

Eight Reasons Why "No-Authorized-Generic" Promises Constitute Payment

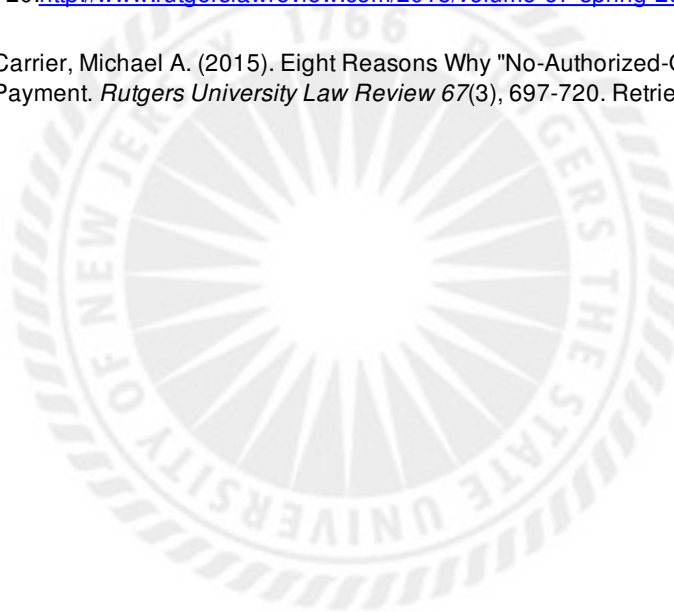
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EIGHT REASONS WHY “NO-AUTHORIZED-GENERIC” PROMISES CONSTITUTE PAYMENT

*Michael A. Carrier**

I. INTRODUCTION

Drug patent settlements present some of the most nuanced issues in patent and antitrust law today. Does a brand-name drug company’s payment to a generic firm cause delayed entry? Does a brand’s forgiveness of a generic’s potential damages constitute payment? How should courts evaluate parties’ simultaneous settlement of multiple cases?

To this universe of complex questions, courts have added one that is embarrassingly easy: Is there a payment when a brand promises not to introduce its own generic (known as an “authorized generic” or “AG”), which could be worth millions of dollars to the generic? Under any reasonable interpretation of economics, the Supreme Court’s 2013 decision in *FTC v. Actavis*,¹ or common sense, such a promise constitutes payment.

In two recent cases, however, courts held that brands’ no-AG promises did not count as payment. The New Jersey district court in *In re Lamictal Direct Purchaser Antitrust Litigation* found that “nothing in *Actavis*” indicated that “a no-AG agreement is a ‘payment.’”² And in *In re Loestrin 24 FE Antitrust Litigation*, the Rhode Island district court found

* Distinguished Professor, Rutgers Law School. I would like to thank participants in the Tel Aviv University Law & IT Colloquium for helpful comments. Copyright © 2015 Michael A. Carrier.

1. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).
2. *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 567 (D.N.J. 2014).

that *Actavis* “fixates on the one form of consideration that was at issue in that case: cash.”³

This article first provides background on drug patent settlements and authorized generics. It then examines the *Lamictal* and *Loestrin* cases. Finally, it offers eight reasons why a no-AG promise constitutes payment. First, such a conclusion is consistent with the language of *Actavis*. Second, it accords with the facts of *Actavis*. Third, a no-AG pledge typically provides significant value to generics. Fourth, generics receive more through such promises than they would by winning patent litigation. Fifth, brands act against their self-interest in making no-AG promises, which reveals generics’ gain from the pledges. Sixth, treating no-AG promises as payment emphasizes substance over form. Seventh, such pledges can be more coercive than cash payments. And eighth, the clauses present a classic example of market division.

II. DRUG PATENT SETTLEMENTS

Analysis of drug patent settlements involving authorized generics requires an understanding of the Hatch-Waxman Act, Congress’s framework for increasing generic competition and innovation in the pharmaceutical industry.⁴ Before the Act’s passage in 1984, a generic firm was required to engage in lengthy and expensive clinical trials replicating brand trials that it could not begin during the patent term. As a result, roughly 150 drugs had no generic equivalent even after the brands’ patent terms had expired.⁵

The Hatch-Waxman Act created a new legal framework, with a more expedited approval process by the U.S. Food and Drug Administration (“FDA”), by which generics could rely on brand trials in filing an Abbreviated New Drug Application (“ANDA”) and enter the market during the patent term.⁶ A central element was the “Paragraph-IV certification,” by which a generic certifies that the brand’s patent is invalid or will not be infringed by the generic.⁷ To encourage entry, the drafters created a 180-day period of marketing exclusivity reserved for

3. *In re Loestrin 24 FE Antitrust Litig.*, No. 1:13-md-2472-S-PAS, 2014 WL 4368924, at *7 (D.R.I. Sept. 4, 2014).

4. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

5. H.R. REP. NO. 98-857, pt. 1, at 17 (1984).

6. FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 5 (2002) [hereinafter *FTC, GENERIC DRUG ENTRY*].

7. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2013).

the first generic to make a Paragraph-IV filing.⁸ During this period, the FDA cannot approve other generic applications for the same brand drug.

Although the 180-day period was designed to encourage patent challenges and early entry, brands have settled patent litigation by paying generics (especially first-filing generics)⁹ not to enter the market. As discussed below,¹⁰ such agreements present dangers similar to market division.¹¹ But instead of allocating geographic space, in which the parties reserve territories for themselves, they allocate time.¹² And these harms are more likely because of the parties’ aligned incentives, as brands can increase monopoly profits by delaying generic entry and use a portion of these gains to pay generics.

One concern with brand payments to generics (which I refer to as “exclusion payments”)¹³ is that they provide patentees with more protection than is provided by the patent itself. An agreement concerning the generic entry date, without any cash payment, tends to reflect the odds of the parties’ success in patent litigation.¹⁴ But a brand is likely to gain additional exclusivity by supplementing an entry-date agreement with a payment to the generic. And the monopoly profits the brand earns in this period of delay typically exceed the reduced profits it would earn from sharing the market with the generic.

From 2005 to 2012, nearly all the appellate courts that had examined exclusion-payment settlements concluded that they did not present antitrust concern because they fell within the “scope of the patent.”¹⁵ As

8. 21 U.S.C. § 355(j)(5)(B)(iv) (2013).

9. BUREAU OF COMPETITION, FED. TRADE COMM’N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2012 1–2 (2013) [hereinafter FTC, FY 2012 AGREEMENTS], available at <http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf> (noting that 23 out of 40 potential “pay for delay” settlements in 2012 involved first-filing generics).

10. See *infra* Section IV.H.

11. See *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49 (1990) (per curiam), cited in *Actavis*, 133 S. Ct. at 2227.

12. *In re Schering-Plough Corp.*, 136 F.T.C. 956, 971 (2003), vacated, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005).

13. The phrase “exclusion payments” captures the exclusion that brands obtain by paying generics to delay entry. The payments have also been called “reverse payments” because the payment flows from patentee to alleged infringer (unlike typical settlements in which alleged infringers pay patentees).

14. Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 660 (2004).

15. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006); *Schering-Plough Corp.*, 402 F.3d at 1076.

applied by these courts, the mere existence of a patent—even one that was invalid or not infringed—justified any payment.¹⁶ The courts also deferred to the policy supporting settlements, presumption of patent validity, and frequency of settlements in applying excessively deferential analysis.¹⁷

In contrast to the majority of appellate courts, the Supreme Court, in the landmark case *FTC v. Actavis, Inc.*, offered a more nuanced and appropriate analysis, recognizing the anticompetitive effects of a payment for a potential rival to delay entering the market.¹⁸ The Court held that the existence of a patent did not immunize exclusion-payment settlements from antitrust scrutiny. In particular, it found that it “would be incongruous to determine antitrust legality by measuring [a] settlement’s anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well.”¹⁹

The Court in *Actavis* found that a brand’s payment “amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product.”²⁰ The Court worried that “a party with no claim for damages . . . [would] walk[] away with money simply so it will stay away from the patentee’s market.”²¹ And it lamented that “payment in return for staying out of the market [] . . . simply keeps prices at patentee-set levels,” which leads to gains for the patentee and generic challenger but losses for the consumer.²²

In recent years, brand firms have ventured away from naked cash payments for generics to delay entering the market. Instead, they have paid generics for IP licenses, for supplying raw materials or finished products, and for helping to promote products.²³ They have paid

16. The courts only carved out exceptions for fraud before the Patent Office or sham litigation. See *In re Ciprofloxacin*, 544 F.3d at 1337; *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012).

17. See Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 60–67 (2009).

18. *Actavis*, 133 S. Ct. at 2227.

19. *Id.* at 2231.

20. *Id.* at 2234.

21. *Id.* at 2233.

22. *Id.* at 2234–35.

23. BUREAU OF COMPETITION, FED. TRADE COMM’N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2006 4–5 (2007), available at www.ftc.gov/reports/mmact/MMAreport2006.pdf.

milestones, up-front payments, and development fees for unrelated products.²⁴ In many cases, they have guaranteed that the settling generic will enjoy the exclusivity period.²⁵ And, in the latest trend, they have agreed not to launch "authorized generics."²⁶

III. AUTHORIZED GENERICS

Authorized generics are approved by the FDA as brand drugs but marketed as generics.²⁷ In a comprehensive report, the FTC found that authorized generics were marketed during the 1990s but were "reportedly [] not very profitable," which led to brands "abandon[ing] the practice by the end of the decade."²⁸ By 2003, however, because of the increased use of 180-day exclusivity periods (after courts eliminated the requirement that generics "successfully defend" litigation), they returned.²⁹ From 2003 to 2006, there were 19 to 21 launches of authorized generics a year.³⁰

Courts that have analyzed the question have uniformly found that brands are able to introduce authorized generics during the first-filing generic's 180-day period. In *Mylan Pharmaceuticals v. FDA*, for example, the Northern District of West Virginia court held that "the plain and unambiguous language" of the Hatch-Waxman Act "does not prohibit" brand firms from "marketing an 'authorized generic' during the 180-day exclusivity period."³¹ Similarly, in *Teva Pharmaceutical Industries v. Crawford*, the D.C. Circuit concluded that "the Act clearly does not

24. *Id.*

25. See H.R. 1706, *The Protecting Consumer Access to Generic Drugs Act of 2009: Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection of the Comm. On Energy and Commerce*, 111th Cong. 57 (2009) (statement of C. Scott Hemphill, Associate Professor of Law, Columbia University) (contending that legislation should explicitly address retained exclusivity).

26. BUREAU OF COMPETITION, FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2007 2 (2008), available at <http://www.ftc.gov/os/2008/05/mmaact.pdf>; see also C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 684 (2009); Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 RUTGERS L.J. 83, 93 (2009).

27. FEDERAL TRADE COMM'N, AUTHORIZED GENERICS: AN INTERIM REPORT 1 (2009) [hereinafter FTC, INTERIM REPORT].

28. FEDERAL TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 12 (2011) [hereinafter FTC, AUTHORIZED GENERIC REPORT].

29. *Id.* at 12 n.4.

30. *Id.* at 11.

31. *Mylan Pharms. v. FDA*, No. 104CV242, 2005 WL 2411674, at *7 (N.D.W. Va. Sept. 29, 2005).

prohibit the holder of an approved [New Drug Application] from marketing, during the 180-day exclusivity period, its own 'brand-generic' version of its drug."³²

Settlements today are increasingly including provisions by which brands promise to refrain from launching an AG that would compete with the first-filing generic during its exclusivity period.³³ From 2004 through 2010, 75 of 333 settlements filed with the FTC included AG-related provisions that "raised potential competitive concerns."³⁴ Of the 75, 39 involved brand promises not to introduce an authorized generic combined with delayed generic entry. The other agreements lacked one of these elements because (1) they did not include a brand's promise not to compete, (2) the generic was not eligible for the 180-day period, (3) the brand appointed a later filer as an AG marketer, or (4) the brand appointed an AG for a different product than the subject of the patent litigation.³⁵ Of the 39 agreements involving a no-AG promise and delayed entry between 2004 and 2010, 15 took place in 2010 alone.³⁶

No-AG clauses are typical today. In a recent survey, the FTC concluded that 19 of 40 potential exclusion-payment settlements reported in 2012 involved no-AG provisions.³⁷ This was a "record number" that was "significantly greater than" that in previous years.³⁸ Settlements with no-AG clauses have involved some of the most popular drugs, including attention-deficit-hyperactivity-disorder ("ADHD") drug

32. *Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005).

33. Agreements by which brands promise not to compete with first-filing generics often take the form of (1) explicit agreements not to compete during the 180-day period, (2) designating first-filers as exclusive distributors, or (3) granting first-filers exclusive licenses to market authorized generics. FTC, AUTHORIZED GENERIC REPORT, *supra* note 28, at 144; Brief for the Federal Trade Commission et al. as Amicus Curiae, *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-995, 2012 WL 6725580 (D.N.J. Dec. 6, 2012), at *5, available at <http://www.ftc.gov/os/2012/10/121005lamictalamicusbrief.pdf> [hereinafter *FTC Brief*].

34. FTC, AUTHORIZED GENERIC REPORT, *supra* note 28, at 139.

35. *Id.* at 142-43.

36. *Id.* at 145.

37. FTC, FY 2012 AGREEMENTS, *supra* note 9, at 1.

38. *Id.* at 2. The subsequent survey showed a decline in such provisions, to 4 of 29 potential pay-for-delay agreements. BUREAU OF COMPETITION, FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2013 1 (2014) [hereinafter *FTC, FY 2013 AGREEMENTS*], available at <https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf>.

Adderall XR, antidepressant Effexor XR, acid reflux drug Nexium, and clot-preventing Plavix.³⁹

IV. LAMICTAL AND LOESTRIN DECISIONS

The increase in the use of settlements with no-AG clauses has resulted in courts analyzing whether such promises constitute payment under the Supreme Court's *Actavis* decision. Two courts have recently held that they do not.

In *In re Lamictal Direct Purchaser Antitrust Litigation*, brand GlaxoSmithKline agreed not to launch its own generic version of epilepsy- and bipolar-disorder-treating Lamictal during first-filing generic Teva's 180-day exclusivity period.⁴⁰ The plaintiffs argued that a no-AG pledge was equivalent to cash and could constitute an exclusion payment.⁴¹

The court in *Lamictal* disagreed, stating that "nothing in *Actavis* says" that "a no-AG agreement is a 'payment'" or that "a settlement [agreement] contains a reverse payment when it confers substantial financial benefits."⁴² In addition, "[b]oth the majority and the dissenting opinions [in *Actavis*] reek with discussion of payment of money."⁴³ And the court pointed to several passages in *Actavis* that focused on the "exchange of money."⁴⁴

The court addressed the "argument that a 'reverse payment' need not consist of money" by looking to *Black's Law Dictionary*, which defines "payment" to include not just money but also "some other valuable thing."⁴⁵ But it found that "support for this broadened reading of 'payment' is thin."⁴⁶ In particular, "there are only a few scattered indications that the Supreme Court intended its holding to apply to non-monetary 'payments.'"⁴⁷

The court explained that Teva's receipt of consideration in the settlement was not exceptional since, otherwise, "there would be no

39. Hemphill, *supra* note 26, at 684 n.230 (describing agreements containing no-AG terms).

40. *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 562 (D.N.J. 2014).

41. *Id.* at 569.

42. *Id.* at 567.

43. *Id.*

44. *Id.*

45. *Id.* at 568 (emphasis omitted).

46. *In re Lamictal*, 18 F. Supp. 3d at 568.

47. *Id.*

incentive to settle.”⁴⁸ In fact, “there is ‘payment’ in every settlement.”⁴⁹ Nor was plaintiffs’ attempt to turn to the “overall holding and tenor of *Actavis*” availing, as an opinion’s tenor “is a less reliable measuring stick than its actual words.”⁵⁰ In fact, the *Lamictal* settlement fell “within the gestalt of *Actavis*” and did not even have the “potential for genuine adverse effects on competition.”⁵¹ The court found “[t]hat Teva was allowed early entry, that there was no payment of money[,] and that the duration of the No-AG Agreement was relatively brief,” leading it to conclude that “the settlement was reasonable and not of the sort that requires *Actavis* scrutiny.”⁵²

In the second case, *In re Loestrin 24 FE Antitrust Litigation*, brand Warner Chilcott settled with first-filing generic Watson by making promises that included an agreement not to launch an authorized generic version of the oral contraceptive Loestrin 24 during Watson’s first 180 days on the market.⁵³ The *Loestrin* court granted defendants’ motion to dismiss. It asserted that *Actavis* “fixates on the one form of consideration that was at issue in that case: cash.”⁵⁴ The court then cited passages from *Actavis* that discussed money.⁵⁵ Although the court thought it would be “rash” to conclude, based on this language, that *Actavis* applied only to cash payments, it found that “more than merely the choice of words describing the consideration . . . suggests that the majority in *Actavis* intended for it to apply only to cash settlements.”⁵⁶

The court imposed a high bar on plaintiffs, requiring them to calculate a “true value” for a brand’s payment to a generic and punishing plaintiffs that were not able to make such a determination, finding that they would not be able to show anticompetitive effects, unjustified payments, market power, patent weakness, or the “basic reason” for settlement.⁵⁷

For example, the court stated that, under *Actavis*, courts must compare “the anticipated supracompetitive profits associated with

48. *Id.*

49. *Id.*

50. *Id.* at 569.

51. *Id.* at 569–70.

52. *In re Lamictal*, 18 F. Supp. 3d at 569. See generally Michael A. Carrier, *A U.S. Court Issues Formalistic Ruling on Reverse-Payment Settlements After Actavis*, E-COMPETITIONS BULL. (Inst. of Competition L., Art. No. 63588), Feb. 13, 2014.

53. *In re Loestrin 24 FE Antitrust Litig.*, No. 1:13-md-2472-S-PAS, 2014 WL 4368924, at *4 (D.R.I. Sept. 4, 2014).

54. *Id.* at *7.

55. *Id.*

56. *Id.* at *8.

57. *Id.* at *9, *12.

continued monopoly sale of the product, and the sum paid to the generic competitor.”⁵⁸ The *Loestrin* court even claimed that it “would be all but impossible to assess the ‘potential for genuine adverse effects on competition’” without making such a comparison.⁵⁹

Although it claimed that its restriction of *Actavis* to cash was “dictated by the language and meaning of *Actavis* and considerations of public policy,” the *Loestrin* court voiced “significant reservations” with this outcome.⁶⁰ The court recognized the burdens that its framework imposed on plaintiffs. It admitted that the *Twombly* pleading standard requires only “plausible grounds to infer an agreement” and that the plaintiffs had filed “two robust complaints.”⁶¹ And it conceded that the plaintiffs “(understandably) struggle to affix a precise dollar value” to the brand’s non-cash payment for delay and that “[t]his should come as no surprise because pleading facts sufficient to glean the monetary value of non-cash settlements is a tall task, one that would typically require considerable discovery to achieve.”⁶²

Ironically, the court understood that “it is of relatively little import whether a payment for delay is made in the form of cash or some other form of consideration.”⁶³ The reason is that “[w]hen a patent holder pays a would-be generic competitor to stay out of the market—regardless of the form of the payment—value is exchanged and the brand manufacturer is able to continue on with fewer competitors.”⁶⁴

Along these lines, the court recognized the dangers of its “cautious” approach.⁶⁵ In fact, the court admitted that its ruling would result in “pharmaceutical companies tak[ing] the obvious cue to structure their settlements in ways that avoid cash payments,” which would lead to the agreements “evad[ing] Sherman Act scrutiny.”⁶⁶

V. EIGHT REASONS WHY NO-AG CLAUSES COUNT AS PAYMENT

This Article concludes that the *Lamictal* and *Loestrin* decisions were wrong in holding that no-AG promises do not constitute payment. Even

58. *Id.* at *8.

59. *In re Loestrin*, 2014 WL 4368924, at *9.

60. *Id.* at *11.

61. *Id.*

62. *Id.*

63. *Id.* at *12.

64. *Id.*

65. *In re Loestrin*, 2014 WL 4368924, at *10.

66. *Id.* at *12. See generally Michael A. Carrier, *The U.S. District Court for the District of Rhode Island Issues Concerning Ruling on Drug Patent Settlements*, E-COMPETITIONS BULL. (Inst. of Competition L., Art. No. 63588), Sept. 4, 2014.

more, it shows that the issue is not a close call. This Part offers eight reasons why no-AG pledges count as payment.

First, such a conclusion is consistent with the language of *Actavis*. Second, it accords with the facts of *Actavis*. Third, a no-AG pledge typically provides significant value to generics. Fourth, generics receive more through such promises than they would by winning patent litigation. Fifth, brands act against their self-interest in making no-AG promises, which reveals generics' gain from the pledges. Sixth, treating no-AG promises as payment emphasizes substance over form. Seventh, such promises can be more coercive than cash payments. And eighth, the clauses present a classic example of market division.

A. *Actavis* Language

First, the conclusion that no-AG promises constitute payment is consistent with the language of *Actavis*. The *Actavis* opinion never uses the word "cash," but on five occasions, it uses the phrase "millions of dollars." At a minimum, four of the five instances anticipate an interpretation of payment that extends beyond naked cash transfers.

In the first instance, the Court describes a hypothetical example of a payment from "A" to "B."⁶⁷ This example merely introduces the topic the Court was addressing, taking the simplest form (mirrored in the initial generation of settlements) in which brands made cash payments to generics to delay entry until the end (or nearly the end) of the patent term.⁶⁸ In this use of "millions of dollars," Justice Breyer presents the issue, explains why such a payment is typically called a "reverse payment," and poses the "basic question" of whether such a settlement can violate the antitrust laws.⁶⁹ This introduction to a complex issue arising at the intersection of patent, antitrust, and Hatch-Waxman law does not provide much guidance on exactly what form payment must take.

The other four instances show that the Court believed that its framework would apply beyond naked cash transfers. In the second

67. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013).

68. For example, in *In re Tamoxifen Citrate Antitrust Litigation*, the brand paid the generic \$21 million and the generic's supplier \$45 million, and the generic agreed not to enter the market with a breast cancer drug until the patent expired. 466 F.3d 187, 193–94 (2d Cir. 2006). And in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, the brand paid the generic \$398 million to stay out of the market until six months before Bayer's patent on Cipro, a drug treating bacterial illnesses, expired. 544 F.3d 1323, 1328–29 n.5 (Fed. Cir. 2008).

69. *Actavis*, 133 S. Ct. at 2227.

occurrence, the Court describes an alleged overpayment from the brand to the generics.⁷⁰ But, as discussed more fully in the next section, this was not a naked cash payment but an alleged overpayment for generic promotion and backup-manufacturing services.⁷¹

In the third (related) occurrence, the Court states that “[t]he FTC allege[d] that in substance the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market.”⁷² The focus on “substance” indicates that the Court realized that this was not a naked cash payment. Instead, the Court recognized that there could be payments that do not take the form of cash but have a similar economic effect.

In the fourth and fifth instances, the Court uses the phrase “millions of dollars” to highlight the value to first-filing generics of not facing other generic competition during the 180-day exclusivity period. The Court states that the period “can prove valuable, possibly ‘worth several hundred million dollars.’”⁷³ And it asserts that the “special advantage of 180 days of an exclusive right to sell a generic version of the brand-name product . . . can be worth several hundred million dollars.”⁷⁴

These last two examples show the Court’s acknowledgement of the importance of the 180-day period. Such recognition reveals an understanding of generics receiving consideration in a form other than cash. And it provides support for finding a payment when a generic is able to guarantee the value of the 180-day period. The most effective way to obtain such consideration is for the generic to receive a brand’s promise not to introduce an authorized generic.

In short, the Court’s uses of the phrase “millions of dollars” provide significantly more support for a conception of payment that encompasses brands’ overpayments for services and promises increasing the value of the 180-day period than it does for a constriction of the phrase to naked cash transfers.

Despite the indications that the Court envisioned the concept of payment extending beyond naked cash transfers, some courts and defendants have lamented that the Court did not explicitly address each of the non-cash forms that an anticompetitive payment might take. But it is not realistic to expect the Court to address every issue that could arise in any future case, including the form that every such agreement could take. The Court decided numerous contested issues for the first time in

70. *Id.* at 2229.

71. *See infra* Section IV.B.

72. *Actavis*, 133 S. Ct. at 2231.

73. *Id.* at 2229 (citation omitted).

74. *Id.* at 2235.

Actavis, including: (1) the role of antitrust law in reviewing exclusion-payment settlements, (2) the treatment of the “scope of the patent” test, (3) the effect of the policy favoring settlements, (4) whether brands could pay off all the relevant generics, (5) which justifications the Court would allow the settling parties to offer, (6) the feasibility of antitrust analysis of exclusion-payment settlements, (7) whether a payment provides information about the patent merits, (8) the ability of parties to settle without exclusion payments, and (9) the type of analysis that future courts should apply.⁷⁵ It thus should not be a surprise that the Court (which also justified its ruling against three dissenting Justices) did not address every permutation of settlement and conveyance of non-cash consideration.⁷⁶

B. Actavis Facts

The facts of *Actavis* support the Court’s language in making clear that the decision applies beyond naked cash transfers from brands to generics. In the facts at issue, the brand agreed to pay millions of dollars to the generics: \$12 million in total to Paddock, \$60 million in total to Par, and \$19–30 million annually, for nine years, to Watson (now *Actavis*).⁷⁷ In its complaint, the FTC asserted that the brand’s co-promotion deals with generics were not independent business transactions. The FTC explained that before entering into settlement discussions with the generics: (1) “Solvay [the brand firm] had not been looking for a co-promotion partner”; (2) the company’s business plan had “assumed no co-promotion”; (3) “two prior AndroGel co-promotion efforts had been canceled because they had ‘no significant impact’ on sales trends”; and (4) an “analysis from a consulting firm had concluded that future AndroGel co-promotion offered ‘little revenue upside.’”⁷⁸

In addition to the lack of interest in co-promotion, Solvay’s payments “far exceed[ed] the value of the services provided.”⁷⁹ Solvay “projected that it would pay Watson more than . . . \$300 per sales call,” significantly more than a previous co-promotion deal that had “involv[ed] projected

75. *Id.* at 2230–38.

76. Michael A. Carrier, *How Not To Apply Actavis*, 109 NW. U. L. REV. ONLINE 113, 128 (2014).

77. *Actavis*, 133 S. Ct. at 2229.

78. Second Amended Complaint for Injunctive and Other Equitable Relief, *FTC v. Watson Pharm., Inc.*, No. 1:09-cv-00955-TWT, (N.D. Ga. May 28, 2009), ¶ 82 [hereinafter Second Amended Complaint] (citation omitted).

79. *Id.*

payments of around \$30–45 per sales call” and even more than the \$150 per call that a senior Watson executive had called “ridiculous.”⁸⁰

Nor was Solvay’s back-up manufacturing deal with generic Paddock an “independent business transaction.”⁸¹ The FTC alleged that: (1) the deal guarantees the generic “\$2 million per year for six years” even if it did not “ever manufacture[] AndroGel or ever become[] FDA-qualified to manufacture AndroGel”; (2) before Solvay entered into settlement discussions with Par, it “had considered and rejected several options for AndroGel back-up manufacturing” and “had concluded that the \$10–12 million in capital expenditures required to qualify a back-up manufacturer could not be justified in light of” its already-existing “reliable source of supply”; and (3) “[b]efore entering the . . . deal, Solvay conducted no diligence on Paddock’s manufacturing facilities” (which led to “substantial and lengthy efforts to conform [the] facilities and processes to meet FDA-approved standards”).⁸²

It could not be clearer that the FTC did not allege that the brand made naked cash payments to the generics. Instead, it challenged brand overpayments for generic services that “had little value.”⁸³ Along these lines, the Court explained that the FTC “alleges that in substance, the plaintiff agreed to pay the defendants many millions of dollars”⁸⁴ As discussed above,⁸⁵ the Court’s recognition of a payment in substance indicates that it anticipated that its ruling would apply to transfers of consideration that *in substance* were equivalent to cash, in other words, non-cash transfers.

For that reason, assertions like those made by the *Lamictal* and *Loestrin* courts that *Actavis* was limited to naked cash transfers *ignore the facts of the decision itself*. In the *Loestrin* case in particular, the court asserted that *Actavis* precluded scrutiny of an agreement by which a brand paid a generic to co-promote an unrelated drug.⁸⁶ But such a payment took exactly the same form as the agreement in *Actavis* concerning “other services the generics promised to perform,” which the Court held could have “significant adverse effects on competition” and violate the antitrust laws.⁸⁷

80. *Id.* (internal quotation marks omitted).

81. *Id.* at ¶ 84.

82. *Id.* See generally Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7, 24 (2014).

83. *Actavis*, 133 S. Ct. at 2229.

84. *Id.* at 2231.

85. See *supra* note 72 and accompanying text.

86. *In re Loestrin* 24 FE Antitrust Litig., No. 1:13-md-2472-S-PAS, 2014 WL 4368924, at *13 (D.R.I. Sept. 4, 2014).

87. *Actavis*, 133 S. Ct. at 2229, 2231.

Of all the forms of consideration other than cash, no-AG promises have received the most attention in recent years.

C. Value of No-AG Clause to Generic

A brand's promise not to introduce an AG during the first-filing generic's 180-day period has a dramatic effect on the first-filer's sales and profits. The FTC has found that the AG is "a very close substitute" for the first-filer and that it "typically obtains significant market share at the expense of" the generic.⁸⁸

In particular, first-filing generics lose 25% of their market share when they compete with AGs during the exclusivity period.⁸⁹ One reason is that the first-filer is not able to capture the "disproportionately large" share of the market it would otherwise obtain as the first generic on the market.⁹⁰ Because pharmacies generally stock only one generic version of a drug, the first generic to enter is able to "preempt rivals' acquisition of scarce assets" such as retail shelf space.⁹¹

The first-filer also suffers revenue reductions of 39.6% to 52% on average when sharing the 180-day period with an authorized generic.⁹² These effects result from reduced quantities and "increased pricing pressure" from AGs.⁹³ And the effects continue after the 180 days, with revenues of first-filing generics 53% to 62% lower in the thirty months following an exclusivity period shared with an AG.⁹⁴

The effect an AG has on a first-filing generic is heightened given the value of the 180-day period. Generics have estimated that they make "60% to 80% of their potential profit" in the exclusivity period.⁹⁵ And in 2006, the Generic Pharmaceutical Association stated that the "vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period."⁹⁶

88. FTC, INTERIM REPORT, *supra* note 27, at 3.

89. FTC, AUTHORIZED GENERIC REPORT, *supra* note 28, at 57 (comparing figures from fourth month of exclusivity).

90. Thomas Chen, *Authorized Generics: A Prescription For Hatch-Waxman Reform*, 93 VA. L. REV. 459, 478–79 (2007).

91. *Id.* at 477, 479.

92. FTC, AUTHORIZED GENERIC REPORT, *supra* note 28, at 58–59.

93. *Id.* at 59.

94. *Id.* at iii.

95. Daniel F. Coughlin & Rochelle A. Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective: From Ticlid® to Pravachol®, Apotex Has Difficulty Telling Who's on First*, 25 BIOTECHNOLOGY L. REP. 525, 525–26 (2006).

96. *Actavis*, 133 S. Ct. at 2229.

Two examples are illustrative of the value of the 180-day period and the effect an AG can have on a first-filing generic’s revenues. In the first, generic company Apotex explained that the brand’s introduction of an authorized generic version of the anxiety- and depression-treating drug Paxil reduced its revenues by roughly \$400 million.⁹⁷ Before launch, the company expected sales for its generic version of Paxil in the 180-day period “to be in the range of \$530–575 million.”⁹⁸ But “[g]iven [the] competition from” the brand’s AG, “Apotex only generated \$150–200 million in total sales.”⁹⁹ Apotex concluded that “[t]here can be no doubt” that the AG “crippled Apotex’[s] 180-day exclusivity, . . . reduc[ing] Apotex’[s] entitlement by two-thirds—to the tune of approximately \$400 million.”¹⁰⁰

The second example, to similar effect, appeared in a report filed with the Securities and Exchange Commission. In that context, generic manufacturer Teva explained that by being the “only company authorized to sell during the 180-day period,” its “sales, profits, and profitability” could be “substantially increased” before “a competitor’s introduction of an equivalent product.”¹⁰¹ And it made clear that it “frequently benefit[s] from the continuing effect of being the first generic in the market.”¹⁰²

The Supreme Court recognized in *Actavis* that the 180-day period could be worth “several hundred million dollars.”¹⁰³ First-filing generics often make the majority of their profits during this period.¹⁰⁴ But when a brand introduces an AG during this period, the generic loses significant market share and can suffer dramatically reduced revenues. And when a brand agrees that it will not sell an AG, it “essentially hands these revenues back” to the first-filing generic in return for a “delayed generic entry date.”¹⁰⁵ No-AG pledges thus satisfy any reasonable conception of value to the generic.¹⁰⁶ In short, they constitute payment.

97. See Comment of Apotex Corp. in Support of Citizen Petition Docket No. 2004P-0075/CP1 by Tim Gilbert, Gilbert’s LLP, to the Division of Dockets Management (HFA-305), FDA 4 (Mar. 24, 2004) (on file at <http://www.fda.gov/ohrms/DOCKETS/dailys/04/apr04/040204/04P-0075-emc00001.pdf>).

98. *Id.*

99. *Id.*

100. *Id.*

101. TEVA PHARM. INDUS. LTD., ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 (FORM 20-F) 8 (Feb. 15, 2011).

102. *Id.*

103. *Actavis*, 133 S. Ct. at 2231 (citation omitted); see also *id.* at 2235.

104. See *supra* notes 95–96 and accompanying text.

105. *FTC Brief*, *supra* note 33, at 11.

106. See *In re Niaspan Antitrust Litig.*, No. 2460, 2014 WL 4403848, at *11 (E.D. Pa. Sept. 5, 2014) (citing *Black’s Law Dictionary*, which “expansively defines ‘payment’ as

D. No-AG Pledge Provides More than Litigation

Even if no-AG promises provide value, some courts have worried that extending the concept of payment beyond cash could ensnare all settlements. The *Lamictal* court, for example, acknowledged that “[w]ithout doubt” generics “receive[] consideration” in settlements, as “[o]therwise, there would be no incentive to settle.”¹⁰⁷ And it even turned to “law student[s] . . . in the first semester” as a reminder that “consideration is an essential element of any enforceable contract” and thus that there is “‘payment’ in every settlement.”¹⁰⁸ This observation echoes that made by Judge Posner that “*any* settlement agreement can be characterized as involving ‘compensation’ to the defendant, who would not settle unless he had something to show for the settlement.”¹⁰⁹

Despite these assertions, there are different types of consideration that generics can receive through settlement. A generic firm, for example, might receive consideration in the form of a date allowing entry before the end of the patent term.¹¹⁰ Such an “entry-date” settlement provides the generic with consideration that falls within the range of what could be expected in patent litigation. If the brand wins the lawsuit, it is able to exclude competition until the end of the patent term. If the generic wins, it is able to enter immediately. A compromise allowing the generic to enter before the end of the patent term thus falls within the range of expected outcomes in patent litigation.

No-AG agreements are different. 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. The fact that such consideration cannot be

‘performance of an obligation by the delivery of money or *some other valuable thing* accepted in partial or full discharge of the obligation’); *In re Effexor XR Antitrust Litig.*, No. 11-5479 (PGS) (LHG), 2014 WL 4988410, at *19 (D.N.J. Oct. 6, 2014) (“[I]t is widely held that a payment may refer to a transfer of something of value other than money.”); *Time Ins. Co. v. AstraZeneca*, No. 14-4149, 2014 WL 4933025, at *3 (E.D. Pa. Oct. 1, 2014) (“[R]everse payments deemed anti-competitive pursuant to *Actavis* may take forms other than cash payments.”); *In re Lipitor Antitrust Litig.*, No. 3:12-cv-02389(PGS), 2014 WL 4543502, at *18 (D.N.J. Sept. 12, 2014) (same as *Effexor*); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013) (adopting a “broader interpretation of the word ‘payment’ . . . serves the purpose of aligning the law with modern-day realities”).

107. *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 568 (D.N.J. 2014).

108. *Id.*

109. *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (emphasis in original).

110. *Carrier, Payment After Actavis*, *supra* note 82, at 16–17.

explained by the patent shows that exclusion from the market comes from the payment rather than the patent.

The courts have been clear that a brand is able to introduce its authorized generic during the first-filer’s 180-day period. Generics—even those that win patent litigation—cannot prevent this. Even a court ruling that the patent was invalid or not infringed only allows the generic to enter the market. Under no circumstance would the generic’s victory in the patent case prevent the brand from launching an authorized generic.¹¹¹

The *Actavis* opinion itself supports this analysis. The settlement in that case was “unusual” in that it did not reflect a mere compromise on the generic entry date, permitting the generic to enter before the patent expired.¹¹² Instead, the brand’s payment was not something the generic could have received even if it had won the patent case: “the [patent] plaintiff agreed to pay the defendants many millions of dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for damages.”¹¹³

No-AG settlements are not garden-variety entry-split agreements falling within the boundaries of conceivable outcomes in patent litigation. No possible result in a patent case could prevent a brand from introducing its authorized generic. While the *Lamictal* court might have been concerned that all settlements involve consideration, a brand’s conveyance of consideration that the generic could not have received even by winning patent litigation demonstrates that compensation flows from the payment rather than the patent.

E. Value of Authorized Generics to Brands

The fifth reason why AGs constitute payment focuses on brands. Because brands typically benefit from AGs, they act against their self-interest when they make no-AG promises. And when brands do not introduce AGs, the natural accompaniment to their revenue *loss* is the generics’ revenue *gain*.¹¹⁴

111. *Id.* at 40–42.

112. *Actavis*, 133 S. Ct. at 2231.

113. *Id.*; *see also id.* at 2233 (“In reverse payment settlements . . . a party with no claim for damages . . . walks away with money simply so it will stay away from the patentee’s market.”).

114. The figures might not match exactly given that the price falls with more generics on the market. The FTC has found that average retail prices are 4–8% lower and average wholesale prices 7–14% lower in markets in which there is an AG on the market. FTC, AUTHORIZED GENERIC REPORT, *supra* note 28, at ii. For that reason, what the brand is

Brands view AGs as a “cornerstone” of a strategy to “capture value” or a way to recapture lost revenue when their drug faces patent expiration.¹¹⁵ Brands perceive a significant “profit opportunity” from the “limited competition” and “ability to sell [AGs] at a relatively high price” during the 180-day period.¹¹⁶ In fact, brands use AGs to “blunt[] the loss” from patent expiration in a pattern that has “become standard throughout the industry.”¹¹⁷

One reason that the use of AGs is a profitable strategy is that brands can use them to exploit their status in complex markets to lock in gains with patients and doctors. Patients exhibit “irrational brand loyalties” because they “unreasonably believe that generic drugs are of inferior quality” and, because of reimbursement by insurers, are not sensitive to price changes.¹¹⁸

Doctors also prefer brands for reasons not wholly attributable to medical benefit. Some doctors prescribe brands because of inertia or a belief that brands offer better quality control or result in greater patient confidence.¹¹⁹ Doctors also can be “risk-averse, insensitive to cost, and creatures of habit” in prescribing brand drugs instead of effective generic substitutes.¹²⁰

These effects among patients and doctors are magnified by first-mover advantages, as AGs enter the market earlier than generics that are not able to rely on brands’ FDA applications.¹²¹ Pursuant to this advantage, brands can negotiate exclusive supply contracts that lock in customers to certain drugs.¹²² Brands also are more likely to engage in advertising campaigns that take advantage of their first-mover status and marketing capabilities.¹²³

Finally, brands can use AGs to impose switching costs that lock in consumers because AGs are chemically identical (not just bioequivalent)

sacrificing by not introducing an AG at the lower price may be less than what the generic would have gained at the higher price in a market without an AG.

115. FTC, AUTHORIZED GENERIC REPORT, *supra* note 28, at 67–68 (citations omitted); *see also* SHASHANK UPADHYE, GENERIC PHARMACEUTICAL PATENT AND FDA LAW § 13.12 (2009) (“[B]ecause the brand company has usually recovered its costs many times over, additional sales are simply added to the profit.”).

116. FTC, AUTHORIZED GENERIC REPORT, *supra* note 28, at 67.

117. *Id.* at 67–68.

118. Chen, *supra* note 90, at 473–74.

119. *In re Brand Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781, 787 (7th Cir. 1999).

120. F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97, 101 (1993).

121. Chen, *supra* note 90, at 479.

122. *Id.*

123. *Id.* at 484.

to brand drugs and can use the brand’s trade dress.¹²⁴ As one commentator concluded: “By promoting themselves as both chemically and visually identical to the brand-name drug, [AGs] manipulate patient and physician concerns over generic drug quality and appearance”¹²⁵

As a result of all these effects, brands that launch an AG during the 180-day period have increased their profits by 6% to 21%.¹²⁶ Even after the end of the period, the brand benefits. Brands that first introduce AGs during the 180-day period receive the equivalent of an additional 1.9 months of revenues, roughly a 1.5% increase over the first thirteen years the brand drug is on the market.¹²⁷

In short, brands benefit from AGs, which exploit first-mover advantages and irrationalities among patients and doctors, and result in increased profits, often as the end of the patent term looms. When brands sacrifice these revenues by making no-AG promises, first-filing generics benefit from the revenue brands leave on the table.

F. Substance Trumps Form

The sixth reason no-AG promises constitute payment is that substance trumps form in antitrust analysis. The Supreme Court has consistently required antitrust analysis to “be based upon demonstrable economic effect rather than . . . formalistic line drawing.”¹²⁸ In fact, the Court has made clear that “formalistic distinctions” are “generally disfavored in antitrust law.”¹²⁹

Other courts have concurred. For example, the Third Circuit has explained that “economic realities rather than a formalistic approach must govern review of antitrust activity.”¹³⁰ And the Federal Circuit has avoided “formalistic distinctions of no economic consequence” based on the Supreme Court’s position.¹³¹

124. *Id.* at 480.

125. *Id.*

126. FTC, AUTHORIZED GENERIC REPORT, *supra* note 28, at 62.

127. *Id.* at 108.

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

129. *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466–67 (1992); *see also* *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 726 (1988) (noting that departure from rule-of-reason standard “must be justified by demonstrable economic effect . . . rather than formalistic distinctions . . .”).

130. *United States v. Dentsply Int’l, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005); *see also* *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 283 (3d Cir. 2012) (quoting *Eastman Kodak*, 504 U.S. at 466–67); *Weiss v. York Hosp.*, 745 F.2d 786, 815 (3d Cir. 1984) (“Antitrust policy requires the courts to seek the economic substance of an arrangement, not merely its form.”).

131. *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 705 (Fed. Cir. 1992).

Whether substance or form controls in antitrust analysis is a question so easy it defies imagination that it is worth attention. But the *Lamictal* and *Loestrin* courts' holdings that form trumps substance in concluding that only naked cash transfers count as payment require rebuttal.

It does not make economic sense to preclude antitrust scrutiny when a brand, instead of paying with cash, pays with another form of consideration. Or gives the generic a lucrative business deal at a discount or for free. Or agrees not to compete with the generic in some other market. Or agrees not to launch an authorized generic, thereby handing the first-filer millions of dollars.

Even the *Loestrin* court recognized that such a narrow, formalistic position would result in "pharmaceutical companies tak[ing] the obvious cue to structure their settlements in ways that avoid cash payments," which would lead to the agreements "evad[ing] Sherman Act scrutiny."¹³²

Former FTC Chairman Jon Leibowitz has explained how the settling parties could achieve the same goals through no-AG promises as they could through cash:

Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, "if you go away for several years, I'll give you \$200 million." Now, the brand might say to the generic, "if I launch an AG, you will be penalized \$200 million, so why don't you go away for a few years and I won't launch an AG."¹³³

G. Heightened Coercion from No-AG Promise

Antitrust concern with drug patent settlements has historically focused on agreements by which brands pay cash to delay entering the market. But on two levels—coercion and market division—no-AG agreements bear the potential for even more severe anticompetitive effects.

First, in considering the purposes of the Hatch-Waxman Act, the use of no-AG promises is more coercive than cash payments. When a brand offers to pay cash to a first-filing generic to settle patent litigation, the

132. *In re Loestrin* 24 FE Antitrust Litig., No. 1:13-MD-2472-S-PAS, 2014 WL 4368924, at *12 (D.R.I. Sept. 4, 2014).

133. Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics, FTC.GOV. (June 2009), available at <http://www.ftc.gov/os/2009/06/P062105authgenstatementLeibowitz.pdf>.

generic can always decline the invitation and (assuming FDA approval) utilize its 180 days of marketing exclusivity, which begins when the generic enters the market.¹³⁴ The brand has no additional bargaining power by which it could dilute the value of the generic's exclusivity.

In contrast, a brand threatening to introduce an AG during the 180-day period has more leverage to weaken this uniquely valuable period. As discussed above,¹³⁵ generics "estimate that [they make] 60% to 80% of their potential profit" during the period.¹³⁶ And in 2006, the Generic Pharmaceutical Association asserted that the "vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period."¹³⁷

A brand threatening to introduce an AG takes direct aim at this lucrative profit source, threatening to cut generics' revenues in half.¹³⁸ First-filing generics thus could be tempted to settle to preserve the value of the 180-day period. But by settling, the generic would only be getting what the Hatch-Waxman Act provided in the first place: exclusivity reserved for the first generic to challenge a brand's patent.¹³⁹ In other words, settlements with no-AG promises return generics to the starting line envisioned by the Hatch-Waxman Act. In forcing first-filing generics to settle just to preserve what was intended to be their appropriate bounty under the Hatch-Waxman Act, no-AG promises are more coercive than cash payments.

H. Market Division

Eighth, no-AG pledges present a form of market division.¹⁴⁰ Colluding firms have two basic ways to unlawfully allocate a market and split the resulting profits. The first, as was the case in *Actavis*, is for the two to

134. FTC, GENERIC DRUG ENTRY, *supra* note 6, at 7. The generic would enter the market either after a court ruling that the patent is invalid or not infringed or "at risk," before such a ruling.

135. See Coughlin & Dede, *supra* note 95, at 525–26; see also FTC v. Actavis, Inc., 133 S. Ct. 2223, 2229 (2013).

136. Coughlin & Dede, *supra* note 95, at 525–26.

137. *Actavis*, 133 S. Ct. at 2229 (citation omitted).

138. FTC, AUTHORIZED GENERIC REPORT, *supra* note 28, at 58–59.

139. See Carrier, *Unsettling Drug Patent Settlements*, *supra* note 17, at 41–47 (documenting the legislative history of the Hatch-Waxman Act).

140. This section is adapted from Brief *Amici Curiae* of 53 Law, Economics, and Business Professors, the American Antitrust Institute, and Consumers Union in Support of Appellants, at 13–16, *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-995, 2012 WL 6725580 (D.N.J. Dec. 6, 2012) (No. 12-995), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2430496.

agree to allocate the entire market to one, with the firm receiving the market paying the other a share of the profits.

A second way is for the two firms to allocate a part of the market to each of them, with their reciprocal agreements not to compete in each other's part of the market serving as a payment from one to the other. Each conspiring firm keeps the excess profits that accrue to it from the sales it makes in its allocated part of the market.¹⁴¹

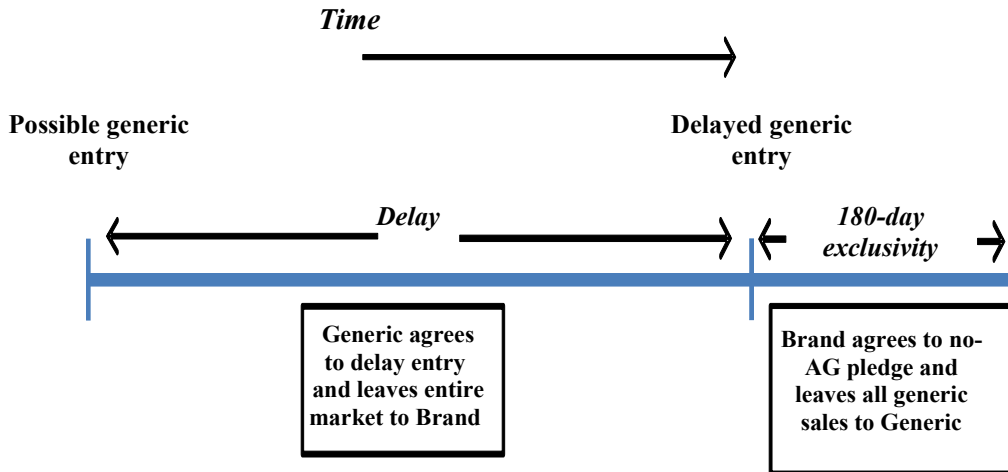
Both ways of unlawfully allocating a market (1) create or preserve prices above competitive market levels and (2) provide a means for the conspirators to share the extra profits extracted from consumers. As a result, it is irrelevant whether the settling parties allocate the entire market to one of them (in exchange for payment in the form of cash or something else of value) or allocate the market between themselves (with their exchange of consideration made up of reciprocal non-competition pledges). Courts have long recognized the severe harms presented by market division in either of these scenarios.¹⁴²

When brands promise not to introduce authorized generics, and generics agree not to enter the market, entry is delayed for not only the settling generic but also other generics. In exchange, the brand agrees not to introduce a generic version of its product that would have competed against the first-filing generic during the 180-day period. The generic's delayed-entry pledge thus transforms a period of two-seller rivalry for the drug into an extended monopoly period for the brand. At the same time, the no-AG pledge transforms the 180-day period from a three-way rivalry to a two-way rivalry (with a monopoly for the first-filer in the generics sector). The exchange of non-compete pledges can be illustrated graphically:

141. Market division among competitors is considered perhaps the most concerning form of anticompetitive business behavior since it completely eliminates all competition between the parties on all grounds. XII HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2031 (3d ed. 2012) [hereinafter HOVENKAMP, ANTITRUST LAW].

142. See, e.g., *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 47, 49–50 (1998) (finding market division “anticompetitive regardless of whether the parties split a market within which both do business or whether they merely reserve one market for one and another for the other”); *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972) (condemning “an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition”). See generally HOVENKAMP, ANTITRUST LAW, *supra* note 141, at ¶ 2030 (cataloging types of market allocation agreements and concluding that “most naked market division agreements are competitively harmful”).

Reciprocal Non-Compete Pledges in a No-AG Agreement



Absent the reciprocal pledges, the entire time period depicted above could be a period of substantial competition marked by the brand selling the brand product, and both the brand and generic selling generics.¹⁴³ Instead, the reciprocal pledges lead to an extended period of brand-only sales, followed by 180 days of sales of the brand and only one generic.

Like all anticompetitive market-allocation agreements, the reciprocal pledges increase the parties' joint profits at the expense of consumers, who pay higher prices than they otherwise would during both of the time periods depicted above. The brand collects and keeps the supra-competitive profits generated during the first period. And the generic collects and keeps the supra-competitive profits generated in the generic sector during the second period.

Finally, these reciprocal market-division promises are even more anticompetitive than cash payments for delayed entry. They are similar

143. In determining the lawfulness of an agreement, it does not matter that it was uncertain whether the generic would have entered earlier, or whether the brand would have launched an authorized generic. It is unlawful to allocate a market with a *potential* competitor as well as with an actual competitor. *See, e.g., Palmer*, 498 U.S. at 49–50; *cf. United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc) (“[T]he exclusion of nascent threats is the type of conduct that is reasonably capable of contributing significantly to a defendant’s continued monopoly power.”). The Court in *Actavis* made clear that a non-compete agreement is anticompetitive if it avoids “even a small risk of [patent] invalidity” because it thereby “prevent[s] the risk of competition,” which is “the relevant anticompetitive harm.” *Actavis*, 133 S. Ct. at 2236.

to cash payments in delaying generic entry. But while cash payments do not limit AGs in the 180-day period, no-AG clauses directly restrict generic competition.¹⁴⁴ Stated differently, cash payments (1) delay generic entry. But no-AG agreements (1) delay generic entry and (2) reduce generic competition after entry.

VI. CONCLUSION

There are many complex issues presented by drug patent settlements. Whether a no-AG promise constitutes a payment is not one of them. This Article offers eight reasons—based on *Actavis*, the economics of authorized generics, standard antitrust analysis, and the heightened concern presented by the agreements—why no-AG promises count as payment.

The case for treating no-AG pledges as payment is clear. With eight rationales, it is redundant. And it is not difficult. But if courts ignore these arguments, they would resign themselves to the role of traffic cops waving anticompetitive settlements through flashing green lights, dutifully executing the *Loestrin* court's roadmap for settling parties to "evade" antitrust scrutiny.

144. See also William O. Kerr & Cleve B. Tyler, *Measuring Reverse Payments in the Wake of Actavis*, 28 ANTITRUST 29, 35–36 (2013) (explaining that brand that pays cash "bears the entire burden of the payment" while brand that offers no-AG agreement "pushes some of the costs of a deal onto consumers by decreasing competition during the 180-day exclusivity period").