Court could have provided more guidance for lower courts in structuring their antitrust analysis. This symposium consists of seven articles that provide some of the clarity missing in the Court's decision. Respectively, the articles:

* Distinguished Professor, Rutgers Law School. Copyright © 2015 Michael A. Carrier. I would like to thank the authors for their contribution to this written symposium, and the University of San Francisco Law School and sponsors for their generous support that enabled the live symposium on February 27, 2015.

1. The agreements are often called "reverse payment" settlements because the payment flows from patentee to alleged infringer (unlike typical settlements in which alleged infringers pay to enter the market).

- (1) explain why courts have misconstrued *Actavis*;
- (2) articulate the “*Actavis* inference” and show how it reveals errors in court opinions and scholarship;
- (3) offer a set of jury instructions that courts can use in reverse-payment cases;
- (4) explain why brand promises not to introduce their own generics constitute payment;
- (5) show how state law can target reverse-payment settlements;
- (6) explain why the *Noerr-Pennington* doctrine does not immunize reverse-payment settlements; and
- (7) demonstrate how *Actavis* can apply beyond the pharmaceutical industry.

I. WHY COURTS HAVE GONE AWRY

In the first article, *Deactivating Actavis: The Clash Between the Supreme Court and (Some) Lower Courts*,² Joshua Davis and Ryan McEwan ask why courts have made fundamental errors in applying *Actavis*. The authors discuss four mistakes: limiting *Actavis* to cash payments; interpreting the Court’s reasons for its holding as the basis of the legal standard; applying the rule of reason analysis rigidly; and applying antitrust standards as “discrete tests” rather than as “a continuum.”³

The authors explain that “[a]ll of these errors appear to derive from a single source: an effort by lower courts to find a set of tools to decide ‘reverse payment’ cases in a relatively mechanical manner.”⁴ Despite these courts’ yearning for guidance, the Supreme Court has “resisted providing” such a “set of tools, . . . not writ[ing] *Actavis* in a way to make management of a ‘reverse payment’ case completely straightforward.”⁵

2. Joshua Davis & Ryan McEwan, *Deactivating Actavis: The Clash Between the Supreme Court and (Some) Lower Courts*, 67 RUTGERS U. L. REV. 557 (2015).

3. *Id.* at 561–62.

4. *Id.* at 562.

5. *Id.*

Actavis “asked lower courts to take into account certain economic realities,” but “[s]ome lower courts seem resistant to that task.”⁶

For one example, the authors point to *In re Loestrin 24 Fe Antitrust Litigation*.⁷ In that case, the judge considered whether *Actavis* included payments in a form other than cash. The authors explain that “[o]n one hand, [the court] seemed to recognize that if the holding applies only to cash, it contains an exception that swallows the rule,” which could “render [*Actavis*] a dead letter.”⁸ But on the other hand, the judge “seemed to think formal legal analysis obligated him to conclude that the holding of *Actavis* extended only to cash.”⁹ The judge “felt caught, then, between what justice demands and what the law requires.”¹⁰

The authors, however, find that the opinion is “remarkably unpersuasive as a matter of positive law.”¹¹ One reason may be that the court believed that “the Supreme Court did not actually provide meaningful guidance but rather merely purported to do so.”¹² The authors find “telling” the court’s “apparent frustration” in “not receiv[ing] the guidance it would have liked.”¹³ They conclude that courts like the *Loestrin* court “may feel the need for better guidance so acutely that they inadvertently treat passages justifying the [*Actavis*] opinion as if they create a test for lower courts to apply.”¹⁴

In the courts’ confusion after *Actavis*, the authors also see “a lesson for the Supreme Court.”¹⁵ In the future, the Court “could be more mindful of the practical needs of trial court judges” and “could try to provide better guidance than it currently does, formulating rules that will be manageable for lower courts.”¹⁶ The authors “ha[ve] a sense that the Court gives a low priority to framing legal doctrines in a way that will work in the courtroom or identifying them clearly when it does.”¹⁷ But they hold out hope that “[t]here is an alternative to leaving lower courts to hunt and peck for key propositions of law in binding Supreme Court opinions.”¹⁸ Additional guidance to lower courts would increase “certainty

6. *Id.*

7. 2014 WL 4368924 (D.R.I. Sept. 4, 2014).

8. Davis & McEwan, *supra* note 2, at 559.

9. *Id.*

10. *Id.*

11. *Id.* at 560.

12. *Id.* at 576.

13. *Id.*

14. Davis & McEwan, *supra* note 2, at 576.

15. *Id.* at 583.

16. *Id.*

17. *Id.*

18. *Id.*

and efficiency” and would decrease “the odds that a trial court would feel compelled to reach an unjust result, particularly when the law actually requires it to do justice.”¹⁹

II. ASSISTANCE FROM *ACTAVIS* INFERENCE

In the second article, *The Actavis Inference: Theory and Practice*,²⁰ Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, and Carl Shapiro seek to “assist courts and counsel” by elaborating upon the “*Actavis* Inference.”²¹ They assert that the inference, reflecting the “core insight of *Actavis*,” provides that “a large and otherwise unexplained payment, combined with delayed entry, supports a reasonable inference of harm to consumers from lessened competition.”²²

The authors explain that a reverse-payment settlement is not “the *only* route an antitrust plaintiff can take.”²³ They address issues relating to payment with which courts have wrestled. For example, they find that limiting *Actavis* to cash payments would “open up a gaping loophole.”²⁴ The authors also explain that agreements by which brands agree not to market their own generics are “clearly costly” since they constrain the brand’s “future business choices.”²⁵ And “focusing on the legality of an exclusive license misses the key issue, the fact of a transfer of value from Brand to Generic.”²⁶

The authors next address pleading issues. They explain that courts can consider issues related to products and services furnished by the brand, settlement of unrelated patent litigation, and “no-authorized-generic” deals.²⁷ In responding to one court’s assertion that a non-monetary payment must be “converted to a reliable estimate of its monetary value,” the authors reply that “*Actavis* never states that the value of the payment must be ascertained, but only that it must be shown to be above reasonably anticipated litigation costs.”²⁸

The authors also show that “the *Actavis* Inference fully applies when multiple generic firms, rather than just one, threaten to enter the

19. *Id.* at 583–84.

20. Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, & Carl Shapiro, *The Actavis Inference: Theory and Practice*, 67 RUTGERS U. L. REV. 585 (2015). [hereinafter Edlin et al.]

21. *Id.* at 585.

22. *Id.*

23. *Id.* at 592.

24. *Id.*

25. *Id.* at 596.

26. Edlin et al., *supra* note 20, at 598.

27. *Id.* at 598–99.

28. *Id.* at 601.

market.”²⁹ Their model reveals that “the *Actavis* Inference becomes stronger and more important in the presence of multiple generic firms,” where “delaying generic entry will boost profits even more, and harm competition even more, than with just one generic entrant.”³⁰ The authors also assert that “the contrary conclusions reached in a recent paper by Bruce Kobayashi, Joshua Wright, Douglas Ginsburg, and Joanna Tsai (KWGT) are incorrect, inconsistent with KWGT’s own analysis, or irrelevant to a faithful implementation of *Actavis*.”³¹

Finally, the authors “clarify the reasons not to litigate the patent in the antitrust case.”³² The authors explain that the “correct antitrust analysis must be based on what was reasonably known to the parties about patent validity and infringement *at the time they entered into their settlement*.”³³ They make clear that the Supreme Court adopted such an *ex ante* approach in *Actavis*, finding that the risk of losing the patent case “is assessed at the time of the settlement” and that “it would make no sense to evaluate such ‘risk’ after the patent has been found valid or invalid.”³⁴ The authors explain that the “best information” available to courts to determine the parties’ *ex ante* beliefs comes from the terms of the agreement itself, with a “large and unexplained payment” serving as a “strong signal that the patent holder had substantial doubt that it would win the underlying patent litigation.”³⁵ As a result, “litigating the patent is thus of limited probative value and not dispositive regarding a potential antitrust violation.”³⁶

III. MODEL JURY INSTRUCTIONS

In the third article, *Model Jury Instructions: Trial by Actavis*, David Sorenson and Steve Shadowen address the lack of clarity in *Actavis* by offering model jury instructions.³⁷ The authors explain that *Actavis* “leave[s] to the lower courts the structuring of the . . . rule-of-reason antitrust litigation.”³⁸ To help provide that structure, the article offers Model Jury Instructions and a Model Verdict Slip for a “typical” reverse

29. *Id.* at 586.

30. *Id.* at 586, 588, 606.

31. *Id.* at 586.

32. Edlin et al., *supra* note 20, at 586.

33. *Id.* at 617.

34. *Id.* at 618.

35. *Id.*

36. *Id.* at 586.

37. David Sorenson & Steve Shadowen, *Model Jury Instructions: Trial by Actavis*, 67 RUTGERS U. L. REV. 637 (2015).

38. FTC v. *Actavis*, 133 S. Ct. 2223, 2238 (2013).

payment case.³⁹ The authors' documents "grew out of [their] experiences in representing plaintiffs in the first post-*Actavis* reverse payment case tried to a jury."⁴⁰

The jury instructions begin by offering a background on the Hatch-Waxman Act, explaining the purpose of the antitrust laws, and situating state-law claims.⁴¹ They next explain that a large payment is a "strong indicator" of market power "because it would be illogical" for a brand otherwise to make a large payment since "there would be no point in making a payment to delay competition if existing competition had already pushed prices down to the competitive level."⁴² The instructions also explain that a "large payment" exceeds a brand firm's "reasonably estimated saved patent litigation costs."⁴³

The instructions point out that "[n]o large payment" is "needed or necessary" to reach a "lawful settlement" by which the parties compromise on the date of generic entry.⁴⁴ To the contrary, a large payment "likely delays the entry date" because the brand "must be getting something from the generic in return" for the large payment.⁴⁵

The instructions make clear that a payment "does not have to be in cash," and that a brand's promise not to launch an authorized generic in exchange for delayed generic entry reveals a large payment "because there is no dispute its dollar value was much larger than any possible saved litigation costs."⁴⁶

The instructions then make clear that impermissible defenses include the existence of a patent, allowance of generic entry before the end of the patent term, settlements for "business reasons," the avoidance of risk, and the question of who would have won the patent case.⁴⁷ The instructions conclude by addressing causation issues and issues of the timing of generic entry.⁴⁸

39. Sorensen & Shadowen, *supra* note 37, at 637.

40. *Id.* at 637–38.

41. *Id.* at 644–49, 651–53.

42. *Id.* at 655–56.

43. *Id.* at 669.

44. *Id.* at 671.

45. Sorensen & Shadowen, *supra* note 37, at 671.

46. *Id.* at 673.

47. *Id.* at 677–82.

48. *Id.* at 685–93.

IV. PAYMENT FROM NO-AUTHORIZED-GENERIC PROMISE

In the fourth article, I offer *Eight Reasons Why “No-Authorized-Generic” Promises Constitute Payment*.⁴⁹ As this symposium demonstrates, there are numerous unresolved issues after *Actavis*. But the question I address in this article is embarrassingly easy.

The first reason why no-authorized-generic (“no-AG”) clauses constitute payment is that such a conclusion is consistent with the language of *Actavis*. The Supreme Court’s use of the phrase “millions of dollars” anticipates an interpretation of payment that extends beyond naked cash transfers.⁵⁰ The Court, for example, pointed to the value to first-filing generics of not facing other generic competition during the 180-day exclusivity period.⁵¹ Second, such a conclusion accords with the facts of *Actavis*, where the Federal Trade Commission (FTC) alleged not that the brand made naked cash payments to the generics, but that it made overpayments for generic services that had little value.⁵²

Third, a no-AG pledge typically provides significant value to generics. When they compete with AGs during the exclusivity period, first-filing generics lose 25% of their market share and suffer revenue reductions of 40% to 52%.⁵³ This is a significant loss given that first filers “often make the majority of their profits during this period.”⁵⁴

Fourth, generics receive more through such promises than they would by winning patent litigation. A brand’s promise not to introduce an authorized generic “provides a type of consideration that a generic could not obtain as a result of winning a court ruling that the patent was invalid or not infringed.”⁵⁵ Fifth, brands act against their self-interest in making no-AG promises since they use AGs to “recapture lost revenue when their drug faces patent expiration.”⁵⁶ For that reason, when brands sacrifice this revenue stream, first-filing generics benefit from the revenue brands leave on the table.⁵⁷

Sixth, treating no-AG promises as payment emphasizes substance over form. The Supreme Court has consistently required antitrust analysis to “be based upon demonstrable economic effect rather than . . .

49. Michael Carrier, *Eight Reasons Why “No-Authorized-Generic” Promises Constitute Payment*, 67 RUTGERS U. L. REV. 697 (2015).

50. *Id.* at 706.

51. *Id.* at 707.

52. *Id.* at 709.

53. *Id.* at 710.

54. *Id.* at 711.

55. Carrier, *supra* note 49, at 712.

56. *Id.* at 714.

57. *Id.* at 715.

formalistic line drawing.”⁵⁸ Whether substance or form controls in antitrust analysis “is a question so easy it defies imagination that it is worth attention.”⁵⁹ But two district courts followed just such a formalistic approach in concluding that payment only takes the form of cash.⁶⁰

Seventh, such pledges can be more coercive than cash payments. First filers can always decline brands’ invitations to settle with cash payments and enjoy their 180-day exclusivity period. But brands promising not to introduce AGs during the period have “more leverage to weaken this uniquely valuable period.”⁶¹ And eighth, the clauses present an example of market division. By delaying its entry into the market, the generic prolongs the brand’s monopoly period. And by agreeing not to compete with the first-filing generic during its exclusivity period, the brand reduces competition in the generics sector of the market. Each of the reciprocal pledges increases the parties’ joint profits at the expense of consumers.⁶²

V. STATE SCRUTINY OF REVERSE-PAYMENT SETTLEMENTS

In the fifth article, *Cipro’s \$400 million Pay-for-Delay: How California Law and Courts Can Make a Difference in Reverse Payment Challenges*,⁶³ Cheryl Johnson uses the *Cipro* litigation as a “case study” to explore the role that California antitrust and unfair competition laws can play in challenges to reverse-payment settlements.⁶⁴

Johnson begins by responding to several critiques of state litigation. First, she explains that there is no exclusive federal jurisdiction for reverse-payment challenges since state courts “are capable of resolving complex cases involving possible patent issues” and the *Actavis* decision ensures that challenges do not present “disputed and substantial patent issues under federal patent laws.”⁶⁵

In addition, claims of federal antitrust preemption “disregard long-established state and federal precedent recognizing that the development

58. *Id.* (quoting *Cont’l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 58–59 (1977)).

59. *Id.* at 716.

60. *Id.* (discussing *In re Loestrin 24 FE Antitrust Litigation*, 2014 WL 4368924 (D.R.I. Sept. 4, 2014); *In re Lamictal Direct Purchaser Antitrust Litigation*, 18 F. Supp. 3d 560, 562 (D.N.J. 2014)).

61. *Carrier*, *supra* note 49, at 717.

62. *Id.* at 719.

63. Cheryl Johnson, *Cipro’s \$400 million Pay-for-Delay: How California Law and Courts Can Make a Difference in Reverse Payment Challenges*, 67 RUTGERS U. L. REV. 721 (2015).

64. *Id.*

65. *Id.* at 733, 735.

of state antitrust law distinct from and independent of federal law is healthy, lawful, and not to be disturbed by federal courts or laws.”⁶⁶ Johnson also responds to the argument that federal patent law preempts state law by pointing to the “strong presumption against preemption,” the absence of federal patent law’s express preemption of California antitrust law, the coexistence of the laws for more than 100 years, and *Actavis*’s instruction that patentees do not have “a right to pay . . . rivals not to compete.”⁶⁷

Johnson then discusses California’s interest in challenging reverse-payment settlements, as “the affordability of healthcare and drugs represents a key state concern” and competition among drug firms is “vital to arrest increasing drug prices.”⁶⁸ California also offers “more favorable law on pleading, juries, experts, and class actions.”⁶⁹

Finally, Johnson explains that California substantive law extends to conduct beyond the reach of federal antitrust law. The Cartwright Act “unambiguously condemns trusts.”⁷⁰ Reverse-payment settlements “plainly appear to be the kind of classic competitor trusts” targeted by the Cartwright Act and present conduct “historically treated as per se unlawful horizontal output limitation or allocation agreements.”⁷¹

Next, California’s Business and Professions Code section 16600 presents an “uncompromising condemnation of virtually all non-competition agreements.”⁷² It “sets out a general rule” that “mak[es] all contracts restraining trade illegal per se under California law (save for statutory exceptions)” and thus “not subject to a rule of reason analysis.”⁷³

Finally, the Unfair Competition Law targets “any unlawful, unfair or fraudulent business act or practice.”⁷⁴ Johnson finds that reverse-payment settlements could violate the UCL under any of three relevant standards: (1) a balancing test could find that “the gravity of the harm of an improperly extended monopoly on a life-saving drug outweighs the benefit of resolving patent litigation”; (2) a reverse payment could violate the “spirit” of Section 16600; and (3) such a payment could “cause substantial consumer injury not outweighed by the benefit of decreased

66. *Id.* at 736.

67. *Id.* at 739–40.

68. *Id.* at 742.

69. Johnson, *supra* note 63, at 744.

70. *Id.* at 746.

71. *Id.* at 747.

72. *Id.* at 748.

73. *Id.*

74. *Id.* at 750 (citing CAL. BUS. & PROF. CODE § 17200).

litigation costs,” with consumers having “no route to avoid the harm of extended monopoly prices on a drug.”⁷⁵

VI. NOERR-PENNINGTON DOES NOT IMMUNIZE SETTLEMENTS

In the sixth article, *Noerr-Pennington and Reverse Payment Agreements: A Match Not Made in Heaven*, Abiel Garcia asks whether *Noerr-Pennington* immunity—which “protect[s] citizens’ right to petition the government for redress of grievances”—applies to reverse-payment settlements.⁷⁶

Defendants have sought *Noerr-Pennington* immunity for settlements on the grounds that a judge “reviewed and approved the settlement” and the settlement “is part of petitioning activity and stems from the government’s consent judgment.”⁷⁷ The three courts faced with this argument in the context of reverse-payment settlements largely have rejected it, with one finding that an earlier court did not “play[] an independent role in drafting the terms in the consent judgments”; another concluding that the doctrine “did not apply to consent judgments”; and a third dismissing the plaintiffs’ complaint on other grounds.⁷⁸

Garcia then explains why settlements do not fall within the scope of *Noerr-Pennington*. He notes that the purpose of the doctrine is to “encourage the populace to inform the government of its desires” and to “protect the people’s First Amendment right to petition.”⁷⁹ But “[t]he decision of whether to settle has little to no bearing on the people’s right to petition its government” and “has no effect on the people’s right to inform their government.”⁸⁰ In fact, the parties “are not petitioning the government for their needs, but rather withdrawing their original petition, in which they were to make their wishes made.”⁸¹ And because “the parties are incentivized in these settlements to collude, extend, and share the branded company’s monopoly at the public’s expense, they have no incentive to inform the court of the damages that their collusive agreement is having on the public.”⁸²

75. Johnson, *supra* note 63, at 752.

76. Abiel Garcia, *Noerr-Pennington and Reverse Payment Agreements: A Match Not Made in Heaven*, 67 RUTGERS U. L. REV. 755, 756 (2015).

77. *Id.* at 761.

78. *Id.* at 761–66.

79. *Id.* at 767.

80. *Id.* at 768.

81. *Id.*

82. Garcia, *supra* note 76, at 769.

Garcia explains that “denying *Noerr-Pennington* immunity to consent judgments does not eradicate, or lessen the incentive of, the parties’ right to petition the government for redress.”⁸³ In fact, granting such immunity “would . . . provid[e] protection to parties’ withdrawal of a petition, which cuts against the reason for the doctrine in the first place.”⁸⁴ It also would “render[] moot” the Supreme Court’s opinion in *Actavis*.⁸⁵

Garcia concludes that “[b]ecause *Noerr-Pennington* provides blanket immunity and a consent judgment potentially covered by such immunity could irrevocably harm consumers in the form of higher drug prices,” courts “should be rigorous in their scrutiny of pay-for-delay agreements embodied in consent judgments, and skeptical of any argument in favor of granting *Noerr-Pennington* protection.”⁸⁶

VII. APPLYING *ACTAVIS* BEYOND PHARMACEUTICALS

In the seventh article, *Beyond Hatch-Waxman*, Shubha Ghosh considers the applicability of *Actavis* beyond the pharmaceutical industry.⁸⁷ He considers three possible readings of Justice Breyer’s decision: “antitrust scrutiny of all settlements,” “antitrust treatment of regulated industries,” and the general “relationship between patent and antitrust.”⁸⁸

Ghosh dismisses the first reading because Justice Breyer’s analysis reaches beyond settlements to “other potential abuses giving rise to antitrust liability.”⁸⁹ Ghosh also dismisses the second reading, as Justice Breyer only “oblique[ly]” cites the Court’s earlier *Trinko* decision⁹⁰ (which is a “key precedent” in determining the relationship between antitrust and regulation), and does not discuss “the role of antitrust in industries subject to alternative forms of Congressional regulation.”⁹¹

Ghosh then finds support for the third, most expansive, reading in the stark divide between the two opinions in *Actavis*. Ghosh explains that, in dissent, “[Chief] Justice Roberts’ minimalist role for antitrust

83. *Id.* at 774.

84. *Id.*

85. *Id.*

86. *Id.* at 773.

87. Shubha Ghosh, *Beyond Hatch-Waxman*, 67 RUTGERS U. L. REV. 779 (2015).

88. *Id.* at 780.

89. *Id.*

90. *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004).

91. Ghosh, *supra* note 87, at 781–82.

scrutiny contrasts with Justice Breyer's more expansive view."⁹² In fact, the majority opinion "shifts our understanding of how antitrust and patent laws connect."⁹³ Ghosh finds additional support for the third reading in the "notable number" of decisions after *Actavis* in which the opinion's arguments are extended to non-reverse-payment settings, which "raise issues of copyright law, trademark law, and licensing."⁹⁴ And he traces references to *Actavis* in administrative speeches, guidelines, and filings, as well as litigation documents.⁹⁵

Ghosh recommends that *Actavis*'s reasoning be applied to the settlement of *inter partes* review proceedings at the U.S. Patent and Trademark Office.⁹⁶ These proceedings "allow[] a party other than the patent owner to challenge the validity of a patent on novelty and non-obviousness grounds based on new prior art."⁹⁷ At the time of Ghosh's article, there had been nearly 700 motions to settle *inter partes* review.⁹⁸ Although only two of these motions cited *Actavis*, Ghosh's "main conclusion" in the article is to focus "future antitrust enforcement actions . . . on *inter partes* settlements."⁹⁹ The reasons are that patents "that should not have been granted provide no benefit for innovation" and "impose limits on competition," the procedure "was designed to protect against the harmful effects of invalid patents," and "[s]ettlements to *inter partes* proceedings would potentially fail under the rule of reason."¹⁰⁰ *Inter partes* settlements are "suspect" under antitrust law because they "requir[e] the challenger, often an alleged infringer," to not pursue invalidity claims "in exchange for the dropping of a lawsuit," thus allowing "invalid patents to continue."¹⁰¹

VIII. CONCLUSION

The Supreme Court left important issues unresolved in its landmark *Actavis* decision. The seven articles in this symposium fill some of the gaps, offering inferences, jury instructions, reasons for errors, analyses of no-AG promises, state law frameworks, and evaluation beyond the Hatch-Waxman Act. The contributions in this symposium promise to

92. *Id.* at 782.

93. *Id.*

94. *Id.*

95. *Id.* at 783–95.

96. *Id.* at 799.

97. Ghosh, *supra* note 76, at 800.

98. *Id.* at 801.

99. *Id.*

100. *Id.*

101. *Id.* at 802.

offer guidance as courts and scholars elaborate on these issues for years to come.