

Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation

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ABSTRACT: In a recent policy reversal, the Department of Justice has, for the first time, pursued antitrust liability for “reverse payment” settlements. These settlements occur in the pharmaceutical industry when brand-name and generic drug companies settle patent-infringement litigation. In a reverse-payment settlement, the generic drug company agrees not to enter the market for some period of time and the patent holder agrees to give it something of value—often quarterly cash payments. The DOJ claims that such settlements should be analyzed under the rule of reason but in fact seeks an unwarranted presumption that reverse payments are unreasonably anticompetitive. At first glance, reverse-payment settlements do seem bad—they resemble anticompetitive market-division arrangements where one party pays another to stay out of the market. However, this Article’s more context-specific economic analysis reveals that the effects of reverse payments are not obvious, can be procompetitive, and that a presumption of anticompetitive effect is thus unwarranted. Instead, courts should analyze them under the traditional rule of reason with no presumption for or against such settlements.

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I. INTRODUCTION

A recent change in policy by the U.S. Department of Justice (“DOJ”) articulates a new direction for courts to take in evaluating settlements to pharmaceutical patent-infringement litigation in which an allegedly infringing generic drug manufacturer agrees, for a time, to not market its product, and the patent holder agrees to give something of value, often a cash payment, to the alleged infringer. These settlements are called “reverse-payment,” “exclusion-payment,” or “pay-for-delay” settlements. They are called reverse-payment settlements because the payment goes from the patent holder to the alleged infringer—the reverse direction from a typical patent-infringement suit in which the alleged infringer is likely to pay the patent holder damages.¹ The terms “exclusion payment” and “pay for delay” suggest that settlements of this type are arrangements in which the patent holder pays the potential generic competitor to stay out of the market.² Reverse payments have created significant antitrust concern. These settlement agreements have been challenged by private litigants, the Federal Trade Commission (“FTC”), and, most recently, the DOJ. These suits allege that reverse-payment settlements are agreements that unreasonably restrain trade in violation of section 1 of the Sherman Act.³

Policy surrounding reverse-payment settlements falls at the intersection of two areas of the law—patent and antitrust. Both bodies of law generally seek an optimal competition environment—patents provide incentives for innovation and market entry, while antitrust law ensures efficient competition between market participants. In considering the intersection between these two bodies of law, it is important to carefully scrutinize the policies of government administrators, who often have an institutional bias to realize short-term political gains while either ignoring future costs or not carefully considering long-term consequences for innovation and, ultimately, consumer welfare. This myopic bias alone suggests that courts should lead the way in developing the application of the antitrust laws to

1. Reverse-payment settlements fit neatly with the parties’ incentives. *See infra* Part II.A. This Article uses the term “reverse-payment settlement” because it is the most commonly used term for this type of settlements. The authors do not intend to imply that reverse payments are backwards or against the parties’ interests; only that the payment goes in the opposite direction from the typical patent-infringement case. Some have criticized the “reverse payment” term as suggesting that the settlement is against the parties’ interests or is in some way backwards. *See* Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 388 (2010).

2. We do not adopt these terms because although some settlement payments may be in exchange for exclusion from the market, a reverse payment does not necessarily have that effect.

3. 15 U.S.C. § 1 (2006). The FTC challenges come under section 5 of the FTC Act. *See, e.g.,* Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).

reverse payments without ceding judicial analysis to the political appointees in the executive branch.

For years, the FTC has vigorously challenged reverse-payment settlements as anticompetitive.⁴ While the FTC challenged settlements of patent-infringement litigation involving reverse payments, the DOJ abstained from using its power to prosecute the same type of settlements.⁵

The FTC has been largely unsuccessful in the courts, and its efforts have resulted in a split in the circuit courts over whether reverse payments warrant antitrust scrutiny. The Second, Eleventh, and Federal Circuits have focused on the exclusionary zone of the patent, resulting in minimal exposure to antitrust liability.⁶ The Sixth Circuit has held that reverse-payment settlements are per se illegal, allowing antitrust liability under section 1 of the Sherman Act.⁷

Recently, the DOJ, now under the Obama administration, switched its policy and, for the first time, joined the FTC in pursuing antitrust liability for reverse-payment settlements. The DOJ argues for a rebuttable presumption that reverse payments are unlawful under the antitrust laws.⁸ The DOJ claims that its position is a traditional rule of reason analysis that weighs the procompetitive and anticompetitive consequences of the practice, but this claim is misleading.⁹ In reality, the DOJ seeks a truncated, structured analysis which, unlike the traditional rule of reason, includes a

4. See, e.g., *Schering-Plough Corp.*, Docket No. 9297 (F.T.C. June 27, 2002), <http://www.ftc.gov/os/adjpro/d9297/020627id.pdf>, *rev'd*, 136 F.T.C. 956 (2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005).

5. The substantive laws under which the FTC and the DOJ challenge reverse payments are similar. The FTC challenges reverse payments under the power granted by section 5 of the FTC Act. See 15 U.S.C. § 45 (2006) (allowing the FTC to prevent “unfair methods of competition”). The DOJ challenges reverse payments under section 1 of the Sherman Act. 15 U.S.C. § 1. Because of the Commission’s bipartisan nature, it is less directly controlled by the President, so the DOJ and FTC positions have at times diverged.

6. E.g., *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir.) (per curiam), *reh'g en banc denied*, Nos. 05-2851-cv(L), 05-2852-cv(CON), 05-2863-cv(CON), 2010 WL 3464382 (2d Cir. Sept. 7, 2010); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *Andrx Pharm., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005); *Schering-Plough*, 402 F.3d 1056; *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003); see *infra* Part II.B.

7. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 900 (6th Cir. 2003); see *infra* Part II.B.

8. Brief for the United States in Response to the Court’s Invitation at 10, *Ark. Carpenters*, 604 F.3d 98 (Nos. 05-2851-cv(L), 05-2852-cv(CON)), 2009 WL 2429249.

9. The rule of reason analysis “forbid[s] only those arrangements the anticompetitive consequences of which outweigh their legitimate business justifications.” *Clamp-All Corp. v. Cast Iron Soil Pipe Inst.*, 851 F.2d 478, 486 (1st Cir. 1988) (Breyer, J.). For a classical statement of the rule of reason, see *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977), where the Court stated: “[T]he factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.”

presumption that reverse-payment settlements are unreasonably anticompetitive.

It remains to be seen whether this recent convergence in policy between the DOJ and the FTC will increase the government's success rate in challenges to reverse-payment settlements. In the only case to test the DOJ's new position, it has not been successful. In *Arkansas Carpenters*, the case in which the DOJ adopted its new policy, the Second Circuit stood by its precedent, refusing to accept the DOJ's new position. However, in the per curiam opinion, the panel urged an en banc rehearing, identifying "several reasons why this case might be appropriate for reexamination by our full Court."¹⁰

Courts, including the Second Circuit in *Arkansas Carpenters*, should not follow the DOJ's new position. This position, if adopted by the Supreme Court, by a consensus of circuit courts, or by legislation, would end the process through which the courts have slowly moved from extreme rules that reverse payments are either always procompetitive or always anticompetitive to a more nuanced middle ground that would allow examination of allegedly anticompetitive settlements in the contexts in which they occur. Much antitrust doctrine has evolved through this type of process and has benefitted from analysis unfettered by the short-term bias of the political branches. The DOJ policy is inferior to the policy toward which the circuit courts are evolving—a position that allows context-specific examination of reverse-payment settlements. The misleading DOJ position claims to advocate a "rule of reason" when it in fact seeks a presumption against reverse payments.¹¹ The reality of such a presumption is that it will effectively prohibit reverse payments given the threat of antitrust enforcement and the possibility of treble damages in private suits.¹² This de facto prohibition will negate the procompetitive benefits achieved by settlement, rather than litigation.¹³

This Article argues for a return to the traditional rule of reason in analyzing reverse-payment settlements, rather than adoption of the DOJ's presumption or the severely limited antitrust scrutiny used by some courts. Reverse payments can be procompetitive or anticompetitive under different conditions. In arguing that they are anticompetitive, the DOJ misses several aspects of the context in which reverse-payment settlements occur, including the high costs of litigation, generic manufacturers with few liquid assets, differences in parties' estimates of trial risks, the potential for decreased

10. 604 F.3d at 108.

11. See *infra* Part II.B for a description of the DOJ position. The rule of reason is an antitrust analysis that includes no presumption that an activity is procompetitive or anticompetitive. See *infra* Part II.B.

12. See 15 U.S.C. § 15(a) (2006).

13. See *infra* Part III.B (discussing the procompetitive benefits of reverse-payment settlements).

marketing upon generic entry, the existence of bona fide side deals, and the incentive effects of any proposed rule. These elements demonstrate that reverse payments may, at times, be procompetitive. The traditional rule of reason analysis provides an inquiry flexible enough to take account of these contextual nuances and allows courts to develop simplified analyses once they gain experience with reverse payments. Courts that limit the antitrust analysis of reverse payments by applying per se rules risk committing significant errors. These errors will be costly to brand-name drug manufacturers seeking to create and market new drugs, to generic manufacturers seeking to enter markets, and ultimately to consumers seeking to purchase medications.

This Article proceeds as follows: Part II examines the legislative and judicial history of reverse-payment settlements, detailing the state of the law and the circuit split over the appropriate antitrust analysis. Part III presents an economic model of reverse-payment settlements and applies that model to the analyses of prominent scholars who have examined reverse-payment settlements. Part IV argues that courts should not follow the DOJ position, but instead should continue their evolution toward the rule of reason—a rule that would require careful examination of the contexts in which reverse payments occur.

II. THE DOJ REVERSAL ON REVERSE PAYMENTS: THE HATCH–WAXMAN ACT AND PHARMACEUTICAL PATENT LITIGATION

A. THE HATCH–WAXMAN ACT

Reverse-payment settlements occur in the unique setting of the Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch–Waxman Act.¹⁴ The Act sought to provide greater incentives for manufacturers to market generic versions of existing brand-name pharmaceuticals. The primary incentive that the Act created is an exclusivity period, granted to the first manufacturer to bring a generic drug to market.¹⁵ A generic drug manufacturer that receives this exclusivity period may sell its generic version of the drug for 180 days before any other generics are allowed to enter the market.¹⁶

Reverse-payment cases follow a typical framework. First, under the Hatch–Waxman Act, each brand-name manufacturer must file an extensive New Drug Application (“NDA”) with the Food and Drug Administration (“FDA”) prior to market entry.¹⁷ The Act lowers the filing requirements for generic versions of existing drugs, allowing them to file an *Abbreviated* NDA

14. Pub. L. No. 98-417, 98 Stat. 1585 (the sections most relevant to reverse-payment settlements are codified as amended in scattered sections of 21 U.S.C.).

15. 21 U.S.C. § 355(j) (2006).

16. *Id.*

17. *See id.* § 355.

(“ANDA”), rather than a full NDA.¹⁸ The ANDA filer must certify that: (1) no patent has been filed that covers the drug; (2) any patent that has been filed has expired or will expire prior to marketing the generic version; or (3) the patent is invalid or will not be infringed by the generic drug.¹⁹ Nearly all reverse-payment settlements stem from patent-infringement litigation where the generic entrant certifies that the patent is either invalid or not infringed. This is known as paragraph IV certification.²⁰ When a generic manufacturer files an ANDA to market a generic version of a patented drug, it must give notice to the patent holder.²¹ Because the Hatch–Waxman Act makes simply filing the ANDA an act of patent infringement, this notice alone may serve as the basis for a patent-infringement suit.²² Generally, parties then settle the patent-infringement litigation, agreeing to a payment schedule from the patent holder to the ANDA filer and a date on which the generic drug may enter the market. Once settled, the basic issues of the patent-infringement case—validity and infringement—remain undecided. Typically, though not always, the FTC challenges the reverse payment and loses its antitrust case in a federal circuit court of appeals.²³

Whether a patent-infringement suit is filed and then settled through a reverse-payment agreement or not, the first ANDA filer, upon approval, is rewarded with the 180-day exclusivity period.²⁴ During this period the generic entrant shares a duopoly with the brand-name drug—no other generic may enter the market until this period expires. This period of exclusivity is extremely lucrative for generic drug manufacturers and is a major incentive for them to attempt to bring generic drugs to market.²⁵

18. *Id.* § 355(j).

19. *Id.* § 355(j)(2)(A)(vii).

20. *See id.* § 355(j)(2)(A)(vii)(IV).

21. *Id.* § 355(j)(2)(B).

22. *Id.* § 355(j)(5). The FDA will not approve an ANDA until forty-five days have passed, giving the patent holder a chance to file a patent-infringement suit if it wishes. *Id.* If the patent holder does file an infringement suit, there is an automatic thirty-month stay of the ANDA, keeping the generic drug off the market while litigation is conducted. *Id.* Though the Hatch–Waxman Act provides incentives for generic drugs to enter the market, it also provides brand-name drug manufacturers significant protection, allowing them to maintain their market share while patent-infringement litigation commences.

23. Private and state actions may be subsequently filed.

24. § 355(j)(5)(B)(iv). The process for ANDA approval is much simpler than the process through which new drugs are approved. ANDA filers need not conduct clinical trials—instead, “generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug).” *Abbreviated New Drug Application (ANDA): Generics*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm> (last updated Aug. 20, 2010).

25. David A. Balto, *We'll Sell Generics Too: Innovator Drug Makers Are Gaming the Regulatory System and Harming Competition*, LEGAL TIMES (D.C.), Mar. 20, 2006, at 39 (“The bounty from challenging a patent is very important. Pharmaceutical patent litigation is a multimillion-dollar

The first reverse-payment settlement agreements took place under an oddity in the law that has since been amended. As initially enacted, the Hatch–Waxman Act allowed a first ANDA filer to hold its exclusivity period indefinitely. The exclusivity period would not begin to run until the ANDA filer actually marketed their product. No other generic could enter the market until after the first filer had brought the drug to market and the 180 days had run. Thus, if a patent holder was able to settle the patent-infringement suit with the first ANDA filer, and the ANDA filer agreed to delay entry, all other generics would also be delayed from entering the market.²⁶ If the agreement allowed the generic to enter at least 180 days prior to patent expiration, the generic would give up relatively little because most of its profits are garnered in the 180-day duopoly.²⁷ The brand-name manufacturer, on the other hand, had much to gain, since by delaying just a single ANDA filer, it could delay all would-be generic entrants without the expense and uncertainty of patent-infringement litigation.

The law has since been amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.²⁸ Under the current version of the Hatch–Waxman Act, a first ANDA filer must market its generic drug within seventy-five days of ANDA approval and within thirty months of its initial filing.²⁹ Failure to market results in forfeiture of the 180-day exclusivity period.³⁰ Once forfeited, the exclusivity period is gone and may not be used by any subsequent ANDA filer.³¹ When a patent holder settles with an ANDA filer, any delay in generic marketing that the parties agree upon can no longer delay all other ANDA filers. However, the 180-day exclusivity period is a very valuable incentive for generic drug companies to enter the market. Absent that incentive, generic drug manufacturers may not attempt to enter some drug markets, and if they do file an ANDA, they may not be willing to face the expense of a patent-infringement trial without the reward of an exclusivity period at the end. This is a key element of patent holders' incentive to settle patent-infringement suits. If the brand-name drug company settles with the first ANDA filer, the law no longer allows patent holders to legally preserve their monopoly by arranging a settlement in which the first ANDA filer agrees to delay market entry, but

proposition. But for the potential reward of six-month exclusivity that represents the vast majority of potential profits from generic entry, many firms might forgo challenging patents.”).

26. See Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585–92 (codified as amended at 21 U.S.C. § 355(j)); Wansheng Jerry Liu, *Balancing Accessibility and Sustainability: How To Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases*, 18 ALB. L.J. SCI. & TECH. 441, 452–53 (2008).

27. Balto, *supra* note 25.

28. Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 21 U.S.C.).

29. 21 U.S.C. § 355(j)(5)(D)(i)(I).

30. *Id.*

31. *Id.* § 355(j)(5)(D)(iii).

the monopoly may be de facto preserved by the reduced incentive that subsequent ANDA filers have to attempt to enter the market. After patent holders reach an agreement that keeps a first filer off the market, subsequent market entrants are not eligible to receive the 180-day exclusivity period.

B. *THE CIRCUIT SPLIT OVER THE ANTITRUST ANALYSIS OF
REVERSE-PAYMENT SETTLEMENTS*

Reverse payments create a clear dilemma for courts. On one hand, patents give their holders exclusive rights to use the patented good, spurring innovation. Patent owners need not share profits received from their patents or license others to use the patent. On the other hand, reverse-payment settlements include agreements that reduce or eliminate competition, potentially violating the Sherman Act's section 1 prohibition of unreasonable restraints of trade.³² The outcome of any antitrust analysis in this context may depend on how much protection the patent provides from antitrust scrutiny. Some courts have held that settlements of patent-infringement litigation are subject to little antitrust scrutiny, while others have held that more extensive antitrust scrutiny is appropriate and have applied different antitrust analyses. Whether any antitrust analysis should take place, and the type of analysis courts should use, are matters of doctrinal uncertainty. The split among circuit courts has resulted in three different rules to apply to reverse-payment settlements: no antitrust analysis; a per se rule against reverse-payment settlements; and a rule of reason analysis. Cases considering reverse-payment settlements are recent phenomena—the first few appeared in the early 2000s, and of the handful that have been decided, few have been decisions at the federal court of appeals level. Thus far, the Supreme Court has denied all petitions for certiorari in reverse-payment cases.³³

1. The First Cases Held Reverse Payments To Be Per Se Illegal

The first courts to consider antitrust challenges to reverse-payment settlements held that settlements in which the patent holder gave something of value to the generic manufacturer, which in turn agreed to delay market entry, were per se illegal. This per se rule creates an irrebuttable presumption that the type of conduct at issue violates section 1 of the Sherman Act. The per se approach is appropriate in situations that “facially

32. 15 U.S.C. § 1 (2006).

33. See, e.g., *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 129 S. Ct. 2828 (2009), *denying cert. to* 544 F.3d 1323 (Fed. Cir. 2008) (per curiam); *Joblove v. Barr Labs, Inc.*, 551 U.S. 1144 (2007), *denying cert. to* 466 F.3d 187 (2d Cir. 2005); *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006), *denying cert. to* 402 F.3d 1056 (11th Cir. 2005); *Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004), *denying cert. to* 332 F.3d 896 (6th Cir. 2003); *Valley Drug Co. v. Geneva Pharm., Inc.*, 543 U.S. 939 (2004), *denying cert. to* 344 F.3d 1294 (11th Cir. 2003).

appear[] to . . . always or almost always tend to restrict competition and decrease output.”³⁴ In 2000, two federal district courts came to the conclusion that reverse payments are per se unreasonable restraints on trade.

First, in *In re Cardizem CD Antitrust Litigation*, the Eastern District of Michigan considered a section 1 Sherman Act challenge to an agreement between a brand-name and generic manufacturer regarding the prescription drug Cardizem CD.³⁵ In 1998, Andrx Pharmaceuticals received FDA approval to enter the market with Cartia XT, a generic version of Cardizem CD.³⁶ However, shortly before Andrx received its approval, Hoechst Marion Roussel, the patent holder and brand-name manufacturer, filed a patent-infringement suit against Andrx, initiating the thirty-month waiting period mandated by the Hatch–Waxman Act.³⁷ Plaintiff drug stores brought a class action suit against Hoechst Marion Roussel and Andrx on behalf of stores and customers who had purchased Cardizem CD after Cartia XT received FDA approval.³⁸ The *Cardizem* plaintiffs alleged that less than a year before that waiting period was to expire, Hoechst Marion Roussel and Andrx reached an agreement whereby Andrx agreed not to enter the market and Hoechst Marion Roussel agreed to pay Andrx \$40 million per year of non-entry.³⁹

The district court denied the defendants’ motions to dismiss,⁴⁰ holding that the antitrust suit was not preempted by amendments to the Hatch–Waxman Act⁴¹ and that plaintiffs had pled sufficient injury⁴² to state an antitrust claim under either a per se or a rule of reason analysis.⁴³ The district court then granted partial summary judgment to the plaintiffs, holding that the payment and agreement to delay entry constituted a per se

34. *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 19–20 (1979).

35. 105 F. Supp. 2d 682, 685 (E.D. Mich. 2000), *aff’d*, 332 F.3d 896. Cardizem CD is a treatment for chest pain, high blood pressure, and heart attack and stroke prevention. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 622 (E.D. Mich. 2000), *aff’d*, 332 F.3d 896 (earlier order on motions to dismiss). Prior to generic entry, the brand-name drug manufacturer, Hoechst AG, was the only supplier in the over \$700 million market for these conditions. *Id.* at 622–23.

36. *Cardizem*, 105 F. Supp. 2d at 622–23.

37. *Cardizem*, 105 F. Supp. 2d at 687.

38. *Cardizem*, 105 F. Supp. 2d at 625–26.

39. *Cardizem*, 105 F. Supp. 2d at 687, 697. The agreement further stated that if Andrx were to obtain a judgment that the Cardizem CD patent was either invalid or not infringed by Cartia XT, the payments from Hoechst Marion Roussel to Andrx would increase to \$100 million per year. *Id.* at 698.

40. *Cardizem*, 105 F. Supp. 2d at 624.

41. *Id.* at 659. The amendments allowed the alleged infringer to maintain the 180-day exclusivity whether they succeeded in a patent-infringement suit, were not challenged by such a suit, or settled the suit. *Id.*

42. *Id.* at 647.

43. *Id.* at 676–81.

unreasonable restraint on competition.⁴⁴ The court used per se analysis⁴⁵ because it characterized the reverse payment at issue as an allocation of the market between horizontal competitors, an act that had already been declared illegal per se.⁴⁶

Unlike courts in later cases, the district court in *Cardizem* was unswayed by the argument that an agreement that might be anticompetitive in another context is not subject to antitrust scrutiny in the unique context of the settlement of a patent-infringement suit.⁴⁷ The court noted that rather than requiring Andrx to cease its allegedly patent-infringing action, the agreement between Hoechst Marion Roussel and Andrx “required Andrx to diligently prosecute its ANDA, the very act of infringement that triggered the . . . patent suit.”⁴⁸ The court saw this requirement as extending the anticompetitive nature of the agreement by ensuring that no other generic could access the lucrative 180-day exclusivity period.⁴⁹

The Sixth Circuit affirmed the district court in *Cardizem*, becoming the first circuit to hold that reverse payments are subject to antitrust scrutiny and to select a method of analysis.⁵⁰ Like the district court, the Sixth Circuit characterized the agreement as a horizontal market allocation and thus per se illegal.⁵¹ The Sixth Circuit did not consider the possibility that the patent could protect the agreement from antitrust scrutiny.⁵²

The next case to consider a reverse-payment settlement also found such settlements per se unlawful. In *In re Terazosin Hydrochloride Antitrust Litigation*, the Southern District of Florida considered a section 1 Sherman Act challenge to a patent-infringement settlement agreement between Abbott Laboratories, manufacturer of the hypertension and prostate drug Terazosin Hydrochloride, and two potential generic competitors, Zenith and Geneva

44. *Cardizem*, 105 F. Supp. 2d at 685. After the antitrust case had been filed, but before the order had been issued, the FTC filed a separate complaint against the parties to the settlement, alleging that the agreement violated the FTC Act. *Id.* at 690.

45. *Id.* at 685.

46. *Id.* at 693.

47. *Id.* at 705.

48. *Id.*

49. *Id.*

50. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 900 (6th Cir. 2003).

51. *Id.* It held that horizontal market allocations are per se illegal “because they ‘have such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit.’” *Id.* at 906 (quoting *State Oil v. Khan*, 522 U.S. 3, 10 (1997)).

52. Under the law at the time, the settlement of the patent-infringement suit and the agreement not to market the generic “also delayed the entry of other generic competitors, who could not enter until the expiration of [the ANDA filer’s] 180-day period of marketing exclusivity.” *Id.* at 907. Under current law, other competitors would not be barred indefinitely from entering the market, but since the 180-day exclusivity is not available to them, they lack a major incentive to bring a generic drug to market. See *supra* notes 29–32 and accompanying text.

Pharmaceuticals.⁵³ The facts of *Terazosin* were similar to those in *Cardizem* and involved an agreement not to enter the market in exchange for quarterly payments. The court granted partial summary judgment for the plaintiffs, holding, like the court in *Cardizem*, that the reverse payment at issue was per se unlawful as a horizontal market allocation and a “classic example[] of a *per se* violation.”⁵⁴

On appeal, the Eleventh Circuit entered the fray. In *Valley Drug v. Geneva Pharmaceuticals*, it reversed the *Terazosin* district court decision and held that reverse-payment settlements of patent-infringement litigation are not per se illegal.⁵⁵ Unlike the two prior courts to consider antitrust challenges to reverse payments, the Eleventh Circuit focused on the unique setting of the settlement—that the paying party held a patent.⁵⁶ According to the Eleventh Circuit, the patent changed the nature of antitrust analysis because patents grant the right to exclude others from the market for the patented good.⁵⁷ To the extent that a patent provides monopoly power, the Eleventh Circuit found that monopoly to be legitimate. This legitimate exclusion destroyed the analogy to horizontal market allocations.⁵⁸ Under its reasoning, since the exclusion allowed by the agreement went no further than the exclusion allowed by the patent, the restraint on trade was reasonable.⁵⁹ According to the Eleventh Circuit, the very fact that the patent *may* have been upheld had the parties not settled negated any antitrust scrutiny of activity that would be legal if the patent *were* upheld. Because the patents at issue were declared invalid only *after* the agreements were made, the agreements were valid when made within the scope of the patent.⁶⁰

This limited analysis—comparing the agreement to the facial scope of the patent—is all that the Eleventh Circuit called for.⁶¹ The court did not go so far as to say that no patent settlement could be unreasonably anticompetitive, but it is clear that it intended to set a high bar—quite

53. 164 F. Supp. 2d 1340, 1343 (S.D. Fla. 2000), *rev'd sub nom.* Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294 (11th Cir. 2003).

54. *Id.* at 1343, 1349 (quoting *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972)) (internal quotation marks omitted).

55. *Valley Drug*, 344 F.3d at 1295.

56. *Id.* at 1304 (“If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court’s order. This is not such a case, however, because one of the parties owned a patent.”).

57. *Id.* at 1305.

58. “[A] patentee can choose to exclude everyone from producing the patented article or can choose to be the sole supplier itself or grant exclusive territorial licenses carving up the United States among its licensees.” *Id.* at 1305 (citations omitted).

59. *Id.* at 1306.

60. *Id.* at 1305 (“To the extent that Zenith and Geneva agreed not to market admittedly infringing products before the . . . patent expired or was held invalid, the market allocation characterization is inappropriate.”).

61. *Id.* at 1308.

different from the Sixth Circuit's per se rule against reverse-payment settlements in *Cardizem*.⁶² Ultimately, the court saw the payment as irrelevant to antitrust consideration of the settlement:

If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. The failure to produce the competing terazosin drug, rather than the payment of money, is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.⁶³

The court left the door open to the possibility that some payments may be large enough to have an anticompetitive effect, but did not find one in this case.⁶⁴

The difference between the Sixth and Eleventh Circuits' decisions in *Cardizem* and *Valley Drug* appears to be one of focus. The Sixth Circuit's focus was on the delay in generic entry; the Eleventh focused on the exclusionary power of the patent. Most subsequent courts to consider reverse payment adopt one of these two general analyses, though there is variation within each.

On remand from *Valley Drug*, the district court analyzed the agreement under the exclusionary scope of the patent focus mandated by the Eleventh Circuit, but again granted partial summary judgment to the plaintiff.⁶⁵ The district court's focus was slightly different from that of the court of appeals. The Eleventh Circuit suggested that there may be *some* reverse payment with significant anticompetitive effects that go beyond the exclusionary power of the patent, but its more direct statement was that if the exclusion does not go beyond the duration of the patent, there is no antitrust problem.⁶⁶ On remand, the district court interpreted the term "exclusionary scope of the patent" not as the period of time for which the patent could be valid, but as an invitation to analyze the specifics of the patent-infringement case to determine this exclusionary scope. It applied the exclusionary-focus analysis as part of a threshold to traditional antitrust analysis, finding that, at the time of the agreement, the exclusionary scope of the patent was small,⁶⁷ the

62. "There may be circumstances under which the unreasonableness of a settlement agreement regarding a subsequently-invalidated or unenforceable patent would be sufficiently apparent that antitrust liability would not undermine the encouragement of genuine invention and disclosure." *Id.*

63. *Id.* at 1309.

64. *Id.* at 1309-10.

65. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005).

66. *See Valley Drug*, 344 F.3d at 1309.

67. *Terazosin*, 352 F. Supp. 2d at 1298 ("[T]he mere fact that the patent was, at the time, not set to expire until October 2014 cannot immunize Defendants from antitrust scrutiny of their Agreement.").

chance that Abbott's patent would be held invalid was high,⁶⁸ and the agreement was not a reasonable implementation of the patent's provisions.⁶⁹ The district court then proceeded to analyze the agreement using the same per se analysis that it had conducted in the first *Terazosin* case.⁷⁰ The court again relied on its characterization of the agreement as a "horizontal agreement between competitors" to justify the per se approach.⁷¹ The court *re*-implemented the per se approach after finding that "the appellate-stay provision exceeded the statutory grant of patent protections to Abbott."⁷² This case demonstrates that even when faced with a more stringent threshold for antitrust analysis, it is possible for courts to reach an antitrust analysis and apply a per se rule to reverse-payment settlements. However, this case marks the end of the first wave of reverse-payment cases in which courts used the per se rule. Subsequent courts considering reverse-payment settlements have applied less stringent antitrust scrutiny.

2. The Next Wave of Cases Extended the Exclusionary Power Analysis

Since the *Terazosin* case, most courts have focused on the exclusionary effect of the patent and have not engaged in additional antitrust analysis if the settlement agreement does not extend beyond this exclusionary power. The Eleventh Circuit has led the way in refining the exclusionary-power analysis that started this trend. On remand from that circuit's decision in *Valley Drug*, the district court interpreted the question of the exclusionary scope of the patent as a threshold question for antitrust analysis. In *Schering-Plough Corp. v. FTC*, the Eleventh Circuit wholly replaced traditional antitrust analysis with exclusionary-scope analysis.⁷³ There, the court considered a drug company's appeal of a finding by the FTC that its reverse-payment settlement agreements were unreasonably anticompetitive under the rule of reason.⁷⁴ The FTC considered the competitive effects of these two settlements in a decision by an administrative law judge ("ALJ") in 2002 and an appeal to the full FTC in 2003. In the first case, the ALJ rejected the per

68. *Id.*

69. *Id.* at 1307–08 (considering the costs of the settlement against the savings and reductions in risk afforded by the settlement, the court found that, since the patent-infringement trial was nearly over, the parties had relatively little to gain by settlement).

70. *Id.* at 1312–13.

71. *Id.* at 1313 ("[H]orizontal agreements between competitors are antitrust's most 'suspect' classification, which as a group provoke closer scrutiny than any other arrangement.").

72. *Id.* at 1314.

73. 402 F.3d 1056, 1066 (11th Cir. 2005).

74. *Id.* at 1058. The plaintiff in the underlying patent-infringement suit, Schering-Plough, was the patent holder of K-Dur 20, a potassium supplement. *Id.* Two settlements were at issue—one involved a licensing agreement between the parties, and the other, a more typical reverse payment from the patent holder to the ANDA filer. *Id.* at 1059–61.

se analysis because the reverse-payment settlements involved novel issues.⁷⁵ Instead, the ALJ considered the settlements under the rule of reason. The rule of reason is a “flexible enquiry, examining a challenged restraint in the detail necessary to understand its competitive effect.”⁷⁶ Because there was no evidence that the generic companies would have entered the market sooner under some other settlement or no settlement at all, the ALJ held that the complaint counsel had not demonstrated any anticompetitive effects.⁷⁷

On appeal, the full Commission also considered the reverse payments using the rule of reason, but reached the opposite conclusion as the ALJ and ordered that the parties not participate in any settlement in which “an ANDA Filer receives anything of value; and . . . the ANDA Filer agrees not to research, develop, manufacture, market, or sell the ANDA Product for any period of time.”⁷⁸ The major difference between the decisions of the ALJ and the Commission is that the Commission held that it was possible to identify an anticompetitive effect, even in the absence of evidence that the patent would have been found to be invalid or infringed.⁷⁹ In considering the anticompetitive effect, the Commission did not compare the settlement to all other possible outcomes of the litigation, but to a hypothetical settlement with no payment from the brand name to the generic.⁸⁰ It found that the likely effect of the payments was to allow the parties to reach a settlement with a later entry date than a settlement without a reverse payment.⁸¹

The Eleventh Circuit came to a radically different result.⁸² Rejecting the rule of reason approach in reverse-payment cases, the Eleventh Circuit expanded and modified its decision in *Valley Drug* to prohibit *any* antitrust scrutiny into most patent-settlement agreements.⁸³ In *Schering-Plough*, the court established that examination of a patent’s exclusionary power is not a threshold question but rather is the only analysis available.⁸⁴ The court’s

75. Schering-Plough Corp., Docket No. 9297, slip op. at 97–98 (F.T.C. June 27, 2002), <http://www.ftc.gov/os/adjpro/d9297/020627id.pdf>, *rev’d*, 136 F.T.C. 956 (2003), *rev’d*, 402 F.3d 1056.

76. *Id.* at 101–02 (quoting *Cal. Dental Ass’n*, 121 F.T.C. 190, 308 (1996)) (internal quotation marks omitted).

77. *Id.* at 99. The judge also specifically found that the license deal for Niacor between Upsher and Schering-Plough was a “bona fide side deal for fair value,” and thus the settlement with Upsher was not a reverse-payment settlement, but rather a traditional settlement with a side deal. *Id.* at 108.

78. *Schering-Plough*, 136 F.T.C. at 1070.

79. *Id.* at 998; *see also infra* Part III.D.1 (discussing Shapiro’s theory that reverse-payment settlements are anticompetitive by nature).

80. *Schering-Plough Corp.*, 136 F.T.C. at 1003.

81. *Id.* For a more detailed examination of the economic incentives involved in a reverse-payment settlement, *see infra* Part III.

82. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

83. *Id.* at 1076.

84. *Id.*

three-part analysis examined: “(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.”⁸⁵ This test is very different from the FTC’s rule of reason analysis because it grants dispositive weight to the presumptive validity of the patents at issue. The Eleventh Circuit extended the presumption of patent validity⁸⁶ to a presumption of infringement without identifying any support for the presumption.⁸⁷ Given the court’s presumption that the patent was both valid and infringed, it was easy to conclude that there could not be an antitrust violation if the agreement did not extend beyond the nominal life of the patent. It is unclear why the Eleventh Circuit took this significant and unfounded legal step when it could so easily have reversed the outcome of the case based simply on its characterization of the facts.⁸⁸

Again, the ultimate difference between the Eleventh Circuit and the FTC opinions is one of focus. The Commission focused on antitrust law, seeing the possibility of anticompetitive effects in the settlement of a legitimate patent-infringement suit. The Eleventh Circuit, on the other hand, looked to patent law, allowing little analysis of the anticompetitive effects of a settlement that did not extend the life of a patent beyond its nominal dates.

The Eleventh Circuit applied the exclusionary-power test as modified by *Schering-Plough*, in *Andrx Pharmaceuticals, Inc. v. Elan Corp.*⁸⁹ In *Andrx*, the Eleventh Circuit found that the settlement, as alleged by the plaintiff, went beyond the exclusionary scope of the patent because it could bar third parties to the settlement from *ever* marketing a generic version of the drug at issue.⁹⁰ Based on the presumption of validity of the patent, the court declined to engage in any meaningful antitrust inquiry.⁹¹

No court in the Eleventh Circuit has revisited the reverse-payment issue since *Andrx*. However, another circuit has applied a similarly lenient analysis to a reverse-payment settlement. The Second Circuit went a step further than the Eleventh by declining to subject reverse-payment settlements to antitrust analysis, regardless of the scope of the settlement. In *In re Tamoxifen Citrate Antitrust Litigation*, the Second Circuit simply found no antitrust case to be stated in the case of a reverse-payment settlement between brand-name

85. *Id.* at 1066.

86. There is some debate as to whether the validity presumption extends to the antitrust setting. *See infra* Part II.B.4.a.

87. *Schering-Plough*, 402 F.3d at 1068.

88. The court, like the ALJ, found that the settlement payments were not payments for delay but characterized them as bona fide side deals. *Id.* at 1070.

89. 421 F.3d 1227 (11th Cir. 2005).

90. *Id.* at 1235.

91. *Id.*

manufacturer Zeneca and its generic competitor Barr.⁹² The settlement at issue followed a patent-infringement trial in which the district court had held the patent invalid, and the parties reached a settlement while an appeal was pending.⁹³ Though not among the settlement terms, the “plaintiffs allege[d] that as a part of the Settlement Agreement, Barr ‘understood’ that if another generic manufacturer attempted to market a version of tamoxifen, Barr would seek to prevent the manufacturer from doing so by attempting to invoke the 180-day exclusivity right possessed by the first [ANDA] filer.”⁹⁴ From the plaintiff’s perspective, this indefinitely barred it from competing with its own generic version of tamoxifen, because under the law at the time, the generic manufacturer held the 180-day exclusivity period until it actually marketed the drug, and Barr did not do so until shortly before Zeneca’s patent was to expire.⁹⁵ As part of the settlement, the parties obtained vacatur of the district court decision invalidating Zeneca’s tamoxifen patent, and thus subsequent ANDA filers could not rely on the initial finding that the patent was invalid, nor could they enter the market until Barr used its 180-day exclusivity period.⁹⁶ As the Second Circuit notes, Barr had little reason to run its 180-day exclusivity period because it was already able to market Zeneca-manufactured tamoxifen under the terms of the settlement agreement.⁹⁷

In *Tamoxifen*, the district court, like the Eleventh Circuit in *Valley Drug*, focused on the fact that one of the defendants held a patent and that the settlement did not extend beyond the life of this patent and granted the defendants’ motion to dismiss for failure to state a claim.⁹⁸ On appeal, the Second Circuit also found that the plaintiffs had no antitrust claim to state.⁹⁹

92. 466 F.3d 187 (2d Cir. 2006).

93. *Id.* at 190.

94. *Id.* at 194.

95. *Id.* Under today’s law, if an ANDA filer fails to actually market the generic drug within a given period of time, it forfeits the exclusivity period. *See supra* notes 29–31 and accompanying text.

96. *Id.* at 195.

97. Much of the anticompetitive effect of the tamoxifen settlement is a result of the law as it stood at the time, which allowed the parties to obtain vacatur for the finding of patent invalidity and allowed Barr to maintain the 180-day exclusivity period without using it. Under this law, holding the exclusivity without using it prevented other generic drug manufacturers from entering the market indefinitely, creating a bottleneck through which other generic manufacturers could not pass. To the extent that the courts’ decisions rest on these other anticompetitive effects, they are not directly relevant here; however, in holding that the plaintiffs had not stated an antitrust cause of action, they necessarily include analyses of the reverse-payment element of the case. *See* Bruce H. Kobayashi, *An Economic Analysis of Relitigation Rules in Intellectual Property Litigation* (Apr. 21, 2010) (unpublished manuscript), http://www.law.northwestern.edu/searlecenter/uploads/Kobayashi_Relitigation_Final.pdf.

98. *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 128–29 (E.D.N.Y. 2003), *aff’d*, 466 F.3d 187.

99. *Tamoxifen*, 466 F.3d at 199.

Like the Eleventh, the Second Circuit refused to speculate as to what may have happened absent the settlement: “We cannot judge this post-trial, pre-appeal settlement on the basis of the likelihood *vel non* of Zeneca’s success had it not settled but rather pursued its appeal.”¹⁰⁰

The Second Circuit did consider the plaintiffs’ argument that the settlement was anticompetitive because the “value of the consideration provided to keep Barr’s product off the market . . . greatly exceeded the value Barr could have realized by successfully defending its trial victory on appeal and entering the market with its own competitive generic product.”¹⁰¹ In considering this value, the court stayed the course set by the Eleventh Circuit and gave patent law priority over antitrust law where it saw the two intersect: “[S]o long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly”¹⁰² Ultimately, the Second Circuit rested its decision on the uncertainty as to the outcome of the patent-infringement case: “[E]ven if large reverse payments indicate a patent holder’s lack of confidence in its patent’s strength or breadth, we doubt the wisdom of deeming a patent effectively invalid on the basis of a patent holder’s fear of losing it.”¹⁰³ This logic seems directed at an argument that reverse payments should be *per se* illegal, an argument that the parties in *Tamoxifen* did not make.¹⁰⁴ The Second Circuit seemed to miss the availability of the rule of reason analysis—which would have allowed for consideration of the overall procompetitive and anticompetitive effects of the settlement. Instead, the *Tamoxifen* court conducted a *Schering-Plough*-style analysis of the terms of the settlement agreement and the exclusionary power of the patent to find that the settlement did not extend beyond the life of the patent.¹⁰⁵

The Second Circuit recently followed its *Tamoxifen* ruling by dismissing an antitrust challenge to a reverse payment in the very case in which the DOJ announced its reversal on reverse payments. In *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, the court granted summary judgment to

100. *Id.* at 203 (citing *Whitmore ex rel. Simmons v. Arkansas*, 495 U.S. 149 (1990) (holding that one death-row inmate does not have standing to challenge the execution of another)).

101. *Id.* at 208 (quoting Brief for Plaintiffs Appellants at 15, *Tamoxifen*, 466 F.3d 187 (No. 03-7641), 2004 WL 3564422) (internal quotation marks omitted).

102. *Id.*

103. *Id.* at 210.

104. *Id.* at 206 (“Heeding the advice of several courts and commentators, we decline to conclude (and repeat that the plaintiffs do not ask us to conclude) that reverse payments are *per se* violations of the Sherman Act . . .”).

105. *Id.* at 213–14. Judge Pooler dissents from the Second Circuit’s *Tamoxifen* ruling. She does not directly endorse a different analysis of reverse payments but argues that the court improperly dismissed the case by granting too much deference to the patent invalidated by the district court and failing to allow discovery on the conspiracy and injuries alleged by plaintiffs. *Id.* at 224 (Pooler, J., dissenting).

the defendants (the parties to the reverse-payment settlement).¹⁰⁶ The Second Circuit panel refused to go against the *Tamoxifen* precedent and did not allow the case to proceed.¹⁰⁷ “Plaintiffs do not argue that the patent infringement lawsuit was a sham or that the [patent at issue] was procured by fraud. Thus, the only reasonable basis for distinguishing *Tamoxifen* would be if plaintiffs demonstrated that the settlement agreement here, unlike in *Tamoxifen*, exceeded the scope of the . . . patent.”¹⁰⁸ However, the panel did open the door to reconsideration of *Tamoxifen*.¹⁰⁹

3. The Rule of Reason Analysis

For the most part, reverse-payment cases have avoided extensive antitrust analysis,¹¹⁰ as courts have either applied a per se rule against such settlements¹¹¹ or avoided in-depth analysis of their competitive effects by reading the law to prevent this inquiry.¹¹² There is a middle ground that courts have, for the most part, avoided: the rule of reason.

The rule of reason is the deepest available analysis of the procompetitive and anticompetitive effects of a challenged action. The Supreme Court has held that it is the default analysis that courts must use when there is no positive reason to engage in a less detailed analysis.¹¹³ “*Per se* rules . . . are appropriate only when they relate to conduct that is manifestly anticompetitive.”¹¹⁴ “*Per se* rules . . . require the Court to make broad generalizations about the social utility of particular commercial practices.”¹¹⁵ *Per se* rules are to be established only for situations that are likely to recur and that “facially appear[] to be one that would always or almost always tend to restrict competition and decrease output.”¹¹⁶ The per se analysis is the exception, not the rule. It removes limited types of activities

106. 604 F.3d 98, 106 (2d Cir. 2010) (per curiam).

107. *Id.*

108. *Id.*

109. *See id.* at 110.

110. Scholars, too, have sought ways to dispose of reverse-payment cases without extensive litigation. However, while scholars have identified potential shortcuts to identify the competitive nature of reverse payments, courts have tended to adopt standards that require no close examination of reverse payments' competitive effects.

111. *See supra* notes 34–54 and accompanying text.

112. *See supra* Part II.B.2 (discussing how the *Schering-Plough* and *Tamoxifen* courts looked only at whether the effects of the settlements extended beyond the time period covered by the patents). On the one side, *Cardizem* and *Terazosin* make it easy to stop a reverse payment with relatively little analysis; on the other, *Schering-Plough* and *Tamoxifen* make it difficult to demonstrate that a reverse-payment settlement has unlawful anticompetitive effects.

113. *Cont'l T.V., Inc., v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977).

114. *Id.* at 49–50.

115. *Id.* at 50 n.16.

116. *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 19–20 (1979).

from the detailed analysis of the rule of reason to conserve judicial and litigation resources.

Most potentially anticompetitive activity does not fall into this per se category and therefore requires application of the rule of reason. Rule of reason analysis “forbid[s] only those arrangements the anticompetitive consequences of which outweigh their legitimate business justifications.”¹¹⁷ The Supreme Court has characterized the rule of reason as the “familiar . . . judicial gloss” on the statutory language of section 1 of the Sherman Act.¹¹⁸ This analysis is conducted on a case-by-case basis: “[T]he factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.”¹¹⁹ As opposed to a per se rule, the rule of reason is used when the procompetitive or anticompetitive effects of a specific action are not clear.¹²⁰

The rule of reason has seldom been applied in the reverse-payment setting.¹²¹ When it has been used by trial courts, the decisions have often been reversed on appeal. In the first *Schering-Plough* decision, the ALJ conducted a rule of reason analysis¹²² to conclude that the settlement at issue did not demonstrate an anticompetitive effect.¹²³ On reconsideration, the full Commission held that the rule of reason was the correct analysis, but held that the settlement was anticompetitive based on its finding that “the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.”¹²⁴ The Eleventh Circuit overruled both of these decisions.¹²⁵

Only one appeals court decision has since considered applying the rule of reason. In *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, the Federal Circuit suggested that the rule of reason is the correct analysis but then severely limited that analysis based on the presence of a patent. The analysis

117. *Clamp-All Corp. v. Cast Iron Soil Pipe Inst.*, 851 F.2d 478, 486 (1st Cir. 1988) (Breyer, J.).

118. *Cont'l T.V.*, 433 U.S. at 49.

119. *Id.*

120. *Id.* at 50.

121. We argue below that because the procompetitive and anticompetitive effects of reverse payments are neither clear nor consistent, the rule of reason is the appropriate analysis in such cases. *See infra* Part III.

122. *Schering-Plough Corp.*, Docket No. 9297, slip op. at 96 (F.T.C. June 27, 2002), <http://www.ftc.gov/os/adjpro/d9297/020627id> (“[B]ecause an agreement to settle patent litigation must be examined in the context in which the agreement arose, the per se approach is not appropriate.”), *rev'd*, 136 F.T.C. 956 (2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005).

123. *Id.*

124. *Schering-Plough*, 136 F.T.C. at 988.

125. *Schering-Plough*, 402 F.3d 1056. Instead, it subjected the settlement to an analysis of the exclusionary power of the patent and found that because the settlement was within the bounds of the patent, it thus was not subject to antitrust scrutiny. *See supra* notes 82–88 and accompanying text.

it ultimately settled on is very similar to the exclusionary scope analysis established by the Eleventh Circuit. At issue in *Cipro* was a reverse-payment settlement of patent-infringement litigation over the antibiotic Cipro.¹²⁶ The district court used a rule of reason analysis to dismiss the case in the defendants' favor.¹²⁷ Its analysis focused not simply on the anticompetitive effects of the agreement, but, following the Eleventh Circuit's lead, on whether these effects were outside the "exclusionary zone" of the patent.¹²⁸ The court recognized that the key question was whether the power of the exclusionary zone to cut off antitrust analysis was tempered by the potential invalidity of the patent and determined that it was not.¹²⁹ On appeal, the Federal Circuit confirmed that the rule of reason was the appropriate analysis, and that the plaintiffs had failed to demonstrate any anticompetitive effect.¹³⁰ Like the district court, the Federal Circuit refused to look beyond the facial extent of the patent in its exclusionary-scope analysis.¹³¹ These cases are closer to the Eleventh Circuit's analysis than to the rule of reason. They suggest the rule of reason but limit the analysis to agreements extending beyond the facial dates of the patent. The rule of reason has not since been applied by any court to a reverse-payment case without this significant limitation.

4. The Issue Does Not Arise on a Blank Slate: Authority from Other Areas of the Law

Cases in these four circuits considering reverse-payment settlements have thus failed to reach a consensus on two main points: whether any antitrust scrutiny may be applied to the settlement of a patent-infringement case and, if so, what the appropriate antitrust analysis should be.¹³²

126. 544 F.3d 1323, 1327 (Fed. Cir. 2008).

127. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 541 (E.D.N.Y. 2005), *aff'd in part*, 544 F.3d 1323, and *aff'd in part sub nom.* Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir.) (per curiam), *reh'g en banc denied*, Nos. 05-2851-cv(L), 05-2852-cv(CON), 05-2863-cv(CON), 2010 WL 3464382 (2d Cir. Sept. 7, 2010).

128. *Id.* at 523 ("The ultimate question—and this is the crux of the matter—is not whether Bayer and Barr had the power to adversely affect competition for ciprofloxacin as a whole, but whether any adverse effects on competition stemming from the Agreements were outside the exclusionary zone of the . . . [p]atent. It goes without saying that patents have adverse effects on competition.").

129. *Id.* at 535 ("Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.").

130. *Ciprofloxacin*, 544 F.3d at 1332.

131. *Id.* at 1332–33.

132. The Sixth Circuit has held reverse payments to be per se illegal. *See supra* Part II.B.1 (discussing the *Cardizem* case). The Federal, Eleventh, and Second Circuits have held that no antitrust scrutiny is available to such settlements. *See supra* Part II.B (discussing the *Terazosin*,

Compounding this circuit split, the courts use different rationales in arriving at their decisions regarding the level of antitrust scrutiny to apply.

a. Patents Do Not Provide Protection from Antitrust Scrutiny

The courts considering whether reverse-payment settlements should be subject to antitrust scrutiny have cited few cases to support whatever position they adopt. For example, in *Schering-Plough Corp. v. FTC*, the Eleventh Circuit acknowledged the interaction between patent and antitrust law and stated that “a delicate balance must be drawn between the two regulatory schemes” but concluded, with little explanation, that patent law takes precedence.¹³³ This balance between patent and antitrust law is at the center of the reverse-payment debate. On one hand, patent law seeks to provide incentives for innovation by rewarding new technologies with limited monopolies. On the other, antitrust law seeks to ensure that agreements between potential competitors do not mask unreasonable restraints on trade. Whether settlement agreements are protected from antitrust scrutiny may depend on whether the patent at issue is valid and infringed.¹³⁴ These two goals need not be in conflict, but the privilege granted by the patent may influence the degree of antitrust scrutiny that is appropriate. However, courts have been hesitant to engage in close scrutiny of the underlying patent-infringement suit when examining settlements for antitrust violations. Instead, they have sought broader rules that allow them to either engage in antitrust scrutiny immediately or avoid it altogether.¹³⁵

In *Schering-Plough*, the Eleventh Circuit held that settlements that do not extend beyond the facial scope of the patent pose no antitrust problem.¹³⁶ The opinion cites and quotes dicta from a price-fixing case that did not involve a patented good: “Patent laws . . . ‘are in pari materia with the antitrust laws and modify them pro tanto’.”¹³⁷ In other words, patent and antitrust laws consider the same subject and patent laws may modify antitrust

Schering-Plough, and *Ciprofloxacin* cases). The Supreme Court has also declined to impose such a consensus. *See supra* note 33.

133. 402 F.3d 1056, 1067 (11th Cir. 2005).

134. *See* Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1725 (2003) (“[T]hese cases should be decided on IP grounds because the agreements . . . are pro-competitive if, but only if, the patent in question is valid and infringed.”).

135. *See, e.g., In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 203 (2d Cir. 2006) (“We cannot judge this post-trial, pre-appeal settlement on the basis of the likelihood *vel non* of [the patent holder’s] success had it not settled but rather pursued its appeal.”).

136. *Schering-Plough*, 402 F.3d at 1067.

137. *Id.* (quoting *Simpson v. Union Oil Co. of Cal.*, 377 U.S. 13, 24 (1964)). In their original context, Justice Douglas used these phrases to distinguish the non-patent price fixing at hand from a 1920s case in which the court allowed General Electric to fix the price of light bulbs, a good for which it then held an active patent. *See United States v. Gen. Elec. Co.*, 272 U.S. 476 (1926) (involving no challenge to General Electric’s patent and no administrative scheme to encourage such a challenge).

laws to the extent that they overlap. The *Schering-Plough* opinion restates the intersection between the two bodies of law that reverse payments present but does not explain the Eleventh Circuit's decision to focus on one body of law rather than the other. This is typical of the limited support that courts have provided for decisions to either impose or not to impose antitrust scrutiny.

Several courts have identified one potential basis for the decision to restrict antitrust scrutiny. These courts make use of a presumption of patent validity found in 35 U.S.C. § 282.¹³⁸ This section states simply that a "patent shall be presumed valid."¹³⁹ Several courts have held that this presumption prevents antitrust scrutiny into reverse-payment settlement agreements because the patent allows its holder to take actions to protect whatever market share it has captured. Any settlement that maintains the patent holder's market share and does not extend beyond the patent's end date cannot, according to these courts, be unreasonably anticompetitive. For example, in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, the Federal Circuit considered the extent to which the patent and the presumption of validity protected the settlement from antitrust scrutiny.¹⁴⁰ It held that any settlement agreements that fall within the nominal scope of the patent do not pose an antitrust problem.¹⁴¹ "This is because a patent by its very nature is anticompetitive . . ."¹⁴² The court read § 282 to protect patent-infringement settlements from antitrust scrutiny because the potentially anticompetitive nature of the settlement goes no further than the inherently anticompetitive nature of the patent itself.¹⁴³

The Federal Circuit in *Cipro*, and other courts using its logic,¹⁴⁴ reach too far in their reliance on § 282. The court seems to believe that since a patent entitles its holder to exclusive use of the patented good, any activity in which it engages to protect its market share is protected by the patent. This is plainly not the case. For example, were multiple patent holders

138. See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1337 (Fed. Cir. 2008).

139. 35 U.S.C. § 282 (2006).

140. 544 F.3d at 1328–34.

141. *Id.* at 1333 ("The district court did not treat the Agreements as per se legal. Rather, the court simply recognized that any adverse anti-competitive effects within the scope of the . . . patent could not be redressed by antitrust law.")

142. *Id.*

143. *Id.* at 1337 ("We disagree that analysis of patent validity is appropriate in the absence of fraud or sham litigation. Pursuant to statute, a patent is presumed to be valid, 35 U.S.C. § 282, and patent law bestows the patent holder with 'the right to exclude others from profiting by the patented invention.'" (quoting *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980)); see also *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005) ("[T]he Patent Act essentially provides the patent owner 'with what amounts to a permissible monopoly over the patented work.'" (quoting *Telecom Technical Servs. Inc. v. Rolm Co.*, 388 F.3d 820, 828 (11th Cir. 2004))).

144. See, e.g., *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 208–09, 209 n.22 (2d Cir. 2005); *Schering-Plough*, 402 F.3d at 1066.

competing with different medications, all treating the same disease, to agree on a minimum price for all of their drugs, their patents would provide no protection from antitrust prosecution.¹⁴⁵ There are two more technical reasons that the presumption of validity is not likely to protect patent-infringement settlements from antitrust scrutiny. First, patent invalidity is not necessary for the defendant to prevail in the underlying patent-infringement suit. To the contrary, the defendant may prevail in the face of a valid patent that is not infringed. Even if the property right granted by a patent is perfect, a property right alone says nothing about the antitrust analysis that is required.¹⁴⁶ Second, the presumption determines procedural burdens in a patent-infringement case and is not likely to apply in other types of proceedings.

In *Cipro*, the Federal Circuit held that no antitrust scrutiny is available because the presumptively valid patent entitles the holder to “a monopoly over the manufacture and distribution of the patented invention.”¹⁴⁷ Notwithstanding the Federal Circuit’s misunderstanding that a patent does not necessarily grant a monopoly,¹⁴⁸ patent validity is not the only element of a patent-infringement case in which the legitimacy of a patent’s monopoly is tested. A party alleging patent infringement must demonstrate that the patent is valid and that it has been infringed. In barring antitrust scrutiny of the patent-infringement settlement at issue in *Cipro*, the Federal Circuit relied on § 282 not only for patent validity but for infringement as well. Reliance on the presumption of patent validity as substantive evidence of infringement is a rare but recurring error in patent law.¹⁴⁹ Nothing in § 282 suggests a presumption of infringement, and the Federal Circuit has repeatedly clarified that the patent owner must demonstrate infringement in a patent-infringement trial. For example, in *Stratoflex, Inc. v. Aeroquip Corp.*, the Federal Circuit considered a patent holder’s claim that it did not receive

145. See, e.g., *Standard Oil Co. v. United States*, 283 U.S. 163, 169 (1931).

146. It is important to note that the exclusionary right granted by a patent does not have the same meaning as the antitrust term “monopoly.” Just because a patent grants a right to exclude does not mean that the patent holder is protected from antitrust scrutiny. See *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 37–42 (2006) (distinguishing between a patent and market power—where antitrust scrutiny requires a showing of market power, the presence of a patent does not lead to a presumption that market power exists).

147. 544 F.3d at 1337 (citing *Tamoxifen*, 466 F.3d at 208–09). “[T]he essence of the Agreements was to exclude the defendants from profiting from the patented invention.” *Id.* at 1333.

148. Cf. *Indep. Ink*, 547 U.S. at 32–33 (noting that the Federal Circuit upheld the respondent’s illegal tying claim, suggesting its patent gave it a monopoly over how it was used).

149. See Recent Cases, *Patents—Presumed Validity of Defendant’s Patent Relied On as Indicating Noninfringement*, 63 HARV. L. REV. 1437, 1460–61 (1950); see also Lucy Grace Dearce, *Deconstructing and Recalibrating the Valley Drug Analysis of Reverse Payments*, 47 IDEA 587, 588 (2007) (“While the exclusionary power of a patent cannot be ignored, the courts have improperly presumed infringement and overextended the presumption of validity of a patent merely because one exists.”).

the full benefit of the presumption of validity at trial.¹⁵⁰ It determined that the trial judge had adequately required the alleged infringer to state a case sufficient to overcome the presumption.¹⁵¹ The Federal Circuit then clarified that the alleged infringer had only to overcome a presumption on the validity issue, and not the infringement issue because on this issue, “the burden is borne throughout by the patent owner.”¹⁵²

Relying upon the presumption found in § 282 to establish the legitimacy of a settlement that would otherwise be subject to antitrust scrutiny is unwarranted. Even if the presumption does include a presumption of infringement, it is unlikely that the presumption is applicable outside of the context of a patent-infringement case. The statutory presumption appears in chapter 29 of title 35, titled “Remedies for Infringement of Patent, and Other Actions.” Were the presumption to apply generally in any setting, it would likely be found in a chapter not focused narrowly on the infringement of patents.¹⁵³

Few courts outside of the reverse-payment context have directly considered whether the presumption extends beyond patent-infringement cases, but when the issue has been presented, courts have held that it is inapplicable outside of infringement.¹⁵⁴ In fact, reverse payments appear to be a rare situation in which several courts have applied the presumption of validity to cases deciding issues other than infringement.

In *Standard Oil Co. v. United States*, the Supreme Court affirmed that antitrust law does not require litigation of patent-infringement cases but held that the presence of patents in the underlying dispute does not protect settlement agreements from antitrust scrutiny.¹⁵⁵ The Court examined a series of contracts which holders of patents for processes used to create gasoline set minimum royalties that they could charge licensed sellers of their gasoline.¹⁵⁶ Together, these contracts could have had the effect of maintaining high gasoline prices.¹⁵⁷ The Court held that the patents did not

150. 713 F.2d 1530, 1534 (Fed. Cir. 1983).

151. *Id.*

152. *Id.* at 1534 n.4; see also *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1321–22 (Fed. Cir. 2009); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990).

153. Were the language of § 282 clear in its applicability or inapplicability to various proceedings, the title of the chapter would be irrelevant. But here, where there is ambiguity as to the application of the statutory text, the chapter’s title may guide interpretation of the statute. See *INS v. Nat’l Ctr. for Immigrants’ Rights, Inc.*, 502 U.S. 183, 189 (1991) (“[T]he title of a statute or section can aid in resolving an ambiguity in the legislation’s text.”).

154. See, e.g., *Stratoflex*, 713 F.2d at 1534 (“The presumption, like all legal presumptions, is a procedural device, not substantive law. It . . . require[s] the decisionmaker to employ a decisional approach that starts with acceptance of the patent claims as valid and that looks to the challenger for proof of the contrary.”).

155. 283 U.S. 163, 174–75 (1931).

156. *Id.* at 168.

157. *Id.*

protect the agreements from section 1 Sherman Act scrutiny, because the agreements still had the potential to unreasonably restrict competition.¹⁵⁸ While a single patent holder may license the patented product and demand whatever price it desires, a group of patent holders may not enter into reciprocal agreements that keep all prices in the market above a certain level.¹⁵⁹ Similarly, in the reverse-payment context, an agreement not to compete may extend beyond the monopoly provided by the patent, in which case some antitrust scrutiny of reverse-payment settlements would be necessary. Ultimately, the *Standard Oil* Court found that the agreements did not create an anticompetitive effect, but it is clear that the patents did not protect them from this antitrust inquiry:¹⁶⁰ “The limited monopolies granted to patent owners do not exempt them from the prohibitions of the Sherman Act and supplementary legislation.”¹⁶¹ The agreements at issue in *Standard Oil* did not contain reverse payments, but because the Court found that these settlements of patent-infringement litigation were subject to antitrust scrutiny,¹⁶² there is no reason that antitrust scrutiny could not be applied in a similar situation involving reverse payments.

In a few recent cases, the Federal Circuit has again considered the presumption of patent validity in other contexts and reaffirmed that it is procedural and applies only to a decision on the merits of the validity question in a patent-infringement trial. For example, in *In re Etter*, the en banc Federal Circuit considered application of the presumption to patent reexamination proceedings.¹⁶³ The patent holder, facing reexamination, sought to invoke the presumption of validity to prevent invalidation of the patent.¹⁶⁴ Chief Judge Markey was both clear and sweeping, holding that the presumption is narrowly confined to patent-infringement litigation:

[T]he presumption is operative to govern procedure in *litigation* involving validity of an *issued* patent. A statute setting rules of procedure and assigning burdens to litigants in a court trial does not automatically become applicable to proceedings before the [Patent and Trademark Office]. Nor can it acquire an independent evidentiary role in any proceeding.¹⁶⁵

158. *Id.* at 174–75.

159. *Id.*

160. *Id.* at 175–76.

161. *Id.* at 169. “[T]he necessary effect of patent interchange agreements, and the operations under them, must be carefully examined in order to determine whether violations of the Act result.” *Id.* at 169–70.

162. *Id.* at 168–69.

163. 756 F.2d 852, 855–56 (Fed. Cir. 1985).

164. *Id.*

165. *Id.* at 856.

This analysis would appear to apply to antitrust consideration of reverse payments, where some courts *have* granted the presumption an independent evidentiary role.¹⁶⁶

In another line of cases, the Federal Circuit has held that the presumption does not apply to the preliminary-injunction stage of a patent-infringement trial but that the patent holder seeking a preliminary injunction carries the burden to demonstrate likely validity. For example, in *Nutrition 21 v. United States*, the Federal Circuit considered a patent holder's claim that it was entitled to a preliminary injunction.¹⁶⁷ To obtain a preliminary injunction, the party seeking the injunction must demonstrate, *inter alia*, likely success on the merits.¹⁶⁸ In the face of evidence that the patent might be found invalid, the patent holder sought to invoke the presumption of validity to demonstrate likely success on the validity issue.¹⁶⁹ The Federal Circuit again clarified that the § 282 presumption does not apply outside of a decision on the merits in a patent-infringement case:

The presumption of validity of a patent is a procedural device that places the burden of going forward and the ultimate burden of persuasion at trial on one attacking the validity of a patent. However, at the preliminary injunction stage, because of the extraordinary nature of the relief, the *patentee* carries the burden of showing likelihood of success on the merits with respect to the patent's validity, enforceability, and infringement.¹⁷⁰

That the court shifted the burden to the patentee makes it clear that § 282 does not necessarily apply to proceedings outside of infringement trials.

No case has definitively established the extent to which the presumption of validity found in § 282 applies to antitrust scrutiny of reverse-payment settlements, but the cases examined here strongly suggest that it should not apply and that such settlements should be open to antitrust scrutiny despite the presence of patents. These cases suggest that the presumption of patent validity found in 35 U.S.C. § 282 does not prevent antitrust scrutiny of patent-infringement settlements: first, because it includes no presumption of infringement that would legitimize the

166. See, e.g., *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 209 n.22 (2d Cir. 2005).

167. 930 F.2d 867, 868 (Fed. Cir. 1991).

168. *Id.* at 869.

169. *Id.*

170. *Id.* at 869 (citations omitted); see also *Amazon.com, Inc. v. BarnesandNoble.com, Inc.*, 239 F.3d 1343, 1359 (Fed. Cir. 2001) ("When moving for the extraordinary relief of a preliminary injunction, a patentee . . . must . . . present a clear case supporting the validity of the patent in suit."); *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555-56 (Fed. Cir. 1994) ("A movant seeking a preliminary injunction must establish a reasonable likelihood of success on the merits both with respect to validity and infringement of its patent.").

monopoly maintained by the settlement; and second, because the presumption is not applicable outside the infringement context.

b. Default Standard: The Rule of Reason

The second issue on which the courts of appeals disagree is what level of antitrust scrutiny to apply if some antitrust scrutiny is appropriate. Antitrust cases set clear standards for when each level of analysis should be used. The rule of reason is the default standard—all section 1 Sherman Act cases are analyzed under this standard unless the court identifies a positive reason to apply a different analysis.¹⁷¹ For a court to apply some other method of analysis, the party alleging the harm must demonstrate that its case fits into one of the recognized exceptions to the rule of reason.¹⁷²

When courts depart from the rule of reason, it is generally to apply a *per se* rule. The requirements of *per se* analysis are clearly not met in reverse-payments cases. “*Per se* rules of illegality are appropriate only when they relate to conduct that is manifestly anticompetitive.”¹⁷³ The court has set a very high bar for establishing that conduct is manifestly anticompetitive, limiting it to “certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable.”¹⁷⁴ As demonstrated in Part I, reverse payments are not a type of agreement that “lack[s] any redeeming virtue.” Thus, most courts have appropriately not applied a *per se* rule against this type of agreement.¹⁷⁵ That some courts *have* found reverse-payment settlements to be *per se* illegal while others have approached a *per se* legal standard is evidence that the rule of reason is necessary. By reaching opposite conclusions as to what type of analysis is appropriate, courts have demonstrated that the effects that reverse payments have on competition are not clear. As this Article argues, in some contexts, reverse payments may be very anticompetitive, while in others, significantly procompetitive.

The other exception to the general rule in favor of the rule of reason falls somewhere between rule of reason and *per se* analyses. Under this “quick look” rule of reason, slightly less antitrust scrutiny may be available than under the traditional rule of reason. Using the quick look rule of

171. *Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977) (“The traditional framework of analysis under § 1 of the Sherman Act is familiar and does not require extended discussion. . . . Under [the rule of reason], the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.”).

172. *Id.* at 49–50.

173. *Id.*

174. *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958).

175. *But see In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005).

reason, courts apply a presumption that the activity in question is anticompetitive and the defendant bears the burden of demonstrating counterbalancing procompetitive effects.¹⁷⁶ As with the traditional rule of reason, it is *possible* for either side to prevail under the quick look, but it sets a much higher bar for the defendant. Like the *per se* rule, the quick look is only applicable in situations where the anticompetitive nature of the agreement at issue is clear. It must be so clear that “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.”¹⁷⁷ For reverse payments, economic experts have reached diametrically opposed conclusions regarding their economic effects. Our own analysis confirms that the effects of reverse payments are not clear but rather are context specific.

Reverse-payment cases are clearly not appropriate candidates for quick look or *per se* analyses. Instead, courts should use full rule of reason analysis to evaluate reverse-payment cases contextually.

C. POLICY REVERSAL ON REVERSE PAYMENTS

As the previous discussion illustrates, the reverse-payment cases seem to oscillate between the two poles of *per se* analysis and the rule of reason, while moving slowly toward the more detailed analysis required by the rule of reason.¹⁷⁸ Despite this steady judicial movement toward the rule of reason standard, the DOJ has recently attempted to push courts back toward a *per se* illegal rule. In its brief to the Second Circuit in *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, the Obama Administration’s DOJ reversed its longstanding position that reverse payments do not warrant antitrust scrutiny.¹⁷⁹ Previously, the DOJ had declined to exercise its authority to pursue antitrust cases against reverse payments.¹⁸⁰ The DOJ here argued that reverse-payment settlements must withstand a rule of reason analysis, but that this analysis requires a presumption that reverse payments are unlawful.¹⁸¹

176. See, e.g., *Gordon v. Lewistown Hosp.*, 423 F.3d 184, 210 (3d Cir. 2005) (“[T]he competitive harm is presumed and the defendant must set forth some competitive justification for the restraints.”).

177. *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 770 (1999).

178. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1332–36 (Fed. Cir. 2008) (giving an example of a court’s hinting toward a more nuanced rule of reason analysis).

179. See Brief for the United States, *supra* note 8.

180. See Steven Seidenberg, *The Flip Side of “Reverse Payments,”* A.B.A. J., Feb. 1, 2010, at 17, 18; see also Helen Cho Eckert, *DOJ Formally Aligns Itself with FTC in Opposition To Reverse Payment Settlements*, ANTITRUST L. BLOG (Aug. 12, 2009), <http://www.antitrustlawblog.com/2009/08/articles/doj-formally-aligns-itself-with-ftc-in-opposition-to-reverse-payment-settlements/>.

181. Brief for the United States, *supra* note 8, at 21–27.

The DOJ's stated position is misleading. It is not a traditional rule of reason and in practice will effectively ban all reverse payments. In reality, the DOJ seeks something between the rule of reason, which carries no presumption, and a per se rule, which is a conclusion of illegality. This change in position brings the DOJ's views closer to the longstanding position of the FTC, which has sought to make reverse payments per se illegal.¹⁸² Both of these positions are misguided and would divert courts from their evolution toward the rule of reason. The rule of reason is the optimal standard for analysis of novel issues like reverse payments because it allows courts to develop expertise in an area where effects on competition are unclear. Once courts have developed expertise, the rule of reason is sufficiently flexible to allow courts to develop reasonable and less intensive methods of analysis.

The DOJ argument begins with the assumption that in enacting the Hatch–Waxman Act, Congress intended to strike a delicate balance between encouraging generic pharmaceuticals and protecting valid patents and the incentive to innovate.¹⁸³ It further assumes that this delicate balance does not anticipate, and is upset by, the existence of reverse payments. Though settlements are generally encouraged, the DOJ argues that as private agreements, they are not protected from antitrust liability.¹⁸⁴ The DOJ argues that brand-name drug manufacturers should not be able “to contract their way out of the statutorily imposed risk that patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract.”¹⁸⁵ This argument is different from those considered by courts in that it sees the risk of patent litigation as a vital part of the Hatch–Waxman Act and one that is upset by reverse-payment settlements.¹⁸⁶

The DOJ argues that reverse-payment settlements upset the balance struck by the Hatch–Waxman Act in a way that is likely to inhibit competition,¹⁸⁷ and thus a presumption against their legality is appropriate

182. See Press Release, FTC, FTC Chairman Leibowitz: Eliminating “Pay-for-Delay” Pharmaceutical Settlements Would Save Consumers \$3.5 Billion Annually (June 23, 2009), <http://www.ftc.gov/opa/2009/06/capspeech.shtm>.

183. Brief for the United States, *supra* note 8, at 9.

184. *Id.* at 9–10. This point is well supported. Nearly all courts have been willing to submit reverse payments to *some* level of antitrust scrutiny. *But see In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 208 (2d Cir. 2006) (“[S]o long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly . . .”).

185. Brief for the United States, *supra* note 8, at 14. The economic theories presented in Part I do not necessarily go against this assumption, but each theory balances the sides differently. For example, Shapiro believes the intent is that any agreement that makes consumers worse off than they otherwise would have been violates the law. See *infra* note 233 and accompanying text.

186. The argument is drawn from the scholarship of Professor Carl Shapiro. See *infra* notes 233–44 and accompanying text.

187. Brief for the United States, *supra* note 8, at 9–10.

in a “rule of reason” analysis.¹⁸⁸ Though the rule of reason is a balancing test between the efficiency-promoting and anticompetitive effects of a given agreement, the DOJ argues that under a rule of reason analysis, reverse-payment settlements should be presumptively illegal. This presumption appears to rest on the idea that this is how reverse payments are “naturally viewed.”¹⁸⁹ The DOJ’s argument is based on this concept of a “shared view of the likelihood” that one party will prevail. In any given reverse-payment settlement, the DOJ argues, “[w]ithout the payment, the settlement would likely have allowed earlier entry, or the litigation would have continued, with the possibility of an invalidity determination.”¹⁹⁰ The DOJ makes a further unwarranted assumption that the patent holder has monopoly power in the relevant drug market and does not face meaningful noninfringing competition.¹⁹¹ This assumption eliminates an important step in evaluating whether a given reverse payment actually harms consumers. If a reverse payment occurs in a context that already has robust competition, it is implausible that settlement terms with a single competitor would harm overall competition.

The DOJ’s proposed analysis presumes that reverse payments are unreasonable, but this presumption may be rebutted. “The defendants’ burden is to show that, despite the reverse payment, the agreed upon entry date and other terms of entry reasonably reflected their contemporaneous evaluations of the likelihood that a judgment in the patent litigation would have resulted in generic competition before patent expiration.”¹⁹² By the DOJ’s reasoning, a patent that the parties thought would likely be upheld should result in a settlement that allows very little competition, but if there is a reverse payment, “[t]he defendants cannot carry their burden simply by showing that they thought that the patent’s validity very likely would be upheld.”¹⁹³ It is unclear how the defendants could possibly meet their burden, if not by demonstrating their assessment that the patent-infringement case was strong. A major problem with this analysis is that it

188. The DOJ concedes that reverse-payment settlements may, in some cases, be procompetitive and so should not be condemned by a per se rule. *Id.* at 20–21 (citing *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 103–04 (1984)).

189. *Id.* at 22. “Absent another explanation for it, such a payment is naturally viewed as consideration for the generic’s agreement to delay entry beyond the point that would otherwise reflect the parties’ shared view of the likelihood that the patentee would ultimately prevail in the litigation.” *Id.* For an argument that reverse payments are not clearly (or “naturally”) procompetitive or anticompetitive, see *infra* Part III.

190. *Id.* at 26.

191. *Id.* at 17 n.4 (“[W]e assume throughout that the patented drug at issue lacks substantial competition from other, non-infringing, products so that the patent holder has monopoly power While a large reverse payment may strongly suggest such power, market power cannot be presumed to follow from the existence of a patent, but must be proven.”).

192. *Id.* at 30–31.

193. *Id.* at 31.

requires the patent holder to prove something that would largely negate its interest in settling the case at all. The DOJ position would put a stop to most reverse-payment settlements, whether anticompetitive or not, simply by raising the litigation costs of choosing to settle.

The DOJ position misconstrues the rule of reason by attempting to move it close to a *per se* rule while disavowing the use of such a rule. Although the DOJ cites no precedent for the type of analysis it proposes, what it proposes is the “quick look” rule of reason, which is supported by a well-developed body of caselaw.¹⁹⁴ Under the quick look rule, if an activity is established to have a clear and obvious anticompetitive nature—i.e., so obvious that an observer with a rudimentary understanding of economics could see the anticompetitive effect—it is rebuttably presumed to be unreasonably anticompetitive, shifting the burden to the defendant to demonstrate countervailing efficiencies.¹⁹⁵ The quick look has well-articulated standards that clearly are not met by reverse payments. As our economic analysis below demonstrates, reverse payments have no clear or obvious effect in all settings. To the contrary, their effects are context specific. The quick look’s one-size-fits-all approach is an ill-suited analysis of reverse-payment cases.

III. ECONOMIC ANALYSIS OF REVERSE PAYMENTS

Consumer welfare is the focus in antitrust law. Consumers benefit from generic entry because drug prices tend to fall dramatically. At first glance, then, reverse payments do *seem* bad. As the Second Circuit noted, “There is something on the face of it that does seem ‘suspicious’ about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn”¹⁹⁶ However, the economic model below demonstrates that reverse payments may be procompetitive or anticompetitive and therefore pro-consumer or anti-consumer, depending on the context in which they occur.

We first specify the incentive effects of patents and how they may be impacted by reverse payments under the Hatch–Waxman Act. We then

194. See, e.g., *Cal. Dental Ass’n v. FTC*, 526 U.S. 756 (1999) (reversing an application of the quick look rule of reason to restrictions on price and quality claims in advertising); *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 109 (1984) (stating that “no elaborate industry analysis is required to demonstrate the anticompetitive character of” naked restrictions on competition (quoting *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 692 (1978)) (internal quotation marks omitted)); *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346 (5th Cir. 2008) (quick look as an appropriate analysis for price-fixing scheme), *cert. denied*, 129 S. Ct. 1313 (2009).

195. *Cal. Dental Ass’n*, 526 U.S. at 770, 776; see *supra* Part II.B.4.b (discussing quick look analysis).

196. *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 392 (2d Cir. 2005), *amended by* 466 F.3d 187 (2d Cir. 2006).

engage in a simplified economic analysis of reverse payments. We then enhance this model by taking into account factors that change the procompetitive and anticompetitive aspects of reverse payments in the real world. We next examine economic analyses presented by other commentators. These careful economic analyses of reverse-payment settlements are a necessary backdrop to any policy discussion of such settlements.

A. INCENTIVE EFFECTS

Ultimately, any analysis of reverse-payment settlements must be considered in light of the incentives it creates and the Hatch–Waxman Act’s balance between incentives to innovate and consumer access to pharmaceuticals. James Langenfeld and Wenqing Li argue that any short-term reduction in competition created by reverse payments must be weighed against increases in innovation by brand-name drug manufacturers.¹⁹⁷ Because reverse-payment settlements increase the value of the underlying patent to the patent holder, they also increase the brand-name company’s incentive to innovate, as well as its financial ability to research, develop, and market future drugs.¹⁹⁸ Future innovations will in turn lead to more consumption of pharmaceuticals and more competition in the brand-name pharmaceutical industry.¹⁹⁹ Consumer welfare is enhanced by these activities. This does not answer the question of whether reverse payments on the whole increase or decrease competition and output, but it suggests that they may do both.

The Hatch–Waxman Act changed the incentives for bringing a patented product to market and for challenging a patent. First, the Act provides the 180-day exclusivity period to the first ANDA filer, which is a strong incentive to challenge existing patents. Second, the Act allows patent holders to challenge potential infringements of their patents as soon as an ANDA is filed, before any damages accrue. This increases the value of patents by increasing their protective power. Reverse payments do not change the incentives provided to generic drug manufacturers through the exclusivity period, but they do incrementally increase the value of the patent to the patent holder by granting it another method to protect a patent’s value in an infringement suit.

Reverse payments may also maintain the incentives for firms to file ANDAs and attempt to market generic versions of existing drugs by providing increased value to the parties to a patent-infringement suit. Since

197. James Langenfeld & Wenqing Li, *Intellectual Property and Agreements To Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 ANTITRUST L.J. 777, 778 (2003).

198. *Id.* at 778–801.

199. *Id.*

reverse-payment settlements may be the most profitable course for ANDA filers, they may increase the incentives for generic manufacturers to file ANDAs.²⁰⁰ Though negotiations for reverse-payment settlements may cause an initial delay, increased competition could result from the greater number of ANDA filings. These incentive effects do not demonstrate whether reverse payments are procompetitive or anticompetitive; they simply illustrate that strong rules either allowing or prohibiting reverse payments are likely to upset the current balance between providing an incentive for drug manufacturers to innovate and for generic drug companies to bring cheaper drugs to the market. In passing the Hatch–Waxman Act, Congress intended to shift this balance to provide incentives for generic entry. Without clear evidence that reverse payments are procompetitive or anticompetitive, courts should be hesitant to create a similar sea change in the incentives faced by brand-name and generic drug manufacturers.

B. “SUSPICIOUS” FINANCIAL TERMS OF SETTLEMENT: A ONE-DIMENSIONAL MODEL OF SUIT, SETTLEMENT, AND REVERSE PAYMENT

Settlements in the patent-infringement context, including reverse-payment settlements, may allow the alleged infringer to enter the market at a wide range of negotiated entry dates.²⁰¹ As Figure 1 shows, the range of possible entry dates in a settlement extend from the date on which the settlement is executed (immediate entry upon settlement) to the date when the patent expires (no entry allowed by settlement).

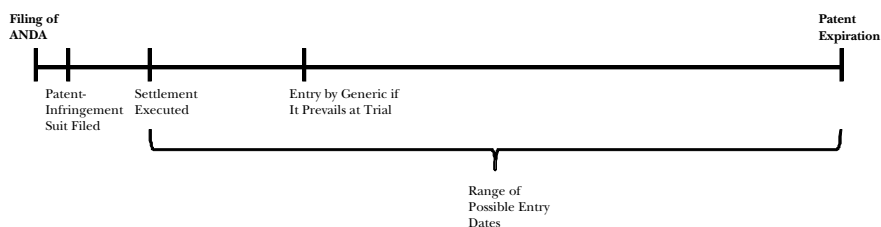


Figure 1: Delayed Entry? A negotiated entry date in a patent-infringement settlement may substantially precede the date of patent expiration.

200. See *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (“A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger’s settlement options should he be sued for infringement, and so might well be thought anticompetitive.”).

201. The Hatch–Waxman Act presents a special incentive for patent holders to attempt to reach settlements with alleged infringers. If the patent holder can delay the first ANDA filer, other generic manufacturers will face lesser incentives to attempt to enter the same market because the 180-day exclusivity period will not be available to them. See Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

These possible settlement entry dates fall both before and after the date on which the generic would enter the market were it to prevail at trial.

Under one theory of settlements, the outcome of the settlement is primarily determined by the parties' estimations of their likelihood of success at trial.²⁰² Thus, in a settlement that includes no reverse payment, the negotiated entry date should represent a compromise between the parties' opinions of their likelihood of success at trial. Figure 2 represents one such scenario. In this scenario, at the end of discovery there would be ten years remaining on the patent.²⁰³ For convenience, we assume that each party estimates its chance of victory at fifty percent. Taking only this factor into account, a negotiated entry date would allow the alleged infringer to bring its product to market five years prior to patent expiration.

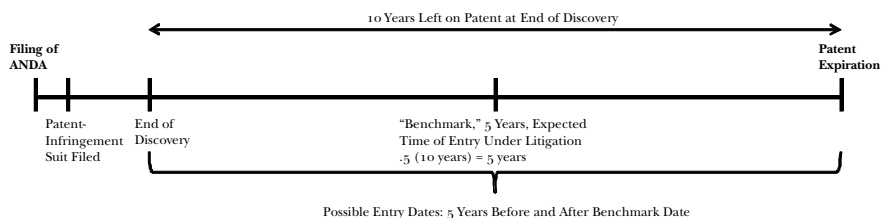


Figure 2: Potential entry dates and “benchmark” entry date if ten years remain on patent at the end of discovery and each side has a fifty percent chance of prevailing.

A settlement could allow the generic drug to enter the market any time after the settlement²⁰⁴ and before the expiration of the patent.²⁰⁴ The chances that either side will prevail represent an estimation of the entry date that negotiating parties will reach in a traditional settlement without a reverse payment. This estimated entry date can be seen as a “benchmark” for evaluating other potential settlements. Those agreements that allow entry before the benchmark create more competition, on average, than would be expected if the case were fully litigated and those that allow for entry after the benchmark allow less competition, on average, than would be expected

202. See Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 397–99 (2003); see also Robert J. Rhee, *A Price Theory of Legal Bargaining: An Inquiry into the Selection of Settlement and Litigation Under Uncertainty*, 56 EMORY L.J. 619, 620–21 (2006) (describing the “conventional wisdom” that settlement terms are primarily determined by the damages expected and each side’s probability of prevailing).

203. A settlement is more likely to occur at the end of discovery, at which point the parties will have as much information as possible regarding their chances of prevailing at trial.

204. Because the Hatch–Waxman Act automatically precludes the generic manufacturer from entering the market for thirty months after filing a patent-infringement suit, negotiated entry during this time is unlikely because even a patent holder that does not believe it will prevail at trial could maintain its exclusivity for these thirty months.

if the case were fully litigated. The presumption is that all entry prior to patent expiration increases output above the monopoly quantity.²⁰⁵

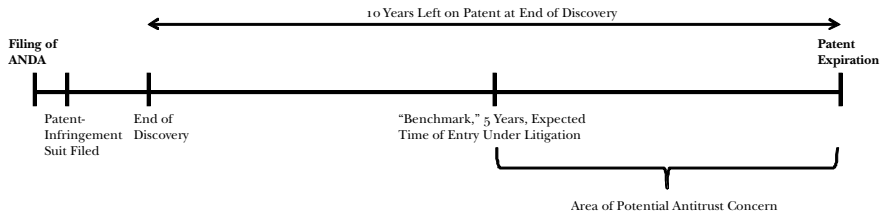


Figure 3: Area of antitrust concern: It is not possible to know with certainty whether the entry date allowed by a settlement falls into the area of antitrust concern without actual litigation of the underlying infringement suit.

In these simple models, reverse payments allow negotiation to include a tradeoff between entry date and the amount of a reverse payment. This tradeoff may alter the balance that results in the negotiated entry date without a reverse payment. Instead of each side giving up its perceived chance of prevailing in the litigation, there is also an exchange of money from the patent holder to the generic manufacturer. Without taking any other potential consideration for the payment into account, the payment appears to be in exchange for an agreement to shift the entry date towards the patent expiration date, into the range of antitrust concern.²⁰⁶

1. Asymmetric Payoffs Provide Incentives for Reverse-Payment Settlement

The parties to a pharmaceutical patent-infringement case have clear incentives to engage in just this type of payment in exchange for delayed entry. In the pharmaceutical industry, the patent holder generally receives much more income from monopoly rents than the generic stands to make by competing on the market.²⁰⁷ Each year of patent protection is worth more in sales to the branded company than each year of earlier entry is worth to the generic. As a result of this asymmetry, the patent holder has an incentive to share a portion of its monopoly rents with the generic in exchange for the generic's agreement not to compete with the brand-name drug. As long as the reverse payment falls somewhere between what the patent holder expects to lose and what the generic challenger stands to gain with generic entry, both parties are better off with a reverse payment and

205. This presumption may not be valid in all circumstances. *See infra* Part III.C.5 (discussing the decreased marketing efforts by a patent holder after a generic entry).

206. *See* Shapiro, *supra* note 202, at 407–08.

207. Before generic entry, the brand's profits from a drug can be large because of its ability to restrict output and raise prices. *See* Figure 3. Once the generic enters, much of the market shifts away from the brand to the generic.

later generic entry than they are settling without a reverse payment and allowing earlier generic entry.

As an example of this asymmetry, assume that both parties to the settlement estimate that the ANDA filer has a ten percent chance of victory at trial, the generic stands to earn \$10 million if it wins and enters the market, and the patent holder stands to lose \$200 million if it loses its monopoly. The ANDA filer's expected value is \$1 million (\$10 million multiplied by a ten percent chance of victory). The patent holder's expected loss is \$20 million (\$200 million multiplied by a ten percent chance of loss at trial). These different expected values establish a bargaining range of \$1 million to \$20 million. Both parties are better off with a settlement anywhere in that range than they would be following a patent-infringement suit. The size of a reverse payment alone, therefore, does not prove any anticompetitive effect. A reverse payment does not harm consumers unless it leads to meaningfully delayed generic market entry. In this example, where the generic has only a small chance of winning at trial, this is unlikely to be the case.

Because of these incentives, reverse payments may provide an incentive for generic drug manufacturers to seek to be the first to be paid off, rather than to be the first to bring a generic drug to the market.²⁰⁸ The promise of a 180-day exclusivity period should create an incentive for generic drug manufacturers to be first to enter the generic market, but certain reverse payments may pervert this incentive by making it more profitable for generic manufacturers to extract a payment for delayed entry than to actually market a generic drug. The patent holder similarly has an incentive to pay a generic to stay out of the market to preserve some of its monopoly rents without taking the risk of losing them at trial. There is evidence that some generic drug companies see the pursuit of reverse payments in exchange for not marketing a drug as a viable business model. One analyst estimated in 2001 that such settlements accounted for over sixty-five percent of generic manufacturer Barr's revenue in the preceding four years.²⁰⁹ Of course, the Hatch–Waxman Act has since been modified, but the perverse incentive created by reverse payments still exists.

C. COMPLETING THE ECONOMIC MODEL: REVERSE PAYMENTS
AS PART OF A COMPLEX DEAL

To be practically relevant, the simplified picture of reverse-payment settlements must be modified to take into account real aspects of settlement agreements, including highly risk-averse patent holders, the high costs of

²⁰⁸ This possibility motivates a recently proposed bill. See *infra* note 313 and accompanying text.

²⁰⁹ Bethany McLean, *A Bitter Pill*, FORTUNE, Aug. 13, 2001, available at http://money.cnn.com/magazines/fortune/fortune_archive/2001/08/13/308077/index.htm.

litigation, generic manufacturers with few liquid assets, differences in parties' estimates of trial risks, the potential for decreased marketing upon generic entry, the existence of bona fide side deals, and the incentive effects of any proposed rule. Many of these complicating factors represent situations in which reverse-payment settlements may have procompetitive effects.

1. Risk Aversion

The simple model presented above treats the parties to a reverse-payment settlement as risk neutral by simply weighing the value of a settlement against the parties' chances of prevailing at trial. In their examination of reverse-payment settlements, Sumanth Addanki and Alan Daskin argue that rather than representing a quid pro quo agreement whereby generic manufacturers are paid to delay their market entry, a reverse-payment settlement may be driven by a patent holder's aversion to litigation risks:

A patentee who has built a substantial business around a patent is very likely to be risk averse exactly in that fashion: when choosing between a settlement and pursuing litigation to its final outcome, the patentee would recognize that the nonzero probability associated with 'losing it all' creates very real risk, regardless of the expected value associated with litigation.²¹⁰

According to Addanki and Daskin, this risk aversion affects the patent holder's analysis of any settlement terms.²¹¹ It might be willing to accept an entry date significantly before the hypothetical benchmark or it might be willing to pay a reverse payment simply to avoid the risks of losing everything at trial. Similarly, it might be willing to pay a large portion of its monopoly rents to avoid competition for its remaining profits.²¹² Addanki's and Daskin's argument demonstrates that even reverse payments that are larger than avoided litigation costs may, if the patent holder is very risk averse, not be payments for delay, but rather payments to avoid the risk that the patent will be held invalid.

An example of risk-averse parties' incentives with and without reverse payments demonstrates that given risk aversion, reverse payments may be either procompetitive or anticompetitive. Were reverse payments not a possibility, as in Figure 4, very risk-averse patent holders would likely settle patent-infringement cases, allowing generic entry prior to the benchmark date. While this would result in earlier generic entry, it would also create an environment in which risk-averse patent holders receive relatively little value

210. Sumanth Addanki & Alan J. Daskin, *Patent Settlement Agreements*, in 3 ABA SECTION OF ANTITRUST LAW, ISSUES IN COMPETITION LAW AND POLICY 2127, 2131 (2008).

211. *Id.*

212. *Id.*

from their patents, because upon challenge, they must give up much of the life of that patent in settlements that may not include reverse payments.

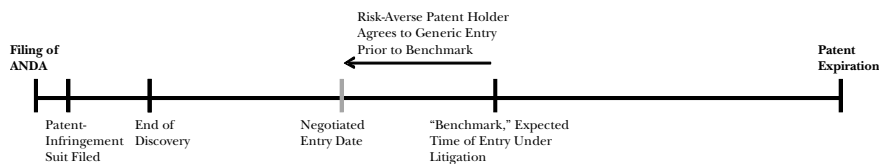


Figure 4: If no reverse payment is allowed, a risk-averse patent holder will negotiate a generic entry date prior to the benchmark date.

If reverse payments are allowed, then the risk-averse patent holder will still try to settle the litigation but will now have two variables on which to negotiate: entry date and payment. In this scenario, it is likely that there will be some payment and that the negotiated entry date will be later. It is not possible to know whether the new entry date will be before or after the benchmark date. As Figure 5 demonstrates, it could be either before or after the benchmark date.²¹³

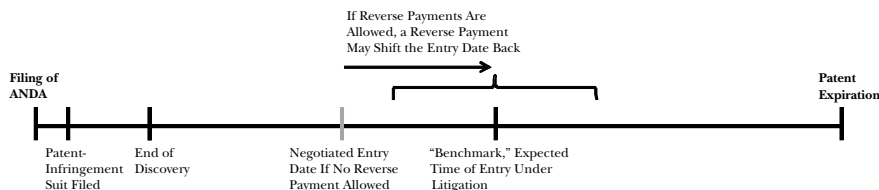


Figure 5: If a reverse payment is allowed, a risk-averse patent holder will negotiate a reverse payment that allows a later entry date. This entry date may be either before or after the benchmark date.

Parties' risk aversion makes it clear that reverse-payment settlements may be either procompetitive or anticompetitive.

A related argument suggests that rather than representing compensation for delayed market entry, reverse payments may be compensation for a shift in the risk assumed by the ANDA filer and the patent holder.²¹⁴ The expected payoff from a given drug often declines over the life of the patent, as closer substitutes are developed. An ANDA filer that agrees to a negotiated entry date with a patent holder assumes the risk that the market for the specific drug will shrink before the negotiated entry date arrives. For example, upon agreeing to a negotiated entry date, a newly developed treatment may make the now-profitable drug obsolete before

213. See *infra* Part IV.A for our proposed methods of determining whether a given reverse-payment settlement is procompetitive or anticompetitive.

214. See, e.g., Addanki & Daskin, *supra* note 210, at 2131.

generic market entry. Rather than payment for delay, a reverse payment may represent compensation to the generic for assuming this risk, rather than pushing forward with the patent-infringement litigation.²¹⁵

It is important to note the bounds of the argument that risk aversion makes reverse payments procompetitive in some situations. First, it is premised on the idea that the patent holder is *very* risk averse. As Addanki and Daskin note, such risk aversion is likely to be found in firms that rely on a single patent for much of their business and is less likely to be present in firms that have diversified sources of income.²¹⁶ Second, the existence of risk-averse patent holders questions the inference that reverse payments are in exchange for delayed market entry, but it does not absolve an agreement that is demonstrably anticompetitive in some other way. That an agreement may be driven by aversion to risk does not demonstrate that the agreement itself is not anticompetitive.²¹⁷ Although it may partially explain it, risk aversion does not make payment for delay procompetitive, but it may undercut the inference that a given payment is made in exchange for delay. Nor does Addanki and Daskin's argument reach the largest reverse payments. Professor Daniel Crane argues that reverse payments that comprise a large portion of the patent holder's monopoly rents are inherently suspect.²¹⁸ Risk aversion alone cannot explain a patent holder giving up most of its monopoly rents, because the risk to which it is averse is the loss of those very rents.

2. The High Costs of Patent-Infringement Litigation

Some scholars have suggested that the high costs of patent litigation are a reason to give greater leeway to patent-infringement settlements.²¹⁹ The costs of litigation do not fall entirely on the parties, since litigation imposes significant costs on the court and society.²²⁰ Any anticompetitive effects of settlements are offset by societal gains in avoided litigation. Also, the costly nature of patent-infringement litigation may undercut Professor Carl Shapiro's assumption that reverse payments are "naturally viewed" as payments in exchange for delayed market entry.²²¹ As Gregory Leonard and

215. This context can only apply to reverse payments of a certain magnitude. For example, a reverse payment that is more than the generic could make by entering the market cannot be compensation for a shift in the risk assumed.

216. Addanki & Daskin, *supra* note 210, at 2130–31.

217. See Hovenkamp, Janis & Lemley, *supra* note 134, at 1758.

218. See *infra* text accompanying note 279.

219. See, e.g., Gregory K. Leonard & Rika Onishi Mortimer, *Antitrust Implications of Pharmaceutical Patent Litigation Settlements*, in NERA ECON. CONSULTING, ECONOMIC APPROACHES TO INTELLECTUAL PROPERTY POLICY, LITIGATION, AND MANAGEMENT 251, 261–64 (Gregory K. Leonard & Lauren J. Stiroh eds., 2005).

220. See *id.* at 264 (“[A] settlement that is consumer welfare reducing may nevertheless be social welfare enhancing.”).

221. See *infra* text accompanying Figure 6.

Rika Onishi Mortimer demonstrate, any payment in a settlement agreement that is less than the cost of continued litigation is a rational payment *simply to end the litigation*, not a payment in exchange for any delayed entry.²²² For example, a reasonable patent holder, facing litigation costs of \$1 million, would be willing to pay up to \$1 million to reach a settlement in which it receives no more than its expected litigation value (i.e., a settlement in which the generic enters the market at the benchmark date). Most scholars do not consider payments that are less than the expected litigation costs to be anticompetitive.²²³

3. Liquidity-Cash Positions

The high costs of litigation may have another, more indirect, undesirable effect. Some generic companies are small and cash poor. This leads to two problems in the context of patent challenges. First, the generic company may not be able to afford to litigate a claim brought by a patent holder, even if it has an otherwise valid claim. Second, if the parties agree to a traditional negotiated settlement without a reverse payment, the generic may not have sufficient resources to both survive until the negotiated entry date and to market the generic drug.²²⁴ A reverse payment could solve the problems faced by cash-poor generic drug manufactures by providing an immediate payment that allows the company to survive until it enters the market. To the extent that a given reverse payment allows a generic drug manufacturer to survive and to later market a generic drug when it otherwise would not have been able to do so, reverse payments may have procompetitive rather than anticompetitive effects. A prohibition of reverse payments in such situations would stifle generic entry.

4. Differences in the Parties' Estimations of Trial Risk

The basic model presented above assumes that the parties have the same estimations of the likely trial outcome and that the entry date reflects this convergence. However, in many cases, it is likely that the parties will not share the same assessment of their likelihood of trial success. Each side may envision a different benchmark date, with the patent holder estimating a later date than the ANDA filer.²²⁵ In such cases, a settlement is only possible if the two sides can reach a compromise between their differing estimations of their chances of victory. When the parties' estimations are too far apart, a

222. Leonard & Mortimer, *supra* note 219, at 261–64.

223. See, e.g., Hovenkamp, Janis & Lemley, *supra* note 134, at 1759.

224. In a well-functioning capital market, an ANDA filer with insufficient resources to pursue a meritorious claim should be able to find financing. In reality, differences in perceptions of the value of the claim may raise the transaction costs of such financing to a prohibitive level.

225. See Leonard & Mortimer, *supra* note 219, at 257.

traditional negotiated settlement may not be possible.²²⁶ Reverse payments may help the parties reach a settlement. Because any movement of the negotiated entry date toward the patent expiration date is worth more to the patent holder than it costs the ANDA filer,²²⁷ a payment may help bridge the gap between the entry dates that the two sides are willing to accept. For example, if each side believes that it has a sixty percent chance of winning at trial, a simple compromise might allow the generic to enter the market with fifty percent of the patent life remaining. However, if the parties are unable to reach this compromise, the patent holder might be willing to allow entry when only forty percent of the patent life is remaining and also pay the ANDA filer some portion of the profits that it would have earned had it been able to enter the market when sixty percent of the patent life was remaining.

Whether such payments that bridge the gap between the two sides' estimations of their chances of victory at trial are procompetitive or anticompetitive depends on which party's estimation of its chances of victory at trial is accurate. It is obviously not possible to know whose predicted chances of victory are accurate without actually holding a trial. The ability of parties to reach a settlement at all is itself beneficial. As long as the parties are not too far apart in their initial estimations, any entry date that is not later than the one represented by the patent holder's benchmark is likely to be procompetitive because the savings inherent in avoiding a trial likely outweigh the delay in generic entry.²²⁸

5. Brand-Name Marketing and Decreased Consumption with Generic Entry

Increased market competition with generic entry may, paradoxically, decrease consumption of the drug. Although generic entry generally increases market competition and consumption, it may be accompanied by a significant drop in the patent holder's marketing expenditures.²²⁹ Patent holders have strong incentives to vigorously market their drugs during the life of the patent to maximize sales at monopoly prices. Vigorous marketing may increase consumption of the drug more than any increases in consumption due to cheaper prices when a generic drug enters the market. Because brand-name drug manufacturers face lower prices and lose a significant portion of their market share upon generic entry, they also lose

226. *See id.* at 264 ("We conclude that, with potential disagreements concerning the probability that the plaintiff will win the lawsuit, a settlement may not be feasible without reverse payments.").

227. *See supra* notes 208–09 and accompanying text.

228. A settlement, however, that allows entry later than either side's benchmark cannot be explained by these different estimates of chances at trial.

229. *See, e.g.,* Keith N. Hylton & Sungjoon Cho, *Injunctive and Reverse Settlements in Competition-Blocking Litigation* 14 (Bos. Univ. Sch. of Law, Working Paper No. 09-47, 2009), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1490013.

much of their incentive to market the drug. With the loss of consumption driven by brand-name marketing, generic entry may lead to decreased overall consumption of the drug. As a result, this decrease harms consumer welfare as the duopoly quantity falls below the monopoly quantity.

6. Bona Fide Side Deals

Reverse payments are not always simple to identify. They may take the form of a naked payment from the patent holder to the ANDA filer, but they may also take the form of a side deal, which could include licensing the patented drug (or some other drug, not at issue in the underlying litigation) to the ANDA filer.²³⁰ If the ANDA filer receives more than it gives up in the side deal, it may be an attempt to mask a reverse payment to avoid antitrust scrutiny. If, however, the side deal is bona fide, its mere existence does not warrant antitrust scrutiny. Courts should be very hesitant to impede upon bona fide side deals, which benefit both brand-name and generic manufacturers, as well as consumers. Some have suggested that *any* side deals between the patent holder and the ANDA filer should be considered evidence of an anticompetitive effect.²³¹ Such a conclusion is unwarranted. Professor C. Scott Hemphill argues that side deals are unlikely to be legitimate because patent holders and ANDA filers seldom engage in deals like those that comprise side deals to patent-infringement settlements.²³² But because patent-infringement settlements are a rare situation in which market competitors are forced to sit at the same negotiating table, it is not surprising that some bona fide deals arise from these unique negotiations. A presumption against side deals is unwarranted unless the side deal, standing alone, is demonstrably not legitimate but is clearly an attempt to hide a payment from the patent holder to the ANDA filer.

D. OTHER COMMENTATORS' INTERPRETATIONS OF THE REVERSE-PAYMENT DYNAMIC

Several scholars have contributed their own interpretations to the basic model presented above. These interpretations suggest a variety of conclusions as to the procompetitive or anticompetitive nature of reverse-payment settlements.

230. See *Schering-Plough Corp.*, Docket No. 9297, slip op. at 107 (F.T.C. June 27, 2002), <http://www.ftc.gov/os/adjpro/d9297/020627id.pdf> (finding that the side deal was bona fide), *rev'd*, 136 F.T.C. 956 (2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005).

231. E.g., C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking To Preserve Drug Competition*, 109 COLUM. L. REV. 629, 633 (2009) ("An aggregate approach . . . reveals that these sorts of deals are a frequent component of settlements, but rare outside of settlement. Thus, the overall pattern suggests they provide a disguised means to confer payment."); cf. *Schering-Plough*, slip op. at 107 (finding that the side deal was bona fide).

232. Hemphill, *supra* note 231, at 633 (explaining how side deals rarely happen in other contexts).

1. Professor Carl Shapiro

In an early argument concluding that reverse payments are anticompetitive, Professor Carl Shapiro, currently Deputy Assistant Attorney General for Economics at the Antitrust Division of the DOJ, dissected reverse payments' effects on patent-infringement settlements. Shapiro began with a unique test for whether a given type of settlement is anticompetitive: "[A] settlement must leave consumers at least as well off as they would have been from ongoing patent litigation."²³³ His method of analysis, focusing not on evaluating individual settlements but instead on the overall concept of reverse payments, rests on his idea that consumers as a group have a sort of property right in the level of competition that would exist without reverse payments. "Effectively, consumers have a 'property right' to the level of competition that would have prevailed, on average, had the two parties litigated the patent dispute to a resolution in the courts."²³⁴ Shapiro grants very broad rights in competition to consumers but argues that patent holders have somewhat narrower property rights in the patents they hold. Shapiro believes that patent rights "are inherently uncertain or imperfect, at least until they have successfully survived a challenge in court."²³⁵ In other words, a patent does not grant a right to exclude but a right to *attempt to exclude*. This is intuitive—all else equal, a patent that has survived a challenge to its validity or has successfully halted an infringement action is more valuable than an untested patent.²³⁶ Given that he sees consumers as having an absolute right in competition, but patent holders as only having a probabilistic right in the exclusionary power of their patents, Shapiro's analysis focuses on whether all reverse payments, as a group, lead to more or less competition than would be present in a hypothetical world with no settlements of patent-infringement litigation. He sets the baseline goal that patent settlements not make average drug prices higher and finds that reverse-payment settlements violate this goal.²³⁷

233. Shapiro, *supra* note 202, at 391.

234. *Id.* at 396. Shapiro defines the phrase "well off" according to the prices paid by consumers for a specific drug. However, because reverse-payment policy balances two worthy goals—keeping drug costs low and encouraging new drug innovation—it is not clear that creating maximum competition in the short term will make consumers the most "well off" in the long term.

235. *Id.* at 393. Shapiro's shift here is subtle. Rights are traditionally found when *enforceable*, but Shapiro argues that whatever right a patent grants does not reach full strength until *actually enforced*.

236. *Id.* at 395 ("What the patent grant actually gives the patentholder is the right to sue to prevent others from infringing the patent."). The patent right is imperfect, Shapiro argues, because, *inter alia*, there are significant costs associated with enforcing a patent. *Id.*

237. Notably, the existence of patents would seem to go against Shapiro's test. Any legal monopoly will serve to make available drugs more expensive, but the policy we have chosen falls somewhere between absolute competition (cheapest possible drugs) and absolute monopolies (greatest possible incentive to innovate new drugs).

From the consumer's perspective, any later-negotiated entry date represents a later entry date than the one that *could* have resulted from a trial—a trial at which the patent could be found either invalid or not infringed. However, some patent holders will prevail. A traditional patent settlement (without reverse payment) will increase competition in cases where the patent holder would have prevailed and decrease competition in cases where the generic entrant would have prevailed. Shapiro does not try to differentiate between these two sets of cases: those where any settlement that allows early entry is procompetitive (because the patent holder would have prevailed) and those where any settlement that delays entry at all is anticompetitive (because the alleged infringer would have prevailed at trial and entered the market immediately).

Without examining individual cases, Shapiro analyzes the effects of reverse-payment settlements in the aggregate.²³⁸ He focuses on the overall level of competition in which he believes consumers have a property right. In settlements that do not include reverse payments, the negotiated entry date represents the chance that either side will prevail (the same as the “benchmark” date discussed above).²³⁹ Some settlements will allow earlier entry than those that would have occurred at trial (if the patent holder would have won) but others will allow later entry (if the alleged infringer would have prevailed). Overall, traditional non-reverse-payment settlements where the parties only consider their chances of prevailing at trial meet Shapiro's goal of not leaving consumers worse off because negotiated settlements that allow less competition than would have resulted at trial are balanced out by those that allow more.²⁴⁰ According to Shapiro, reverse payments of more than avoided litigation costs upset the balance represented by a typical negotiated entry and violate his goal of leaving consumers no worse off. “Presumably, the patentholder would not pay more than avoided litigation costs unless it believed that it was buying later entry than it expects to face through the litigation alternative.”²⁴¹

238. See Shapiro, *supra* note 202, at 396.

239. *Id.*

240. *Id.* at 408. Note that the assumption that settlements represent only estimated chances of victory at trial may be unfounded. See *supra* Part III.C.4.

241. *Id.* at 407–08.

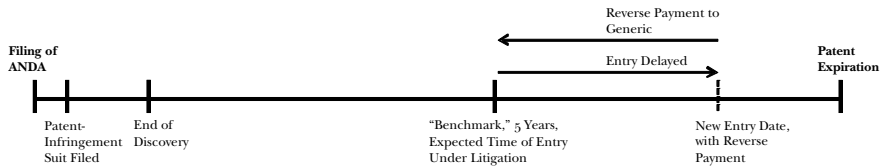


Figure 6: Shapiro characterizes reverse payments as payments in exchange for delayed entry. Thus, if there is a reverse payment, market entry will necessarily be later than the benchmark date.

Shapiro's argument is that reverse payments are payments in exchange for delayed entry, and they produce less overall competition. For those cases where any early entry is procompetitive because the infringer would have lost at trial, delayed entry prior to patent expiration still increases competition, but not as much as it would have with earlier entry and no reverse payment.²⁴² Similarly, cases in which delayed entry reduces competition because the alleged infringer would have prevailed at trial delay competition even more due to reverse payments. Such settlements reduce competition more than they would have without a reverse payment.

Importantly, Shapiro is not interested in determining whether a specific reverse-payment settlement is or is not anticompetitive compared to the trial outcome. He argues only that reverse payments *in general* have an anticompetitive effect and thus should be prohibited.²⁴³ This makes his method somewhat imprecise. It prohibits reverse payments both when the negotiated entry date increases competition compared to a trial outcome (because the generic would have won at trial) and when it decreases competition (because the patent holder would have prevailed at trial). Other scholars attempt to differentiate between these two groups and argue that reverse payment should be prohibited only for the latter settlements, but Shapiro avoids any analysis of the likely trial outcome.²⁴⁴

Unfortunately for Shapiro's argument, courts, which are in the business of deciding cases and controversies, are hesitant to embrace arguments based on likely average outcomes. This hesitancy may be premature in the antitrust context, where liability may be imposed based on a finding that an activity has anticompetitive effects on average. Whether an agreement is an unreasonable restraint of trade is an inquiry that necessarily looks to a hypothetical world in which the agreement did not take place and asks whether this hypothetical world has more or less competition. But there are many alternative outcomes that could have occurred in the absence of a

242. Note that even with reverse payments, for cases where the generic would not have prevailed at trial, the settlement does increase overall competition, as compared to the outcome had there been a trial.

243. Shapiro, *supra* note 202, at 397.

244. *See id.*

given agreement and the court must consider which of these are more or less likely. Shapiro's analysis either ignores or summarily dismisses these issues.

Others have picked up on the arguments for strict antitrust scrutiny of reverse payments initiated by Shapiro. Professor Joshua Davis follows logic close to Shapiro's, arguing that generally, reverse payments skew entry dates "away from the expected value," or the parties' predicted outcome of the case.²⁴⁵ Like Shapiro, he follows this logic to the conclusion that reverse payments should be per se illegal.²⁴⁶ Compared to either the rule of reason or per se legality, Davis argues, making reverse-payment settlements per se illegal has low transaction costs.²⁴⁷

Davis argues that a per se illegal rule also has low error costs.²⁴⁸ But a per se rule in either direction allows for costly errors. For a per se legal rule, the error costs will be borne by consumers in the form of higher drug costs due to delayed competition. The error costs of the per se illegal rule for which Davis argues will be borne by litigating parties, who in some cases will be unable to execute settlement agreements. These error costs, too, may ultimately be borne by consumers in the form of higher drug costs. Other relatively intense methods of analysis may be effective at separating settlements that are anticompetitive from those that are not, but Davis argues that they negate any efficiencies that the parties may gain by settling, and so may ultimately harm consumer welfare.²⁴⁹

2. Professors Herbert Hovenkamp, Mark Janis, and Mark Lemley

Other scholars have reached conclusions similar to Shapiro's using a slightly different focus in their analyses. In an argument that reverse-payment settlements should be subject, in some situations, to antitrust scrutiny, Professors Herbert Hovenkamp, Mark Janis, and Mark Lemley begin with the recognition that patent settlements frequently give rise to antitrust suspicion.²⁵⁰ Hovenkamp et al. propose another model that they argue should be applied to cases in which the settlement would be anticompetitive if the patent were invalid or not infringed but not

245. Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal*, 41 RUTGERS L.J. (forthcoming 2010) (manuscript at 41), available at <http://ssrn.com/abstract=1489090>.

246. *Id.* at 17.

247. *Id.* at 7.

248. *Id.* at 17.

249. *Id.* at 27.

250. Hovenkamp, Janis & Lemley, *supra* note 134, at 1720 ("[Patent] settlements involve agreements between the patentee and the accused infringer Because these competitors may agree to stop competing . . . settlements of IP disputes naturally raise antitrust concerns.").

anticompetitive if it were valid and infringed.²⁵¹ This model provides a valuable insight for the analysis of reverse payments but ultimately leads to a conclusion that would outlaw too many potentially procompetitive reverse payments.

Under this group's model, whether a given reverse payment is procompetitive or anticompetitive depends on whether the patent at issue is valid and/or infringed: Reverse-payment settlements "are pro-competitive if, but only if, the patent in question is valid and infringed."²⁵² Hovenkamp et al. characterize reverse-payment settlements as belonging to a group of agreements "where the agreement itself looks like an antitrust violation but the presence of IP rights might absolve it."²⁵³ Though Shapiro's model finds that reverse payments overall are anticompetitive, it does not question this basic assumption of Hovenkamp et al.'s analysis—that a patent, if valid and infringed, could absolve an otherwise anticompetitive agreement.²⁵⁴ Hovenkamp et al., however, follow this insight to a conclusion that is slightly different from Shapiro's. They argue that the antitrust issues are clear—the reverse-payment settlement is procompetitive if the patent is valid and infringed and anticompetitive if it is invalid or not infringed.²⁵⁵

Since the competitive nature of a settlement depends on the patent's validity, this determination is the first step of Hovenkamp et al.'s analysis. They propose a two-step analysis of the patent dispute to determine whether the settlement falls within its protection: "First, there must have been a legitimate dispute concerning an IP right and likely infringement of a valid IP right. Second, the settlement agreement must be within the range of likely outcomes of litigation, or no more anticompetitive than such an outcome would have been."²⁵⁶ Within the reverse-payment settlement context, they further define how these tests may be met and require that the infringement plaintiff (a defendant in the antitrust setting) meet the test by imposing a presumption that reverse payments are unlawful: "The infringement plaintiff can defend by showing both (1) that the *ex ante* likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit."²⁵⁷ The first part of the test speaks to

251. *Id.* Reverse payments are clearly such a case. Were the patent at issue in the settlement either invalid or not infringed, the agreements not to compete inherent in reverse-payment settlements would be clearly and unreasonably anticompetitive. *Id.*

252. *Id.* at 1725.

253. *Id.* at 1724.

254. *See generally* Shapiro, *supra* note 202 ("If the patent is very strong . . . the challenger is unlikely to offer much independent competition to the patentholder if litigation proceeds.").

255. Hovenkamp, Janis & Lemley, *supra* note 134, at 1725.

256. *Id.* at 1734. "Unfortunately, these inquiries may be the very ones that the settlement agreement itself sought to forestall because of their complexity and uncertainty. That is why it is critical that these inquiries be made no more often than necessary." *Id.*

257. *Id.* at 1759.

the underlying patent-infringement suit, but the second part is drawn from the antitrust context. Unlike Shapiro, who would make all payments from the patent holder to the alleged infringer per se illegal, Hovenkamp et al. would allow payments that represent the costs of continued litigation. These more limited payments may not delay entry. Instead of suggesting a quid pro quo of payment for later entry, a rational patent holder would be willing to pay the cost of continued litigation simply to end the litigation, without any additional consideration in the form of delayed entry.²⁵⁸

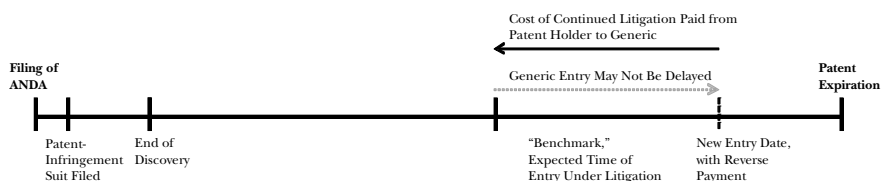


Figure 7: In the model as described by Hovenkamp et al., payments from the patent holder that are no greater than the cost of continued litigation are not evidence of payment for delayed market competition.

Leonard and Mortimer engage in an economic analysis of reverse payments to reach the similar conclusion that reverse payments less than or equal to the costs of continued litigation may in fact be procompetitive.²⁵⁹ Like Hovenkamp et al., Leonard and Mortimer adopt an economic model that demonstrates that “the agreement that is best for the parties makes consumers worse off than continued litigation.”²⁶⁰ However, because continued litigation (whatever the outcome) will ultimately impose the litigation cost on consumers, a reverse payment that is less than the cost of continued litigation will not reduce overall consumer welfare.²⁶¹

Ultimately, Hovenkamp et al. condemn most reverse-payment settlements by adopting a model similar to Shapiro’s: They argue that settlements without reverse payments “split the uncertainty costs of litigation,” but that reverse payments do not “represent the expected outcome of litigation, but rather [are] biased toward later entry by the payment.”²⁶² Though similar, Hovenkamp et al. do not go quite as far as Shapiro. Hovenkamp et al. seek to outlaw only those reverse payments that

258. *Id.* at 1758–59.

259. Leonard & Mortimer, *supra* note 219, at 260–64.

260. *Id.* at 260.

261. *Id.* at 261. Leonard and Mortimer also consider the effects that parties’ aversion to risk have on reverse-payment settlements. They find that while risk aversion may make parties more likely to engage in a reverse-payment settlement, it does not make that settlement more or less anticompetitive. *Id.* at 264; see Addanki & Daskin, *supra* note 210. They argue that a per se rule prohibiting all reverse payments is inappropriate. Instead, reverse payments must be evaluated in context under the rule of reason. Leonard & Mortimer, *supra* note 219, at 261.

262. Hovenkamp, Janis & Lemley, *supra* note 134, at 1762.

are actually likely to be anticompetitive, while Shapiro would outlaw all reverse payments as activities that are anticompetitive by nature.

3. Professor Daniel Crane

Shapiro and Hovenkamp et al. build models suggesting that reverse payments are always or often anticompetitive. These conclusions are in tension with a key insight by Hovenkamp et al.—that an otherwise anticompetitive agreement is not anticompetitive if it is protected by a valid and infringed patent.²⁶³ Professor Daniel Crane creates a model that begins with this insight—reverse-payment settlements may be either procompetitive or anticompetitive, and any legal rule must attempt to differentiate between the two:

[A] patent system should seek to strike the optimal balance between rewarding the patentee's inventive efforts and minimizing the losses imposed on society as result of the patent monopoly. In order to understand the net social consequences of a legal rule regarding patents and achieve the optimal ratio, equal attention must be given to the numerator (monopoly losses imposed on society) and the denominator (the legal rule's effect on inventive activity).²⁶⁴

Crane seeks to find a method to differentiate between cases where the costs of limiting reverse payments are low and the benefits are high and cases where the costs of limiting reverse payments are high and the benefits are low.²⁶⁵ Crane rejects the “prevailing [good faith] approach”²⁶⁶ as “flawed” because the parties’ subjective intentions when entering into a reverse-payment settlement are certain to be in line with their pecuniary interests.²⁶⁷ As discussed above, when parties enter into an agreement that preserves their monopoly rents, identifying their subjective intention to extend that monopoly is obvious and sheds no light on whether the agreement is unreasonably anticompetitive under the law.²⁶⁸ Any time that parties enter into a reverse-payment settlement, the patent holder’s intention will likely be to extend market power—this frames the question but does not answer it. Though reliance on the good-faith standard is common in reviewing patent settlements generally, courts considering

263. See *supra* notes 251–55 and accompanying text.

264. Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 751–52 (2002) (footnote omitted).

265. See *id.* at 776 (“The optimal legal position regarding such settlements requires taking into account all of the relevant costs and formulating a rule that harmonizes the competing strands of public policy.”).

266. See *id.* at 749 (citing *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963)).

267. *Id.* at 778–79.

268. *Id.*

reverse-payment cases have tended to recognize that parties acting in good faith according to their interests may take actions that are both procompetitive and anticompetitive.²⁶⁹

Instead of this subjective approach, Crane wants courts to make an “ex ante judgment about the merits of the infringement lawsuit.”²⁷⁰ This method would allow courts to split all reverse-payment cases between those where the patent holder would likely win, and those where the alleged infringer would likely win. For cases in which the patent holder would win, the legitimate monopoly of the patent protects the settlement (allowing the generic to enter the market before the end of that lawful monopoly) from being anticompetitive.²⁷¹ On the other hand, for cases in which the alleged infringer would likely have won, the reverse payment may truly be a payment to delay market entry. In such a case, further antitrust scrutiny of the settlement is necessary.

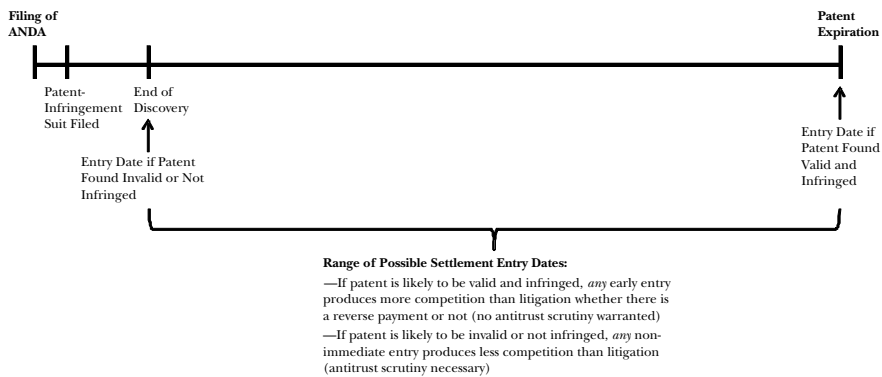


Figure 8: In Crane’s model, whether antitrust scrutiny is warranted is not determined by the date of entry but by the likelihood that the patent is valid and infringed.

Crane recognizes the key difficulty in determining the likely outcome of a trial—it is difficult to determine the likely outcome of a trial without *actually holding a trial*.²⁷² The more extensive the non-trial determination of the merits, the closer it comes to being an actual trial. This “mini-trial”

269. *But see* Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1307 (11th Cir. 2003) (“Good faith procurement furnishes a complete defense to the antitrust claim.”).

270. Crane, *supra* note 264, at 780.

271. *Id.* at 779 (“Courts and antitrust enforcers easily see the costs of permitting the settlement of unmeritorious patent infringement claims—deadweight losses in the form of monopoly pricing that could be avoided if litigation were required and the patentee’s monopolistic claims rejected.”).

272. *Id.* at 782 (“The difficulty is in formulating a way of determining the expected outcome of the lawsuit without requiring a full-blown inquiry into the merits, which would effectively mean the adoption of a no-exit-payment rule.”).

threatens to swallow the benefits of settlement that parties seek and that Crane seeks to preserve.

To prevent the examination of the merits of the infringement suit in the antitrust setting from becoming an actual patent-infringement suit, Crane proposes four general standards for evaluating the merits of the underlying suit.²⁷³ His method is unique and practical. Rather than seeking a perfect method for distinguishing between procompetitive and anticompetitive settlements, he seeks a rule that imposes antitrust scrutiny when the likelihood of an anticompetitive effect justifies the costs of that scrutiny.²⁷⁴ The four methods that Crane proposes to distinguish between settlements where antitrust scrutiny is warranted and those where it is not are discussed in turn.

First, if the patent holder received a preliminary injunction against the alleged infringer, this should constitute evidence of likely success on the merits. “The criteria for the granting of a preliminary injunction require the court to consider whether the patentee has shown a reasonable likelihood of success on the merits.”²⁷⁵ This factor allows the court to make use of a mini trial on the merits that has already occurred in the patent-infringement case to avoid rehashing the merits in antitrust.

Second, if no preliminary injunction has issued, Crane suggests that the antitrust court conduct its own mini trial on the patent-infringement merits.²⁷⁶ While conducting this examination of the merits would maintain Crane’s goal of deciding the reasonableness of the settlement based on the likely validity of the patent, it has two major problems. First, conducting an examination of the merits of the patent issue is the onerous task that the parties sought to avoid by settling. Forcing the issue reimposes the costs of the trial and reduces the chances that settlements will occur. Second, the parties to the patent-infringement case face very different incentives in the antitrust setting. Prior to settlement, the patent holder and the alleged infringer are true adversaries—the patent holder wants the patent to be found valid and infringed, and the alleged infringer wants it to be held invalid or noninfringing. In the antitrust setting, following a reverse-payment settlement, the parties with the relevant information to the likely outcome of the infringement case are no longer adversaries. Under Crane’s second factor, both parties want the antitrust court to believe the patent is both valid and infringed so that the reverse-payment settlement will stand.

273. This Article, too, proposes guidelines for when a court should consider a reverse-payment settlement to be anticompetitive and when it should not. Crane’s standards focus on the underlying patent-infringement suit; our standards forego this analysis, which would nullify the value of the settlement, in favor of an examination of the context in which the settlement occurs. *See supra* Part III.

274. Crane, *supra* note 264, at 779–80.

275. *Id.* at 783.

276. *Id.* at 785–88.

In this nonadversarial setting, the outcome of the antitrust suit is near certain.

Crane's third method looks at which parties are affected by the reverse-payment agreement. Settlements that "seek . . . to eliminate competition not only by the infringing defendants, but also by third parties against whom the patentee would have less certain claims of infringement" are inherently suspect.²⁷⁷ This factor is fairly straightforward. For example, previous iterations of the Hatch–Waxman Act allowed generics to hold their exclusivity period and bar other would-be entrants from the market. A settlement that required the ANDA filer to create a bottleneck in this way would be clearly anticompetitive.²⁷⁸

Lastly, settlements in which the patent holder pays a large proportion of its monopoly rents to the alleged infringer are suspect. Crane argues that such settlements "reflect[] a low probability that the patent is valid or that the defendant's use is actually infringing."²⁷⁹ We agree. Settlements in which the patent holder pays a large portion of its monopoly rents are likely to be unreasonably anticompetitive. A reexamination of our model makes this clear. Figure 2 presented a model of a patent-infringement settlement if the parties had equal chances of winning the case. Figures 7 and 8 present the model if the patent holder is either very likely to lose or very likely to win the underlying case.

Figure 9 presents a scenario that Crane has targeted for likely antitrust enforcement, one in which the patent would likely be held invalid or not infringed, yet the parties reach a reverse-payment settlement agreement. In Figure 9, the parties jointly estimate that the patent holder has a ten percent chance of prevailing at trial. In this scenario, the value of the litigation to the patent holder is ten percent of the monopoly rents. As Figure 10 shows, the patent holder would likely be willing to pay for the remaining monopoly rents.

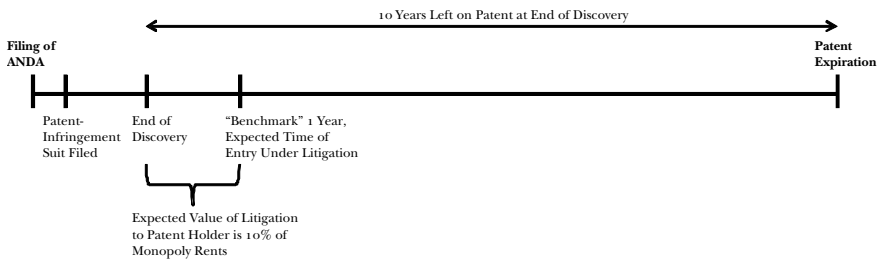


Figure 9: Settlement benchmark if there are ten years remaining on the patent at the end of discovery, and there is a ten percent chance that the patent holder will prevail.

277. *Id.* at 792.

278. *See id.* at 794–95.

279. *Id.* at 788.

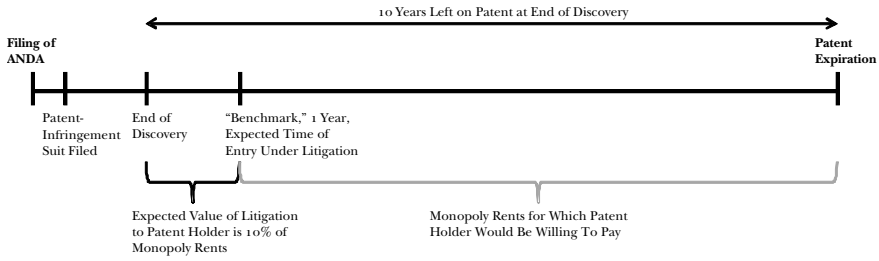


Figure 10: The patent holder would likely be willing to pay for the monopoly rents beyond its expected value of litigation—those occurring after the benchmark date.

The patent holder likely would be willing to pay a significant portion of the value of the remaining life of the patent to maintain that monopoly period if its expected loss from the litigation is ninety percent of the value of the patent. This is why Crane argues that settlements in which the patent holder pays an amount that is close to their monopoly rents are likely to be anticompetitive. As Figure 11 demonstrates, such settlements are only likely to occur if the likely outcome of the trial is in favor of the alleged infringer.

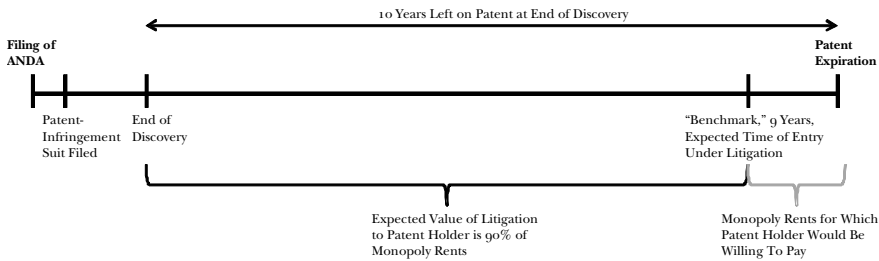


Figure 11: If the chances that the patent holder will prevail at trial are ninety percent, the patent holder would likely be willing to pay, at settlement, only for a small amount of monopoly rents that lie outside of its expected litigation value.

If the patent holder believes that it is ninety percent likely to prevail at trial, its expected value of litigation will be ninety percent of the remaining monopoly rents at trial end and its expected loss will be ten percent of its profits. While it will be willing to pay for its expected loss of ten percent of its monopoly rents, the patent holder will not be willing to pay much more than its expected loss, which is a small portion of its monopoly rents.

Critics of this approach argue that patent holders' risk aversion and uncertainty as to the outcome of litigation undercut Crane's inference that reverse payments approaching the patent holder's monopoly rents are likely to be anticompetitive.²⁸⁰ Because pharmaceutical patent holders may be very

²⁸⁰. See, e.g., Addanki & Daskin, *supra* note 210, at 2130–32.

risk averse, they might be willing to pay much more to preserve their monopoly than the monopoly rents *after* the benchmark are actually worth. Such risk aversion does indeed warrant some flexibility in the inference that larger payments suggest an anticompetitive effect; however, risk aversion alone cannot explain a patent holder paying the majority of its monopoly rents to maintain the value of a patent that it believes will likely be held valid and infringed at trial. Similarly, patent holder uncertainty as to the likely outcome of a trial makes it impossible to recreate the model above in a concrete setting; we can never know the true likelihood that either party will prevail in patent-infringement litigation. Nonetheless, only a patent holder who thinks its litigation chances are very slim would be willing to make a reverse payment that approaches its expected monopoly rents. In such a case, the payment is more likely aimed primarily at excluding the would-be generic entrant from the market.

If Crane's four factors suggest that the patent would likely have been upheld, then Crane argues that the settlement, regardless of the entry date and reverse payment, is not sufficiently likely to be anticompetitive to warrant antitrust scrutiny. If, however, these factors suggest that the patent would not have been upheld, Crane argues that the costs of prohibiting the patent will be outweighed by the likely anticompetitive effects of the agreement, and the payment should be illegal.²⁸¹

Though the premise of Crane's model is that courts should determine whether to impose antitrust enforcement on reverse-payment settlements based on the likelihood that the patent would have been held valid and infringed, only two of his four factors speak to the merits of the underlying suit. Recognizing that the third and fourth factors, which focus on the terms and context of reverse-payment settlements, are more promising methods for distinguishing anticompetitive from procompetitive settlement agreements, in Part IV we argue that courts should not reexamine the underlying merits of the case but should instead engage in a broader analysis of the context and terms of the settlement.

E. EMPIRICAL STUDIES OF THE EFFECTS OF REVERSE PAYMENTS

The economic analysis above demonstrates that it is possible, and likely, that reverse-payment settlements may be either anticompetitive or procompetitive. This *a priori* economic analysis is a useful starting point for deciding upon an antitrust analysis, but it is not the end of that analysis. Before selecting an analysis other than the default rule of reason, courts must identify empirical evidence that the activity does, in practice, have an anticompetitive effect. In *California Dental Ass'n v. FTC*, the Supreme Court considered restrictions that a nonprofit trade association placed on dentists'

²⁸¹. Crane, *supra* note 264, at 782.

advertising practices.²⁸² The Ninth Circuit had held the trade association's restrictions unlawful after conducting a "quick look" rule of reason inquiry.²⁸³ The Supreme Court reversed the Ninth Circuit, finding that an *a priori* economic analysis demonstrated that the restrictions could be procompetitive in some situations.²⁸⁴ Because the Ninth Circuit had not relied upon any evidence that *in practice* the restrictions were or would be anticompetitive, the Supreme Court held that imposition of an abbreviated antitrust analysis was not warranted.²⁸⁵

The reverse-payments context is strikingly similar to the advertising restrictions at issue in *California Dental Ass'n*. Our economic analysis demonstrates that it is possible for reverse payments to be either strongly procompetitive or anticompetitive. In the absence of empirical evidence that they are either procompetitive or anticompetitive in practice, courts should not deviate from the traditional rule of reason.

There is very little empirical evidence on the competitive effects of reverse payments. In 2002, the FTC published a study examining the circumstances surrounding patent-infringement cases in the Hatch-Waxman context, but it did not approach the issue of whether reverse payments increase or decrease competition.²⁸⁶ A more recent study by Hemphill collects a new dataset of 143 settlements between brand-name and generic drug companies.²⁸⁷ Hemphill seeks to solve a "troubling lack of information about the frequency and costliness of anticompetitive activity."²⁸⁸ Unfortunately, Hemphill's "aggregate approach" assumes that reverse payments are anticompetitive payments for delay prior to evaluating their cost.²⁸⁹ He demonstrates that reverse payments are increasing in number and argues that side deals should be seen as reverse payments but provides no empirical analysis of the anticompetitive or procompetitive effects that reverse payments have.

Given the absence of meaningful empirical evidence on the aggregate effects that reverse payments have on competition or output and the demonstrated fact from our economic analysis that reverse payments may be either procompetitive or anticompetitive, courts should not depart from the traditional rule of reason. This method of analysis provides the flexibility necessary to evaluate reverse-payment settlements on a case-by-case basis.

282. 526 U.S. 756 (1999).

283. 128 F.3d 720, 727-28 (9th Cir. 1997), *vacated*, 526 U.S. 756.

284. *Cal. Dental Ass'n*, 526 U.S. at 774.

285. *Id.*

286. FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

287. Hemphill, *supra* note 231.

288. *Id.* at 631.

289. *See id.* at 634.

IV. THE SUPERIORITY OF TRADITIONAL RULE OF REASON ANALYSIS

The DOJ seeks a judicial analysis of reverse-payment settlements that presumes that they are anticompetitive. However, courts have wisely refrained from adopting this proposal. Due to a split in the positions of the circuit courts, there is uncertainty regarding whether such settlements are subject to antitrust scrutiny and, if so, what level of scrutiny should be applied.²⁹⁰ In the absence of a clarifying Supreme Court decision, Congress has considered passing a bill that will decide the issue. The Preserve Access to Affordable Generics Act (“PAAG”) is under consideration, but its passage is uncertain.²⁹¹ Those who wish to strike a different balance should consider alternate policy options, including enacting no legislation, and thereby allowing courts to continue their evolution toward the rule of reason. Only the traditional rule of reason allows courts to analyze specific reverse-payment settlements contextually and then develop the analysis as they gain experience in distinguishing between procompetitive and anticompetitive reverse payments.

A. OPERATIONALIZING THE RULE OF REASON

Because errors in applying either too much or too little antitrust scrutiny have significant costs, the law sets a high bar for rules that allow only cursory examination of an allegedly anticompetitive activity. For per se rules, which allow no scrutiny of the context of an activity but simply deem activities unreasonably anticompetitive or not, the activity must be “manifestly anticompetitive.”²⁹² The Supreme Court maintains a strict standard for conduct to qualify as manifestly anticompetitive, limiting it to “certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable.”²⁹³ Reverse payments clearly do not meet this standard, which may be either procompetitive or anticompetitive; nor is the slightly less stringent standard for application of the quick look rule of reason met. To apply the quick look, courts must find activity that has a clear and obvious anticompetitive nature.²⁹⁴ Because these exceptions to the rule of

290. See *supra* Part II (describing the case history of reverse-payment settlements).

291. S. 369, 111th Cong. (2009). The U.S. Senate introduced the PAAG bill in February 2009 and placed it on the Senate calendar as item No. 183 by the Senate Judiciary Committee on October 15, 2009. Library of Cong., *Bill & Summary Status*, THOMAS, <http://www.thomas.gov> (search “S. 369” in “Bill Number” search field; then follow “All Congressional Actions” hyperlink). The House of Representatives has a similar bill, the Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009), which is still in the House Judiciary Committee.

292. *Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 50 (1977).

293. *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958).

294. *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 759 (1999).

reason clearly do not apply, we argue that courts must examine reverse-payment cases under the rule of reason.

To mitigate the significant costs that the rule of reason does impose, we provide a number of relevant, but not dispositive, areas on which courts should focus their analyses. Specific findings in any of these areas should not be dispositive as to the procompetitive or anticompetitive nature of the settlement at issue, but they are strong indicators in one direction or another. These factors provide a starting point for examining the whole picture of whether a given reverse payment is procompetitive, anticompetitive, or simply neutral. They should not be used to the neglect of other relevant evidence, but they may simplify the analysis by focusing it on the most relevant areas. In fact, one of the benefits of the rule of reason is that as courts gain experience with specific types of agreements, they may simplify or focus their analysis on the most relevant areas.

To avoid trial of the underlying patent-infringement suit while maintaining courts' abilities to identify anticompetitive settlement agreements, our focus is on the context and characteristics of the settlement, not the merits of the infringement case.²⁹⁵ As demonstrated by our economic analysis, the context of a reverse-payment settlement can be a strong indicator of whether that settlement is procompetitive or anticompetitive. We identify six factors that courts should examine:

- 1) Market power;
- 2) The entrance date allowed by the reverse-payment settlement;
- 3) The relative size of the reverse payment;
- 4) The ANDA filer's ability to market the drug without a reverse payment;
- 5) Sham litigation; and
- 6) Suspect side deals.

²⁹⁵ Other scholars, most notably Crane and Hovenkamp et al., have proposed methods for simplifying the rule of reason inquiry. Unlike the suggestions we present here, Crane and Hovenkamp et al. focus on the strength of the underlying patent-infringement suit. Crane argues that the rule of reason analysis should be guided by the likely outcome of the patent-infringement suit, had it not settled, and provides guidelines for identifying the likely outcome of that case. Crane, *supra* note 264, at 783. Hovenkamp et al. suggest that a reverse payment must be "no more than the expected value of litigation and collateral costs attending the lawsuit." Hovenkamp, Janis & Lemley, *supra* note 134, at 1759. These methods, focusing on the underlying suit, have a major problem—the outcome of a trial is not knowable without conducting something that closely resembles a trial. Examining the underlying patent-infringement suit in anything other than a cursory way will eliminate the efficiencies that parties hope to gain by settling rather than litigating the underlying suit. Imposing a reexamination of the underlying suit on a settlement would essentially create a *per se* rule against reverse-payment settlements, simply because parties would have little incentive to settle a case if they will have to litigate the same issues within the context of an antitrust suit.

1. Market Power

The first step should be an examination of the patent holder's market power.²⁹⁶ A showing that the ANDA filer could not meaningfully increase the overall competition faced by the patent holder, even if it was to enter the market immediately, suggests that a reverse payment has no anticompetitive effect. This may be the case if the brand-name drug already operates in a competitive market, competing with close substitute brand-name drugs and generics. In such a case, the patent holder has little incentive to pay the generic manufacturer to delay its entry into an already competitive market. If the brand name is already unable to charge monopoly rents because it does not have market power, then a reverse-payment settlement is unlikely to be anticompetitive.²⁹⁷ In its brief in *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, the DOJ sidesteps this issue to avoid an analysis of the patent holder's market power. It "assume[s] throughout that the patented drug at issue lacks substantial competition from other, non-infringing products."²⁹⁸ This is a fatal assumption. Without market power, there is no evidence that the reverse-payment settlement could have any adverse effects on consumer welfare. For that reason, market power should be the first step of the analysis, and judicial resources should be reserved for agreements between parties who do have market power, since without this, reverse payments do not harm consumers.

2. The Entrance Date Allowed by the Reverse-Payment Settlement

If the negotiated entry date is significantly before the date that the patent will expire, the agreement is not likely to be anticompetitive. If the patent holder were truly paying the ANDA filer to exclude it from the market, rather than allowing entry long before the expiration of the patent, the patent holder would likely have paid more to exclude more. On the other side, if the agreement does not allow the ANDA filer to enter the market until shortly before the patent expires, the reverse-payment agreement is more likely to be anticompetitive. Market entrance very near patent expiration suggests that the ANDA filer is getting little in the settlement other than the reverse payment. Unless the paragraph IV certification in the ANDA is very weak, very late entry cannot reasonably represent the parties' positions at trial.²⁹⁹ Where a patent holder stands in

296. Though market power is not a necessary element of a section 1 Sherman Act case, it may be relevant.

297. This is not to suggest that market power is a necessary element of an unreasonably anticompetitive agreement. See generally Mark R. Patterson, *The Market Power Requirement in Antitrust Rule of Reason Cases: A Rhetorical History*, 37 SAN DIEGO L. REV. 1 (2000) (discussing the roles that courts have allowed market power to play in antitrust litigation).

298. Brief for the United States, *supra* note 8, at 17 n.4.

299. See *supra* notes 19–20 and accompanying text (discussing ANDA applications and paragraph IV certification).

such a strong position that it could demand a settlement with very late generic market entry, it is unlikely that it will be willing to settle the case with a large reverse payment going to the alleged infringer.

3. The Relative Size of the Reverse Payment

This factor has been suggested by others. Crane, for example, argues that reverse payments that make up “a large percentage of [the patent holder’s] monopoly rents from the patent” strongly suggest that the settlement is anticompetitive.³⁰⁰ We agree. Others have inappropriately set a numerical threshold. For example, the FTC has set a dollar limit of \$2 million; settlements with reverse payments that exceed this amount will be considered for antitrust challenge.³⁰¹ Strict numerical limits, without reference to the value of the patent or the cost of the litigation, are not a reliable indicator of whether a given settlement is anticompetitive. The DOJ acknowledges that a payment that is reasonably related to the costs of avoided litigation is not likely to be anticompetitive.³⁰² “The defendants should have considerable leeway in comparing the payment to avoided litigation costs.”³⁰³ If the comparison is reasonable, such a payment is more likely to be compensation to the generic for the litigation costs it has already incurred, rather than a payment to delay generic entry, and thus less likely to be anticompetitive. The ANDA filer is likely able to extract such an amount from the patent holder without any agreement to delay entry. Ultimately, courts should not be overly concerned about reverse payments that do not significantly exceed typical litigation costs.³⁰⁴

On the other side, as Crane argues, relatively large reverse payments may suggest the need for closer scrutiny of an agreement for an anticompetitive effect.³⁰⁵ A showing that the generic has received more than it would likely have earned had it entered the market suggests an anticompetitive effect. Only two things can account for a settlement agreement in which the ANDA filer receives more than it could have earned on the market: (1) the payment is in exchange for the generic manufacturer’s agreement not to compete; or (2) there is some asymmetry in power between the parties that allows the ANDA filer to extract large sums from the patent holder simply for its willingness to settle—not in

300. Crane, *supra* note 264, at 788.

301. See *Schering-Plough Corp.*, 136 F.T.C. 956, 1062 (2003), *rev’d*, 402 F.3d 1056 (11th Cir. 2005).

302. See Brief for the United States, *supra* note 8, at 28.

303. *Id.* at 29.

304. See *Leonard & Mortimer*, *supra* note 219, at 261.

305. Crane, *supra* note 264, at 788–91; see also *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1309–10 (11th Cir. 2003) (“It may be that the size of the payment to refrain from competing, sometimes called a ‘reverse payment’ or an ‘exit payment,’ raises the suspicion that the parties lacked faith in the validity of the patent . . .”).

exchange for settlement and delayed market entry. In some situations, this could be explained by extreme risk aversion on the part of the patent holder. For example, if a patent holder risks going out of business if it loses the patent-infringement suit, but can afford a very large reverse payment, a savvy ANDA filer would be able to extract a large payment without agreeing to delay market entry beyond the date represented by its estimation of its chances of winning the underlying suit.

4. The ANDA Filer's Ability To Market the Drug Without a Reverse Payment

A showing that the alleged infringer likely would never have been able to market the generic drug without the reverse payment suggests that there is no anticompetitive effect.³⁰⁶ Absent a reverse payment, some generics may not ever be able to market their generic drug, regardless of the outcome of the case or the settlement negotiated. This may be the case for cash-poor generics that either cannot afford the significant expense of a patent-infringement trial, even if they are likely to win, or might go out of business before a traditional negotiated settlement entry date arrives. In either circumstance, a reverse payment can only increase competition by allowing the company to survive to market its generic drug. Without the reverse payment, there would be less competition because the ANDA filer would go out of business prior to marketing its drugs. In this situation, the reverse payment allows generic entry prior to patent expiration where otherwise it would never market the drug. Here, reverse payments enhance competition and consumer welfare.

5. Sham Litigation

A showing that the underlying patent-infringement suit is a sham, or is not based on any legitimate case or controversy, strongly suggests that the agreement is anticompetitive (as well as an abuse of the enforcement power of the courts). Consideration of this factor is already well established by caselaw.³⁰⁷ Sham litigation cannot produce legitimate settlement agreements. It is clear that if a patent-infringement suit is unfounded, it may not serve as the basis for an agreement that excludes a generic drug from entering the market.³⁰⁸

306. See *supra* Part III.C.5.

307. See, e.g., *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

308. This factor comes the closest to an examination of the underlying suit but only engages in a cursory examination to determine whether it was a sham. Any suit that proceeds past the motion-to-dismiss phase is not likely to be a sham.

6. Suspect Side Deals

Inequitable or severely unbalanced side deals suggest a payment for delay. As previously discussed, some have suggested that *any* side deals—often licensing agreements between the patent holder and the ANDA filer that are part of the settlement agreement—should be considered evidence of an anticompetitive effect.³⁰⁹ Hemphill argues for a presumption that side deals are not bona fide based on the idea that patent holders and ANDA filers seldom engage in deals like those that comprise side deals to patent-infringement settlements.³¹⁰ Such a presumption is unwarranted unless the side deal, standing alone, is demonstrably meant to hide a reverse payment rather than serve a legitimate business agreement. If compensation flows in both directions in a settlement—both from the patent holder to the alleged infringer and also back to the patent holder—the party asserting the antitrust violation should bear the burden of demonstrating that these exchanges disguise a payment for delay and do not represent a bona fide side deal. If the party alleging the antitrust violation can demonstrate that a side deal is manifestly unfair or one sided, this may be evidence that the settlement is an anticompetitive payment for delay.

Under the factors enumerated above, as in any other antitrust case decided under the rule of reason, the party alleging the antitrust violation bears the burden of proof.³¹¹ The factors discussed above fit neatly with that burden. If all of the factors suggest that the agreement is anticompetitive, the court should usually find that the agreement is anticompetitive. However, if any of the factors suggest that the agreement is not anticompetitive, this is likely sufficient to allow it to survive antitrust scrutiny. We do not propose a precise test, or even a balancing act—simply different contextual factors surrounding a reverse-payment settlement that courts should examine to determine if the reverse payment can be explained as anything other than a naked agreement not to compete.

309. See *supra* notes 231–32 and accompanying text.

310. Schering-Plough Corp., Docket No. 9297, slip op. at 107 (F.T.C. June 27, 2002), <http://www.ftc.gov/os/adjpro/d9297/020627id.pdf> (finding that the side deal was bona fide), *rev'd*, 136 F.T.C. 956 (2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005); Hemphill, *supra* note 231, at 633 (“An aggregate approach . . . reveals that these sorts of deals are a frequent component of settlements, but rare outside of settlement. Thus, the overall pattern suggests they provide a disguised means to confer payment.”).

311. See Yuki Onoe, Comment, ‘Pay-for-Delay’ Settlements in Pharmaceutical Litigation: Drawing a Fine Line Between Patent Zone and Antitrust Zone, 9 JOHN MARSHALL REV. INTELL. PROP. L. 527, 536 (2009) (“[The rule of reason] involves a detailed three-step analysis starting with the requirement for the plaintiff to prove an ‘actual adverse effect on competition as a whole in the relevant market.’ If the proof is acceptable, then the defendant must demonstrate pro-competitive effects. When the defendant meets the burden, the plaintiff must present ‘less restrictive’ alternatives. The first step of this analysis is essential and requires determination of whether the ‘harm is not only possible but likely and significant.’” (footnotes omitted)).

Examining these factors will allow courts to come to a reasonable, context-specific conclusion as to whether a given settlement is anticompetitive, without relitigation of the underlying patent dispute. Because reverse payments may in some contexts be procompetitive, or at least not anticompetitive, this is not the optimal result. To the extent that anti- and procompetitive agreements can be separated without secondary litigation of the underlying dispute, the value of settlement will be preserved.

B. OTHER ANTITRUST ANALYSES ARE INFERIOR

The full rule of reason analysis is the only option that allows courts to reach the optimal result in each case. Other analyses may abbreviate the analysis to preserve judicial resources, but the errors that these abbreviated analyses create outweigh judicial efficiencies. In particular, a per se or presumptive rule in either direction allows for significant and costly errors. Selecting the wrong antitrust analysis may result in either prosecution of procompetitive or neutral business conduct (“Type I error”)—or failure to prosecute activity that is anticompetitive (“Type II error”).³¹² In the reverse-payment context, either type of error is costly, and thus absolute per se rules in either direction are inappropriate. Only the rule of reason gives judges the context-specific ability to balance these two error types.

1. Type I Errors: Antitrust Prosecution of Activity
That Is Not Anticompetitive

The DOJ position would lead to a significant increase in Type I errors, condemning legitimate business conduct that is not anticompetitive. This is the risk of any per se or presumptive rule that makes reverse payments always or nearly always unlawful, especially one that allows treble damages. The negative effects of such a rule fall first and most immediately on the parties to the settlement, who in some cases will be unable to execute procompetitive settlements. As demonstrated in Part II, overenforcement will reduce the value of patents to patent holders and will lower the incentives to research, develop, and market new drugs. Any harm to the brand-name drug industry achieved by underprotection of patents will eventually flow to the generic industry in the form of fewer new drugs to make generic versions of, and to consumers who will have access to fewer, yet more expensive, drugs. In the long term, Type I errors may reduce competition by reducing the rewards of competing.

312. See Frank H. Easterbrook, *The Limits of Antitrust*, 63 TEX. L. REV. 1, 14–16 (1984) (outlining the two possible error types and arguing that prosecuting legitimate conduct is more costly than allowing some anticompetitive conduct to go unchallenged); see also Geoffrey A. Manne & Joshua D. Wright, *Innovation and the Limits of Antitrust*, 6 J. COMPETITION L. & ECON. 153, 159–68 (2010) (providing a technical analysis of Easterbrook’s error-cost framework).

Type I errors are also a likely consequence of the recently proposed PAAG Act which would outlaw all reverse-payment settlements.³¹³ The major effect of the legislation would fall on brand names, which would immediately lose a valuable tool that they frequently use to protect their intellectual property and avoid the uncertainty of trial. The Act would likely lead to earlier generic market entry by forcing settlements without reverse payments or full patent-infringement trials, some of which generics would win. This Act might push the goals of Hatch–Waxman too far, reducing the incentive for brand names to research, develop, and market new drugs and putting both the brand-name and the generic industries at risk. In the face of some reverse payments that are anticompetitive, the PAAG Act would ban *all* reverse payments, sacrificing those that are neutral or procompetitive. Any option that weeds out the anticompetitive, while preserving other settlements, is preferable to simply banning all reverse-payment settlements.

2. Type II Errors: Tolerating Activity That Is Anticompetitive

Allowing anticompetitive behavior to go unchallenged also has significant costs that have been comprehensively covered by other commentators.³¹⁴ For a *per se* or presumptive rule making reverse payments legal, the error costs fall immediately to consumers in the form of higher drug costs due to delayed competition. Consumer welfare, and the economy in general, will be harmed by artificial maintenance of monopoly rents and payment by brand-name drug companies to exclude generic competition that would be allowed if the patent were litigated. Under a *per se* legal rule, payments for delay would significantly reduce competition in all cases where the alleged infringer would have prevailed at trial.³¹⁵

Some commentators have argued that reverse-payment settlements are generally procompetitive and should be subject to only limited antitrust scrutiny.³¹⁶ This option allows a good deal of anticompetitive activity to occur in order to avoid hindering settlements that are neutral or procompetitive. This option is based on the assumption that Type I error costs should be a greater concern of antitrust than Type II error costs. If enacted, this option would immediately lead to an increase in reverse-payment settlements. On one hand, this could increase the expected value of patents, increasing incentives to develop brand-name drugs. On the other, the generic drug industry might become parasitic off the brand-name drug industry, marketing fewer and fewer drugs but receiving significant

313. S. 369, 111th Cong. (2009); *see also* Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009) (making reverse payments *per se* illegal under the FTC Act).

314. *See, e.g.*, Shapiro, *supra* note 202.

315. Of course, this error must be weighed against increased competition between brand-name drugs when high profits attract research, development, and marketing of new drugs.

316. *See, e.g.*, Addanki & Daskin, *supra* note 210.

income from brand-name companies simply by invoking the threat of competition. In this scenario, generics would raise the prices of brand-name drugs without allowing early generic entry and without meaningfully increasing competition.

3. Other Proposals

We argue that Type I and Type II errors are best balanced by judicial analysis using the rule of reason. Obviously, the *per se* legal and *per se* illegal approaches discussed above do not meet that standard. However, there are other ways that the current rules could be reformed to bring greater clarity and attempt to distinguish between procompetitive and anticompetitive settlements. One option, similar to our proposal but significantly more rigid, is to create statutory safe havens. Reverse-payment settlements that fall within one of these safe harbors would be immune from antitrust liability; those that did not would engage in reverse-payment settlements at the risk of facing antitrust scrutiny. For example, a safe harbor could allow settlements that provide for generic entry three years or more before patent expiration to avoid antitrust scrutiny. Another could protect any settlement between a patent holder and any ANDA filer other than the first, since these subsequent settlements hold less anticompetitive potential than first settlements because they cannot directly alter the incentives for other generic drug manufacturers to enter the market. A third potential safe haven could protect reverse payments that fall below a certain dollar amount. Reverse-payment settlements that do not fit within one of these safe havens would be analyzed under the full rule of reason. The effect of these safe havens would be to eliminate uncertainty in a group of reverse-payment settlements. Settlements would only extend beyond these safe havens when they are so favorable to the parties that they are willing to risk antitrust scrutiny.

The major problem with the safe havens is that in order to avoid detailed analysis, they draw arbitrary lines, making settlements on one side seem anticompetitive, and allowing settlements on the other to escape antitrust scrutiny altogether. None of these safe havens are perfect, and any settlement must be analyzed contextually. Imposing these bright lines would inevitably protect some anticompetitive activity, while exposing neutral and procompetitive activity to heightened scrutiny.

Other possibilities involve altering the incentives associated with the 180-day exclusivity period granted to the first ANDA filer. A recently proposed bill seeks to maintain a strong incentive for generic drug manufacturers to enter the market, even after a patent holder has settled a patent-infringement suit with an ANDA filer.³¹⁷ Under current law, the 180-day exclusivity period is an incentive to file an ANDA on the first day that

317. S. 1315, 111th Cong. (2009).

any manufacturer files an NDA for the brand-name drug.³¹⁸ Generic manufacturers may file ANDAs at later dates, but they will not receive the valuable exclusivity period.³¹⁹ If the generic manufacturers who file ANDAs on the first day possible lose patent-infringement litigation, or settle and agree not to market the drug, then no generic manufacturer will receive the exclusivity period. The Drug Price Competition Act of 2009 seeks to amend the Hatch–Waxman Act to extend the exclusivity period to a broader group of ANDA filers.³²⁰

This bill would allow some generic drug manufacturers to share in the exclusivity period, even if they file their ANDAs days or months after another generic manufacturer.³²¹ To get the exclusivity period in such a case, a generic manufacturer would have to file before any other generic begins commercially marketing the drug, and would need to either succeed in a challenge by the patent holder or not be challenged at all.³²² Since these ANDA filers would be eligible to receive the 180-day exclusivity period even after the first ANDA is filed, other generics will still have the incentive to file an ANDA for the drug before any generic begins actually selling the drug, and they will have an incentive to bring their generic drugs to market, not simply to settle patent-infringement litigation.

Under another possible change to the law, the rules could be reformed to require the first ANDA filer to choose between the 180-day exclusivity and the ability to participate in a settlement agreement in which any compensation goes from the patent holder to the ANDA filer. This could be accomplished in either one of two ways. First, the paragraph IV certification could be split into two similar, but new, certifications (perhaps paragraphs IV and V). One option would allow the ANDA filer to engage in reverse-payment settlements that would not be subject to antitrust scrutiny; however, a filer who chose this option would not be entitled to the 180-day exclusivity period, which would be available to the next ANDA filer. Under the other option, the ANDA filer would receive the exclusivity period, but for it, reverse payments would be per se illegal.³²³ Like the Drug Price Competition Act, these options allow reverse payments to occur but reduce their potential to be anticompetitive by maintaining strong incentives for other generics to enter the market.

318. See Hatch-Waxman Act, 21 U.S.C. § 355(j)(5) (2006) (allowing the exclusivity period for the generic manufacturer to start immediately following the NDA filing).

319. See *id.* § 355(j)(5)(D)(iii).

320. S. 1315.

321. See *id.*

322. *Id.*

323. Of course, if the first filer chose to forego the exclusivity option, and a subsequent filer opted to take the 180 days, its exclusivity period would exclude all manufacturers except previous ANDA filers who opted to forego the exclusivity period.

Alternatively, a similar result could be reached without forcing the parties to choose beforehand between exclusivity and reverse payments. Instead of altering the certification system, ANDA filers could be free to enter into reverse-payment settlement agreements without antitrust scrutiny; however, on a finding that a settlement included a reverse payment, the settling ANDA filer would lose the exclusivity, which would then be available to the next ANDA filer.³²⁴ This option would not meaningfully change the incentives for the ANDA filer. It may still stand to receive more money through reverse payment than it could possibly make by marketing the generic drug. It will accept that payment regardless of entry date. However, this option would make reverse payments more costly to brand-name companies in some situations. The parties to reverse payments often say the goal of the payment is simply to reach a mutually acceptable settlement that avoids the high costs and uncertainty of trial, not to hinder competition. This option would put that statement to the test by allowing any settlement to avoid antitrust scrutiny, but to wholly remove the bottleneck effect created by the 180-day exclusivity in the case of a reverse payment. In situations with several ANDA filers, a reverse-payment settlement would give the second ANDA filer a strong incentive to move forward with its generic drug, potentially forcing the brand name to file a second patent-infringement suit. This second suit could perhaps be avoided by disposing of the first case without using a reverse payment.

These options are attractive in that they give the parties free reign to settle patent-infringement litigation as they see fit but maintain the incentives for competition established by the Hatch–Waxman Act. These potential reforms are also much less sweeping and disruptive than either of the nuclear options representing across-the-board legality or illegality. Unfortunately, these solutions have significant drawbacks as well. Most notably, these reforms would further complicate an already complicated system. They would also force the parties to decide between reverse payments and exclusivity without complete information as to which option will ultimately be the most beneficial. Forcing this choice would not be a problem if reverse payments were always anticompetitive; however, since their competitive effects are context specific, forcing this choice will sometimes result in suboptimal competition and will lower consumer welfare. However, if the legislature does decide to muddy the waters and alter the current incentive structure, these options would be much less disruptive than the currently proposed PAAG Act.

³²⁴ Of course, the exclusivity period would only bar subsequent entrants, not previous ANDA filers who settled with reverse payments.

V. CONCLUSION

This Article has examined the economic contexts in which reverse-payment settlements occur and has demonstrated the folly of arguments that reverse payments are either universally anticompetitive or procompetitive. The recent DOJ policy shift advocating a presumption of illegality under the rule of reason would impose significant error costs by burdening some procompetitive settlements with antitrust scrutiny to prevent other anticompetitive settlements. Instead of truncating the development of doctrine surrounding reverse-payment settlements with legislation, courts should be left to continue their analysis and evolution toward an efficient rule. Inevitably, this evolution will lead to the rule of reason. By examining the specific contexts in which reverse payments occur, the error costs of stronger rules in either direction can be avoided. To that end, this Article argues that courts should analyze reverse-payment settlements under the rule of reason. We have proposed a series of factors related to the contexts in which reverse-payment settlements occur, on which courts should focus this analysis. Our proposal, moreover, allows courts to distinguish between procompetitive and anticompetitive reverse-payment settlements without litigating the underlying patent-infringement suit that the parties sought to avoid by entering into such settlements in the first place.