

THE ANTITRUST LEGALITY OF PHARMACEUTICAL PATENT LITIGATION SETTLEMENTS

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I. INTRODUCTION

Several federal courts of appeal have recently ruled on the issue of whether a pharmaceutical patent infringement settlement, pursuant to which a generic drug manufacturer agrees to forgo marketing a particular drug in return for monetary payments from a patent-holding “pioneer” drug manufacturer, is a violation of antitrust law.¹ These payments are termed “reverse payments” because, contrary to normal settlements, the plaintiff makes a lump sum payment to the defendant.² Reverse payments have sparked considerable academic comment and controversy.³ Even more recently, the Federal Trade Commission

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1. See *Andrx Pharms., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) *petition for cert. filed*, 2006 WL 3694387 (U.S. Dec. 13, 2006) (No. 06-830); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

2. See, e.g., *Schering-Plough Corp.*, 402 F.3d at 1068.

3. See, e.g., Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Applications*, 54 *FLA. L. REV.* 747 (2002); Herbert Hovenkamp et al., *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 *MINN. L. REV.* 712 (2004); Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 *U.S.F. L. REV.* 33, 36–37 (2004); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 *RAND J. ECON.* 391, 395 (2003). See also Joshua P. Davis & Steig Olson, *Efforts to Delay Competition from Generic Drugs: Litigation Along a Seismic Fault Between Antitrust and Intellectual Property Law*, 39 *U.S.F. L. REV.* 1 (2004); Stephen Roy Jenkins, *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.: Enlarging the Patent Exclusionary Right Through Hatch-Waxman Settlement Agreement Is Not Per Se Anticompetitive?*, 6 *TUL. J. TECH. & INTELL. PROP.* 295, 297 (2004); Richard D. Chaves Mosier & Steven W. Ritcheson, *In re Cardizem and Valley Drug: A View from the Faultline Between Patent and Antitrust in Pharmaceutical Settlements*, 20 *SANTA CLARA COMPUTER & HIGH TECH. L.J.* 497, 500 (2004); Larissa Burford, Note, *In re Cardizem & Valley Drug Co.: The Hatch-Waxman Act, Anticompetitive Actions, and Regulatory Reform*, 19 *BERKELEY TECH. L.J.* 365 (2004). See also Editorial, *Return of the Drug Company Payoffs*, *N.Y. TIMES*, Jan. 24, 2007, at A22 (observing that “the F.T.C. reported last week that—after a five-year hiatus—brand-name companies made 3

(“Commission”) and the Solicitor General have expressed views on the issue, in the context of the *Schering-Plough* litigation.⁴

Patents, by definition, create a legal monopoly and an environment of exclusion in order to reward innovation.⁵ However, when a patent extends beyond its scope or is used to dominate and abuse competitors, the result can be an antitrust violation.⁶ The cases and academic commentary discussed in this Article necessarily raise questions about how courts should handle the intersection of patent and antitrust law and their conflicting underlying policies. These questions are important because drug manufacturers appear to use the suspect agreements in order to exclude competition and share monopoly profits, resulting in higher prices and harm to consumers.

Courts have failed to develop a consistent and sensible approach to cases involving reverse payments.⁷ While some courts apply traditional antitrust precedent in cases involving payments from pioneer drug manufacturers to generic drug manufacturers, other courts take a deferential, hands-off approach.⁸ This deference leads to increasing manipulation of the legal system by drug manufacturers and less competition in the market.

such do-not-compete settlements in fiscal year 2005 and 14 more last year . . .” and speculating that “the better approach for congress to take as it moves toward corrective legislation would be a ‘bright line’ prohibition against making any payments to delay introduction of a generic drug.”)

4. The Supreme Court of the United States invited the Solicitor General to offer the views of the United States in the context of the petition for a writ of certiorari in *FTC v. Schering-Plough Corp.*, 126 S. Ct. 544 (2005). In response, the Solicitor General advised the Court to deny certiorari, stating that although

[t]he petition raises important and complex issues concerning the antitrust treatment of settlements in patent cases[.] . . . [it] does not present an appropriate opportunity for this Court to determine the proper standards for distinguishing legitimate patent settlements, which further the important goals of encouraging innovation and minimizing unnecessary litigation, from illegitimate settlements that impermissibly restrain trade in violation of the antitrust laws.

Brief for the United States as Amicus Curiae, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 544 (2005) (No. 05-273), 2006 WL 1358441, at *8. In a separate but similar case involving reverse payments, the FTC submitted an amicus curiae brief to the Second Circuit, released on Nov. 30, 2005, urging a rehearing en banc, contending that the divided Second Circuit panel opinion, upholding the dismissal of an antitrust challenge, “conflicts with basic principles of antitrust law.” Brief of Amicus Curiae Federal Trade Commission in Support of Plaintiffs-Appellants’ Petition for Panel Rehearing and Rehearing En Banc, *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) (No. 3-7641), 2005 WL 3332374.

5. See 35 U.S.C. § 261 (2000); *Valley Drug*, 334 F.3d at 1304 (“A patent grants its owner the lawful right to exclude others.”).

6. See *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196 (1963) (“[B]eyond the limited monopoly which is granted, the arrangements by which the patent is utilized are subject to the general law.” (quoting *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942))); *id.* at 196–97 (“[T]he possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly.” (quoting *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948))).

7. Compare *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003), with *Valley Drug*, 344 F.3d at 1310.

8. See, e.g., *Valley Drug*, 344 F.3d at 1310–11 (“[W]e do not think that a payment from the patentee to the alleged infringer should be automatically condemned under the antitrust laws . . .”).

Part II of this Article describes the regulatory framework underlying reverse payment settlement agreements and the patent infringement litigation from which they derive. Next, Part III examines cases that have addressed the antitrust issues created by reverse payments. Part IV compares academic commentary on the relevant antitrust issues. Finally, Part V assesses the most recent decisions by the Second and Eleventh Circuits.

II. REGULATORY BACKGROUND

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, provides a process by which generic drug manufacturers can enter the market for a particular drug without having to comply with the onerous safety and effectiveness studies normally required by law.⁹ Under the Hatch-Waxman Act, a generic manufacturer may file an Abbreviated New Drug Application (“ANDA”), which incorporates the safety and effectiveness data developed and submitted by the original pioneer drug manufacturer in the relevant market.¹⁰ If the ANDA establishes that the new drug is bioequivalent to the pioneer’s drug, the Food and Drug Administration (“FDA”) may approve the drug.¹¹

The use of ANDAs often results in patent infringement accusations. Many times, the pioneer manufacturer, upon whose safety and effectiveness data the generic manufacturer relies, contends that the new drug infringes a valid patent held by the pioneer manufacturer. In order to protect the patent rights of the pioneer drug manufacturer, the Hatch-Waxman Act requires the ANDA to certify that: (1) no patent for the pioneer drug is listed in the records; (2) the patent listed in the records is expired; (3) the ANDA filer will seek FDA approval only after the listed patent expires; or (4) the listed patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug.¹²

The most interesting cases arise when the generic manufacturer certifies that the listed patent is either invalid or will not be infringed by the generic drug (called a “paragraph IV certification”).¹³ An ANDA containing a paragraph IV certification has “important legal ramifications. It automatically creates a cause of action for patent infringement.”¹⁴

When a generic manufacturer makes a paragraph IV certification, it must immediately notify the owner of the listed patent about its filing of

9. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355 (2000)).

10. *See* 21 U.S.C. § 355(j)(2)(A).

11. *See id.* § 355(j)(4).

12. *Id.* § 355(j)(2)(A)(vii).

13. Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 32 (D.D.C. 2000).

14. *Id.*

the ANDA and its paragraph IV assertions.¹⁵ The pioneer manufacturer then has forty-five days to initiate a patent infringement suit.¹⁶ If the pioneer manufacturer does not initiate suit within the allotted timeframe, the FDA is free to approve the ANDA.¹⁷ If, however, a lawsuit is initiated, a thirty-month stay on FDA approval results.¹⁸ The stay is lifted at the earlier of thirty months or a district court determination that the patent at issue is invalid or not infringed.¹⁹ The court also has discretion to extend the thirty-month period if either party fails to reasonably cooperate in expediting the action.²⁰

The Hatch-Waxman Act further grants the first company to file a paragraph IV certification for a particular patent a 180-day period of exclusive rights to market a generic form of the pioneer drug in the event that the company either prevails in the patent infringement litigation or survives for forty-five days after notification of the pioneer manufacturer without challenge.²¹ This exclusivity period gives the generic manufacturer an incentive to challenge listed patents for brand name drugs via the ANDA process in the face of potential infringement litigation costs.

During the course of patent infringement actions based on paragraph IV certifications, parties sometimes decide to settle their lawsuits. The most controversial form of settlement from an antitrust perspective occurs when the pioneer manufacturer (the plaintiff in the infringement action) offers the generic manufacturer (the defendant and alleged infringer) a lump sum payment in return for an agreement by the generic manufacturer to exit the market for the drug at issue for the remaining life of the patent.²²

This form of settlement, referred to as a “reverse payment” or an “exit payment,”²³ seems anticompetitive because it results in an extension of a potentially invalid monopoly granted by the patent. The uncertainty inherent with regard to the scope and validity of patents has been termed the “probabilistic” nature of patent rights.²⁴ Keith and Cristofer Leffler, two of the many scholars who have weighed in on the reverse payment

15. 21 U.S.C. § 355(j)(2)(B).

16. *Id.* § 355(j)(5)(B)(iii).

17. *Id.*

18. *Id.*

19. *See id.*

20. *See id.*

21. *See id.* § 355(j)(5)(B)(iv).

22. *See generally* Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004) (analyzing the “reverse payment” phenomenon). Problematically, in the event that the first filer settles without relinquishing its first filer status, no other drug companies can receive the 180-day exclusivity period. *See Mova Pharms. Corp. v. Shalala*, 140 F.3d 1060, 1069–70 (D.C. Cir. 1998) (eliminating the successful defense requirement). Accordingly, other generic manufacturers are deprived of the 180-day exclusivity incentive to further challenge the patent at issue.

23. *See generally* Crane, *supra* note 3 (terming such payments “exit payments”).

24. *Id.* at 51.

issue, suggest that one should presume that Congress, by providing for this uncertainty, intended to strike an optimum balance between giving incentives for innovation (“dynamic efficiency”) and protecting consumers from monopolies (“static efficiency”):

Prior to a final court resolution of the validity and scope of a patent, the uncertainty as to the exact rights possessed by a patent holder under the rules enacted by Congress implies that the expected profits from a patent are in practice necessarily less than the full monopoly profits with complete exclusion. This is because of the “discount” to the full monopoly profits for the likelihood that the patent is invalid or limited in scope. The presumption that Congress correctly balanced static and dynamic efficiency implies that it is this expected profit, which is less than the full monopoly profit that creates the proper and efficient innovation incentive. Similarly, the presumption that Congress correctly balanced static and dynamic efficiency implies that increases in the expected profit to a patent holder through private agreements with potential competitors creates inefficient innovation incentives.²⁵

Therefore, as a result of settlement, the monopoly granted by the patent (originally subject to challenge by the generic manufacturer’s paragraph IV certification) extends beyond its intended scope.

Rather than incur the risks of its “probabilistic” patent rights, the pioneer manufacturer may opt to pay the generic manufacturer to refrain from the challenge and to stay out of the market.²⁶ Consenting to the agreement makes economic sense to the generic manufacturer (absent the risk of antitrust penalties) if the pioneer is able to offer more money through reverse payments than the generic manufacturer would be able to earn if it manufactured and marketed the drug.²⁷ The pioneer manufacturer is capable of offering such a large sum of money due to the large profits it makes as a result of its monopoly on the relevant drug.²⁸ It makes economic sense for the pioneer manufacturer (absent the risk of antitrust penalties) to offer such a large sum of money if the money it pays by way of the settlement is less than the amount it anticipates to lose if the generic manufacturer entered the market.²⁹ Thus, the generic manufacturer receives a portion of the monopoly profits of the pioneer manufacturer.³⁰

25. *Id.* at 36–37. *See also* Shapiro, *supra* note 3, at 395 (theorizing that a patent “does not give the patentee the ‘right to exclude’ but rather the more limited ‘right to *try* to exclude’ by asserting its patent in court.”).

26. *See* Leffler & Leffler, *supra* note 3, at 37.

27. *See id.*

28. *See id.*

29. *See id.*

30. *See id.*

Judicial treatment of this type of settlement has ranged from per se condemnation to virtual per se legality.³¹ Other courts take a middle-of-the-road approach, applying a rule of reason analysis.³² As explained *infra* in Part III.B, the Eleventh Circuit has taken the position that settlement agreements in situations involving the Hatch-Waxman Act are virtually per se legal. An examination of the various approaches to handling the patent and antitrust issues illustrates the important policy considerations that take place.

III. CIRCUIT COURT DECISIONS

Two federal courts of appeals, the Sixth and Eleventh Circuits, initially offered diametrically opposing views of allegedly anticompetitive reverse payment settlements of pharmaceutical patent infringement cases.

A. *The Sixth Circuit*

In *In re Cardizem CD Antitrust Litigation*,³³ brought before the Sixth Circuit Court of Appeals, Andrx, a generic manufacturer, filed an ANDA paragraph IV certification asserting that its formulation did not infringe a pioneer manufacturer's patent on Cardizem CD, a once-a-day release dose of the drug Cardizem.³⁴ In response, the pioneer manufacturer and patent holder, HMR, sued Andrx for patent infringement, triggering the thirty-month stay on FDA approval.³⁵ HMR and Andrx subsequently entered into an agreement under which Andrx agreed not to enter the market with its generic version of Cardizem until the earliest of: (1) Andrx obtaining a favorable, final, and unappealable determination in the patent infringement case; (2) HMR and Andrx entering into a licensing agreement; or (3) HMR entering into a licensing agreement with a third party.³⁶ Andrx further agreed to diligently prosecute its ANDA and to not relinquish or transfer the 180-day exclusivity period.³⁷ In return, HMR agreed to pay Andrx \$10 million per quarter in the event that Andrx obtained FDA approval of its

31. Compare *In re Cardizem CD Litig.*, 332 F.3d 896, 908 (6th Cir. 2003), with *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294, 1310 (12th Cir. 2003) and *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065–66 (11th Cir. 2003).

32. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 231–32 (E.D.N.Y. 2003).

Under the rule of reason, the factfinder must decide whether a challenged practice is an unreasonable restraint of trade, 'taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect.'

Id. at 232–33 (quoting *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997)).

33. 332 F.3d 896.

34. *Id.* at 901–02.

35. *Id.* at 902.

36. *Id.*

37. *See id.*

generic drug.³⁸ The payments were scheduled to end when a final and unappealable order or judgment in the patent infringement case was rendered, or when Andrx obtained a license to market the drug.³⁹ As a result, Andrx agreed not to market its generic drug despite obtaining FDA approval, and HMR dropped its patent infringement action and began paying Andrx \$10 million per quarter.⁴⁰

The Sixth Circuit held that the agreement between Andrx and HMR constituted a per se illegal market allocation agreement between competitors.⁴¹ The court found that the agreement not only eliminated competition from Andrx in the market of Cardizem, but it also eliminated competition from all other potential competitors.⁴² The court so held because Andrx's delayed entry into the market postponed the start of the 180-day exclusivity period, which Andrx agreed not to relinquish or transfer.⁴³

B. The Eleventh Circuit

In contrast to the Sixth Circuit's approach, the Eleventh Circuit held similar agreements to be virtually per se lawful in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*⁴⁴ and *Schering-Plough v. FTC.*⁴⁵ More recently, however, the Eleventh Circuit appears to have clarified its views, moving somewhat closer to the Sixth Circuit, in *Andrx Pharmaceuticals, Inc. v. Elan Corp.*⁴⁶

1. Valley Drug

In *Valley Drug*, a consolidation of several antitrust lawsuits against Abbott Laboratories ("Abbott"), Geneva Pharmaceuticals ("Geneva"), and Zenith Goldline Pharmaceuticals ("Zenith"), the Eleventh Circuit ruled that agreements between Abbott, the pioneer manufacturer and holder of the patent for the drug Hytrin (made of the compound terazosin hydrochloride), and Zenith and Geneva, generic manufacturers, in the context of patent litigation, were not per se antitrust violations.⁴⁷

Valley Drug involved ANDA filings based on Hytrin by Zenith and Geneva and subsequent patent infringement suits by Abbott.⁴⁸ In the

38. *See id.*

39. *See id.* at 903 n.3.

40. *Id.*

41. *Id.* at 908.

42. *Id.* at 907.

43. *Id.*

44. 344 F.3d 1294 (11th Cir. 2005).

45. 402 F.3d 1056 (11th Cir. 2005).

46. 421 F.3d 1227, 1236 (11th Cir. 2005).

47. *Valley Drug*, 344 F.3d at 1309.

48. *Id.* at 1296.

course of the patent infringement litigation between Abbott and Geneva, “Geneva admitted infringement [of the patent] but contested the patent’s validity.”⁴⁹ Under the allegedly anticompetitive settlement agreement, Geneva agreed to refrain from selling or distributing any form of terazosin hydrochloride until: (1) Abbott’s patent expired; (2) another entity introduced a generic form of the drug; or (3) either Geneva obtained a final, unappealable judgment that its generic version for which it had filed an ANDA did not infringe Abbott’s patent or a court found Abbott’s patent invalid.⁵⁰ Geneva also agreed not to transfer or relinquish its rights as first ANDA filer to the 180-day exclusivity period.⁵¹ In return, Abbott agreed to pay Geneva \$4.5 million each month until either another generic manufacturer brought a terazosin hydrochloride drug into the market or Abbott won a favorable decision in the district court on its patent infringement claim against Geneva.⁵² Thus, litigation of the patent validity issue continued in the interim, while Abbott paid Geneva \$4.5 million per month.

Ultimately, the district court held Abbott’s patent invalid, the Eleventh Circuit affirmed,⁵³ and the Supreme Court denied certiorari.⁵⁴ The parties had by this time already terminated their agreement, however, as a result of an FTC investigation.⁵⁵

The agreement between Abbott and Zenith consisted of Zenith acknowledging the validity of Abbott’s patent claims and agreeing not to sell or distribute any terazosin hydrochloride drug until Abbott’s patent expired or another generic manufacturer entered the market.⁵⁶ In return, Abbott agreed to pay Zenith “\$3 million up front, \$3 million after three months, and \$6 million every three months thereafter” for two years.⁵⁷

In the antitrust litigation, brought by wholesale and retail drug companies, the district court found that the agreements in question violated § 1 of the Sherman Act,⁵⁸ characterizing the settlements as horizontal market allocation agreements.⁵⁹ The Eleventh Circuit reversed, permitting the settlement agreement because it was no broader than the potential exclusionary effects of the patent.⁶⁰ The court stated, “[u]nlike some kinds of agreement that are *per se* illegal whether engaged in by patentees or anyone else, such as tying or price fixing, the

49. *Id.* at 1299.

50. *Id.* at 1300.

51. *Id.*

52. *Id.*

53. *Abbott Labs. v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319 (Fed. Cir. 1999).

54. *Abbott Labs. v. Geneva Pharms., Inc.*, 528 U.S. 1078 (2000).

55. *In re Abbott Labs.*, No. C-3925, 2000 WL 681848 (F.T.C. May 22, 2000).

56. *Valley Drug*, 344 F.3d at 1300.

57. *Id.*

58. Sherman Act, 15 U.S.C. §1 (2000).

59. *See In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1354 (S.D. Fla. 2000).

60. *Valley Drug*, 344 F.3d at 1305.

exclusion of infringing competition is the essence of the patent grant.”⁶¹ According to the Eleventh Circuit, at the time the agreements were entered into, the patent had not been invalidated, so exclusion of competitors merely represented an exercise of the pioneer manufacturer’s patent rights.⁶² Consequently, the court held that the case would be remanded for “appropriate antitrust analysis.”⁶³

The court suggested that on remand the district court apply neither a rule of reason analysis nor a per se rule.⁶⁴ Rather, the court proposed a “consideration of the scope of the exclusionary potential of the patent, the extent to which the provisions of the [a]greements exceed that scope, and the anticompetitive effects thereof.”⁶⁵ Thus, “the appropriate analysis on remand will likely require an identification of the protection afforded by the patents and the relevant law and consideration of the extent to which the [a]greements reflect a reasonable implementation of these.”⁶⁶

On remand, the district court held that the component of the agreement that guaranteed that Geneva would not enter the Hytrin market even if the district court decided against Abbott in the patent litigation (i.e., when the district court found Abbott’s patent to be invalid, but the settlement agreement provided that Geneva would stay out of the market until Geneva obtained a final, unappealable judgment), was not a reasonable implementation of the protection afforded by the patent.⁶⁷ The court applied the per se rule of illegality, concluding that “‘there is simply no escaping the conclusion that the [a]greement . . . was, at its core, a horizontal agreement to eliminate competition’ in the domestic market for terazosin hydrochloride drugs, a ‘classic example’ of an output-reducing, naked restraint on trade that qualifies for per se treatment.”⁶⁸ In so holding, the court stressed the fact that the agreement also resulted in delaying the entry of other generic competitors, that, under the Hatch-Waxman Act, could not enter the market until 180 days after Geneva began marketing its generic drug.⁶⁹

2. Schering-Plough

These issues came before the Eleventh Circuit more recently in *Schering-Plough Corp. v. FTC*.⁷⁰ The underlying facts of the case suggest

61. *Id.* at 1306.

62. *Id.*

63. *Id.*

64. *Id.* at 1306–08.

65. *Id.* at 1312.

66. *Id.* (citation omitted).

67. See *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319 (S.D. Fla. 2005).

68. *Id.* at 1315 (quoting *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003)).

69. *Id.*

70. 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

that pharmaceutical companies may be adapting their settlement practices in an attempt to avoid potential antitrust violations. In *Schering-Plough*, the Federal Trade Commission challenged payments in the context of patent litigation settlements from Schering-Plough, Inc. (“Schering”) to Upsher-Smith Laboratories (“Upsher”) and ESI Lederle, Inc. (“ESI”).⁷¹ Upsher and ESI sought FDA approval under paragraph IV ANDA certifications to market generic versions of K-Dur 20, a potassium chloride drug.⁷² Schering sued for patent infringement and, before trial, the parties settled.⁷³ Pursuant to the settlement, Schering agreed to make payments to Upsher totaling over \$60 million, and Upsher agreed not to enter the market for K-Dur 20 for over three years.⁷⁴ Upsher also granted Schering licensing rights for the global market outside of North America for Upsher’s drug Niacor, a cholesterol-reducing niacin product.⁷⁵ Schering made a similar agreement with ESI under which Schering paid \$10 million to ESI, and ESI agreed not to enter the K-Dur 20 market for a period of time.⁷⁶

The Commission reversed the administrative law judge’s initial decision to dismiss the complaint, finding that, while the reverse payments were not per se illegal, they constituted a quid pro quo for an agreement to delay entry in the market.⁷⁷ The Commission rejected the defense that the \$60 million payment to Upsher was for licenses because the payment substantially exceeded Schering’s reasonable expectation of the value of the licenses.⁷⁸

The Eleventh Circuit reversed the opinion of the Commission, holding that the evidence did not support the conclusion that the settlement agreements unreasonably restrained competition beyond the exclusionary scope of the patent.⁷⁹ Citing *Valley Drug*, the court ruled that the “proper analysis of antitrust liability requires an examination of: (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.”⁸⁰ Relying heavily on the policies of protecting patent rights and encouraging settlements, the court vacated the Commission’s ruling and found the agreements to be lawful.⁸¹ The court concluded that:

[g]iven the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative

71. *Id.* at 1061.

72. *Id.* at 1058–59.

73. *Id.* at 1059–60.

74. *Id.*

75. *Id.* at 1060.

76. *Id.* at 1060–61.

77. *Id.* at 1062.

78. *Id.*

79. *Id.* at 1075–76.

80. *Id.* at 1066.

81. *Id.* at 1076.

public and private benefits of settlements, we fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and, in an ancillary transaction, pays for other products licensed by the generic.⁸²

On August 29, 2005, the Commission petitioned the Supreme Court of the United States for a writ of certiorari.⁸³ After receiving briefs from the Commission and Schering, the Supreme Court asked the Solicitor General to submit an amicus brief on behalf of the United States.⁸⁴ In response, the Solicitor General recommended that the Court deny certiorari.⁸⁵ This response sparked an unusual disagreement between the Commission and the Solicitor General. In fact, the Commission subsequently filed a supplemental brief stating "the economic impact of the ruling below on consumers of prescription drugs—including the states—is staggering. . . . Billions of dollars in added prescription drug costs *annually* are at stake. The decision below has 'opened a Pandora's box' of anticompetitive settlements between brands and generic competitors."⁸⁶ The FTC also indicated that:

although there was a five-year lull in pay-offs to potential competitors after the Commission commenced enforcement actions aimed at exclusion-payment settlements, pharmaceutical companies have once again started entering into settlement agreements that include both compensation in various forms to generic challengers and restrictions on generic market entry. Harm is very likely ongoing each day that the decision below prevails.⁸⁷

On June 26, 2006, the Supreme Court denied the Commission's petition for certiorari.⁸⁸ Thereafter, on June 27, 2006, Senators Herb Kohl (D-WI), Patrick Leahy (D-VT), Chuck Grassley (R-IA), and Charles Schumer (D-NY) proposed legislation to prohibit brand name pharmaceutical drug manufacturers from paying generic drug manufacturers cash settlements to keep generic drugs off the market.⁸⁹ Senator Leahy commented:

It is stunning that the U.S. Supreme Court would refuse a request by the Federal Trade Commission to hear a case so important to

82. *Id.*

83. Petition for a Writ of Certiorari at 1, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273), 2005 WL 2105243.

84. Brief for the United States as Amicus Curiae at 1, *Schering-Plough Corp.*, 126 S. Ct. 2929 (No. 05-273), 2006 WL 1358441.

85. *Id.*

86. Supplemental Brief for the Petitioner at 2, *Schering-Plough Corp.*, 126 S. Ct. 2929 (No. 05-273), 2006 WL 1647529.

87. *Id.* at 2-3.

88. *Schering-Plough Corp.*, 126 S. Ct. 2929.

89. S. 3582, 109th Cong. (2006).

senior citizens and others needing lower-cost generic medicines. It is also regrettable that the Administration has sided with big drug companies over seniors and the FTC in pushing for this outcome.⁹⁰

Schering-Plough and its fallout demonstrate that lawmakers and courts continue to grapple with the concerns that arise in connection with reverse settlement payments. Accordingly, the debate over the proper judicial and congressional action with regard to pharmaceutical drug patent issues and the appropriate reach of antitrust enforcement has increased in significance.

3. *Andrx Pharmaceuticals*

In *Andrx Pharmaceuticals, Inc. v. Elan Corp.*,⁹¹ the Eleventh Circuit reviewed the dismissal of claims brought by a generic manufacturer, Andrx Pharmaceuticals, Inc. (“Andrx”), alleging antitrust violations by Elan Corp. (“Elan”) in Elan’s prior patent litigation settlement agreement with another potential generic competitor, SkyePharma.⁹² Elan owned a patent that gave it the exclusive right to manufacture and sell in the United States a controlled-release naproxen medication.⁹³ When SkyePharma filed its ANDA application to manufacture and sell a generic version, it also made a paragraph IV certification, leading to Elan’s initiation of patent infringement litigation against it, thereby triggering a 30-month stay on FDA approval.⁹⁴ This litigation was settled by entering into an agreement in which SkyePharma admitted to infringing the patent in exchange for a license from Elan to manufacture the generic version.⁹⁵ Because SkyePharma was the first ANDA applicant, the license agreement gave it the 180-day exclusive marketing period.⁹⁶

Andrx also sought to introduce a generic naproxen to the market, and Elan, in turn, initiated patent infringement proceedings against it.⁹⁷ As a result, Andrx brought a complaint against Elan, making two claims against it: (1) the settlement agreement between Elan and SkyePharma had the effect of preventing any generic competition in the controlled release naproxen market and constituted a conspiracy to restrain trade, in violation of §§ 1–2 of the Sherman Act;⁹⁸ and (2) Elan’s patent infringement proceedings were really “sham litigation[s]” with the true

90. Press Release, Kohl, Leahy, Grassley, and Schumer Introduce Bill to Stop ‘Payoffs’ that Delay Generic Drugs (June 26, 2006), <http://leahy.senate.gov/press/200606/062606a.html>.

91. 421 F.3d 1227 (11th Cir. 2005).

92. *Id.* at 1230.

93. *Id.* at 1231.

94. *Id.*; 21 U.S.C. § 355(j)(5)(B)(iii) (2000).

95. *Andrx Pharmaceuticals, Inc.*, 421 F.3d at 1231.

96. *Id.*

97. *Id.*

98. Sherman Act, 15 U.S.C. §§ 1–2 (2000).

intent of invoking the thirty-month rule and preventing Andrx's entrance into the market for a potential of two and a half more years.⁹⁹

The Eleventh Circuit found that the district court had properly dismissed the "sham litigation" claim for several reasons.¹⁰⁰ First, it held that Elan's initiation of patent infringement proceedings was not "objectively baseless."¹⁰¹ The court held that Elan was afforded immunity from antitrust liability by virtue of the Noerr-Pennington doctrine, which immunizes such First Amendment activities as petitioning the government for redress of grievances.¹⁰² Next, the court reversed the district court's finding that Andrx had not sufficiently pled an antitrust violation in relation to the licensing agreement that Elan signed with SkyePharma to settle the patent infringement litigation.¹⁰³ The court concluded that the notice pleading standard of Federal Rule of Civil Procedure 8(a)¹⁰⁴ applied, and that given the fact-intensive nature of antitrust cases, dismissals on the pleadings were "particularly disfavored," absent some doctrine immunizing the conduct from antitrust liability.¹⁰⁵

In citing the analysis established by *Valley Drug*, the court first found that, based on its complaint, Andrx's allegations established the scope of the patent.¹⁰⁶ Second, the court determined that Andrx's allegation that SkyePharma agreed to refrain from ever marketing a generic controlled release naproxen, after having been granted the license, would, if proven, exceed the scope of exclusion intended by the Elan patent by preventing any generic competitors from entering the market.¹⁰⁷ Finally, Andrx's allegations that depriving the public of a less expensive generic product and "foreclosing" entry by competitors into the controlled-release naproxen market, if proven, could demonstrate anticompetitive effects.¹⁰⁸ The court thus concluded that Andrx sufficiently pled facts for a claim based on § 1 of the Sherman Act.¹⁰⁹

Finally, with regard to Andrx's claim based on § 2 of the Sherman Act, the court concluded that Andrx had stated a claim, showing specific intent to bring about a monopoly and, given Elan's market power, "a dangerous probability of success."¹¹⁰ The court then remanded the case back to the district court for further proceedings.¹¹¹

99. *Andrx Pharmaceuticals, Inc.*, 421 F.3d at 1233–34.

100. *Id.* at 1234.

101. *Id.*

102. *Id.*

103. *Id.*

104. Fed. R. Civ. P. 8(a).

105. *Andrx Pharmaceuticals, Inc.*, 421 F.3d at 1234–35 (quoting *Covad Commc'ns Co. v. BellSouth Corp.*, 299 F.3d 1272, 1279 (11th Cir. 2002), *vacated on other grounds*, 540 U.S. 1147 (2004)).

106. *Id.* at 1235.

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.* at 1236.

111. *Id.* at 1237.

IV. RECONCILING POLICY CONFLICTS

A. Policy Considerations

The important antitrust and patent issues in the cases described *supra* have given rise to much scholarly and judicial debate.¹¹² At least three policies come into conflict when one analyzes these cases.

First, the law encourages innovation through the patent laws.¹¹³ Some scholars suggest that if courts become overly zealous when enforcing antitrust laws and protecting consumer welfare, those courts could discourage innovation and product research and development because companies will be unable to fully realize the profits they could gain under a system that allows reverse payments.¹¹⁴ Second, the law also encourages settlement of lawsuits in order to promote judicial economy.¹¹⁵ If courts regularly permit reverse payments, judicial economy may be fostered because no infringement case will occur, thereby conserving judicial resources.¹¹⁶ Third, however, the law also encourages efficiency in the marketplace by prohibiting market allocation and price fixing.¹¹⁷ When a patentee, who bears the burden of proving that an alleged infringer is in violation of its patent, pays the alleged infringer not to market the product, potential consumer benefits are denied.¹¹⁸

These policies must be considered within the framework of traditional antitrust analysis, which allows courts to further the policies of market efficiency and consumer welfare without ignoring competing policies. Section 1 of the Sherman Act provides that “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several states, or with foreign nations, is declared to be illegal.”¹¹⁹ Most restraints are evaluated using the rule of reason.¹²⁰ Sometimes, however, restraints of trade are deemed unlawful *per se* because they “have such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit.”¹²¹ For example, when competitors agree to geographically divide a market, the agreement is *per se* illegal.¹²² Scholarly debate has centered around whether reverse payments should be considered *per se*

112. See, e.g., Crane, *supra* note 3, at 748.

113. See *id.* at 751.

114. *Id.* at 760–62.

115. *Id.* at 751.

116. *Id.* at 757.

117. *Id.* at 751.

118. See *id.* at 753.

119. Sherman Act, 15 U.S.C. § 1 (2000).

120. See *supra* note 32.

121. *Id.* (citing *N. Pac. R.R. v. United States*, 356 U.S. 1, 5 (1958)).

122. See *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49 (1990). The lead author of this Article was co-counsel for plaintiffs/petitioners in *Palmer*.

illegal under antitrust laws, and, if not, what sort of analysis should take place.

B. The Antitrust-Defendant-Friendly Approach

Some scholars and judges advocate an approach that would generally permit “reverse payments” in patent litigation.¹²³ This is the approach generally accepted by the Eleventh Circuit.¹²⁴ Under this theory, payments from pioneer manufacturers to generic manufacturers are justified as ancillary to the procompetitive act of settling a patent dispute.¹²⁵ Thus, proponents of this approach argue that “[t]oo great a willingness to find antitrust violations in settlement arrangements would significantly inhibit settlements of many types of cases at real cost to the administration of justice, with little likelihood of any countervailing benefit to the public interest.”¹²⁶ In addition, if pioneer and generic manufacturers are not allowed to settle patent cases in this context, the incentives to innovate might be reduced as a result of the lower expected payoff from invention.

However, with regard to the rationale that this will promote settlements, in many cases, at least under the analysis suggested by the Eleventh Circuit, the merits of the patent litigation suits are litigated when the agreement is challenged on antitrust grounds anyway, even if by the “wrong plaintiff” (i.e., the antitrust plaintiff rather than the more knowledgeable patent infringement plaintiff).¹²⁷ Accordingly, the benefit to society resulting from the settlement may be outweighed by the cost of protracted antitrust litigation, during which the validity of the patent represents part of a court’s analysis. Furthermore, in the event that a patent settlement agreement is found to be anticompetitive after an antitrust challenge and appeal, the harm suffered by the consumer has already occurred and cannot be rectified by payment of damages to the antitrust plaintiff.¹²⁸ This factor is especially significant given the importance of affordable drugs for many consumers.

123. See, e.g., Schildkraut, *supra* note 22 at 1033–34; Robert D. Willig & John P. Bigelow, *Antitrust Policy Towards Agreements That Settle Patent Litigation*, 2004 ANTITRUST BULL. 655, 677.

124. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1074–76 (11th Cir. 2005).

125. See *id.* at 1073.

126. Harry M. Reasoner & Scott J. Atlas, *The Settlement of Litigation As a Ground for Antitrust Liability*, 50 ANTITRUST L.J. 115, 126 (1981).

127. See Leffler & Leffler, *supra* note 3, at 54–55 (“[A]ntitrust plaintiffs taking on the burden of demonstrating invalidity have to start from scratch and re-learn much of what the generic challenger likely knew before accepting the settlement. In addition, as antitrust plaintiffs, purchasers are likely to be at an information disadvantage compared to the generic challenger because the generic challenger is in the business of researching pharmaceuticals, understanding pharmaceutical patents, and assessing patent validity.”).

128. See *id.* at 55. See, e.g., *Schering-Plough*, 402 F.3d at 1059 (regarding an allegedly anticompetitive agreement that was entered into in 1997, the final adjudication for which occurred in 2005).

With regard to the policy of promoting innovation through patent rights, it is clear that patent rights only extend so far as a court finds them valid and encompassing. While the possibility of monopoly profits flowing from a valid patent encourages innovation, companies and individuals engaging in research, development, and other innovative activities should keep in mind *ex ante* that patent laws do not give them absolute monopolies. To the extent that the scope of a patent is enlarged to cover more than a court would determine, it extends beyond the reach that Congress intended.¹²⁹

C. The Antitrust-Plaintiff-Friendly Approach

A more antitrust-plaintiff-friendly position is held by judges and scholars who suggest that a *per se* rule of presumptive illegality is a better approach.¹³⁰ They argue that because the pioneer manufacturer is willing to pay a large sum of money for the generic manufacturer to stay out of the market, there is some uncertainty as to the scope or validity of the patent.¹³¹ Although the patentee might offer a settlement in order to avoid high litigation costs, the settlements at issue in *Valley Drug* and other cases far exceed those costs.¹³² The inflated value of payments can be attributed to the probability that the patent will be held invalid and a generic product will be allowed to enter the market.¹³³

Thus, if the patentee is certain to win its infringement suit, it will not pay the generic manufacturer more than the cost of litigation to stay out of the market.¹³⁴ However, if the patentee is only 75% sure that it will win the case, it will be willing to pay the generic manufacturer up to 25% of the value of its monopoly, because the result of the settlement would preserve its monopoly.¹³⁵ While this seems facially anticompetitive, antitrust defendants regularly assert procompetitive justifications for reverse payments.¹³⁶ That being the case, do reverse settlement payments constitute restraints of trade that have such predictable and pernicious anticompetitive effects warranting application of the *per se* rule of illegality?

129. See Leffler & Leffler, *supra* note 3, at 37–38.

130. See, e.g., *id.* at 54.

131. See Symposium, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1757–58 (2003).

132. See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 904 (6th Cir. 2003); *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294, 1300 (11th Cir. 2003). See generally, *Schering-Plough*, 402 F.3d 1056.

133. See *In re Cardizem*, 332 F.3d at 911.

134. See Symposium, *supra* note 131, at 1759.

135. *Id.*

136. Thomas F. Cotter, *Refining the “Presumptive Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkap, Janis & Lemley*, 87 MINN. L. REV. 1789, 1800–1802 (2003) [hereinafter Cotter, *Refining*].

D. *Per Se Rule Applicability to Reverse Payments*

Courts have generally been willing to apply a per se rule of illegality when certain factors are present.¹³⁷ The practice in question must facially appear to be a practice “that would always or almost always tend to restrict competition and decrease output.”¹³⁸ These practices include, for example, price fixing, horizontal output restraints, and market-allocation agreements.¹³⁹ A per se rule of illegality is the appropriate mode of analysis when “experience with a particular kind of restraint enables the court to predict with confidence that the rule of reason will condemn it.”¹⁴⁰

It appears that reverse-payment settlements probably should not categorically fall under the per se rule. Although some courts have categorized reverse payments as market-allocation agreements (i.e., the pioneer manufacturer and the generic manufacturer agree that the product market will be allocated to the pioneer manufacturer in exchange for money),¹⁴¹ sometimes the agreements are justified and could even result in an increase in overall competition.¹⁴² This is the case if the plaintiff takes the increased monopoly profits resulting from the settlement, the defendant takes the settlement proceeds, and they each invest these funds in research and development. In this event, society benefits because, theoretically, each company will develop new drugs and medicines. The result would be more drugs and more competition, resulting in lower costs to consumers.¹⁴³

Notwithstanding the potential benefits that reverse payments may provide to society, the Hatch-Waxman Act includes provisions that encourage anticompetitive activity in patent litigation.¹⁴⁴ For example,

137. See *In re Cardizem*, 332 F.3d at 906–907.

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

139. See *id.*

140. *Arizona v. Maricopa County Med. Soc’y*, 457 U.S. 332, 344 (1982) (holding that it is the court’s experience with the type of restraint (e.g., market-allocation) that is relevant in applying the per se rule, not the particular industry at issue or the specific facts of the case). As a result, antitrust defendants may not rely on the defense that courts have insufficient experience in the pharmaceutical industry or in cases involving alleged Hatch-Waxman Act infringements to apply the per se rule.

141. See *Schering-Plough v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 237–38 (E.D.N.Y. 2003).

142. See generally Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069 (2004) [hereinafter Cotter, *Antitrust*].

143. This conclusion depends on some assumptions. One concerns the extent to which drug companies actually invest money gained as a result of settling Hatch-Waxman Act patent infringement lawsuits in research and development. This is an empirical question, for which no data exist. Another assumption here concerns one’s views on the importance and legitimacy of patent incentives and the need to preserve the integrity of the patent system. See Josh Lerner, *150 Years of Patent Protection*, 92 AM. ECON. REV. 221 (2002) (finding that strengthening a patent system did not significantly impact inventions); Mariko Sakakibara & Lee Branstetter, *Do Stronger Patents Induce More Innovation? Evidence from the 1988 Japanese Patent Reform Laws*, 32 RAND J. ECON. 77 (2001) (finding only a very small effect on research and development activity from expanding the scope of Japanese patents).

144. See 21 U.S.C. § 355 (2006).

the ANDA filer must certify that its product either will not infringe the patent on which it relies for safety and efficiency data or that the patent holder's patent is invalid.¹⁴⁵ This suggests that the patent infringement case might not be as meritorious as patent infringement cases in other contexts. In addition, the patent holder is encouraged to sue within the forty-five-day period because doing so automatically stays any entry into the market for thirty months.¹⁴⁶ This thirty-month period gives the patent holder time to evaluate the strength of its patent in the face of the ANDA's challenge and weigh the costs and benefits of continuing the infringement litigation. Given the high costs of patent litigation and the uncertainty involved, the result of this analysis might often be a decision to offer settlement.¹⁴⁷ Therefore, the scheme presented by the Hatch-Waxman Act gives special incentives for parties to collude in order to share monopoly rents.¹⁴⁸

Because of the incentives for drug manufacturers engaged in a patent infringement suit to agree to an anticompetitive reverse-payment settlement, some scholars argue that these types of agreements should almost never be upheld when subject to antitrust challenge.¹⁴⁹ For example, one group of analysts suggests that reverse-payment settlements should only be permitted to the extent that they reflect the parties' actual avoided litigation costs.¹⁵⁰ This group reasons that payments in excess of avoided litigation costs indicate that the patent owner enjoys a better outcome by sharing monopoly profits than it would get through litigation.¹⁵¹ However, this approach fails to adequately consider other factors that are relevant when negotiating settlements, such as risk aversion and informational asymmetries.¹⁵²

The best argument against application of the per se rule is spelled out in *In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("In re Cirpo"),¹⁵³ a case in which purchasers of an antibiotic drug and advocacy groups sued pioneer and generic drug manufacturers for violation of antitrust laws.¹⁵⁴ Pioneer drug manufacturer Bayer held a patent for a particular drug, and generic drug manufacturer Barr filed an ANDA and accompanying paragraph IV certification alleging that Bayer's patent was invalid and unenforceable.¹⁵⁵ Bayer subsequently commenced a

145. See generally *id.*

146. See generally *id.*

147. This is especially true to the extent that the patent holder is risk averse.

148. It has been suggested that these "perverse [statutory] incentives" should be removed from patent laws in order to reduce the likelihood that drug manufacturers will come to anticompetitive settlement agreements. See, e.g., Cotter, *Antitrust*, *supra* note 142, at 1093–94.

149. See Symposium, *supra* note 131, at 1759.

150. *Id.* at 1758.

151. *Id.* at 1758–59.

152. *Id.* at 1761–62.

153. 261 F. Supp. 2d 188 (E.D.N.Y. 2003).

154. *Id.* at 191–92.

155. *Id.* at 194.

patent infringement suit against Barr.¹⁵⁶ Prior to trial, the parties reached a settlement under which Barr acknowledged the validity of Bayer's patent, and Bayer paid Barr \$49.1 million.¹⁵⁷

The court declined to apply the per se rule of illegality, and distinguished the situation from *In re Cardizem*, pointing out that, in *In re Cardizem*, the agreement effectively delayed market entry by other generic manufacturers as a result of the generic manufacturer's promise to attempt to block other generic competitors by indefinitely maintaining its ANDA paragraph IV certification.¹⁵⁸ By contrast, the drug companies in *In re Cipro* did not create such a bottleneck for future ANDA paragraph IV filers because Barr agreed to relinquish its right to the exclusivity period.¹⁵⁹ The court went on to explain other reasons why the per se rule should not apply:

It is uncontested that parties settle cases based on their perceived risk of prevailing in the litigation. . . .

[I]n creating an artificial act of infringement . . . , the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from infringing commercial sales. This statutory scheme affects the parties' relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, Barr's exposure in the patent litigation was limited to litigation costs, but its upside—exclusive generic sales—was immense. The patent holder, however, has no corresponding upside, as there are no infringement damages to collect, but it has an enormous downside—losing its patent. Moreover, patent holders realize that it is a “gamble” to place “a technology case in the hands of a lay judge or jury.” In settling the patent litigation, Bayer not only saved litigation expenses but achieved essentially all that it could hope to achieve by continuing to litigate, *i.e.*, a determination [that its patent was valid and Barr would not infringe it in the future]. . . .

. . . .

. . . Accordingly, so-called reverse payments are a natural by-product of the Hatch-Waxman process, and—even if such payments were not contemplated or intended by the amendments—plaintiffs have not shown that they are so nefarious in this case as to subject the challenged agreements, which provide for such payments, to *per se* treatment.¹⁶⁰

156. *Id.*

157. *Id.* at 196.

158. *See id.* at 242.

159. *See id.* at 243.

160. *Id.* at 251–52 (citations omitted).

Despite the incentives that the Hatch-Waxman Act gives patent holders and generic manufacturers to engage in arguably anticompetitive activities, many scholars argue along with *In re Cipro* and the Eleventh Circuit that reverse payments should only be deemed illegal in egregious cases.¹⁶¹ Thus, it is suggested that reverse payment settlements should be permitted unless the underlying patent infringement litigation was a “sham,”¹⁶² or that they should be permitted so long as the amount of the reverse payment does not exceed the profit that the defendant would have earned had it successfully defended the infringement suit.¹⁶³ Others emphasize that in some patent infringement cases involving traditional settlements, with money flowing from defendant to plaintiff, the effects are more anticompetitive than settlements involving reverse payments.¹⁶⁴ Therefore, perhaps courts should consider antitrust challenges of patent infringement settlements on a case-by-case basis rather than focus on the reverse payment issue.

Just as there are reasons to reject a categorical application of the *per se* rule to reverse payments, there are several reasons to reject the above-noted deferential approaches. First, patent settlement agreements that involve payments from the plaintiff to the defendant in return for the defendant exiting the market are a potentially burgeoning threat to competition. Potential procompetitive justifications notwithstanding, the Hatch-Waxman Act gives incentives for patent holders and patent infringement defendants to engage in anticompetitive conduct.¹⁶⁵ If some drug manufacturers share monopoly rents, competitors will be forced to do the same, and reverse payments could become a commonly used tool for drug companies to monopolize and raise prices.

Second, when patent holders pay large sums of money to alleged patent infringers, they essentially share monopoly rents. This harms consumers because if a court could hold that the scope of the patent did not reach the allegedly infringing product or that the patent was invalid, competition in the relevant market would increase and prices would fall. Pioneer manufacturers should not be able to expand the scope of their “probabilistic” patent monopoly by paying potential competitors to stay out of the market.

At least one commentator has recently argued that basing antitrust liability on speculative anticompetitive effects is inconsistent with traditional burdens of proof in antitrust decisions and that, accordingly,

161. See, e.g., Cotter, *Refining*, *supra* note 136, at 1793.

162. See Yee Wah Chin & Thomas G. Krattenmaker, *Antitrust Update*, 2 MERGERS & ACQUISITIONS TAX J. 30, 30 (2001).

163. See Blair & Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491, 523 (2002).

164. See Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698, 706 (2004).

165. See, e.g., Cotter, *Antitrust*, *supra* note 142, at 1093–94.

reverse payments should be permitted.¹⁶⁶ However, in a recent case, the Court of Appeals for the District of Columbia Circuit clarified that anticompetitive effects can be shown by alleging that it was probable that the alleged monopolist's conduct resulted in consumer injury.¹⁶⁷ The court stated "as a general matter the exclusion of nascent threats is the type of conduct that is reasonably capable of contributing significantly to a defendant's continued monopoly power."¹⁶⁸ Thus, the anticompetitive act of foreclosing competitors from developing distribution channels to consumers coupled with the probability that consumers were deprived of a competitive product was not immune from antitrust liability. Similarly, the probability that consumers and retailers are deprived of the benefits of competition as a result of reverse payments should suffice as an antitrust injury.

Third, the pharmaceutical drug market is particularly price inelastic.¹⁶⁹ Consumers need pharmaceutical drugs to live and be healthy, and are therefore unable to demand lower prices or rely on alternative products in order to satisfy their needs.¹⁷⁰ Health care costs are already enormous, partly because of the high cost of prescription drugs.¹⁷¹ Courts can help reduce these costs by applying strict antitrust scrutiny to reverse payments. These factors (low cross-elasticity of demand and the troubled state of the existing health care market) suggest that courts should use the discretion granted them by Congress under the Sherman Act to diligently safeguard consumer welfare in the market of pharmaceutical drugs.

E. The Middle-of-the-Road Approach

Given the policy considerations described above, the question remains of precisely which approach courts should apply when considering antitrust cases concerning reverse payment. A beneficial and workable approach is as follows. Courts should apply a rebuttable presumption of unlawfulness when a patentee pays an alleged infringer for preservation of the patentee's monopoly in the course of patent infringement litigation. The patentee should then bear the burden of proof to show that it would likely prevail in the infringement litigation

166. See Schildkraut, *supra* note 22, at 1050 ("Given the economic foundations of the antitrust laws, one might argue, however, that antitrust decisions and awards could be based on probabilities rather than the prevailing civil standards of proof. This, however, has not been the path antitrust tribunals have taken, applying instead traditional burdens of proof."). Mr. Schildkraut represented Schering-Plough Corporation in *In re Schering-Plough Corp.*, No. 9297 (F.T.C. Dec. 8, 2003), <http://www.ftc.gov/os/adjpro/d9297/03128commissionopinion.pdf>.

167. See *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001).

168. *Id.*

169. See PATRICIA M. DANZON, PRICE COMPARISONS FOR PHARMACEUTICALS: A REVIEW OF U.S. AND CROSS-NATIONAL STUDIES 32 (1999).

170. See generally *id.*

171. SHARON SILOW-CARROLL & TANYA ALTERAS, STRETCHING STATE HEALTH CARE DOLLARS: POOLED AND EVIDENCE-BASED PHARMACEUTICAL PURCHASING 1 (2004).

and that the amount of the settlement payment was in proportion to the expected litigation costs of the lawsuit.¹⁷² This approach would conserve judicial resources, promote competition, and result in lower costs to consumers in the pharmaceutical drug market. An analysis of the effect of our suggested approach is demonstrated in its application to the *Schering-Plough* case as follows.

V. SCHERING-PLOUGH RECONSIDERED

In *Schering-Plough*, the Federal Trade Commission reversed on appeal the dismissal of the antitrust complaint by an administrative law judge. The Commission adhered to the approach that once the conduct at issue produced anticompetitive effects, the respondent must then show that the conduct was justified by procompetitive benefits.¹⁷³ Both drug companies expected that generic entry into the market would impact Schering's sales.¹⁷⁴ Therefore, the payments by Schering to Upsher exceeded the fair consideration for the licenses transferred, which delayed entry of the generic manufacturers into the market.¹⁷⁵ Thus, the Commission found that the evidence supported the claim of anticompetitive effects.¹⁷⁶ Further, given the enormous size of the settlement, the defendants were unable to, by emphasizing hypothetical benefits to the market of the settlement, rebut the initial demonstration of anticompetitive effects.¹⁷⁷

As explained *supra*, the Eleventh Circuit reversed the holding of the Commission because it failed to consider the exclusionary scope of the patent, and the Supreme Court denied certiorari.¹⁷⁸ However, as the Commission noted, the issue in the case was not whether the pioneer manufacturer had the right to exclude competition for the life of the patent, but whether the generic products infringed the pioneer manufacturer's patent, an issue for which the plaintiff bears the burden of proof.¹⁷⁹ Although the Eleventh Circuit in *Valley Drug* held that the exclusionary effect of the patent must be considered first,¹⁸⁰ and while it is true that a patent holder does have the right to try to exclude alleged infringers by suing them, as the Commission noted in *Schering-Plough*, a "presumptively valid patent [does] not necessarily confer a right to

172. A similar approach has also been argued for by Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 24–25 (2004). See also Cotter, *Refining*, *supra* note 136.

173. In re *Schering-Plough Corp.*, No. 9297 (F.T.C. Dec. 8, 2003), at 8.

174. *Id.* at 19.

175. *Id.* at 17.

176. *Id.* at 25.

177. *Id.* at 39.

178. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

179. In re *Schering-Plough Corp.*, No. 9297, at 30–31.

180. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003).

exclude generic entry.”¹⁸¹ This reasoning is especially appealing when it appears that a patent holder is buying off a potential generic challenger by agreeing to share the increased profits gained by the existing monopoly.

It is interesting that Schering allegedly paid millions of dollars to the infringing defendants for licenses to market drugs that were not the subject of the litigation.¹⁸² Especially noteworthy is that Upsher never marketed the drugs for which Schering purchased licenses.¹⁸³ Although Upsher points to a downturn in the market for these drugs as a justification for never marketing them,¹⁸⁴ it is questionable whether Schering would be willing to actually pay for licenses to market such speculative drugs, or alternatively, whether it would completely refrain from marketing the drugs despite the costs already incurred in purchasing the licenses. Perhaps an examination of the pre-settlement market in the drugs for which the licenses were transferred would show that the licenses were not really worth the amount of money paid for them, and that the transfer was merely an attempt to veil what was otherwise a clear monopoly rent sharing agreement. The Commission appears to have been convinced that this was the case.¹⁸⁵

The approach suggested by the Eleventh Circuit in *Valley Drug*¹⁸⁶ and implemented in *Schering*¹⁸⁷ not only gives drug companies a free pass with regard to antitrust law, it needlessly expends judicial resources. When antitrust plaintiffs are forced to litigate the merits of a patent infringement suit that was settled, sometimes years ago, the result is likely a more costly and time-consuming trial than if the original infringement parties had argued the case.

However, the court in *Schering* suggested that holding patent settlement agreements to be unlawful might actually reduce competition because it would discourage generic companies from challenging patents with ANDAs in the first place.¹⁸⁸ To illustrate, the court in *Schering* analyzed Judge Posner’s statement:

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. . . . But any settlement agreement can be characterized as involving “compensation” to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to

181. *In re Schering-Plough Corp.*, No. 9297, at 30.

182. *Id.* at 5.

183. *Id.* at 70.

184. *Id.* at 75.

185. *Id.* at 79.

186. *Valley Drug*, 344 F.3d at 1306–07.

187. *Schering-Plough v. FTC*, 402 F.3d 1056, 1065–66 (11th Cir. 2005).

188. *Id.* at 1075.

be classified as involving a forbidden “reverse payment,” we shall have no more patent settlements.¹⁸⁹

An easy way to allay these concerns is simply to create a special, middle-of-the-road, rule that applies only in situations in which there is a large lump sum reverse payment from the infringement plaintiff to the defendant. Reverse payments would be presumed illegal, and antitrust defendants would bear the burden of proving otherwise by showing that they were bona fide settlements of intellectual property disputes (i.e., the size of the payment was not too far above prospective litigation costs, third party potential competitors were not affected, etc.). Although some potentially anticompetitive settlements, which do not involve reverse payments, might still occur, this is a small price to pay for the corresponding benefit to consumers resulting from scrutiny of reverse payments. Further, there are good reasons to be more skeptical of the anticompetitive nature of agreements in the Hatch-Waxman Act context in particular.

Had the court of appeals in *Schering-Plough* applied this middle-of-the-road approach, the result probably would have been to defer to the Commission’s findings. The reverse payment would have been presumed unlawful, and the parties would then have had an opportunity to justify it as a bona fide settlement of the patent infringement suit. Given that the Commission was unconvinced that the reverse payments constituted a fair value for the licenses granted to the infringement plaintiffs by the generic manufacturers,¹⁹⁰ the huge settlement payments do not seem justifiable.

So long as this rule is applied only to reverse payments, the concern that it would discourage generic companies from entering the market for a particular drug is inapposite. In the Hatch-Waxman Act context, when the patent infringement litigation occurs, the generic manufacturer has not yet entered the market. Accordingly, there is not a risk of paying large damages. The result of the generic manufacturer losing the case is merely a loss of administrative costs of filing the ANDA and the costs of litigating the case. There is not a significant risk to the generic manufacturer because the possible results are either: (1) the court finds that the patent is infringed, in which case the generic company does not enter the market; or (2) the court finds that the patent was not infringed, in which case the generic may enter the market. Therefore, the only real cost to the generic manufacturer in attempting to compete involves administrative and litigation expenses. Furthermore, the only public cost is the time spent by the court in adjudicating the validity and scope of the

189. *Asahi Glass Co., v. Pentech Pharms. Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (emphasis omitted). See *Schering-Plough*, 402 F.3d at 1074–75 (quoting and paraphrasing Judge Posner’s statement, and advocating the allowance of reverse payments unless the underlying infringement suit was objectively baseless).

190. *In re Schering-Plough Corp.*, No. 9297 (F.T.C. Dec. 8, 2003), at 30–31.

patent, which would quite possibly take place anyway in an antitrust lawsuit if the parties settled. Regardless, the costs borne by society through the use of judicial resources in the infringement act is likely outweighed by the potential benefit to society in increasing competition and reducing the cost of pharmaceutical drugs.

VI. CONCLUSION

Reverse payment settlement agreements probably result in the expansion of legal monopolies, decreased competition, and higher prices for prescription drugs. Thorough enforcement of antitrust law is one way of increasing competition and potentially reducing costs. On balance, while there are good reasons to reject a per se approach to reverse-payment settlements, the policy in favor of antitrust enforcement seems to outweigh the policies regarding patent incentives and judicial economy. Accordingly, an approach that presumes reverse-payment settlements illegal and gives antitrust defendants a chance to rebut the presumption by proving the agreements were justified represents an appropriate compromise.