Innovation and Reverse Payments

Ramsi A. Woodcock

University of Kentucky College of Law

Follow this and additional works at: https://ir.law.fsu.edu/lr

Part of the Antitrust and Trade Regulation Commons, Food and Drug Law Commons, and the Intellectual Property Law Commons

Recommended Citation

https://ir.law.fsu.edu/lr/vol44/iss2/7

This Article is brought to you for free and open access by Scholarship Repository. It has been accepted for inclusion in Florida State University Law Review by an authorized editor of Scholarship Repository. For more information, please contact efarrell@law.fsu.edu.
INNOVATION AND REVERSE PAYMENTS

RAMSI A. WOODCOCK

ABSTRACT

Settlements of patent litigation between branded and generic drug makers that include a promise by the generic maker to stay out of the market, sometimes in exchange for a 'reverse' payment, increase the profits of drug makers at the expense of consumers. Some commentators argue that drug makers will invest these profits in innovation, ultimately making consumers better off. Drug market data suggest, however, that the resulting gains to consumers may still be insufficient to offset consumer losses from delayed access to generics. Even when innovation is taken into account, antitrust can most efficiently eliminate the risk of consumer harm from delayed access to generics only by banning all settlements that fix a date of generic entry, including all reverse payment settlements. If antitrust seeks to maximize consumer welfare, rather than merely to eliminate the risk of consumer harm, then antitrust should instead intervene directly in settlement negotiations to defend the interests of consumers, because only intervention both preserves the innovation benefits of settlement while minimizing the opportunity of drug makers to settle for delayed generic entry. In no case, however, should antitrust challenge only settlements involving large reverse payments, as other commentators have suggested antitrust should do.
I. INTRODUCTION

For nearly twenty years, antitrust enforcers in the United States have tried to stop branded drug makers from suppressing challenges to their drug patents by paying the generic drug makers who bring the cases to drop them and stay out of the market until the expiration of the patent term. These kinds of settlements of drug patent litigation, which cost consumers about $3.5 billion per year in higher drug prices, are part of a broader class of agreements in which the branded maker (‘Brand’) obtains a commitment to delay entry from a generic maker (‘Generic’) that may or may not include a payment, sometimes called a reverse payment, from Brand to Generic as inducement.

Entry settlements can harm consumers because the U.S. Patent and Trademark Office does not do a good job of reviewing patent applications, allowing branded drug makers to obtain patents to which they are not actually entitled under the law, and which therefore would be held invalid by a reviewing court. And because, even when a patent is valid, a generic drug may not infringe the patent, but a branded maker may assert incorrectly that the generic drug does infringe. As a result, the real test whether a patent protects a drug is the judgment of the court that hears an attempt to assert the patent.

By binding a generic maker to stay out of the market, a settlement of patent litigation allows a branded drug maker to enjoy protection from competition for a longer period than a court might allow. The date of entry to which drug makers agree is likely to be later than the date a court would choose because a major interest protected by patent law,
that of consumers, is not represented at settlement negotiations. Thus
the interest of consumers in early competition and lower prices is not
taken into account in the date of entry chosen by the drug makers.

The debate over the merits of entry settlements, which has played
out almost entirely in the context of settlements that include a reverse
payment, has for the most part ignored the relationship between delay
and innovation that is the reason for the existence of patent law.5 One
consequence of that relationship, however, is that the harm to consum-
ers from delaying entry on an invalid patent might be only apparent,
but not real. The extra delay might generate profits that fund research
and development that leads to better drugs and an improvement in the
welfare of consumers in the long run. That welfare improvement may
compensate for the higher prices associated with delay in the short run.6

This Article is the first to take gains from innovation into account
in determining the proper rule that antitrust should apply to regulate
entry settlements.7 The foundation for the antitrust analysis of gains
from innovation in the patent context is the assumption that the date
of entry that a court would choose using patent law is the date that
maximizes the welfare of consumers, after balancing the innovation
benefits of delay against the harm of higher prices. Courts may not
actually choose the welfare-maximizing date of entry in practice, but
as a matter of institutional deference, antitrust must assume that the
courts, following patent law, succeed in this undertaking.8 The job of
antitrust is to ensure that in colluding via their settlement agreement

5. For contributions to this debate that do not account for innovation, see infra notes
  14, 16. For antitrust’s conscious aversion to considering gains from innovation, see Douglas
  H. Ginsburg & Joshua D. Wright, Dynamic Analysis and the Limits of Antitrust Institutions,
  78 ANTITRUST L.J. 1, 21 (2012) (discussing reasons for which antitrust does not normally take
dynamic efficiency into account); J. Gregory Sidak & David J. Teece, Dynamic Competition in
Antitrust Law; 5 J. COMPETITION L. & ECON. 581, 586 (2009) (lamenting same). For an intro-
duction to the economic justification for patent, see Richard A. Posner, Intellectual Property:

6. For a graphical treatment of the relationship between profits, innovation, and con-
sumer welfare, see Ramsi A. Woodcock, Inconsistency in Antitrust, 68 U. MIAMI L. REV. 105,
126-33 (2013) [hereinafter Woodcock, Inconsistency in Antitrust].

7. Langenfeld and Li consider returns to innovation in concluding that a payment from
Brand to Generic in exchange for Generic’s agreement to stay out of the market during penden-
cy of patent litigation (so-called ‘partial payments’) should not be banned. See James
Langenfeld & Wenqing Li, Intellectual Property and Agreements to Settle Patent Disputes:
The Case of Settlement Agreements with Payments from Branded to Generic Drug Manu-

8. See infra Section III.C; see also Einer Elhauge & Alex Krueger, Solving the Patent
Settlement Puzzle, 91 Tex. L. Rev. 283, 295 (2012) (arguing that antitrust should “assume
that substantive patent law is optimal”).
to set their own date of entry, the drug companies do not leave consumers worse off than they would be if the courts had been allowed to determine the welfare-maximizing date of entry under patent law.9

Under this standard, a ban on all drug patent settlements that limit the date on which a generic maker may enter the market, regardless whether the settlement includes a reverse payment, is the best rule for antitrust to apply to entry settlements.10 A ban on all entry settlements protects consumers against harm by giving the courts the opportunity to impose the welfare-maximizing entry date in all cases. Although a rule limiting reverse payment size is an attractive alternative, because it requires only scrutiny of the size of any reverse payment for enforcement, it allows harm to consumers under certain circumstances, and must therefore be rejected. The rule that the U.S. Supreme Court adopted in FTC v. Actavis, which calls for case-by-case review of settlements for consumer harm, does prevent harm to consumers.11 But the rule, which is known as a rule of reason, is more expensive to enforce than an entry settlement ban, which requires only a determination that a settlement limits entry. The same is true for another alternative, a rule of settlement supervision by an administrative agency, such as the U.S. Federal Trade Commission (‘FTC’).

A rule of reason protects consumers from harm by weeding out all those settlements that in fact delay entry relative to the date of entry that a court would choose.12 The disadvantage of a rule of reason is that it offers no benefits cognizable by antitrust in exchange for the greater expense associated with case-by-case review.13 Its proponents defend it on the ground that it allows firms to make settlements that might benefit consumers while freeing up funds for investment in re-

---

9. See infra note 69.

10. I reach this conclusion in Section IV.B.9. Whether each of a number of alternative rules allows harm to consumers is reported in column ‘Meets uncertainty corollary’ in Table 1. Elhauge and Krueger also suggest that a ban may be an appropriate rule, although they do so without taking gains from innovation into account. See Elhauge & Krueger, supra note 8, at 292 (“If direct inquiry into probabilistic patent strength is too unreliable, then the best substantive solution would be categorical condemnation . . . .”).


12. See infra Section IV.B.6.

search and development that would otherwise be wasted on litigation. Indeed, it is for this reason that the Court adopted it. But, as I indicated above, antitrust’s mission is not to improve on the outcome that would otherwise be achieved by the courts and patent law, but only to prevent drug makers from detracting from it. So the rule costs more without offering antitrust any advantage.

A rule either banning outright, or limiting the size of, any reverse payment that Brand makes to Generic as part of an entry settlement eliminates the incentive that a payment creates for Generic to agree to greater delay. But it does not prevent the parties from making settlements that delay entry relative to what a court would order. Whether this rule harms consumers depends on how much delay firms will agree to under the rule and the extent to which the investment in innovation it makes possible compensates for the higher prices that result. This question can be answered only by actually predicting the effect on consumer welfare of settlements allowed under the rule. In another work, I use a model of innovation and entry settlements to make such predictions for the average drug. These predictions show

14. See Bruce H. Kobayashi et al., Actavis and Multiple ANDA Entrants: Beyond the Temporary Duopoly, 29 ANTITRUST, no. 2, Spring 2015, at 89, 93-94 (suggesting that full blown rule of reason analysis, rather than an abbreviated version that uses the size of a reverse payment as a proxy for harm, is the appropriate standard because using payment size as a proxy “will not produce settlements that increase consumer welfare net of litigation costs”); Robert D. Willig & John P. Bigelow, Antitrust Policy Toward Agreements That Settle Patent Litigation, 49 ANTITRUST BULL. 655, 662 (2004) (rejecting a rule “condemn[ing] . . . agreements with financial payments” and arguing that “[a]ntitrust policy should encourage settlement agreements with dates of entry that are socially advantageous”).

15. See Actavis, 133 S. Ct. at 2236 (observing that “offsetting or redeeming virtues are sometimes present” in a reverse payment settlement).

16. This approach has many advocates. See, e.g., Joshua P. Davis, Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal, 41 RUTGERS L.J. 255, 261-64 (2009) (advocating a reverse payment ban); Aaron Edlin et al., Activating Actavis, 28 ANTITRUST, no. 1, Fall 2013, at 16, 21-22 [hereinafter Edlin et al., Activating Actavis] (arguing that the Supreme Court’s opinion in FTC v. Actavis should be interpreted to make unexplained reverse payments in excess of litigation cost presumptively illegal); C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. REV. 1553, 1596 (2006) [hereinafter Hemphill, Paying for Delay] (advocating a presumption of illegality for settlements that involve a large reverse payment or that allow the generic firm to make use of the 180-day first-filer exclusivity afforded it under the Hatch-Waxman Act, but advocating balancing of harms and benefits for other entry settlements).

17. See Elhauge & Krueger, supra note 8, at 312-23 (arguing that entry settlements that involve no reverse payment are often anticompetitive).

that even when no reverse payment at all is permitted and innovation is taken in account, it is sometimes profitable for drug makers to make settlements that harm consumers.

Whether drug makers make harmful settlements under a rule limiting reverse payments depends on the sort of competition that prevails if the generic firm is able to enter the market before the expiration of the putative patent term.\textsuperscript{19} If entry by one generic triggers entry by many other generic makers, then these firms will compete price down to competitive levels, and the benefit to consumers of early entry will be great, making the harm to consumers from delay great as well. In this case, my estimates suggest that gains from innovation are too meager to compensate consumers for the harm associated with delay, even when a reverse payment in any amount is banned. By contrast, if only a small number of generics enter before patent expiry, price falls only modestly after the firms enter, and consumers are not greatly harmed by delay, because their gains from generic entry are small. In that case, a ban on reverse payments in excess of Brand's cost of litigating the case through to judgment is sufficient to guarantee that settlement will not harm consumers.

I also consider a rule that would install a representative of the consumer interest at the settlement bargaining table.\textsuperscript{20} The FTC, for example, might play that role, intervening in drug patent litigation on behalf of consumers and ensuring that any entry date negotiated in settlement not harm consumers relative to the outcome that the courts would choose. This rule would have an effect similar to a rule of reason, ensuring, on a case-by-case basis, that settlements not harm consumers, but operating before the settlement is made, rather than afterward. The cost of administering the rule would be high because the rule would require government supervision of every patent settlement.\textsuperscript{21}

\textsuperscript{22}ECON. POL’Y 680 (2007) (an example of the standard model). I am not aware of any other formal dynamic treatment of drug patent entry settlements.

Langenfeld and Li’s work does not model the effect of delay on research and innovation directly, but instead assumes that delay will increase the number of future innovative drugs that will be brought to market, estimates the consumer welfare of new drugs, and then considers the effect of delay on consumer welfare assuming various guesses regarding the number of new drugs that will reach market as a result of delay. Langenfeld & Li, supra note 7, at 800, 802, 804.

\textsuperscript{19}See infra Section IV.B.5.

\textsuperscript{20}See infra Section IV.B.7.

\textsuperscript{21}Elhauge and Krueger also appear to want to bring the consumer interest into the patent litigation. They suggest that consumers be given standing to challenge patents that become the subject of an entry settlement that does not involve a reverse payment. See Elhauge & Krueger, supra note 8, at 292, 324-25. If consumers would be allowed to use such standing to intervene in patent litigation before a settlement is reached, then this proposal is equivalent to my own, differing only in that private parties, rather than a government
The problem of drug patent settlements cannot be divorced from the question how much profit must be allowed to branded drug makers to create the best incentive for investment in research and development, because the purpose of the patent laws is to create such an incentive.\(^{22}\) But this does not mean, as the literature on drug patent settlements sometimes suggests, that the additional profits afforded by settlements contribute enough to research and development to justify the delay in generic entry and higher prices that may come with them.\(^{23}\) This Article shows that because, even after taking gains to innovation into account, settlements that fix a date of entry cannot always be expected to preserve consumers from harm, relative to the welfare consumers would enjoy without settlements, a ban on settlements that fix a date of entry is an appropriate antitrust rule.

This Article builds on my argument in another work that the entry settlement debate is focused too narrowly on settlements that involve a reverse payment from Brand to Generic.\(^{24}\) Generic drug makers can find it profitable to agree to delay entry even in the absence of a reverse payment, and even after gains from innovation are taken into account. So the proper objects of concern for antitrust are settlements that limit the ability of drug makers to enter the market, not just those that include a large payment.\(^{25}\)

This Article also builds on that other work by interpreting antitrust law to require that settlements pose no risk of harm to consumers, a doctrine that I call the ‘uncertainty corollary’ to antitrust’s consumer agency, would carry out the supervision of settlements. I differ from Elhauge and Krueger in that they suggest that this is the best solution under a standard that measures harm relative to welfare under litigation. Because of the costliness of supervision, I view an entry settlement ban as the better rule under that standard. I conclude, however, that if the goal is to maximize welfare under settlement, then a supervision rule is the best approach. See infra Section IV.D.

\(^{22}\) For sources that attempt this divorce, see supra note 5.

\(^{23}\) See, e.g., Kobayashi et al., supra note 14, at 95 (defining as “the costs of ‘dynamic’ Type I errors . . . the costs of forgone innovation due to the reduced incentives that result from the erroneous invalidation of patents” and observing that “because patent terms are not set optimally, but are based upon the arbitrary statutory rule of 20 years from filing, it is possible that a full error cost analysis, taking dynamic Type I errors into account, would find that settlement agreements where generic entry is not allowed before the expiration of the patent in fact increase dynamic welfare, which would support the scope of the patent test.”).

\(^{24}\) Ramsi A. Woodcock, Uncertainty and Reverse Payments, 84 TENN. L. REV. 99, 105 (2016) [hereinafter Woodcock, Uncertainty and Reverse Payments]. Elhauge and Krueger also argue for greater attention to entry settlements that involve no reverse payment. See Elhauge & Krueger, supra note 8, at 292 (“Many, including the FTC and DOJ, have assumed that settlements with no reverse payments will likely set exclusion periods that equal the expected litigation exclusion period. However, we prove that this conventional wisdom is untrue.” (footnote omitted)).

\(^{25}\) See Woodcock, Uncertainty and Reverse Payments, supra note 24, at 112-19.
'protection standard' in patent settlement cases. The literature has appeared to favor a different rule, which would tolerate a risk of harmful settlement in order to make possible settlements that might benefit consumers. This alternative rule should be rejected because it would substitute antitrust law for patent law as the ultimate decider of the right amount of delay to use to stimulate innovation. As I indicated above, antitrust's job is not to try to make consumers better off than they would be under the court's application of patent law. Antitrust must therefore seek to eliminate all types of settlements that pose a risk of harm.

Outside of the patent settlement context, antitrust quite appropriately uses a different baseline in measuring harm. That baseline is the highest welfare that antitrust might possibly use its regulatory powers to achieve, rather than the welfare that the courts would achieve in the absence of settlement. The baseline amounts to the requirement that any antitrust rule force firms to choose a settlement entry date that maximizes consumer welfare. A settlement ban does not meet this requirement because it only maintains consumer welfare at the level the courts would achieve in litigation. The maximum a court would achieve through litigation must fall below welfare under the best settlement because litigation wastes resources that branded drug makers could spend on research and development.

A rule of reason can do only slightly better than a settlement ban. A rule of reason would continue to use the welfare consumers would achieve under litigation as baseline, weeding out only those settlements that reduce welfare relative to that baseline, and therefore allowing suboptimal settlements. Unlike a ban, however, it would allow

---

26. See id. at 129-33. I discuss the uncertainty corollary and the protection standard in Section II.C.


29. See infra Section IV.D. The creator of the litigation welfare baseline sometimes seems tempted to abandon it in favor of this maximization standard. See Edlin et al., Activating Actavis, supra note 16, at 16; Edlin et al., The Actavis Inference, supra note 27, at 609.

30. See infra Section IV.D. The column of Table 1 titled 'Meets maximization standard (rank)' provides a ranking of antitrust rule options under the maximization standard.

31. See infra Section IV.D.
settlements that make consumers better off relative to litigation, giving it the potential to achieve better outcomes for consumers and perhaps to make up for its greater cost.

A rule limiting the size of a reverse payment can do even better than a rule of reason, depending on the maximum amount of delay it allows.\(^\text{32}\) If the amount allowed is not too great, then it may permit less delay than a rule of reason. This would ensure that settlements make consumers better off than under litigation, because a rule of reason ensures no delay sufficient to harm consumers relative to litigation. But in this case, as in the case of a litigation welfare baseline, the effect of a rule limiting reverse payment size depends on the amount of competition after generics enter the market. It is possible for the delay allowed even by a complete ban on payments to make consumers worse off than under a rule of reason or a ban on entry settlements generally.

The best choice under a maximization standard is a rule that requires supervision of settlements by the FTC or other regulator.\(^\text{33}\) Because supervision allows the consumer interest to be reflected in the settlement bargain, it is the option most likely to produce settlements that successfully balance the gains from innovation against the harm of higher prices and thus to maximize consumer welfare. Accordingly, if institutional deference to patent law is rejected, and antitrust is asked to maximize consumer welfare, then antitrust enforcers must intervene in all drug patent litigation settlements to ensure that the parties negotiate the optimal settlement from the perspective of consumers.

I proceed by first providing some background on the regulation of drug patent settlements and the economic models employed in evaluating them.\(^\text{34}\) I then discuss the shortcomings of a model that does not take gains from innovation into account and how a model that does take them into account explains the prevailing antitrust standard, which requires the avoidance of harm to consumers relative to consumer welfare under litigation.\(^\text{35}\) I then show that a settlement ban is the best antitrust rule under a standard that requires the avoidance of harm to consumers and that allowing the government to intervene in settlement negotiations is the best rule under a standard that requires the maximization of consumer welfare.\(^\text{36}\)

\(^{32}\) See infra Section IV.D.

\(^{33}\) See infra Section IV.D.

\(^{34}\) Part II.

\(^{35}\) Part III.

\(^{36}\) Part IV.
II. THE REGULATION AND THEORY OF DRUG ENTRY SETTLEMENTS

A. Regulation

Drug patent litigation is the subject of a regulatory regime designed to force a judicial resolution of patent disputes before a generic maker enters a drug market.\(^{37}\) The Hatch-Waxman Act\(^{38}\) requires that a branded drug maker declare patents covering a drug for which it has obtained FDA approval.\(^{39}\) A generic maker wishing to introduce a generic version of the drug into the market before the expiration of a declared patent must state its intention to do so in what is known as a Paragraph IV certification, giving Brand the chance to sue to assert any patents it believes prevent entry.\(^{40}\) The Act provides that Brand may treat this certification as patent infringement, immediately file suit, and obtain a stay on introduction of the drug into the market of up to 30 months while its claim of infringement is pending in court.\(^{41}\) Generic may defend by arguing that Brand’s patent is invalid or not infringed. By way of incentive to generic makers to challenge patents, the Act provides 180 days of exclusivity to the first generic to file a Paragraph IV certification for a particular drug if the generic is eventually able to enter the market. The Act grants this exclusivity regardless whether the first generic enters as a result of winning the litigation, the decision of Brand not to sue, or pursuant to a settlement with Brand.\(^{42}\)

It is not clear when branded and generic makers started agreeing to delay entry as part of settlements of these suits, but around the year 2000 private and public plaintiffs started to challenge settlements between Brand and Generic pursuant to which Generic would agree to stay out of the market for a period of time in return for a payment from

---

37. See Colleen Kelly, Note, The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond, 66 FOOD & DRUG L.J. 417, 424 (2011) (stating that the purpose of the regime was to ensure that “the infringement dispute could be resolved before the generic drug hits the market”).


42. 21 U.S.C. § 355(j)(5)(B)(iv); see also C. Scott Hemphill & Mark A. Lemley, Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act, 77 ANTITRUST L.J. 947, 955 (2011) (“Since 1998, a first-to-file generic drug maker has been eligible for the bounty provided that it does not lose the patent suit, even if it never actually wins the patent litigation. Indeed, it may earn the exclusivity even if it was never sued, so long as it was the first to file an ANDA.”).
Brand. Such payments became known as ‘reverse’ payments because through them value flows from plaintiff to defendant instead of from defendant to plaintiff, as typically happens when a settling defendant acknowledges infringement, agrees to respect the patent going forward, and pays damages for its attempt to enter prematurely. Enforcers alleged that these settlements amounted to blatant market division agreements pursuant to which Brand would monopolize the drug market and use the payment to give Generic a cut of its illegal profits.

After a period during which the courts refused to intervene out of respect for what they took to be the intention of patent law to allow Brand to do anything short of inducing Generic to stay out of the market past the expiration of the patent term, the Court in Actavis held that the settlements could be subject to scrutiny under antitrust’s rule of reason standard. That standard provides that a potentially anticompetitive practice, such as a reverse payment settlement, may be reviewed on a case-by-case basis, and treated as a violation of antitrust law only where it can be shown that the practice harms consumers under the circumstances of a particular case.

B. The Static Model

The mission of antitrust is to prevent harm to consumers, where harm has the economic meaning of a reduction in consumer welfare.

43. See Complaint, In re Abbott Labs., 2000 WL 681848 (F.T.C. May 22, 2000) (No. C-3945) (early FTC reverse payment administrative complaint); Hemphill, An Aggregate Approach, supra note 1, at 657, 657 n.112 (stating that the FTC started enforcement actions in 2000 and that the first private lawsuit of which the author was aware was filed in 1998).

44. See, e.g., In re Cardizem CD Antitrust Litig., 332 F.3d 896, 910 (6th Cir. 2003) (“The plaintiffs . . . allege that they were deprived of a less expensive generic product, forcing them to purchase the higher-priced brand name product, because of a per se illegal horizontal market restraint.”).

45. See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1333-35 (Fed. Cir. 2008); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1311-13 (11th Cir. 2003).


47. See RICHARD A. POSNER, ANTITRUST LAW 38 (2d ed. 2001) (“[A] ‘Rule of Reason’ . . . allow[s] a fuller and more flexible inquiry into the economic consequences of a challenged agreement . . . .”)

Academic debate about the merits of reverse payment settlements has been carried out by reference to an economic model that does not incorporate gains from innovation into the calculation of consumer welfare. The absence of innovation effects in the model earns it the moniker ‘static’ to contrast it with the dynamic character of a model that would incorporate the feedback effect of higher prices on innovation and consumer welfare. In this static model, consumer welfare is always falling as the date of generic entry grows later.49 Before Generic enters, Brand charges a monopoly price for the drug, which keeps consumer welfare at a minimum because the high price both denies access to the drug to some consumers who cannot afford it and forces those who can afford it to pay more. Once Generic enters the market, price falls to a duopoly level until the expiration of the patent (the ‘single entry case’). If many additional generic firms are able to enter the market after the expiration of Generic’s first-filer exclusivity, price falls to a competitive level after 180 days of duopoly (the ‘multiple entry case’).50 When price falls, consumers pay less for the drug, and their welfare increases. Thus the earlier that Generic enters, the shorter the low-welfare period of high pricing and the greater the overall welfare consumers obtain from the drug before patent expiry.

Because delay harms consumers, academic debate regarding reverse payment settlements has focused on the problem of determining whether the date of entry that firms choose in settlement is later than the ‘litigation entry date.’51 This is the date of entry that reflects the probability that the patent would hold up in court, also known as its ‘strength.’52 Thus a patent with a 50% chance of being upheld and eight years remaining on its term has a litigation entry date of four years (50% times eight years). In this example, the question for antitrust is whether a settlement between Brand and Generic would postpone Generic’s entry by more than four years.53

49. See, e.g., Edlin et al., Activating Actavis, supra note 16, at 22; Willig & Bigelow, supra note 14, at 680-81.
50. For models of the multiple entry case, including one not treated in this article in which multiple generics enter only after settlement, see Edlin et al., The Actavis Inference, supra note 27, at 621-34.
51. See Aaron Edlin et al., Actavis and Error Costs: A Reply to Critics, 14 ANTITRUST SOURCE, no. 1, Oct. 2014, at 1, 4 [hereinafter Edlin et al., Actavis and Error Costs] (“We define a settlement in a reverse payment case as anticompetitive if consumers are worse off under the settlement than they would be under one of two benchmarks: (1) the outcome of litigation, in expectation . . . .”); Willig & Bigelow, supra note 14, at 679 (“[T]he benchmark for [evaluating settlements] may necessarily be the expected outcome of the patent litigation.”).
52. See Willig & Bigelow, supra note 14, at 664.
53. This can also be seen in Figure 1 infra. Consumer welfare, \( C_S \), is falling. Under litigation, consumers are at the level corresponding to the entry date labeled ‘expected entry,’ which is the litigation entry date. Because \( C_S \) is declining, consumers are worse off if entry
Brand prefers delay because it permits Brand to charge a high price for a longer period. In the absence of a reverse payment, Generic prefers hastening because it permits earning of its share of duopoly profit for a longer period. Antitrust limits the settlements to which Brand and Generic may agree to a settlement range. When no reverse payment or payment from Generic to Brand (an ‘obverse payment’) is permitted, the litigation costs of the parties are the key determinant of which dates of entry fall within this settlement range. The greater the hastening of entry relative to the litigation entry date, the more Brand’s litigation cost savings from settlement are eaten up by its losses from hastening. The range is bounded on the low end by the date of entry that leaves Brand as well off as it would have been paying litigation costs and entering at the litigation entry date.

The greater the delay relative to the litigation entry date, the more Generic’s litigation cost savings from settlement are eaten up by its losses from delay. The settlement range is therefore bounded on the high end by the date of entry that leaves Generic as well off as it would have been paying litigation costs and entering at the litigation entry date. Figure 1 shows consumer welfare (\(C\)) and the settlement range (demarcated by ‘min’ and ‘max’) in the single entry case, and Figure 2 shows it in the multiple entry case, of which more below.

---

54. See, e.g., Willig & Bigelow, supra note 14, at 664 (“There is . . . a range of mutually agreeable potential settlements.”).

55. See id. at 665 (“[T]he incumbent, who prefers later entry to earlier entry, would be willing to accelerate entry relative to the expected date under litigation if the cost in foregone profit were not greater than the saved litigation costs.”).

56. See id. at 664-65 (“The entrant, who prefers earlier entry to later, would be willing to postpone entry somewhat past the expected date of entry under litigation if the postponement were not so protracted that the cost to the entrant in lost profits were more than what it saved in avoided litigation costs.”).
When a reverse payment is permitted, Brand may compensate Generic for the losses Generic suffers from delay, allowing Generic to agree to additional delay. Because monopoly profit exceeds aggregate duopoly profit,\textsuperscript{57} Brand can always afford such compensation, no matter how long the delay.\textsuperscript{58} Thus when there is no cap on a reverse payment, Brand may buy delay right up to expiration of the patent term.\textsuperscript{59} A cap drives down maximum possible delay.\textsuperscript{60} However, as just noted, the settlement range includes some delay even when no reverse payment is possible, that is, when there is a zero cap.

\textsuperscript{57} See, e.g., Willig & Bigelow, supra note 14, at 663 ("The incumbent’s profit... is greater under monopoly than the two firms’ total profits under duopoly.").

\textsuperscript{58} See Woodcock, Uncertainty and Reverse Payments, supra note 24, at 114.

\textsuperscript{59} See Edlin et al., Actavis and Error Costs, supra note 51, at 6 ("The parties have an incentive to push out as far as they can along the Ray of Delay, up to patent expiration, limited only by antitrust risk.").

\textsuperscript{60} See Woodcock, Uncertainty and Reverse Payments, supra note 24, at 114.
In single entry, consumers do not pay litigation costs either directly or indirectly, and therefore settlement at the litigation entry date has no effect on consumer welfare. Only delay can make consumers worse off. In multiple entry, litigation actually makes consumers better off, all else equal. This is because in litigation there is always the chance that Brand will lose, and consumers will obtain the increased value associated with competitive pricing after expiration of Generic’s first-filer exclusivity. By contrast, in settlement, for entry dates that are within 180 days of patent expiry, first-filer exclusivity cannot expire before the expiration of the patent and so consumers cannot enjoy competitive pricing before the expiration of the patent term.61 Because consumers are better off under litigation for any given entry date, some hastening in entry under settlement is required in order to leave consumers as well off as under litigation.62 In multiple entry, therefore, the goal of antitrust is not only to preclude delay, but also to preclude settlements that fail to hasten entry sufficiently to avoid harm to consumers.

61. Cf. Edlin et al., The Actavis Inference, supra note 27, at 623 (“Under settlement, Brand will surely benefit from the partial protection associated with duopoly rather than free entry. . . . Under litigation, Brand will only receive this partial protection if it loses the patent litigation. . . . Settlement gives an additional value equal to the difference between these two . . . .”).

62. Consider Figure 2 infra. The top side of the $C_C$ triangle represents consumer welfare in litigation and the bottom lines give it in settlement. The dashed horizontal line gives the amount of hastening in entry required for a settlement to provide value to consumers equal to what they would obtain at the litigation entry date (which is labeled ‘expected entry’ in the figure).
Scholars have been preoccupied with finding a rule that precludes as many harmful settlements as possible without precluding any settlements that benefit consumers. Thus the goal has in effect been to drive down the maximum limit in the settlement range without reducing or otherwise affecting the part of the range that involves hastening. A rule of reason can do a good job of allowing only good settlements to escape condemnation. But it is expensive to enforce. A limit on the size of any reverse payment is cheaper to enforce, but any limit will allow some harmful settlements to escape condemnation.

The main proposal around which debate has centered is the 'litigation cost rule,' which would cap the allowed reverse payment at

63. See, e.g., Edlin et al., The Actavis Inference, supra note 27, at 633.
Brand’s litigation cost.\textsuperscript{64} A payment in excess of litigation cost by Brand causes Brand to give up all of its gains from the avoidance of litigation cost, plus some additional amount, and Brand therefore must insist on settling for delay in order to avoid making a loss.\textsuperscript{65} The litigation cost rule therefore precludes settlements that necessarily involve delay. The rule is effective at banning only settlements that harm consumers, but not at banning all settlements that harm consumers.\textsuperscript{66} It fails, for example, to prevent settlements for delay that involve no reverse payment.\textsuperscript{67}

\section*{C. The Proper Antitrust Standard}

In the patent settlement context, there are two ways to apply the goal of antitrust to prevent consumer harm.\textsuperscript{68} The first, which is generally accepted in the literature, is to prevent reductions in consumer welfare relative to the value consumers would obtain in litigation.\textsuperscript{69} This ‘protection standard’ is the source of antitrust’s interest in precluding settlements that delay entry relative to the litigation entry date in the static model.\textsuperscript{70} The second possible way to apply the goal of harm prevention is to prevent reductions in consumer welfare relative to the greatest possible value that consumers might possibly achieve, whether in litigation or settlement. This amounts to a rule of consumer welfare

\textsuperscript{64} See, e.g., Edlin et al., Activating Actavis, supra note 16, at 17 (arguing that the rule appears in the Actavis opinion as a presumption); Harris et al., supra note 27, at 87-88 (attacking the rule).

\textsuperscript{65} See Edlin et al., Activating Actavis, supra note 16, at 17 (“The patentee is willing to pay an amount up to litigation costs to get as much protection from competition as it expects to get from litigation. . . . Payment beyond this threshold, however, looks suspiciously like payment to avoid more competition than would be expected from the outcome of the patent case.”).

\textsuperscript{66} See Edlin et al., The Actavis Inference, supra note 27, at 620 (“The [litigation cost rule] will fail to capture some anticompetitive pay-for-delay agreements with payments less than anticipated litigation costs.”).

\textsuperscript{67} For example, the settlement range shown in Figure 1 supra gives the settlement dates to which Brand and Generic can agree in the absence of any reverse or obverse payment. Because the maximum point in the range is to the right of the litigation entry date (marked ‘expected entry’), the range allows some settlements that harm consumers.

\textsuperscript{68} For a more detailed discussion of the points in this Section II.C, see Woodcock, Uncertainty and Reverse Payments, supra note 24, at 127-49.

\textsuperscript{69} See Carl Shapiro, Antitrust Limits to Patent Settlements, 34 RAND J. ECON., no. 2, Summer 2003, at 391, 396 (“I propose . . . the following simple antitrust rule: a patent settlement cannot lead to lower expected consumer surplus than would have arisen from ongoing litigation.”); Elhauge & Krueger, supra note 8, at 296; Herbert Hovenkamp et al., Anticompetitive Settlement of Intellectual Property Disputes, 87 MINN. L. REV. 1719, 1727 (2003).

\textsuperscript{70} See supra text accompanying note 51. For more on the protection standard, see Woodcock, Uncertainty and Reverse Payments, supra note 24, at 128-29.
maximization: antitrust should choose the rule that leads to the greatest possible consumer welfare.\textsuperscript{71} I call this the ‘maximization standard.’

In addition to facing a choice between these two rules, antitrust also faces a decision about how to cope with uncertainty regarding the settlement entry date that firms will choose. One approach is to determine the average entry date that the parties will choose in settlement. Any rule that fails to preclude all harmful settlements meets the protection standard only if it may be assumed that firms will choose enough beneficial settlements to counteract on average the effects of the harmful settlements that may be chosen under the rule. There is, however, no consensus on how often firms choose any given settlement and therefore no way to calculate this average.

In the absence of this information, a dominant strategy is to choose a rule that guarantees no harm to consumers.\textsuperscript{72} I call the requirement that a rule allow no settlements that harm consumers the ‘uncertainty corollary’ to the protection standard.\textsuperscript{73} A ban on all settlements that fix a date of entry is an example of a rule that meets the uncertainty corollary. By forcing the parties to litigate the entry date, a settlement ban guarantees that consumers will never suffer harm relative to a litigation value baseline.\textsuperscript{74} A rule of reason also satisfies the uncertainty corollary because it culls all settlements that harm consumers relative to litigation value on a case-by-case basis.\textsuperscript{75} A dominant strategy in the context of the maximization standard is one that ensures that in every state of the world consumers do at least as well as under every other possible rule.

III. FROM STATIC TO DYNAMIC

A. Shortcomings of the Static Model

The static model is inadequate for antitrust analysis of patent settlements because the model cannot explain why a patent settlement, or even the very institution of patent protection itself, might ever benefit consumers. But a dynamic model, which allows for the possibility that a branded drug maker will use profits to make a better drug,

\textsuperscript{71} Cf. Edlin et al., Activating Actavis, supra note 16, at 16 (“A reverse payment also amounts to a payment for delay if the parties would have settled for an earlier entry date in the but-for world where such large reverse payments were banned.”).
\textsuperscript{72} The strategy is dominant in the sense that it ensures that in each possible state of the world there is no harm to consumers. It therefore avoids the problem of uncertainty regarding which state of the world will actually obtain. See Martin Peterson, An Introduction to Decision Theory 41-42 (2009) (explaining dominance).
\textsuperscript{73} See Woodcock, Uncertainty and Reverse Payments, supra note 24, at 130.
\textsuperscript{74} See id. at 130-31.
\textsuperscript{75} See id. at 135.
thereby increasing consumer welfare, can explain why patents and pa-
tent settlements might be good for consumers. When branded drug
makers spend on innovation, the litigation costs a branded maker
saves through settlement, or the additional profits a branded maker
generates by using a patent to delay generic entry, might finance prod-
uct improvements that ultimately help consumers.

While it is true that in the static model some settlements, namely
those that hasten entry, can benefit consumers, this is true only be-
cause in the static model consumers have nothing to gain from any
amount of delay in generic entry. Consumers do best in the static
model when there is no patent protection and generic entry is imme-
diate, because the branded drug maker does not invest any profits
from delay in improving the product.76 When there is no hastening in-
volved, and the settlement entry date is the litigation entry date, con-
sumers gain nothing from settlement in the static model. The branded
drug maker does save on litigation costs, but in the static model the
branded drug maker does not reinvest those savings in innovation.

It might be thought that in the static model the branded drug
maker might at least directly pass on any savings on litigation costs
to consumers by charging lower prices, but even that benefit to con-
sumers is impossible in the static model. Because consumers do not
themselves pay the litigation costs of drug makers, litigation cost sav-
ings can be passed on to consumers only if drug makers would have
raised prices to cover those costs to begin with. In the static model,
however, firms cannot raise prices to cover litigation costs.77 The mo-
nopoly and duopoly prices charged to consumers under litigation or
settlement before expiration of the patent term represent maximum
possible prices given the level of competition in the market. If fixed
costs, such as litigation costs, increase for producers, producers absorb
those costs entirely, so when those costs are removed, prices remain
unchanged, and the savings are captured entirely by producers. This
is the only possible assumption in a monopoly market, as the monopoly
price generates the greatest possible quasi-profit.78 In a duopoly, it is

76. See, e.g., Willig & Bigelow, supra note 14, at 680-81 (giving expressions for con-
sumer surplus for which it is always falling in delay); Edlin et al., Activating Actavis, supra
note 16, at 22 (implicitly invoking an ever-downward sloping consumer welfare line in stat-
ing that “[w]e consider the settlement anticompetitive if it leads to more monopoly and less
duopoly, thereby harming consumers, compared to litigation”).

77. Because consumer welfare does not change in response to the saving of litigation costs,
the consumer welfare line in Figure 1 supra gives consumer welfare under both litigation and
settlement. Otherwise, if settlement were to make consumers better off, the line representing
consumer welfare in settlement would lie above the line representing it in litigation.

78. Quasi-profit is profit before the deduction of any fixed costs, such as the cost of re-
search and development.
possible that increased fixed costs might lead to an increase in prices.\textsuperscript{79}

It is standard to assume that this is not the case, and all other treatments of reverse payments make this assumption, at least implicitly.\textsuperscript{80}

Indeed, even in a competitive market, litigation costs do not affect prices because those costs are borne only by the parties to the litigation. The other generic drug makers in a competitive market do not bear those costs and will therefore compete price to a level that does not take those costs into account.\textsuperscript{81}

Any discussion of the virtues of settlement in the static model misses the broader implication of the model, however, which is that the entire institution of patent protection can only harm consumers. In the static model, patent protection of any kind allows branded drug makers to extract value from consumers through delayed generic entry without giving consumers anything in exchange, because branded makers are assumed in the model not to spend profits on product improvement.\textsuperscript{82} The fact that antitrust scholars have spent decades defending rules that would preserve the right of firms to settle patents

\textsuperscript{79} For example, suppose that duopolists are prone to Bertrand competition but that each knows that the other will not charge a price below average cost. And suppose that each has identical average cost. Price will equal average cost. As fixed cost, such as litigation cost, rises, average cost and therefore the duopoly price will rise as well.

\textsuperscript{80} See, e.g., Willig & Bigelow, supra note 14, at 680-81 (stating that “each firms’ instantaneous rate of profit is $\beta$ under duopoly” and proceeding to use $\beta$ to model litigation and settlement value). Textbooks employ the Cournot duopoly model. See, e.g., DAVID M. KREPS, A COURSE IN MICROECONOMIC THEORY 326-28 (1990). In a classic Cournot duopoly, a duopolist chooses her output, taking the output of her competitor as given. Thus, given her competitor’s output, a duopolist acts like a monopolist, choosing her own output and the market price. This means that the price that a duopolist chooses gives it the greatest possible quasi-profit. It cannot increase this price in response to higher fixed costs, such as litigation costs, without reducing quasi-profit. Because both duopolists are in this position, fixed costs such as litigation costs do not affect the duopoly price.

\textsuperscript{81} In the case of multiple entry, consumers are better off under litigation for any given entry date. Settling for entry at the litigation entry date in this case not only does not help consumers, it hurts them.

Concern with preserving the ability of producers to save litigation costs makes sense in a static model only under a total, as opposed to a consumer, welfare standard. Total welfare takes not only the welfare of consumers into account but also the welfare of producers. Because drug makers pay litigation costs, these costs reduce producer welfare and therefore total welfare, giving antitrust a reason to try to avoid them under a total welfare standard. Antitrust has not, however, used this standard. See supra note 48.

\textsuperscript{82} This is reflected in Figure 1 supra. The highest point on the CS line occurs when there is immediate entry. Because the line slopes downward, consumers are better off at this point than at any other, including at any other level of hastening of entry relative to the litigation entry date (marked ‘expected entry’ in the figure). See Shapiro, supra note 69, at 396 (“Clearly, a short-run consumer surplus standard is not sensible when intellectual property rights are involved: declaring all extant intellectual property rights invalid could well maximize short-run consumer surplus, but at the obvious expense of longer-term innovation and consumer interests.”). Antitrust cannot tolerate this implication because antitrust tends to be highly deferential toward patent-related activity. See, e.g., HERBERT HOVENKAMP,
for entry at the litigation entry date, and indeed would respect the authority of patent law to delay generic entry, suggests that they are implicitly relying on a dynamic model that incorporates gains from innovation. The static model antitrust scholars prefer to use provides no support for their positions.

B. The Relationship Between Innovation and Delay

There are many theories about the relationship between innovation and competition. As suggested in the forgoing Section, the relationship considered in this Article links profit to the quality of the drug produced by the branded drug maker. Competitive pressures, or the prospect of creating greater demand, impel the branded drug maker to invest some of the quasi-profits the branded maker generates from the monopoly price the branded maker is able to charge before generic entry, as well as any duopoly profit generated after generic entry, in research and development, improving the quality of the drug and therefore the value the drug confers on consumers at any given price. The transformation of delay into profit may happen through expectations rather than in real time. Anticipating the ability to charge higher prices during the period of delay, the branded drug maker may borrow more money to invest in drug development, leading to a more effective product when development is complete and the drug has been introduced into the market. Thus delay in entry stimulates innovation and benefits consumers.

FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE 269 (4th ed. 2011) (observing that “[p]atents enjoy a presumption of validity . . . [and] patent settlement agreements are often approved even if they are competitively suspicious.”).

83. See supra notes 27, 51 and accompanying text.

84. See Willig & Bigelow, supra note 14, at 656 n.3 (“There may be tradeoffs between long-run and short-run consumer welfare due to the effect of preventing settlements on innovation and the impact of innovation on consumer and social welfare, which we do not address in this article.”).

85. See Kenneth J. Arrow, Economic Welfare and the Allocation of Resources for Invention, in THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 619-22 (1962) (arguing that a firm in a competitive market has a greater incentive to innovate than does a monopoly because the competitive firm has more to gain); Jonathan B. Baker, Exclusionary Conduct of Dominant Firms, R&D Competition, and Innovation, 48 REV. INDUS. ORG., no. 3, May 2016, at 269, 270 (presenting a model in which the effect of profit on innovation depends on whether a dominant firm regards the investment of its rival in research and development as a strategic complement or substitute).

86. For a graphical treatment, see Woodcock, Inconsistency in Antitrust, supra note 6, at 126-33.
Against this positive effect on consumer welfare must be balanced the negative effect of higher prices with which the static model is concerned.\textsuperscript{87} If delay is too great, diminishing returns to research and development, and the acceleration in the loss of consumer welfare associated with more units of the drug becoming unaffordable to consumers, make consumers as a group end up worse off than they would be at lower levels of delay.\textsuperscript{88} The date of entry that strikes the balance is the optimal date of entry: the date that makes consumers as well off as they possibly can be.\textsuperscript{89} This theory forms the basis for the standard economic justification for patent protection over a limited term.\textsuperscript{90}

The absence of the positive effect of innovation on consumer welfare in the static model is reflected in the downward slope of the line in Figure 1.\textsuperscript{91} Incorporating the positive effect bends the line, as reflected in Figure 3, because losses to consumers from higher prices are initially offset by gains from innovation. The result is a consumer welfare maximum that lies at an intermediate point between immediate entry and delay until patent expiry.\textsuperscript{92} Because the connection between profit and innovation also allows litigation cost savings to help consumers, that connection also shifts the entire consumer welfare line up in settlement, from $C_{S_{lit}}$ to $C_{S_{set}}$, giving consumers a reason to care whether producers save on litigation costs, even if producers are unable to pass those costs along to consumers through higher prices.

\textsuperscript{87} Hemphill, Paying for Delay, supra note 16, at 1556 (“A substantial literature seeks an optimal reconciliation between these competing values by encouraging innovation without sacrificing too much consumer access.”).

\textsuperscript{88} Cf. Elhauge & Krueger, supra note 8, at 294 (“[T]he economic literature shows that patent profits that exceed the optimal level result in excessive investments in innovation that reduce social welfare . . . .”).

\textsuperscript{89} Cf. id. at 293-94 (“If designed optimally, the patent system will maximize overall consumer welfare by giving patent holders the optimal fraction of ex post total surplus created by their innovations.”).

\textsuperscript{90} See Hemphill, Paying for Delay, supra note 16, at 1556, 1556 n.10 (“The instrumental case for patent law . . . depends upon high prices as a means to reward and thereby encourage innovation, a source of ‘dynamic’ efficiency.”); Justin Hughes, The Philosophy of Intellectual Property, 77 Geo. L.J. 287, 303-04 (1988) (observing that the view that patent law uses personal gain to create an incentive for people to invent “clearly has dominated official pronouncements on American . . . patents. Even the Constitution’s . . . patent clause is cast in instrumental terms.”).

\textsuperscript{91} See Figure 1 supra.

\textsuperscript{92} See Figure 3 infra. A formal model in which this relationship appears may be found in Woodcock, Product Innovation, supra note 18, at 7-16.
C. The Litigation Baseline

In a dynamic model, the maximum possible consumer welfare can be achieved only through the settlement of patent litigation, because settlement allows the branded drug maker to apply not only profits associated with delay, but also savings of litigation costs, toward innovation. If antitrust were to apply a maximization standard in measuring harm, antitrust would then prescribe any conduct that precludes settlement for the optimal amount of delay. Antitrust has chosen instead to apply the protection standard, however, measuring harm relative to the welfare that consumers would expect to enjoy were branded and generic drug makers always to litigate the patent
through to a final judgment, and entry were therefore expected to occur on the litigation entry date without any saving of litigation costs.93

In choosing the protection standard, antitrust defers to patent law in answering the question how much delay is required to maximize consumer welfare after taking innovation into account.94 Patent law may be thought of as using its choice of the rules that judges apply in deciding patent challenges to manipulate the litigation entry date for any given patent. In measuring harm against that date, antitrust accepts the role of ensuring that drug makers not use settlements to change the optimal date chosen by patent law. Antitrust accepts this role of deference because it is the mission of patent law to use delay to maximize the welfare of consumers after taking gains from innovation into account.95

In deferring to patent law, antitrust gives up the opportunity to make consumers better off than they could be under litigation. For any given litigation entry date, a settlement for entry on the same date frees up funds that would otherwise have been spent on litigation for investment in research and development instead, and therefore makes consumers better off. This is reflected in Figure 3, which shows that the settlement consumer welfare maximum is greater than the litigation consumer welfare maximum.96 That is, Point H is higher than Point C.97 A number of commentators do not recognize that consumer welfare in settlement may exceed consumer welfare in litigation after gains from innovation are taken into account, suggesting incorrectly that through maximizing welfare in litigation, patent law maximizes welfare over both litigation outcomes and settlement outcomes.98
There is a tension between the deference required by the protection standard and the inability of patent law to maximize consumer welfare. That tension accounts for antitrust’s quest to ban harmful settlements while still preserving the ability of drug makers to settle in ways that increase consumer welfare. Antitrust’s goal appears to be to respect the protection standard while still leaving open the possibility of improving upon it. This project comes to grief, however, when a trade-off exists between respecting the protection standard and preserving the opportunity for welfare-improving settlements. A trade-off may arise either because an antitrust rule cannot be found that achieves both goals, or because the rule that achieves both is very costly to enforce. The protection standard requires that any trade-off between protecting consumers from harm and preserving the opportunity to make them better off must be resolved in favor of protecting consumers from harm.99

The notion that patent law chooses the litigation entry date to maximize consumer welfare in litigation conflicts with the view that patent law’s choice of the patent term, which is twenty years at present, rep-
resents the amount of delay patent law believes is optimal for any patent.\textsuperscript{100} The value of a patent comes not from the patent term per se but the expected entry date that the term, along with many other factors, creates.\textsuperscript{101} There is always some risk of patent invalidity or non-infringement; so a firm planning its research and development expenditures makes plans based on an expected date of entry that is always somewhat sooner than the date of expiration of the patent term. To the extent that patent law wishes to optimize consumer welfare, it must therefore push the litigation entry date, not the patent term, toward the optimal date. Tools it can use to do this include not just the patent term but also the rules of validity and infringement.

In deferring to patent law’s determination of the optimal level of delay, antitrust is not so naïve as to suppose that patent law succeeds at choosing the optimal date, or even makes a choice consciously in the sense that patent law anticipates how all its rule choices add up to a particular litigation entry date for a particular patent. Rather, antitrust has the role of a functionary who must do her job regardless whether the other bureaucrats succeed at doing theirs. The hope is that one day, once patent law has gotten its act together, patent law’s decisions will maximize consumer welfare and therefore antitrust’s defense of them will become useful.

For a number of reasons, it is unlikely that the litigation entry dates chosen by patent law today in fact maximize expected consumer welfare in litigation. The rules of validity and infringement, as well as the patent term, are of limited use in tailoring the litigation entry date to the details of any particular invention. In order for the entry date to be optimal, judges would need to understand their role to be not only deciding whether a patent is enforceable but also manipulating the expectations of potential litigants to create an optimal expected entry date. For example, if a judge were to know that entry after expiration of half of the patent term is optimal in a particular type of case, then the judge would need to craft her opinions in cases of that type to

\textsuperscript{100} Settlement takes place in the shadow of the law and it is therefore conceivable that patent law might use its rules to produce the welfare maximizing settlement outcome. Assuming this assumes away the patent settlement problem in most cases. It would place consumers at the peak in the settlement value lines in Figure 3 \textit{supra} and in Figure 4 \textit{infra}, even in the absence of antitrust intervention. For a possible exception, see discussion \textit{supra} note 98 ¶ 2.

Firms, however, must also incorporate the possibility of settlement into their expectations. Antitrust regulates settlement to ensure that consumer welfare does not fall below the level that would obtain were litigation the only option. For a discussion of the effect of the probability of settlement upon firm expectations, see Woodcock, Product Innovation, \textit{supra} note 18, at 17-18.

\textsuperscript{101} See Shapiro, \textit{supra} note 69, at 395.
make branded drug makers believe that in future they would win in those cases only half the time.

Judges have a different view of their mission. They understand their mission to be to make as clear as possible to future litigants how judges will rule in particular cases. In the patent context, judges see their mission as making clear whether they will enforce the patent, allowing entry only at the expiration of the patent’s term, or not enforce the patent, allowing immediate entry. Their goal is to drive expectations as close to the extremes of immediate entry or entry at patent expiry as possible.

One might argue that this could still mean that judges drive expectations to optimal levels if the optimal levels are always either immediate entry or entry at the patent expiration date. But to make this argument one must assume that a one-size-fits-all patent term combined with the rules of patent validity and infringement are optimal. In other words, all inventions that confer value on consumers are patentable and the appropriate level of investment in research and development in generating them is induced through the same twenty-year term in all cases. Further, one must assume that all inventions that do not confer value on consumers are not patentable. These are not defensible positions. The deference of antitrust to patent is a matter of institutional division of labor, not of belief that patent law can be relied upon to achieve optimal outcomes.

IV. ENTRY SETTLEMENTS IN A DYNAMIC MODEL

Under antitrust’s protection standard, the best rule for entry settlements is a ban, even when gains from innovation arising from delay in market entry are taken into account. Alternative rules that ban or limit the size of reverse payments create a risk that drug companies

102. See generally Ryan J. Owens & Justin P. Wedeking, Justices and Legal Clarity: Analyzing the Complexity of U.S. Supreme Court Opinions, 45 LAW & SOC’Y REV. 1027, 1030 (2011) (“The U.S. legal system has adopted a host of features that enhance legal clarity, chief of which is the adoption of stare decisis . . . .”).

103. Entry is immediate if the patent is invalid or noninfringed. Entry takes place at patent expiry if the patent is both valid and infringed. See Commil USA, LLC v. Cisco Sys., Inc., 135 S. Ct. 1920, 1928-30 (2015) (distinguishing patent validity and infringement).


105. See William F. Baxter, Legal Restrictions on Exploitation of the Patent Monopoly: An Economic Analysis, 76 YALE L.J. 267, 267-72 (1966) (“It is . . . true that the Congressional judgment of ‘how much’ [protection to give innovation by setting the patent term] was made with no explicit attention to the nature of the problem [of balancing gains from innovation against the social costs of monopoly.’]; Lemley, Rational Ignorance, supra note 3, at 1497 (arguing that “the [U.S. Patent and Trademark Office (PTO), which grants patents] doesn’t do a very detailed job of examining patents . . . . It is ‘rationally ignorant’ of the objective validity of patents, in economics lingo, because it is too costly for the PTO to discover those facts”).
will settle for enough delay to harm consumers, even after gains from innovation are taken into account. Given uncertainty regarding whether drug companies will actually make harmful settlements under alternative rules of this kind, the uncertainty corollary to the protection standard requires that antitrust avoid the risk entirely by not implementing those rules. A settlement ban is not the only rule that guarantees no harm to consumers, but relative to the alternatives of a rule of reason or a rule allowing a representative of the consumer interest such as the FTC to supervise settlements as they are being made, it is the least expensive to enforce.

A settlement ban is appropriate under the protection standard because that standard does not seek to preserve the freedom of drug makers to make settlements that improve the welfare of consumers relative to litigation. The standard that seeks to preserve that freedom is the maximization standard, which requires that antitrust maximize consumer welfare. Antitrust does not employ the maximization standard for patent settlements, but the focus of the reverse payment debate on preserving settlements that might benefit consumers suggests that at least some commentators are partial to that rule. The maximization standard does not, however, support adoption of a rule of reason, as these commentators suggest, even after gains from innovation are taken into account. The maximization standard supports a rule requiring supervision of all settlements by the FTC or some other representative of the consumer interest. Only supervision ensures that the settlement the parties choose in fact maximizes consumer welfare. Other alternatives, such as a rule of reason or a rule limiting the size of any reverse payment, would give drug makers the freedom to choose from a range of settlements that make consumers better off relative to litigation, but none would push the parties to choose a particular settlement that maximizes consumer welfare, as supervision would.

A. The Innovation Grace Period

Incorporating innovation into the static model of entry settlements creates a period of delay in entry under settlement, relative to the litigation entry date, for which consumers are better off under settlement than under litigation. An entry date anywhere within this grace period makes consumers at least as well off as they would be under litigation because over this range the consumer harm from higher prices is not so large as to fully counteract the increase in consumer welfare due to

106. See supra note 73 and accompanying text.
107. See supra note 14.
108. See id.
higher profits and the resulting innovation. In Figure 3, this period is the length of the line from Point C to Point D.\textsuperscript{109}

For delay beyond this period, however, the effect of the higher prices becomes too great, and consumers are better off without the extra innovation. Any antitrust rule that prevents delay beyond the grace period meets the protection standard by rendering consumer harm impossible. Both a settlement ban and a rule of reason meet this requirement: the former because it allows no delay at all, and the latter because it carefully identifies and condemns all those settlements that delay entry too long. Settlement supervision also meets this requirement, assuming that the supervisor does not do too poor a job of protecting the consumer interest in settlement negotiations.

There is no reason to suppose a priori that a limit on the size of a reverse payment prevents delay beyond the grace period. Whether a limit prevents excessive delay depends on the peculiar characteristics of the market for the drug at issue in any given case, including the extent to which price falls after entry of generics. In another work, I estimate the amount of delay to which drug makers would find it profitable to agree. For the average drug, the estimates show that delay sufficient to harm consumers is possible under a rule limiting any reverse payment to Brand’s litigation cost or a rule prohibiting any reverse payment.\textsuperscript{110} This happens when multiple generics enter the market together, driving price to low levels.\textsuperscript{111}

By contrast, in the single entry case, in which only a small number of generic makers enter the market before patent expiry and price falls modestly, firms will not agree to sufficient delay to harm consumers, even when there is a reverse payment equal to litigation cost.\textsuperscript{112} Indeed, I find that in the single entry case settlements involving a reverse payment in excess of litigation cost also may not allow delay sufficient to harm consumers. This adds innovation to the growing list of adjustments to the static model that demonstrate that a rule limiting reverse payments to litigation cost would preclude some settlements that benefit consumers, contrary to the claims of advocates of that litigation cost rule.\textsuperscript{113}

\textsuperscript{109} See Figure 3 supra.
\textsuperscript{110} See Woodcock, Product Innovation, supra note 18, at 28.
\textsuperscript{111} For a discussion of multiple entry, see supra note 50 and accompanying text.
\textsuperscript{112} For a discussion of the single entry case, see supra text accompanying note 50.
\textsuperscript{113} See, e.g., Harris et al., supra note 27, at 85-86 (arguing that a litigation cost rule precludes beneficial settlements when the branded drug maker is risk averse); Willig & Bigelow, supra note 14, at 660 (arguing that reverse payments are necessary for beneficial settlements when firms have inaccurate assessments of the chance of winning the litigation). Suppose in Figure 3 supra that point K represents the maximum amount of delay to which
B. Comparison of Options for Regulating Drug Patent Settlements

I consider whether the following rules meet the uncertainty corollary to the protection standard:114: (1) a rule of reason, which the Court in Actavis imposed on entry settlements containing a reverse payment;115 (2) no regulation of patent entry settlements (‘laissez faire’); (3) a per se rule against all patent entry settlements (‘settlement ban’); (4) a per se rule against all patent entry settlements involving a reverse payment (‘payment ban’); (5) a per se rule against all patent entry settlements involving a payment in excess of litigation cost or some other threshold amount (‘litigation cost rule’ or ‘small payment ban’); and (6) a rule allowing the FTC, acting as consumer representative, to become party to any patent litigation (‘supervision rule’). Only a settlement ban, rule of reason, and supervision rule satisfy the uncertainty corollary in both single and multiple entry.

I undertake the analysis of each rule first by reference to Figure 3, which gives consumer welfare in the single entry case for the average drug, taking my estimates into account.116 I extend the analysis to the multiple entry case in Section IV.B.8.

1. Assumptions

In comparing the rules, I make the following assumptions.

1) The litigation entry date falls before the patent expiration date. My estimates for the average drug show that this holds.117

Generic is willing to agree in exchange for a payment equal to Brand’s litigation cost. Because the delay represented by this intersection is substantially less than the delay associated with consumer harm (point D), there exist payments in excess of litigation cost that buy delay that falls between points K and D and therefore do not harm consumers. See Figure 3 supra.

114. See supra note 73.
116. See Figure 3 supra. I describe the model that generates this figure in Woodcock, Product Innovation, supra note 18, at 7-16.
117. See id. at 63 (reporting estimates of “optimal patent strength”). If the litigation entry date were to fall instead at patent expiry, then delay would be impossible and reverse payments of no concern, given that the courts already ban agreements extending the patent term. By contrast, many argue that inventors capture too little of the gains from innovation, which might suggest that optimal entry lies at or even beyond patent expiry. See, e.g., Denicò, supra note 18, at 713 (finding that patents do not over-compensate innovators at present); William D. Nordhaus, Schumpeterian Profits in the American Economy: Theory and Measurement 22 (Nat’l Bureau Econ. Research, Working Paper No. 10433, 2004) (estimating that only 2.2% “of the total present value of social returns to innovation are captured by innovators”), http://www.nber.org/papers/w10433 [https://perma.cc/8Q89-3YKJ].
2) The uncertainty corollary to the protection standard, which prohibits any rule that allows the possibility of consumer harm, applies.118 Because delay of excessive length leads to harm, the maximum delay allowed by each rule determines whether it meets the standard.

3) Generic’s expectations regarding litigation are either optimistic or accurate, but never pessimistic.119 If Generic is pessimistic, then Generic may agree to large amounts of delay because Generic believes that it will probably lose the litigation and be excluded from the market until patent expiry in any case. By eliminating this scenario, this assumption places a cap on the amount of delay that any reverse payment rule will allow, which preserves the possibility that some rules will meet the uncertainty corollary.120

4) The grace period of delay, during which consumers are not harmed relative to litigation, does not extend until patent expiry. That is, delay until patent expiry harms consumers relative to litigation. This is reflected in Figure 3, which shows consumer welfare at Point A falling below consumer welfare at Point C, which is consumer welfare under litigation.121 This assumption is based on my estimates regarding the grace period for the average drug.122

5) The maximum delay possible under settlement without a reverse payment or with a payment capped at litigation cost is not enough to harm consumers. In Figure 3, settlement without a reverse payment can involve no delay beyond Point B and settlement with a litigation cost payment can involve no delay beyond Point K. This assumption is also based on my estimates.123

118. See supra note 73 and accompanying text.
119. See Willig & Bigelow, supra note 14, at 672-73 (discussing the role of optimism in reverse payment settlements).
120. Cf. Davis, supra note 16, at 299 (arguing that Generic is likely to be pessimistic about its litigation prospects whereas Brand is not).
121. See Figure 3 supra.
122. See Woodcock, Product Innovation, supra note 18, at 26, 28 (reporting “upper bound[s]” on the “delay threshold” for most patent strengths in the cases of both single entry, called “capped duopoly,” and multiple entry, called “fixed duopoly”).
123. See id. (reporting estimates, for the average drug, of the maximum delay to which Generic will agree in exchange for a reverse payment in an amount up to litigation cost). For a discussion of why a maximum level of delay exists, see supra note 60 and accompanying text.
6) Brand’s expectations regarding litigation are always accurate.124

7) No rule allows hastening of entry through settlement. This assumption simplifies the argument, but contributes nothing to the results. It is also highly artificial, because all of the rules considered in this Article in fact allow some hastening, with the exception of the settlement ban.125

8) All cases look like the average case. If not, then assumptions 1, 4, and 5, all of which are based on my estimates for the average case, do not hold for all cases.

A rule complies with the uncertainty corollary if the maximum delay that the rule allows is associated with a level of welfare on the settlement consumer welfare curve, $C_{\text{set}}$ in Figure 3, that is below consumer welfare in litigation, Point C.126 Equivalently, a rule complies if the maximum delay allowed by the rule exceeds the level of delay at Point D on the consumer welfare curve, which gives the point at which welfare in settlement equals welfare in litigation at Point C.127

2. **Laissez Faire**

If antitrust does not regulate patent settlements, then drug makers are free to delay entry until the expiration of the patent, which corresponds to Point A in Figure 3. By Assumption (4), consumers are better off under litigation, putting Point C above Point A. As a result, laissez faire harms consumers and violates the uncertainty corollary. This result establishes a basis for antitrust regulation of entry settlements in a model that accounts for innovation. The result provides support for the Court’s decision in *Actavis* to abandon laissez faire.128

---

124. See Woodcock, Product Innovation, supra note 18, at 11. If Brand’s expectations are not accurate, or at least the same as the researcher who is calculating consumer welfare, then depending on Brand’s expectations any settlement outcome is possible and the model useless. For example, if Brand thinks mistakenly that it will lose the litigation, then it is willing to settle for any entry date. Cf. Willig & Bigelow, supra note 14, at 673, 692-96 (modeling dates at which Brand and Generic are willing to settle when either may have inaccurate expectations of litigation success).

125. For example, under a rule of reason the parties may settle for any entry date that leaves consumers no worse off than they are at Point C in Figure 3 supra. This implies that settlements that delay past point D are illegal under the rule, as are all settlements for entry dates to the right of that date corresponding to Point C and to the left of that date corresponding to the intersection of $C_{\text{set}}$ and a horizontal line drawn leftward from Point C (not shown).

126. See Figure 3 supra.

127. See Figure 3 supra.

3. **Settlement Ban**

If antitrust bans patent settlements, then entry is determined by the courts, which choose the date that corresponds to the welfare maximum under litigation, Point C. Because the uncertainty corollary requires precisely that welfare not fall below Point C, a settlement ban complies with the corollary.

4. **Payment Ban**

If antitrust bans reverse payments, but allows entry settlements that do not involve a reverse payment, then my estimates show that for the average drug the greatest delay does not exceed the grace period, falling instead at Point B, per Assumption (5). The settlement range is HB in Figure 3.\textsuperscript{129} Point H is welfare for a settlement at the litigation entry date, which is the lower bound of the settlement range by assumption (6). No settlement that harms consumers relative to Point C is possible under this rule. It therefore meets the uncertainty corollary.

5. **Litigation Cost Rule/Small Payment Ban**

If antitrust limits the size of a reverse payment to the branded maker’s litigation cost, or any amount less than that, then according to my estimates for the average drug, delay does not exceed the grace period, falling instead at Point K, per Assumption (5). Point K is below point B, which gives settlement under a payment ban, because a rule that allows a payment, even one limited to litigation cost, allows more delay than a rule allowing no payment, and therefore leads to lower consumer welfare. The settlement region is HK. It is clear that, like a payment ban, a litigation cost rule allows no harm to consumers relative to litigation and therefore meets the requirement of the uncertainty corollary.

A cautionary observation regarding this conclusion is in order. The choice of litigation cost as a reverse payment cap is arbitrary. The proponents of the rule developed it in the belief that litigation cost is a marker of consumer harm;\textsuperscript{130} but this Article\textsuperscript{131} and others\textsuperscript{132} have shown that hypothesis to be false. The rule is desirable only to the extent that it provides for a level of payment that is small enough that

\textsuperscript{129} See Figure 3 supra.

\textsuperscript{130} See, e.g., Edlin et al., Activating Actavis, supra note 16, at 22 (insisting that consumer harm arises “if (but only if) the reverse payment exceeds the patent holder’s avoided litigation costs”).

\textsuperscript{131} See supra text accompanying note 113.

\textsuperscript{132} See, e.g., Willig & Bigelow, supra note 14, at 677.
consumers cannot be harmed. Any small payment will do. For this reason, I sometimes refer to the litigation cost rule as the small payment rule.

6. Rule of Reason

A rule of reason condemns only those entry settlements that harm consumers relative to litigation. The greatest delay allowed by the rule therefore corresponds to Point D, the last point before consumers are harmed. The settlement range is therefore HD. Assuming that the rule is applied without error, it allows no harm to consumers and therefore satisfies the uncertainty corollary.

7. Making Consumers Party to Patent Litigation

Another possible solution to the entry settlement problem is to make a consumer representative an indispensable party to any patent suit. Settlement outcomes approximate litigation outcomes only if the balance of interests in settlement negotiations approximates the balance of interests protected by the law. Settlements that harm consumers are possible because consumers are not part of settlement

---

133. The Court in Actavis authorized a rule of reason inquiry into the existence of “unjustified anticompetitive harm,” Actavis, 133 S. Ct. at 2236, but provided no guidance on the baseline against which such harm ought be measured. I assume that the Court would impose the baseline accepted by the literature, that of consumer welfare under litigation. See supra Section III.C.

134. One approach would be for the FTC to intervene in every patent suit that could give rise to an entry settlement. Federal Rule of Civil Procedure 24(a)(2) gives a non-party to a suit a right to intervene if the non-party “claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant’s ability to protect its interest.” Fed. R. Civ. P. 24(a)(2). The FTC could argue that its interest in enforcing the antitrust laws suffices. See Amy M. Gardner, Comment, An Attempt to Intervene in the Confusion: Standing Requirements for Rule 24 Intervenors, 69 U. CHI. L. REV. 681, 687 (2002) (“[I]ntervention is frequently relied upon by groups attempting to protect the public interest. Examples include . . . governmental entities intervening in private litigation . . . .” (footnote omitted)). But see In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 531 (E.D.N.Y. 2005) (observing, in a reverse payment settlement case, that the “concept of a public property right in the outcome of private lawsuits does not translate well into the realities of litigation, and there is no support in the law for such a right”). Another approach would be to allow buyers to challenge patents. See Elhauge & Krueger, supra note 8, at 292 (“Because the underlying problem that allows anticompetitive settlements is that patent law does not ordinarily give buyers standing to challenge dubious patents, a possible procedural solution would provide that when such settlements are reached buyers should have standing to challenge the patent’s validity.”).

135. See Davis, supra note 16, at 261-62 (arguing that when the interests of consumers and Generic are aligned, the settlement entry date will approximate the expected entry date under litigation). For more on the theory that when all the interests represented by the law negotiate settlement the terms will approximate those that would be achieved through litigation, see Woodcock, Uncertainty and Reverse Payments, supra note 24, at 125-27.
negotiations. At present, the judge, as the guardian of a patent regime that incorporates the interests of consumers, is the only defender of consumer interests in patent litigation between drug makers. But the judge is not at the table when a settlement is negotiated and therefore consumer interests are not reflected in settlement terms. The solution might be to make the FTC, acting as a defender of the consumer interest, an indispensable party to any patent litigation. The FTC would therefore also be an essential party to any settlement, bringing the balance of interests in settlement into line with the balance of interests in patent law generally.

In bringing all the interests protected by the law to the settlement table, supervision of settlements drives the entry date under settlement toward the litigation entry date, but because settlement saves litigation costs, consumer welfare increases relative to litigation, from Point C to Point H. There is no consumer harm under a supervision rule, so it meets the uncertainty corollary.

---

136. See Woodcock, Uncertainty and Reverse Payments, supra note 24, at 126-27.

137. See, e.g., Caplan v. Fellheimer Eichen Braverman & Kaskey, 68 F.3d 828, 835 (3d Cir. 1995) (“Our federal courts have neither the authority nor the resources to review and approve the settlement of every case brought in the federal court system. There are only certain designated types of suits, for instance consent decrees, class actions, shareholder derivative suits, and compromises of bankruptcy claims where settlement of the suit requires court approval.”).

138. The FTC is empowered to enforce the antitrust laws, see, e.g., Fed. Trade Comm’n v. Cement Inst., 333 U.S. 683, 694-95 (1948) (stating that “the Sherman Act and the Trade Commission Act provide the Government with cumulative remedies against activity detrimental to competition”), which have the goal of protecting the consumer interest. See supra note 48.

139. The authority of the FTC has been held to extend to stopping anticompetitive practices in their ‘incipiency.’ Fed. Trade Comm’n v. Brown Shoe Co., Inc., 384 U.S. 316, 322 (1966) (“[T]he Commission has power under § 5 to arrest trade restraints in their incipiency without proof that they amount to an outright violation of . . . the antitrust laws.”). Allowing the FTC to represent consumers in patent settlement negotiations, thereby forestalling settlements that harm consumers, is in the spirit of the FTC’s ‘incipiency’ authority. Cf. Cement Inst., 333 U.S. at 693 (“All of the committee reports and the statements of those in charge of the Trade Commission Act reveal an abiding purpose to vest both the Commission and the courts with adequate powers to hit at every trade practice, then existing or thereafter contrived, which restrained competition or might lead to such restraint if not stopped in its incipient stages.”). Whether this could be accomplished without Congressional action is beyond the scope of this article. I note, however, that Congress has already dabbled in the authorization of third-party rights in patent cases by authorizing *inter partes* review. 35 U.S.C. § 311 (2012) (allowing “a person who is not the owner of a patent” to challenge the patent based on prior art before the Patent Trial and Appeal Board).
8. The Options in a Multiple Entry Model

Figure 4

Figure 4 shows consumer welfare, including gains from innovation, in the multiple entry case. In this case, the entry of multiple generics drives price to competitive levels, increasing the benefits of early entry for consumers. As a result, the innovation benefits of delay are overwhelmed at lower levels of delay and the grace period of delay is much reduced. The amount of delay to which drug makers will find it profitable to agree under a payment or small payment ban is also much increased, because the generic maker obtains a profit only during the 180 days after the generic maker enters the market, during which the Hatch-Waxman Act guarantees that the generic maker is the only generic maker in the market. When multiple generics enter thereafter, price falls to competitive levels and the generic maker earns no profit.

140. See Figure 4 supra. The extension is described in detail in Woodcock, Product Innovation, supra note 18, at 18-19.
141. Id. at 28.
142. Id. For a discussion of the 180-day exclusivity period, see supra Section II.A.
The generic maker is therefore willing to agree to any amount of delay demanded by Brand as a condition of settlement, so long as the generic maker obtains those 180 days of exclusivity.143

As a result of the shorter grace period, and increased levels of delay under settlement, maximum delay under the payment and small payment bans is now long enough to harm consumers, causing both of these rules now to fail the uncertainty corollary. In Figure 4, Points B and K, corresponding to the payment and small payment bans, now fall below Point C, reflecting harm to consumers relative to litigation.144 The analyses of the other rules remain the same.

9. Results

Table 1 summarizes my results. A settlement ban, rule of reason, or supervision rule satisfy the uncertainty corollary in both single and multiple entry. Laissez faire fails to satisfy the corollary in both. Payment and small payment bans only guarantee no harm in single entry. Assuming that it is not easy to distinguish single and multiple entry cases in advance, a rule must guarantee no harm to consumers in both cases in order to meet the uncertainty corollary. Compliance with the corollary in both cases is particularly important because multiple entry, for which consumers are harmed under the payment and small payment bans, is common.145 Both types of payment rule therefore fail the uncertainty corollary.146

143. See Hemphill, Paying for Delay, supra note 16, at 1593 (“For the generic firm, an earlier entry date is better, given the higher present value of earlier payment, but only modestly so. Enjoying the exclusivity period with certainty is more important to a generic firm than its timing. In fact, if future market demand is anticipated to increase, a generic firm might prefer the later entry date, so long as the increase in projected profits exceeds the discount from the delay in their receipt.”).

144. See Figure 4 supra.

145. See Edlin et al., The Actavis Inference, supra note 27, at 629; Kobayashi et al., supra note 14, at 89 (describing multiple entry as “typical”).

146. I have not considered a requirement that Generic make a minimum obverse payment to Brand as part of any settlement, even though in theory an obverse payment requirement might prevent settlement for excessive delay. The objections to antitrust adoption of such a requirement apply regardless whether innovation gains are taken into account. See Woodcock, Uncertainty and Reverse Payments, supra note 24, at 146-48 (outlining the rule and objections to it).
### Table 1

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Meets uncertainty corollary</th>
<th>Meets maximization standard (rank)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Single entry</td>
<td>Multiple entry</td>
</tr>
<tr>
<td>Settlement ban</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Supervision rule</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Rule of reason</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Payment ban</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Litigation cost rule / small payment ban</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Laissez faire</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

### C. A Settlement Ban Is the Least Costly Option

Of the three rules that satisfy the uncertainty corollary, antitrust should apply the settlement ban because it is least costly to enforce.\(^{147}\) Enforcement cost is the cost to antitrust enforcers, whether the government or private plaintiffs, of enforcing a rule against parties to an entry settlement. A settlement ban is less expensive to enforce than a rule of reason because it requires only interpretation of the terms of the settlement agreement, whereas a rule of reason requires interpretation of the terms at a minimum and sometimes determination of the litigation entry date as well.\(^{148}\) A settlement ban is less expensive than a supervision rule because, like a rule of reason, a supervision rule requires enforcers to identify the litigation entry date. Otherwise, enforcers cannot know which settlement offers to reject.

Litigation cost is the cost to settling firms of litigating the patent challenge through to a conclusion. Litigation cost provides no basis for choosing between rules that already satisfy the uncertainty corollary because litigation cost savings are already taken into account in deciding compliance with the corollary, which requires a determination whether litigation cost savings from settlement compensate for welfare losses associated with delay.

By contrast, error costs are accounted for here only in part. Error costs are the costs of mistakenly condemning settlements that benefit

\(^{147}\) Many of the points in this Section IV.C follow *id.* at 140-41, 144-48. For more on how a settlement ban might be administered, see *id.* at 141-44.

\(^{148}\) See *id.* at 145-46.
consumers and failing to condemn those that harm them. Error costs implicitly play a role in the formulation of the uncertainty corollary. Under the protection standard, settlements that make consumers better off relative to their welfare under litigation are irrelevant because the standard seeks only to eliminate harm. Therefore there can be no error cost from condemning beneficial settlements. The uncertainty corollary eliminates the cost of failing to condemn harmful settlements by approving only rules that guarantee no harm. To the extent that they are accounted for under the uncertainty corollary in this way, error costs provide no basis for choosing between rules that all satisfy the uncertainty corollary. The uncertainty corollary does not, however, take account of error costs that arise from the imperfect administration of a rule. For example, courts sometimes fail accurately to distinguish good from bad conduct in applying a rule of reason. To the extent that error costs are not accounted for under the uncertainty corollary, I ignore them. I also ignore court administration costs.

D. Results Under a Maximization Rule

The maximization standard requires that antitrust choose the rule that makes consumers best off, rather than any rule that preserves consumers from harm. When there is uncertainty about the amount of delay to which firms will agree in settlement, the best rule under a maximization standard allows the smallest number of entry dates associated with the highest levels of consumer welfare. For the supervision rule, payment bans, or rule of reason, which nest allowed entry dates, this approach to uncertainty makes the level of welfare at the point of maximum delay allowed under a rule the criterion for determining whether a rule meets the maximization standard. The only difference between this criterion and that under the protection standard is that welfare at maximum delay must equal maximum welfare.


151. This may be put another way. Because welfare in settlement is falling with delay, as shown in Figure 3 supra, if one rule allows more delay in settlement than the other, then it allows some settlements with lower welfare than those allowed by the other. Assuming that the choice of rule does not change which cases settle and that settlement entry dates are uniformly distributed over available settlement dates, the rule that allows less delay dominates. When two rules allow the same amount of delay, the rule that affords greater or equal settlement welfare for any given entry date dominates.
in settlement to satisfy the maximization rule, instead of maximum welfare in litigation, as required under the protection standard.

The supervision rule is the best rule under the maximization standard because it guarantees settlement at the litigation entry date, allowing consumers to benefit from avoidance of litigation costs without suffering losses from delay. Next come the payment ban, small payment ban, and rule of reason, in that order, because each allows progressively more delay. A settlement ban comes last because although it allows no more harm to consumers than a rule of reason, it eliminates the possibility of beneficial settlements. In multiple entry, payment and small payment bans cease to be contenders because they allow harm to consumers, but a supervision rule, rule of reason, and settlement ban retain their relative rankings.

E. Consequences for Actavis

1. The Decision Does Not Go Far Enough

The rule of reason imposed by Actavis is defective both because a settlement ban is a less costly alternative that is equally effective at meeting antitrust’s protection standard and because the Court applied the rule of reason only to the subset of entry settlements that involve a reverse payment. Actavis exposes drug patent entry settlements in-

152. I assume that a rule of reason would continue to take litigation welfare as a baseline in condemning settlements that harm consumers, even though as a technical matter under a maximization standard harm is measured against maximum settlement welfare. If a rule of reason were to measure harm in the latter fashion, then only the settlement that maximizes welfare would be legal under a rule of reason, and a rule of reason would have the same effect as a supervision rule. Indeed, it might do better than a supervision rule given that a supervision rule tends to produce entry at the litigation-welfare-maximizing date, but a rule of reason would allow entry only at the settlement-welfare-maximizing date. The two are not necessarily the same.

153. Regulation discourages settlement. Some parties who would do a deal in laissez faire will fail to do a deal under another regime either because the regime causes bargaining over mutually beneficial settlements to break down or asymmetric information prevents settlement. Because the alternative to settlement is litigation, this means that every form of regulation pushes average value in the direction of Point C in Figure 3 supra, which is consumer welfare under litigation, to some extent. This has no effect on analysis under a protection standard because that standard is only interested in reductions in consumer welfare relative to Point C. Whether welfare under a particular regime lies above or below welfare at Point C does not change if it is pushed in the direction of Point C.

But settlement discouragement does complicate analysis under a maximization standard. Consumer welfare at maximum delay can no longer be used to compare regulatory approaches under that standard. If a supervision rule discourages settlement to a much greater extent than a rule of reason, for example, then average settlement value under a supervision rule might fall below that under a rule of reason. My maximization standard rests on assumptions that sidestep this problem. See supra note 151.
volved a reverse payment to rule of reason review and entry settlements involving reverse payments in excess of litigation cost in particular to a rebuttable presumption of illegality as part of this review.\textsuperscript{154} The decision does not cover entry settlements that involve no reverse payment\textsuperscript{155} and therefore reaches only a small part of the universe of drug patent entry settlements. For fiscal year 2014, the FTC reports that of 160 settlements arising out of Paragraph IV litigation, 111, or 69\%, “restrict the generic manufacturer’s ability to market its product but contain no” reverse payment.\textsuperscript{156} Although Actavis appears to have driven down the share of settlements involving a reverse payment,\textsuperscript{157} the share of settlements fixing a date of entry, with or without a reverse payment, has remained roughly constant, suggesting that the entry settlement problem has escaped its reach.\textsuperscript{158} To the extent that

\begin{itemize}
\item \textsuperscript{154} Fed. Trade Comm’n v. Actavis, Inc., 133 S. Ct. 2223, 2237-38 (2013); Edlin et al., The Actavis Inference, supra note 27, at 585 (“The core insight of Actavis is the Actavis Inference: a large and otherwise unexplained payment, combined with delayed entry, supports a reasonable inference of harm to consumers from lessened competition.”); Hovenkamp, Anticompetitive Patent Settlements, supra note 1, at 5-6 (“Actavis holds that a large settlement exclusion payment disproportionate to litigation risk can be unlawful under antitrust’s rule of reason, without inquiry into whether the patent is actually invalid or not infringed, and even if the settlement agreement does not go ‘beyond the scope’ of the patent’s nominal coverage.”).
\item \textsuperscript{155} See Actavis, 133 S. Ct. at 2237 (“[T]he fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee’s market prior to the patent’s expiration, without the patentee paying the challenger to stay out prior to that point.”).
\item \textsuperscript{157} See BUREAU OF COMPETITION, FED. TRADE COMM’N, FED. TRADE COMM’N AGREEMENTS FY 2014, supra note 156, at 1 (“[T]he number of settlements potentially involving pay for delay decreased significantly in the wake of the Actavis decision.”).
\item \textsuperscript{158} Of 140 settlements in the last full year before Actavis, 121 were entry settlements, which may or may not include a reverse payment, and of 160 settlements in the first full year after the decision, 140 were entry settlements, which again may or may not include a reverse payment, constituting an increase in entry settlements of about 1\%. Compare 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 (2013),
entry settlements not covered by Actavis are per se legal,159 which Actavis suggests is the case.160 Actavis permits a laissez faire regime for these settlements that allows harm to consumers, even after accounting for gains from innovation.161 One thing the Court got right in Actavis was avoiding a payment ban or litigation cost rule, both of which fail the uncertainty corollary because they allow consumer harm.162

2. Improving on Actavis

Through an interpretation that is faithful to the economics of the problem, if not necessarily to the understanding of the majority opinion in Actavis, the lower courts may extend Actavis to require rule of reason scrutiny of all entry settlements. Doing so would replace laissez faire treatment for the swath of entry settlements involving no reverse payment that are potentially harmful to consumers, with the better, if not the best, alternative of rule of reason review.

This extension would be accomplished by interpreting any value that Generic derives from an entry settlement, whether from Brand in the form of a traditional cash reverse payment, from the pre-expiry drug market in the form of profit, from the saving of litigation cost, or from anywhere else, as a ‘reverse payment’ for purposes of Actavis. This redefinition would cause all entry settlements to count as reverse payment settlements and thereby to qualify for rule of reason treatment under Actavis.

This approach is faithful to the economics of the reverse payments problem because what is potentially harmful to consumers about a traditional reverse payment is not that it comes from Brand, but that it creates an incentive structure that fails to make settling for harmful levels of delay a loss-making proposition for at least one of the parties.


159. Some appeals courts have held that all anticompetitive conduct is protected from antitrust liability so long as it does not extend the patent term. See Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1308 (11th Cir. 2003); Hovenkamp, Anticompetitive Patent Settlements, supra note 1, at 4-5 (providing an overview of this position and citing cases). To the extent that Actavis merely carves reverse payment settlements out of that rule of per se legality, settlements involving no reverse payment are per se legal.

160. See Actavis, 133 S. Ct. at 2237; Hemphill, Paying for Delay, supra note 16, at 1589, 1589 n.147 (“An agreement that divides up the remaining term into monopoly and competition periods fits the widely accepted rule that an agreement on entry dates raises no anticompetitive concern. The FTC, for example, has provided a safe harbor for agreements that set an entry date but include no cash payment from the innovator to the generic firm.”).

161. See supra Section IV.D.

162. See supra Sections IV.B.4, IV.B.5, IV.B.8.
A reverse payment in the traditional sense is only one of many ways in which value can be had from delay.

Consider the saving of litigation costs, which is a way in which value can be had from delay by both parties without a reverse payment. When the parties settle without a reverse payment, Generic may agree to delay if the litigation costs Generic saves provide sufficient compensation for the profits Generic loses from the delay. The incentive to delay created by the litigation cost savings cannot meaningfully be distinguished from the incentive effect that a reverse payment from Brand to Generic would have. The distinction cannot be that, in the case of a reverse payment, Brand makes a cash transfer to Generic, as simply allowing Generic directly to make a greater portion of future sales counts as a reverse payment. The distinction also cannot be that, in the case of a reverse payment, Brand makes a transfer of value to Generic in the sense that the gain to Generic somehow corresponds to a loss to Brand. Suppose that Brand promises to turn 50% of Brand’s future monopoly profits over to Generic in exchange for delay. That would surely count as a reverse payment, but it is hard to characterize Brand as losing 50% of its future monopoly profits here. Brand might have access to those profits if Brand were to win the litigation. But when Brand settles, Brand has not won the litigation. If the settlement carves out those profits for Generic, then Brand neither ever had them nor ever will.

A more plausible, but still flawed, distinction between a reverse payment and litigation cost savings is that a reverse payment represents the use of the private surplus associated with monopoly to induce Generic to accept delay, whereas litigation cost savings are just that, cost savings, and not the fruits of monopoly. Allowing Generic to make some future sales directly or promising Generic a share of future monopoly profits are both ways of sharing monopoly profits, so they would count as reverse payments under this definition.

The trouble with this definition is underbreadth; it would exclude from the definition of reverse payment many of the settlements that would count as reverse payment settlements under Actavis. Suppose that Brand makes a payment to Generic for delay that is in excess of

---

163. See supra note 55 and accompanying text.
164. See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 394 (3d Cir. 2015) (holding that an agreement that Brand will not introduce its own generic version of a drug [an “authorized generic”] to compete with that of Generic once Generic enters the market counts as a “reverse payment” under Actavis).
165. I differ on this point from Hemphill, Paying for Delay, supra note 16, at 1582 (“[S]ome conferral [of value upon Generic] is necessary in order for the parties to take joint advantage of the gain from trade.”).
Brand’s litigation cost. But suppose further that the delay Brand demands in return is not greater than that to which Generic would agree anyway without a reverse payment in order to save litigation costs. It is not clear that the monopoly profit Brand shares with Generic through the payment is what induced Generic to settle for delay.\(^{166}\) Generic is willing to settle for that level of delay even in the absence of a reverse payment. Under \textit{Actavis}, the settlement would count as a reverse payment settlement and would probably trigger liability because of its size. In sum, it is difficult to characterize the antitrust significance of a reverse payment as anything other than mere membership in a broad set of mechanisms that create an incentive to settlement for delay.\(^{167}\) Extending the definition of reverse payment to include that entire set merely eliminates an arbitrary and unhelpful distinction.

My proposed extension of the definition of reverse payment to include any value that may be realized through settlement sweeps in all settlements because all settlements must have value to the parties in order for the parties to agree to them. The extension does not condemn all settlements, however, but merely subjects them to rule of reason review. It also sweeps in only entry settlements because \textit{Actavis} only applies to settlements that both involve a reverse payment and fix a date of entry.\(^{168}\) Both elements are required.

It was of great importance to the Court in \textit{Actavis} that the size of a reverse payment might be used to avoid the costly inquiry into the litigation entry date that is otherwise necessary in determining whether

\begin{footnotesize}
\begin{itemize}
\item \textbf{166.} See Woodcock, \textit{Uncertainty and Reverse Payments}, supra note 24, at 117 n.66.
\item \textbf{167.} If the trigger for antitrust liability were a sharing of monopoly profit as an inducement to behavior that leads to consumer harm, then many reverse payment settlements condemned under \textit{Actavis} would be spared. Only a reverse payment settlement for delay in excess of the maximum delay to which Generic would agree without a payment would trigger liability. Without such a strict standard, however, it is difficult to think of antitrust as being about prohibiting conduct that exploits monopoly effects for private gain so much as being about a general prohibition on behavior that harms consumers, regardless whether the rewards of monopoly provide a necessary incentive. But much economic behavior may harm consumers incidentally. Laziness at work is an example. Antitrust’s current consumer harm standard seems overbroad; its overbreadth is perhaps remedied by the various non-economic requirements of antitrust law, such as the requirement of the existence of an agreement as a condition for liability under Section 1 of the Sherman Act. 6 PHILLIP E. AREEDA & HERBERT HOVENKAMP, \textit{Antitrust Law: An Analysis of Antitrust Principles and Their Application}, 1-5 (2d ed. 2003) (outlining the requirement of an agreement for liability under Section 1 of the Sherman Act).
\item \textbf{168.} Fed. Trade Comm’n v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013) (giving as a general example of a reverse payment settlement an agreement pursuant to which Brand makes a payment to Generic and Generic is required “not to produce the patented product until the patent’s term expires”).
\end{itemize}
\end{footnotesize}
a settlement is harmful under a rule of reason. Under my proposed expansion in the definition of a reverse payment, the courts would potentially be asked to decide many cases in which the absence of a reverse payment would prevent the courts from using reverse payment size to ascertain harm. I have two observations regarding this problem. First, while the Court seems happy in *Actavis* that reverse payment size might substitute for a costly inquiry into the litigation entry date in many cases, it does not rule out costly analysis where necessary. Second, the burden of subjecting all entry settlements to full rule of reason review could push the Court toward acceptance of the less costly alternative of a settlement ban.

V. Conclusion

An enduring critique of antitrust is that it fails to take innovation into account and in so doing victimizes firms struggling to eke out enough monopoly power to pay for the research and innovation that have dramatically transformed the quality of life of consumers over the past few centuries. This charge would seem to have particular appeal in the context of reverse payment drug patent settlements because the promise of innovation is nowhere more urgent than where health is at stake. It is therefore a matter of some perplexity that the antitrust debate over these settlements has been conducted almost

---

169. *Id.* at 2237 (“[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 . . . .”).

170. *Id.*

171. *See supra* note 154.

172. *See, e.g.,* JOSEPH A. SCHUMPETER, *CAPITALISM, SOCIALISM, AND DEMOCRACY* 106 (1976) (“The firm of the type that is compatible with perfect competition is in many cases inferior in internal, especially technological, efficiency. . . . [I]t is not sufficient to argue that because perfect competition is impossible under modern industrial conditions—or because it always has been impossible—the large-scale establishment or unit of control must be accepted as a necessary evil inseparable from the economic progress which it is prevented from sabotaging by the forces inherent in its productive apparatus. What we have got to accept is that it has come to be the most powerful engine of that progress and in particular of the long-run expansion of total output not only in spite of, but to a considerable extent through, this strategy which looks so restrictive when viewed in the individual case and from the individual point of time. In this respect, perfect competition is not only impossible but inferior, and has no title to being set up as a model of ideal efficiency.”); Ginsburg & Wright, *supra* note 5, at 20 (“The persistent call for more attention to dynamic competition in antitrust analysis is . . . compelling . . . because we all know that static analysis has significant limitations[,]”); Sidak & Teece, *supra* note 5, at 600-02.

173. *See* Kobayashi et al., *supra* note 14, at 95 (arguing that taking account of innovation might transform reverse payment settlement analysis).
entirely by reference to a static model of consumer welfare that does not take gains from innovation into account.174

I show, however, that the conclusions that one might expect to follow from taking innovation into account, namely, that reverse payment settlements and other settlements that delay generic entry ultimately benefit consumers, do not follow.175 In the patent settlement context, antitrust’s role is to protect consumers from harm, relative to the welfare they would enjoy under litigation. Whether a rule that does no more than limit the size of a reverse payment meets this standard depends on the vagaries of the individual case. My estimates for the average drug suggest that even a ban on reverse payments allows consumer harm, even after accounting for litigation.176 Of the rules that allow no harm, a settlement ban is least costly and therefore best. Even if the goal of antitrust in the patent settlement context were to promote maximization of consumer welfare through settlement, it does not follow that entry or reverse payment settlements are good for consumers. Instead, the best rule is intervention by the FTC in settlement negotiations to protect the consumer interest, as this promises not merely to limit delay, as would alternatives, but to negotiate it to the welfare-maximizing level.

174. Ginsburg and Wright argue that in general the absence of dynamic analysis in antitrust is due to a lack of economic tools. Ginsburg & Wright, supra note 5, at 20-21 (“The call for a more dynamic approach is confounding because there is no learning presently available—nothing ready to wear, as it were—to give a greater temporal dimension to the analysis of a proposed merger or to the long-run effects of a business practice.”).

175. Cf. Langenfeld & Li, supra note 7, at 778 (arguing that some patent entry settlements “can be procompetitive because they can increase total consumer welfare in the long run”).

176. See Woodcock, Product Innovation, supra note 18, at 26-28 (providing estimates); cf. Sidak & Teece, supra note 5, at 586 (“[S]tatic analysis appears to dominate [in antitrust], even though thoughtful policymakers are aware of dynamic competition. Unfortunately, policymakers are left wielding static analysis in part because of an incorrect perception that scholars have not yet filled the intellectual void.”).